Do Terpenes Play a Role in the Stress-reducing Effects of a Forest Bathing Intervention?

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UNIVERSITY OF WASHINGTON
CONSENT FORM
Nature Experience

Researchers:

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Introduction:
Your participation in this research is voluntary. We are asking you to be in a research study on health and wellbeing. The overall purpose of the research is to learn more about how various stimuli affect our physiological, cognitive and psychological responses. We are looking at the impacts of forest air on human health and well-being. Study participation will take place over two sessions where we will be filtering out the air to various degrees. The information below will help you decide whether or not you want to participate. You may expect to take 5-10 minutes to go over this form. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

Study Procedures:
You will be asked to do the procedures (i.e. tasks) that are checked below. A description of each procedure is provided, as well as any possible risk(s). Any procedure below may be administered more than once, or in conjunction with other procedures.

☐ Smell Identification Test™: You will be asked to take the Smell Identification Test™ (UPSIT®) test. This is a reliable, valid, and rapid clinical test that evaluates your sense of smell. You will identify a series of smells from a one-time, single-use test. There is no direct risk from smelling the test sheets, but if your ability to smell is below a certain level, you will be ineligible for the study. We will offer you information about what this could mean about your previously undiagnosed smell loss, as well as more information on the test itself and what it has been shown to measure in the scientific literature. **Risks: You may be alerted to a condition of smell loss that was previously unknown to you. This may be upsetting, and you should contact your regular doctor to follow up on the result.**

☐ Surveys: You will be asked to complete surveys on your characteristics and traits, such as demographic information (e.g., age, gender) and health and wellbeing (e.g., mood, stress, anxiety). Additionally, we may ask about certain medication use. For example, you may be asked to rate how often you felt that you were unable to control the important things in your

life on a scale of 0 (Never) to 4 (Very Often); or how upset or afraid you feel (from very slightly or not at all to extremely). Surveys may be administered several times during a single visit, in-lab or in the field by a member of the research team via pen and paper, or via a computer or tablet. **Risks: You may feel some discomfort from answering questions about yourself.**

□ You will be asked to sit in Pack Forest for 60min, two times. The two 60 minute sessions will be at least 8 days apart. **Risks: You may find it inconvenient to travel for multiple visits.**

□ For each session, you will meet with study coordinators at RAIN non-profit organization building or the University of Washington Tacoma and then be driven by a research assistant to/from the study site (Pack Forest). The trip will take around 45-65 minutes each way depending upon traffic conditions. The car itself will be outfitted with a filtration system that includes a filter and a blower fan delivering the filtered air towards you during the ride. There will only be one participant and one driver in the vehicle at a time. You will both follow current infection control policies (including masking). **Risks: You many find that the filter system makes the ride uncomfortable.**

□ Powered air purifying respirators (PAPR): During each session you will be asked to wear a helmet with a pump system that covers your entire head/face and filters the air, for up to 1-2 hours. You will also be asked to wear a battery pack on a belt around your waist. Two different air filters will be used. During the first session one filter will be used, and during the second session the other filter will be used. **Risks: You may feel discomfort from the helmet pressing against your head, or discomfort having your whole face covered.**

□ Physiological responses: The checked measures will be recorded throughout your participation. When needed, one of the researchers will help you to put on the equipment, which may take up to 20 minutes at a time. To put on the equipment, you will place a sensor on your own chest, and afterwards, a researcher will check its placement to be sure it will measure activity correctly. To do this, you will need to lift your shirt to the point that the sensor is visible (around the upper abdomen). The researcher may instruct you to make adjustments and re-check the sensor placement after adjustments have been made.

□ For the physiology data analysis calibration we will ask you about your height, weight, age, and gender.

□ Heart functioning: (electrocardiogram, heart rate, cardiac thoracic impedance): You will be asked to wear a device (chest strap or adhesive electrodes) on your torso. **Risks: You may have sensitivity to the adhesives or band materials.**

□ Skin conductance: You will be asked to wear a device on your wrist and electrodes on your palms to measure sweat. **Risks: You may have sensitivity to the adhesives or band materials.**

□ Blood pressure: You will wear a blood pressure cuff monitor. One of the researchers will administer this procedure at various time points throughout your participation. It should take no more than 5 minutes each time. **Risks: You may experience some discomfort from the pressure of the blood pressure cuff.**

□ Blood draws: At each visit, you will be asked to provide small amounts of blood (approximately 5mls before the forest sitting session and approximately 5mls after the session, this is a little more than 1 teaspoon), which will be used to assess levels of inflammation indicators and absorbed forest air compounds. We will collect 2 blood samples during a single visit, and the two visits will be conducted at least 8 days apart. A qualified person will collect the blood samples. These de-identified samples will then be shipped to a laboratory at the Center for Disease Control and the University of Washington for analysis. Each sample should take no more than 20 minutes to collect. **Risks: You may faint or experience some discomfort, dizziness, or pain from the procedure. The needle puncture might cause a bruise, you might get an infection if the site is not kept clean while it heals.**

