NCT06546956

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study (this "Research Study")?

Developing and Testing a Multicomponent Breathwork Intervention for People with Chronic Pain

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator: Steven Pratscher, Ph.D. (352) 273-9510

4. Who is paying for this research study?

The sponsor of this study is the National Center for Complementary and Integrative Health

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) **In general, what is the purpose of the research, how long will you be involved?** The purpose of this research study is to develop and test a controlled breathing and attention treatment, or breathwork intervention, to see if it improves pain symptoms and well-being in people who have chronic low back pain (cLBP). Although this type of breathwork intervention has been widely practiced in the "real world," no formal research study has examined whether it helps people with chronic pain. Therefore, this initial study is to standardize and refine the treatment, examine its feasibility and acceptability, and see whether and how this 8-week intervention affects your pain and functioning. Your participation in this study will be about 3 months with 2 assessment visits (1-3 hours each, pre-intervention and post-intervention), 8 treatment sessions (1.5-2 hours each, 1 per week for 8 weeks), and an online 1-month follow-up questionnaire. Therefore, your total time commitment is expected to be about 12-22 hours over a 3-month period.

b) **What is involved with your participation, and what are the procedures to be followed in the research?** Participation in this study will involve completing a total of 2 assessment visits, 8 treatment sessions, and a 1-month follow-up survey. The first visit is for baseline assessments, which include 1) questions about how you think and feel and your health and pain history, 2) physical tasks of sitting, standing, lifting, bending, and walking, and 3) sensory and pain tests to measure how you feel cold and pressure sensations. For women of child bearing potential (< 63 years), you will be asked to complete a urine pregnancy test at the beginning of the first visit. If the test is positive, you will be disqualified from the study and ineligible to participate. After the first visit, you will schedule your treatment sessions, which will involve engaging in the breathwork intervention once a week for 8-weeks with a trained facilitator. Each treatment session will last 1.5-2 hours, and we will ask you to answer some questions before and after each session. The final assessment visit will occur within 1-2 weeks of the last treatment session. At this visit, we will repeat many of the questionnaires, physical functioning tasks, and pain sensory testing assessments as in the first visit. We will also ask you to answer questions about your experience participating in the study through a semi-structured interview. Finally, we will ask you to complete an online follow-up survey 1-month after the final visit.

c) **What are the likely risks or discomforts to you?**

- The pain testing procedures may be uncomfortable or unpleasant
- The physical tasks may lead to discomfort
- The questionnaires may make you feel uncomfortable or upset
- The breathing intervention could make you feel uncomfortable and may cause some temporary side effects (tingling, lightheadedness, muscle cramps. headache) and may elicit intense or difficult physical and emotional experiences.

d) **What are the likely benefits to you or to others from the research?** We don't know if this treatment will be helpful, but there is a chance that it might improve your pain, stress, and overall health and well-being.

e) **<u>What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?</u>** The other option is not participating in this study.

Additional and more detailed information is provided within the remainder of this Informed Consent form. Please read before deciding if you wish to participate in this study.

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.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

Any regular medical care for your back pain and/or other medical conditions will continue to be given by your regular doctors, nurses, and other providers. This study does not offer any additional medical care.

7. What will be done only because you are in this Research Study?

You have already completed a brief telephone screening to determine initial eligibility for the study. Now, you will complete up to 2 in-person visits for assessments (pre-intervention and post-intervention) and 8 treatment sessions with a trained facilitator. At the first visit and last visit, we will do some tests to find out more about your pain and function. At your first visit, we will collect more health information from you in order to make sure that you are still eligible for the study. Then, if you are still eligible for the study, the next 8 sessions will involve engaging in a controlled breathing and attention treatment (Sessions 1-8) with a trained facilitator. At your final visit, we will ask you to complete more questionnaires and the same physical functioning tasks as in your first visit.

<u>Procedures for Visit 1</u>: We will do the following at the first visit (1-2 hours)

1) Review this Informed Consent form with you to make sure that you understand everything that is involved in the study
2) A urine pregnancy test in women of childbearing potential (under 63 years)
3) We will ask you to complete several questionnaires about your general health, medications, your thoughts about pain, previous life experiences, and how you think and feel about things. We will ask some personal questions, because this

will help us know about all of the things that might be affecting your symptoms of chronic low back pain or how you respond to the intervention.

