Official Title: Relaxing Environment to Lower Anxiety during Onabotulinum Toxin Chemodenervation of the Bladder: RELAX Trial

NCT06319898

IRB Approved Date: 5/8/24

RELAXING ENVIRONMENT TO LOWER ANXIETY DURING ONABOTULINUM TOXIN CHEMODENERVATION OF THE BLADDER: RELAX TRIAL

Informed Consent Form to Participate in Research

Megan Tarr, MD, Principal Investigator
Atrium Health Department of Obstetrics and Gynecology

Contents

1. SUMMARY

You are invited to participate in a research study. The purpose of this research study is to

determine if a relaxing environment of lavender aromatherapy, calming music, dim lighting, and modest positioning decreases anxiety during office bladder Botox procedures. You are invited to be in this study because you are scheduled to have an office bladder Botox procedure. Your participation in this research study will involve today's visit only and add about 30 minutes of additional time to your visit.

Participation in this study will involve filling out 3 short surveys that ask you to rate your anxiety and pain level before the procedure, as well as pain and satisfaction level after the procedure. All research studies involve some risks. A risk to this study that you should be aware of is exposure to lavender scent. You should not participate if you have an allergy to lavender. Participants may benefit from decreased procedure anxiety or pain due to the relaxation and distraction techniques. Others may not benefit from participation.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Megan Tarr, MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is:

Megan Tarr, MD
[redacted]

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

2. INTRODUCTION

You are invited to participate in a research study. Studies help researchers learn new information that may help other people in the future. You are being asked to participate in this study because you are scheduled for intra-detrusor chemodenervation with onabotulinum toxin A, also known as bladder Botox. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask the researchers to explain any words or information in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

This study will take place at Women's Center for Pelvic Health, Mercy outpatient clinic.

3. WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to determine if a Relaxing Environment Package of

aromatic lavender sticker, calming music, dim lighting, and modest positioning decreases patients' anxiety during office bladder Botox procedures. We will also assess whether pain and patient satisfaction are improved. Finally, we will investigate whether a relaxing environment decreases work-related burnout among staff.

In this study, the Relaxing Environment Package will be compared to a placebo environment. The placebo environment will include a typical office setting with non-aromatic (placebo) sticker, no music, and overhead lighting. It is not thought to have any effect on your condition or procedure. In this study you will either receive the Relaxing Environment Package, or placebo typical office setting. Placebos are used in research studies to see if the environment being studied really does have an effect.

4. Who is Sponsoring this Study?

This study is being sponsored by Atrium Health Department of Obstetrics and Gynecology. The sponsor is providing money or other support to the researchers to help conduct this study.

5. How Many People Will Take Part in the Study?

We expect around 100 people will take part in this study. Some people may be screened for the study but will not be eligible to participate.

6. How Long Will I Be in the Study?

Your participation in the study is planned to last for the length of your scheduled visit for office bladder Botox procedure.

7. What Is Involved in the Study?

If you agree to participate in the study, you will fill out a survey that asks you to rate your current anxiety level regarding this procedure on a scale from 0 to 10 and your pain level on a scale from 0 to 10. We will also ask if you have used aromatherapy or participated in meditation in the last 6 months. You will then be taken to the room where your procedure will take place. Procedure staff will perform the usual preparation including administration of bladder numbing medication. If the room is set to the Relaxing Environment Package, you will be given a lavender scented sticker to wear on your shirt. There will be calming music playing softly in the background via overhead speakers. We will try to avoid using the stirrup footrests for your procedure, although they may be used if deemed necessary by your doctor. The lights will be dimmed while the numbing medication is working. This typically takes about 10 minutes. If the room is set to Typical Office Environment (placebo), you will be given an unscented (placebo) sticker to wear on your shirt. There will be no music playing in the background. Your feet will be placed in stirrup footrests for the procedure. The overhead lights will be on while your numbing medication is working.