□ Sitting: You will be asked to sit in the University of Washington's Pack Forest, in Eatonville, WA. You will be asked to leave your cell phone on silent and not use it during this period. We will offer you the use of insect repellent, if you wish to use it. **Risks: You may experience normal hazards of walking on uneven terrain. You may feel bored or uncomfortable sitting for 60 minutes. You may experience bug or insect bites. You may experience skin irritation from the insect repellent, should you opt to use it.**

□ Air sample: You may be asked to wear or sit near an air sampling apparatus, such as a small battery-operated pump and a filtered tube, for the 60-minute seated session. **Risks: You may feel bored or uncomfortable sitting for 60 minutes.**

□ Dietary and other restrictions: The levels of compounds of interest may be affected by your diet or use of certain consumer products (e.g., scented lotions), cleaning products, and/or use of alcohol, marijuana and/or e-cigarettes for 24 hours before your nature experience. As such, we may ask you to report what you eat and drink. We will also ask you to refrain from eating or drinking certain foods and beverages 1-3 days prior to study procedures, as well as during study participation (i.e. the day(s) of participation). You will be provided with specific instructions explaining which foods and beverages, consumer and cleaning products, and substances we will

ask you to avoid. **Risks: Following these procedures may be challenging and involve a change of habit, which could be uncomfortable and inconvenient.**

☐ Social Security Number: For participant payments above a certain amount we will collect your social security number for University records. If you earn $600 or more in subject payments from the University of Washington during this calendar year, the UW Financial Management Office will report this to the Internal Revenue Service as Miscellaneous Income.

Study Duration:

Your participation will entail a total of ____ sessions/days.

The number of minutes required from you per session/day of participation is _____.

Risks, Stress and Discomfort:
In addition to the risks described above, there is also a risk that the confidentiality of your information could be lost. We will do everything possible to maintain the confidentiality of your information. If you feel uncomfortable you may choose not to answer any questions (for example, survey questions).

Compensation:
You will receive $240 for your full participation in the study ($90 for each of the 2 sessions that are at least 8 days apart plus a $60 bonus for completion of entire study upon completion of your second session). If you wish to drop out of the study at any time you are allowed to do so with no adverse consequences and compensation provided for the duration of the study participation before your dropout.

Communication:
We will communicate with you via email or phone call or text. These communications can (depending on your set of procedures) include appointment reminders.

Benefits of the Study:
We cannot guarantee any benefits to you for participating in this study, beyond any intrinsic satisfaction you may feel in being part of this research.

Source of Funding:
The study team and/or the University of Washington is receiving financial support from National Institutes of Health.

Confidentiality of Research Information:

This information will be kept confidential, and we will remove any identifiable information for publication purposes. The study data (information and specimens) we collect from you will be labeled with a study ID code. A link between the study ID codes and your identifiers will be stored separately from the study data.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
- relevant authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this is August 31, 2024. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

Use of Information & Specimens:

Returning Results to You: During your meeting with the study team at UW Tacoma, your results from the Smell Identification Test™: test may need to be communicated to you, as a lack of smell constitutes exclusionary criteria for this study. Although these specific results will have to be communicated to you, you may choose whether you would like to receive a written summary of the results, including a clear explanation about whether or not the results are clinically actionable and what is known or unknown about the meaning of the result.

Using Your Data in Future Research: The information and/or specimens that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

You may contact the research staff at UW with a request to withdraw your data from secondary use or banking. However, your data cannot be withdrawn from any sharing, analysis or results of analysis (such as publications or presentations) that are already completed. Results from this and related studies may be disseminated (i.e. in research articles, presented at academic conferences) but your identity will NOT be shared.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to withdraw, please contact the researcher listed on page 1 of this consent form.

RESEARCH-RELATED INJURY

You will be asked some questions at your second visit regarding any research-related harms/risks you may have experienced since your initial visit. You may also contact Dr. Gregory Bratman, at (206) 543-7591 or sefsewb@uw.edu if you think you have been harmed from being in this research.

Contact Information:

You may contact us at sefsewb@uw.edu with any questions or concerns.

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this

consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I will receive a copy of this consent form.

Printed name of subject Signature of subject Date

Email:

Phone Number:

Is it okay to text you at this number?

☐ **Yes**
☐ **No**

What is your preferred method of contact(email, text, or phone call)?

_____

Would you like to be contacted by our study team for future research?

☐ **Yes**
☐ **No**

Copies to: Researcher
Subject