1) Pressure Sensations Tests. We will use a handheld device with a small (less than ½ inch wide) rubber tip to apply pressure to your body (e.g., shoulder). The pressure will be slowly increased, and you will be asked to tell the examiner when you begin to feel discomfort or mild pain. As soon as you tell us you feel pain, the pressure will be removed.
2) Mechanical Sensations Tests. We will use a handheld probe that has a small nylon tip to tap your hand and low back. We will ask you how painful this feels.
3) Combined Pressure and Cold Test. We will do the pressure test where you push a button when you first feel pain. Then, we will ask you to do a cold test, by putting your hand in cold water and telling us how painful it feels. While your hand is in the water and after you take your hand out of the cold water, we will repeat the pressure pain test.
4) Physical Activities: We will ask you to do some physical activities, such as standing still for balance, walking a short distance, getting out of a chair, bending down, and lifting a box from the floor.

At Visit 1, we may find out that you have health issues (e.g., high blood pressure) or things that make it unsafe for you to participate in the study that could mean you are not eligible for the rest of the study. If you are eligible for the rest of the study, we will schedule the treatment visits.

Procedures for Treatment Sessions 1-8 (1.5-2 hours): In each of the treatment visits, we will do the following:

1) Questionnaires: You will be asked to complete some brief questionnaires before and after the treatment about your pain and how you are currently thinking and feeling.
2) Breathwork Intervention: You will receive instructions in each session on breathing in certain ways and paying attention to sensations in your body.

Procedures for Visit 2 (2-3 hours): We will do the following at Visit 2, the post-intervention assessment visit:

1) Questionnaires: You will be asked to complete more extensive questionnaires after the treatment about your pain, how you are currently thinking and feeling, and your impression of the treatment.
2) Pressure Sensations Tests: We will repeat the pressure sensations tests as in visit 1.
3) Mechanical Sensations Tests: We will repeat the mechanical sensations tests as in visit 1.
4) Combined Pressure and Cold Tests: We will repeat the same pressure and cold tests as in visit 1.
5) Physical Activities: We will repeat the same physical tests as in visit 1.
6) Semi-Structured Interview: We will ask you questions and may follow-up on your responses to understand more about your perception of the intervention and participation in the study. This interview about your experiences is voluntary.

	Baseline Pre-Int	Treatment	Post-Int	Follow-Up
Study Activities	Visit 1	Sessions 1 - 8	Visit 2	1-Mo
Informed Consent	X			
Baseline Questionnaires	X			
Intervention Session		X		
Acute Treatment Effects		X		
Treatment Acceptability			X	
Clinical Pain Outcomes	X		X	X
Psychological Assessments	X		X	X
Physical Function Assessments	X		X	
Quantitative Sensory Testing	X		X	

1-Month Follow-Up Assessment: We will also ask you to complete an online questionnaire to let us know how you are doing 1 month after you complete your final visit. This questionnaire will ask you questions about your pain, thoughts, feelings, mood, sleep, and activities. This questionnaire will take about 60 minutes to complete. You will be asked to complete the survey on the internet, but we can offer a paper alternative if requested.

More Information About the Breathwork Intervention: A session begins with brief instruction and dialogue with the facilitator, such as what you will be asked to do, checking in about your previous session, and a reminder about the possible experiences that can occur during the breathing (e.g., body sensations). For each session, you will be guided to breathe into your upper chest in a continuous rhythm with no pause between inhale and exhale. This can create physical or somatic sensations in your body, and even emotions, that you will be asked to pay attention to with an orientation of mindfulness, acceptance, and relaxation. For this type of breathwork, you will lay down supine and be instructed to maintain this deep conscious connected breathing technique for one hour, while paying attention to present moment physical sensations in your body and letting go of any tension you notice. The facilitator will observe your breathing pattern and may use touch (if you consent) or encourage breathing into or relaxing certain areas of your body. Each session ends with slower, relaxed breathing and an opportunity to briefly share what happened during the session. This type of intervention may or may not reduce pain and stress for some people.

Video and Audio Recording: As part of your participation in the research, you will be video and audio recorded during the breathwork intervention sessions as well in the semi-structured interview at your final visit. The semi-structured interview will be recorded to transcribe your responses verbatim about your experiences participating in the study. The intervention sessions will primarily be recorded to assess the facilitator's adherence to the treatment manual and protocol. We may also code for other behaviors to understand the types of experiences that are common from this novel intervention or that seem to predict positive or negative outcomes.

Neither your name or personal information will be identified in the video or audio recordings. Confidentiality will be strictly maintained. However, when these video and/or audio recordings are shown or heard, others may be able to identify you.

The Principal Investigator (PI) of this study listed in this informed consent form or his successor will keep the recordings for an indefinite period of time in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. For educational purposes, the recordings will be shown or heard under his direction to students, researchers, doctors, or other professionals and persons.

If any identifiable information was collected as part of this research, it is possible that your research information, with all personally identifiable information removed, could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect the following identifiable health information:

- Demographic information
- Health and pain history
- Results of functional and sensory tests
- Responses to questionnaires
- Video and audio recordings

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information may be shared with:

- The study sponsor (listed in Question 4 of this form);
- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections;

- Government agencies which are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected.