Just prior to performing the bladder Botox procedure we will ask you to fill out a survey rating your current anxiety level on a scale from 0 to 10. The procedure will then be performed by your doctor. After the procedure, you will get dressed. You will then be asked to fill out a final survey rating your pain level experienced during the procedure on a scale from 0 to 10 and your

level of satisfaction with your procedure experience on a scale from 0 to 10. This will conclude your participation in the study and you will be free to leave. With your consent, we will review your electronic medical record for your age, body mass index (BMI), medical history, medication history, and insurance type.

If you take part in this study, you will have the following tests and procedures:

Visit	***During this visit, you will***	***How long is this visit?***	***Reminders***
Visit 1	• *Review and sign this consent form first* • *1st anxiety and pain visual analog scale* • *Urine analysis* • *Pre-procedure preparation including bladder numbing medication* • *2nd anxiety visual analog scale* • *Bladder Botox procedure* • *2nd pain visual analog scale, patient satisfaction visual analog scale*	*About 1 hour*	*None*

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin.

1. Relaxing Environment group with aromatic lavender sticker, calming music, dimmed lighting, no stirrup footrest if possible.

2. Typical Office Environment group with non-aromatic (placebo) sticker, no background music, overhead lights turned on, stirrup footrest used.

8. WILL I RECEIVE THE RESULTS OF THE STUDY?

Research results that are not clinically relevant will not be disclosed to you.

9. WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk/inconvenience to you. You should discuss the risk of

being in this study with the study staff. These can be physical, emotional, financial, or social. Many side effects go away, but sometimes they can be serious, long-lasting, or may never go away. There may be other side effects that we do not know about yet, so be sure to tell the study doctor about any unusual symptoms.

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

There is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

For Example:

Lavender aromatherapy	Lavender allergy is rare, but allergic reaction is possible
Inconvenience	Participating in the study will add about 30 minutes to your visit
Placebo environment	You may be randomized to the placebo Typical Office Environment and not experience the Relaxing Office Environment

10. Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the results of this study will benefit other people in the future. The benefits of participating in this study may be: decreased procedure anxiety or pain due to the relaxation and distraction techniques. Because everyone is different, no one can know in advance if the study will help you.

11. What Other Choices Are There?

You do not have to be in this study.

Your alternative is to not participate in this study and receive your Botox treatment as scheduled using standard office procedures.

12. What Are the Costs?

Study costs, including any study products that would only be done as part of the study will be paid for by the study sponsor. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

13. Will You Be Paid for Participating?

You will receive no payment or other compensation for taking part in this study.

14. Will Your Research Records be Confidential?

Your participation in this research and any study records created about your participation will be kept as confidential as possible. The overall results of this study may be presented at scientific or medical meetings or published in scientific journals. Your identity will not be shared unless you give your permission or is required by law to protect you or others.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. 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 Web site at any time.

15. What if I am harmed from being in the study?

If you get hurt or sick from being in this study, you should seek medical care. Be sure to tell the researcher as soon as possible. You may receive care at Advocate Health. There is no plan to pay for lost income or any non-medical costs that might result from the illness or injury.

Advocate Health - Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for treatment of injuries or illnesses. To the extent research insurance coverage is available under this policy, the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

16. Who will see my Protected Health Information?

Who may have access to my information:	*Purpose:*
Any sponsor, including future sponsors, of the study and anyone working on behalf of a sponsor or future sponsor	To oversee the study and make sure the information is correct.

Consultants and employees of Advocate Health – Wake Forest University School of Medicine, including IRB members.	To protect the rights and safety of subjects and make sure the study information is correct.
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries).	To make sure applicable laws are being followed.
Organizations that grant accreditation to hospitals and research programs.	For Advocate Aurora Health to remain accredited.
Monitors, auditors, IRB or other regulatory agencies may be granted direct access to your medical record.	To verify clinical trial procedures or data.

By signing this form, you are giving the researchers permission to use and share your personally identifiable health information. This includes direct access to your medical records.

Please note that the study doctor or study staff may also share personal information about you if required by law (for example, if the study doctor or study staff suspects that you are going to harm someone or yourself, reporting of communicable disease (HIV, hepatitis, tuberculosis, etc.). If you have questions about this, please ask the study doctor.

