Title: Augmenting Benzodiazepine Receptor Agonist Deprescribing With Acupuncture and Yoga Among Older Adults

NCT: 06197243

Date: 07/09/2024

VUSN-IRB Health Sciences Consent Template

Please complete the survey below.

Thank you!

VUMC Institutional Review Board

Informed Consent Document for Research

Study Title: Augmenting Benzodiazepine Receptor Agonist Deprescribing with Yoga and Acupuncture Among Older Adults: A Single Arm Feasibility Trial of 30 Patients

Version Date: 05/19/2023

Principal Investigator (PI): Gurjeet Birdee, MD MPH

Name of Participant: _____

Age of Participant: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:

The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

Older adults sometimes take medications that are not useful and may have significant risks. Benzodiazepine drugs and related medications are prescribed to older adults to help with sleep and anxiety problems. However, these medications are not useful long-term for sleep and anxiety and have significant risks.

The main purpose of this 12-week study is to see if a new combination of treatments can help patients reduce benzodiazepine or related medication use. The treatment combination consists of 1) medical provider visits to gradually reduce the medication dose over 12 weeks, 2) acupuncture treatments, and 3) private yoga classes. Patients will be offered weekly visits for 12 weeks to receive combined treatments. Each visit will last about 1 1/2 hours. Patients will also be scheduled for 4 research visits to complete surveys which will take about 1 hour. At the end of the study, you will be invited to participate in a focus group to learn about your experience in the study. This visit will last about 1 hour.

You may not receive a direct benefit for participating in this study. Reducing your medication may be difficult and you may experience increased problems with sleep and anxiety. Acupuncture and yoga are generally well tolerated and have low risks treatments in older adults. Both have been shown to help with sleep and anxiety. For acupuncture, patients may experience pain or discomfort, minor bleeding, or bruising at the needle insertion site. For yoga, patients may experience muscle soreness or stiffness, overstretching or minor strains, fatigue or tiredness, or brief dizziness or lightheadedness.

The goal of the study is to learn if patients are willing to participate in the study, how they feel about the treatments to reduce the medications, and if the study runs well. About 30 people will take part in this study at Vanderbilt University Medical Center.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you are taking a benzodiazepine or related medication.

Procedures to be followed and approximate duration of the study:

If you agree to be in this study, you will be asked to read and sign this consent form. After you sign the consent form, the following things will happen:

Research Procedures: If you volunteer to take part in this research study, you will be asked to do the following: Take part in the study which will last for 12 weeks. In the beginning and at 4 weeks and 12 weeks you will have a visit to our study center for: Questionnaires and interview about your health including medications, supplements, other treatments for health, health behaviors, mood and sleep. Each of these study visits will take about 1 hour Weekly visits over 12 weeks at the Osher Center for Integrative Health at Vanderbilt University Medical Center for: Visits with medical provider to help you reduce your use of benzodiazepine or related medications. The provider, with your consent, will write reduced doses of your medication. These visits will be 15 to 30 minutes long. These visits may be provided online if convenient for you. Your regular insurance will be billed for these visits. During the study, the medical provider at the Osher Center will take responsibility for prescribing your benzodiazepine or related medications. The provider will communicate with your regular medical provider regarding any changes in your prescription. At the end of 12 weeks, your regular medical provider will continue to refill your benzodiazepine or related medications as necessary. Visits to receive acupuncture. Acupuncture is a therapeutic technique that has been used for thousands of years in Traditional Chinese Medicine (TCM). The practitioner will then insert thin, sterile, single-use needles into specific points on your body. The needles are typically left in place for up to 30 minutes, during which time you may experience sensations such as warmth, heaviness, or tingling. Visits to learn yoga. Yoga is a form exercise that includes slow movements, breathing, and focused attention. You will meet privately with a certified yoga instructor to learn yoga. Your lesson will be about 30 minutes. You will be asked to practice yoga at home daily for 12 weeks. The practice will take 10 to 15 minutes. After completing the study, we will invite you to participate in a focus group meeting with other study participants to discuss your experience of the study. The focus group will be about 1 hour and be occur online. 2. Monitoring procedures: If you volunteer to take part in this research study, research staff will monitor you as follows:

During the study you will be asked by study staff and providers if you are experiencing any side effects related to participating in the During the study, you will continue on other medications and regular care as prescribed by your regular If you tell us that you have thoughts about hurting yourself or others we will report this to the proper authorities. This may include Emergency psychiatric care or other appropriate You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:

