



RESEARCH CONSENT FORM

Project Title: Aromatherapy for management of low back pain in the Emergency Department

Principal Investigator: Dr. Adam J Singer

Co-Investigators: Sarah Weiss MD / Stephen Meigher BS, Medical Student

Department: Emergency Medicine

You are being asked to be a volunteer in a research study.

You are encouraged to take your time in making your decision. You may want to discuss this study with your friends and family.

PURPOSE

The purpose of this study is:

The purpose of this study is to test if aromatherapy – exposure to a strong-smelling scent - is useful for reducing back pain. Back pain is a common complaint in the emergency department and often difficult to treat. There has been research showing that aromatherapy may help patients with certain kinds of pain and we hope to assess whether or not aromatherapy, in addition to the commonly used pain medication Ibuprofen, is effective in reducing back pain. We expect to recruit a total of 60 patients at Stony Brook Hospital Emergency Department.

PROCEDURES

If you decide to be in this study, your part will involve:

- You will be asked how much pain you are in and mark the level of your pain on a line before treatment.
- You will be given an oral dose of ibuprofen.
- You will be randomly (by chance, like flipping a coin) assigned to one of two groups.
- A cotton ball saturated with one of two natural substances will be placed near you for 30 minutes.
- After 30 minutes, you will be asked to record your pain severity again and to indicate whether your pain was relieved or not.
- The total study time is estimated to be 1 hour.
- At the end of the study your treating physician may give you more pain medicine, if necessary, at their discretion.

RISKS / DISCOMFORTS

The following risks/discomforts may occur as a result of you being in this study:

- You may not like scent that you are exposed to. You may develop an allergic reaction (rash, itching) to the scent, which is very rare. If you develop an allergic reaction you will receive treatment at the discretion of your emergency physician.
- Since this is a research study, not all risks may be known at this time; there may be unforeseen risks associated with study participation.

BENEFITS

The following benefits may occur as a result of being in this study:

Your pain may be lessened by being exposed to the experimental scent. However, you may not receive any benefit. We hope that the information obtained in this study may help future patients, like yourself with back pain.

CONFIDENTIALITY

We will take steps to help make sure that all the information we get about you is kept confidential. Your name will not be used wherever possible. We will use a code instead. All the study data that we get from you will be kept locked up. The code will be locked up, too. If any papers and talk are given about this research, your name will not be used.

While you are in this study we will get data about your health from your medical record. We will also get health data from the results of the tests you will have done in this study. You have a right to privacy but the data we get about your health in this study can be shared with the people referenced above (the study team, Stony Brook University's Committee on Research Involving Human Subjects, applicable institutional officials, and federal offices such as OHRP—*Office for human research protections*, FDA—*food and drug administration*, as well as:

- your insurance company
- your medical doctor

Your health data are shared to make sure the study is being done correctly, costs are charged correctly, and to make sure your rights and safety are protected. Not all of these people are required by law to protect your health data. They might share it with others without your permission.

Some of the health information we get from you in this study cannot be shared with you until the end of the study.

You have the right to stop allowing us to use or give out your health data. You can do this at any time by writing to Dr. Adam Singer, Department of Emergency Medicine, HSC-L4-080, Stony Brook, NY 11794-8350. If you do this, we will stop collecting any new health data from you, except if we need to keep an eye on a bad side effect you were having in the study. We will use any data we collected before you wrote your letter. When you sign the consent form at the end, it means:

- That you have read this section.
- That you will allow the use and reporting of your health data as described above.
- (If the subject is a patient at University Hospital) You have received a form from the University Hospital. It is called the Notice of Privacy Practices form.

COSTS TO YOU

- There are no foreseeable additional costs to you for participating in this study. You or your insurance company will be responsible for all costs related your standard care except for the expense of the aromatherapy.

ALTERNATIVES

- You may elect to not participate in this study. The treatment of your pain will then be decided by you and your attending or resident physician.

IN CASE OF INJURY

- If you are injured as a result of being in this study, please contact Dr. Adam Singer at telephone 631-444-7857. The services of Stony Brook University Hospital will be open to you in case of such injury.
- However, you and/or your insurance company will be responsible for payment of any resulting treatment and/or hospital stay.

YOUR RIGHTS AS A RESEARCH SUBJECT

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason, and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will get a copy of this consent form to keep
- You do not lose any of your legal rights by signing this consent form.

QUESTIONS ABOUT THE STUDY OR YOUR RIGHTS AS A RESEARCH SUBJECT

- If you have any questions, concerns, or complaints about the study, you may contact Dr. Adam Singer, at telephone 631-444-7857.
- If you have any questions about your rights as a research subject or if you would like to obtain information or offer input, you may contact the Stony Brook University Research Subject Advocate, Ms. Lu-Ann Kozlowski, BSN, RN, (631) 632-9036, OR by e-mail, lu-ann.kozlowski@stonybrook.edu
- Visit Stony Brook University's Community Outreach page, <http://research.stonybrook.edu/orc/community.shtml#overview-of-volunteering-in-research> for more information about participating in research, frequently asked questions, and an opportunity to provide feedback, comments, or ask questions related to your experience as a research subject.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

Subject Name (Printed)

Subject Signature

Date/Time

Name of person obtaining consent (Printed)

Signature of person obtaining consent

Date/Time