How will my information be used for this study?
You must authorize the use and sharing of your information by signing this form or you cannot be in the study.

The study principal investigator and study staff will collect, use, and share identifiable health information about you for the following reasons:

- to conduct this research study.
- to review the study, and to check the safety and results of the study.
- to seek government approval of an investigational study drug, vaccine, device or product if such was involved in the trial.
- to assist a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.

Information used and shared may include:

- information from your medical records related to the research or your routine medical care.
- information collected about you during the research and any follow-up related to study visits, tests, procedures, outcomes, etc.

The collected information may contain your name, address, telephone number, health plan number, date of birth, medical record numbers, dates relating to various medical procedures, and/or other identifying information.

How will my information be kept confidential?

We will keep your personal health information as confidential as possible. Your identity will be protected as required by law and according to any policies described in the study consent form. Researchers may share your information with representatives and agents of the sponsor(s) for the purposes of managing and overseeing the study. Usually, the health information sent to sponsors does not directly identify participants (for example, by name or address). Instead initials and a code number are used. Some personal information, such as date of birth, will usually be included but will not be used to identify you.

Once your information leaves the organization we cannot control how it is used, and the law may not require other groups to protect the privacy of your information.

To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally will have access to your health information.

If this study is designed so that you are intentionally not told what treatment or study intervention you are receiving (called a blinded study), you will not have access to health information in your medical record that was collected as part of this study until those who run the study determine it is no longer necessary to keep you blinded. This usually occurs after everyone in the study has completed study treatment or intervention but can sometimes last until all study data is collected and analyzed.

How do I cancel my authorization?

You can cancel your authorization to use and share your information at any time by writing a letter to the study doctor. If you cancel your authorization, you will not be able to continue in the study. If some aspects of the study were optional, you may cancel your authorization for the optional part(s) of the study and still remain in the main study.

Megan Tarr, MD
[redacted]

If you cancel your authorization, no new information will be collected without your permission. The study doctor and study staff will still be able to use and share your information that has already been collected to maintain the integrity of the study.

When will my authorization expire?

This authorization to use and share your information expires at the end of the research study when data analysis is complete, and study records have been destroyed.

If study information is used for scientific publications or educational purposes, all identifying information will be removed.

17. What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part, or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

You may be asked to complete a survey about your experiences participating in a research study.

18. Whom do I call if I have questions or problems?

For questions about the study or in the event of a research-related injury, contact the study investigator,

Megan Tarr, MD
[redacted]

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact [redacted].

19. Signatures

Subject name: _____

- I have read this form and the research study has been explained to me.
- I have had ample time to consider participation in the study and have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.

- I understand the research study and voluntarily agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.
- I agree to follow the investigator's instructions.
- I understand and agree that representatives from the sponsor, regulatory authorities and the institutional review board will be granted direct access to my medical records.
- I understand that I may decide to refuse participation or stop participating at any time without penalty and without affecting the quality of my health care or the relationship with the study doctor.
- I understand that there may be consequences to my withdrawal from the study as noted within this document.
- I understand and agree that personal information about me will be collected in this study and from my medical records, and used and processed (manually and by computer) for the purposes of the study by the manufacturer of a medical device used in my treatment or any other designated party that is involved in the study (e.g. hospital, study doctor, regulatory authorities, ethics committees).
- If I so choose, I have provided the name of a person to be contacted by the principal investigator in case I cannot be reached for follow-up.

Participant signature Date Time AM/PM

For Site Use only:

My signature below certifies the following:

- The subject has been given enough time and an adequate place to read and review this form.
- All elements of the study, as contained in this document, were explained, and discussed with the subject or his/her legally authorized representative **before** research-related procedures began .
- The subject has had a chance to ask questions and receive answers about this study.
- The subject expressed understanding of the study.
- The subject/LAR will receive a copy of the signed and dated consent form/authorization.

_____

Name of person obtaining informed consent (print)

_____

Signature of person obtaining informed consent Date

Time AM/PM