Acupuncture: The risks of acupuncture for older adults are thought to be quite low. Serious risks are unlikely including pneumothorax (collapsed lung), infection at the needle insertion site, allergic reaction to needles or materials used, nerve damage, or hematoma (formation of a large blood clot). Less serious effects are pain or discomfort at the needle insertion site, minor bleeding or bruising, dizziness or lightheadedness, fatigue, and emotional release or mood changes. Yoga: The risks of yoga for older adults are thought to be quite low. Serious risks are unlikely including falls or injuries resulting from loss of balance or dizziness, aggravation of pre-existing conditions, such as herniated discs or joint problems, cardiovascular events, including heart attack or stroke, and severe muscle strains or ligament injuries. Less serious effects are mild to moderate muscle soreness or stiffness, overstretching or minor strains, fatigue or tiredness, brief dizziness or lightheadedness, and mild joint discomfort or pain. Benzodiazepine dose reduction: The risks of deprescribing benzodiazepines for older adults are low. Serious risks are unlikely including seizures, delirium, severe rebound anxiety or insomnia, suicidal thoughts or behaviors, and psychosis. Less serious effects are anxiety, irritability, insomnia, headaches, nausea or gastrointestinal discomfort, muscle aches or stiffness, and changes in appetite or weight. We will make the risks of your participation smaller by careful screening to make sure you are eligible to participate.

Acupuncture will be provided with strict protocols to reduce the risks of complications. This will include using sterile, single-use needles to prevent infection and cross-contamination. Needles will be placed at locations that are at low risk for causing any damage. The yoga being taught will be not too hard and modified to meet your physical capacity and maximal comfort. Weekly practices will slowly progress, and we will watch you for side effects. If you develop new symptoms such as shortness of breath, chest pain, feeling lightheaded, swelling of your body, or muscle cramps, you may stop the Benzodiazepine reduction will occur gradually to reduce side effects to reduce withdrawal effects. Study staff will monitor your progress closely, adjusting the tapering schedule as needed based on your individual response and any potential side effects. If you chose to continue or return to your regular dose, you may stop the medication reduction. There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information. However, if your participation becomes known, it could create a problem or hardship for you depending upon the type of information disclosed.

Risks that are not known:

There may be risks and side effects that are currently unknown and/or unanticipated.

Good effects that might result from this study:

The benefits to science and humankind that might result from this study are the possibility of reducing the amount of benzodiazepine or related prescriptions in older adults. This may reduce the risks of side effects from the medications. You may not receive a direct benefit for participating in this study. Reducing benzodiazepines have been shown to improve health in older adults. Researchers do not expect to cure any diseases or conditions with the study.

Payments for your time spent taking part in this study or expenses:

You will not receive any payment to participate in this study.

Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests, acupuncture treatments, and yoga classes. We will charge your insurance for visits with our medical provider to manage your benzodiazepine or related medications. You are still responsible for paying for the usual care you would normally receive for your health. This includes treatments and tests you would need even if you were not in this study. These costs will also be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator with National Institutes of Health input that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt or the National Institutes of Health to pay for the costs of any additional care. There are no plans for Vanderbilt or the National Institutes of Health to give you money for the injury.

Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Gurjeet Birdee at 615-343-1554 at the Osher Center for Integrative Health at Vanderbilt University Medical Center.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:

If you experience significant side effects or discomfort at any point in this study, you will be withdrawn from the study. This will be done in order to ensure your safety and emotional well-being. If you are taken out of the study, you will be told the reason why.

What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:

A description of this clinical trial will be available on 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 website at any time.

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. To protect confidentiality, all data collected will be stored in a locked file cabinet located in the secured office of the principal investigator. All computers and data files will be password protected. All data, including questionnaires, will be coded with numbers, so your personal information is not linked with the data. Data will be deleted two years following the end of the study. Only the principal investigator and study staff will have access to the data.

This study may have some support from the National Institutes of Health (NIH): If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It doeds not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or shaing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more abo[illegible] prevent this and other health problems.

Study Results:

If you are interested to see your results from surveys we perform, research staff will provide a summary of your results after completion of the study for all participants.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you canceled your authorization.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

Statement by person agreeing to be in this study:

○ I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.
(Please check box to agree to statement.)

Signature of Patient/Volunteer:

(Please click the green "add signature" button, sign, and save)

Date:

Date of IRB Approval: 07/09/2024
Date of Expiration: 07/08/2025

Institutional Review Board

VANDERBILT

Consent obtained by (please enter full name and title):

_____
(Completed by study personnel at time of consent.)

Consent obtained by signature:

_____
(Please click the green "add signature" button, sign, and save)

Date:

_____

Time:

_____