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

Your participation in this research project will last about 3 months. Visit 1, which should take 1-2 hours, is when you sign this consent form and are officially enrolled in this Research Study. After Visit 1, you will be asked to complete 8 treatment sessions, 1 per week for 8-weeks, which each last 1.5-2 hours. Visit 2, which should take 2-3 hours, will be scheduled to occur within 1-2 weeks after the final treatment session. Also, we will ask you to complete a follow-up questionnaire online at one month after Visit 2. Therefore, your total time commitment is expected to be about 20 hours over a 3-month period.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

If you decide to participate, you will be one of approximately 30 people in this research study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

This study might involve the following risks and discomforts to you:

- The pain testing procedures may be uncomfortable or unpleasant. You will experience some temporary discomfort from the stimuli during pain testing. However, if you feel the pain is greater than you wish to tolerate, you can stop any of the procedures at any time.
- The physical exam procedures and activity tests may produce discomfort and possibly pain, but you can stop these procedures at any time.
- The breathwork intervention may elicit strong or intense sensations and emotions which can be uncomfortable. The facilitator will guide you to minimize possible discomfort associated with the breathing.

Risks of the Breathwork Intervention: Expected risks are mild and temporary from the change in body chemistry (e.g., oxygen and carbon dioxide levels) associated with the breathing intervention but may include the following: tingling, dizziness, discomfort, muscle cramps, lightheadedness, headache, changes in body temperature, dry mouth, or ringing in ears. Although unlikely, you may also experience these symptoms between sessions. Strong or intense uncomfortable physical sensations and/or difficult psychological experiences can arise during the intervention sessions, but the facilitators are trained to provide appropriate support. You will be laying down during the intervention so there is no risk of falling. While we expect the interventions to be safe, the facilitator will be prepared in case of emergency. Although unexpected, if you experience severe or very concerning symptoms during the breathing intervention, please alert the facilitator. You may choose to stop the breathing intervention at any time. This type of breathing intervention has been safely practiced with thousands of people of varying ages around the world.

Other possible risks to you may include: You may feel uncomfortable, upset or sad about answering some of the questions on the questionnaires. You do not have to answer those questions. Researchers will take appropriate steps to protect any information they collect about you. However, if the researcher believes it is in your medical best interest, they may share information with other health care providers so that they can help you. Also, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Below in this form we discuss what information about you will be collected, used, protected, and shared.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

To help us protect your privacy, we have requested a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

13a. What are the potential benefits to you for taking part in this Research Study?

You may or may not benefit from participating in this study. A potential benefit is that this breathwork or breathing intervention could improve your pain, stress, and/or well-being. If the treatment does improve your pain, we do not know how much it will help. It is possible that any improvements could be small and may not last very long.

13b. How could others possibly benefit from this Research Study?

The results of this study may help us to better understand whether this breathwork intervention is an acceptable treatment to reduce chronic low back pain. We may also learn more about how and why these treatments are beneficial, which might help us to create better treatments for pain in the future.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

14. What other choices do you have if you do not want to be in this study?

The other option to taking part in this study is not participating. If you do not want to take part in this study, tell the Principal Investigator or a member of the Research Team and do not sign this Informed Consent Form.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- You no longer meet the eligibility criteria for the study
- You have had too many side effects or an unexpected negative reaction to the study
- You have failed to follow instructions
- The entire study has been stopped
- The study team believes that your continuing in the study could cause problems for you or for the study

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

No, all research related costs and services will be covered. All other medical services provided to you that are not directly required by this study will be billed to you or your insurance company in the usual manner.

17. Will you be paid for taking part in this Research Study?

You will be paid for your participation in this study. We will pay you $50 for completing all components of the first visit, $50 for completing all components of the last visit, $25 for completing the semi-structured interview at the last visit, and $25 for completing the 1-month follow-up survey after treatment. Therefore, the total amount possible you can receive from completing all study procedures is $150. Your compensation will be prorated based on the number of visits/study activities completed following that schedule ($50 for pre-intervention visit 1, $50 for post-intervention visit 2, $25 for completing the semi-structured interview at visit 2, and $25 for the 1-month follow up). You will also receive the treatment at no cost to you. Prorated payment will be disbursed after confirmation that you have withdrawn or discontinued with the study. Compensation will occur at the end of Visit 2 and after the 1-month Follow-up.

Study Activity	Amount
Visit 1	$50
Visit 2	$50
Semi-Structured Interview	$25
1-Month Follow-Up	$25
Total Possible Payment	$150

Your payment for participation in this research study is handled through the University of Florida's Research Participant Payments (RPP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the RPP Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment, contact the Research Team listed in question 3.

18. What if you are injured while in this Research Study?

If you are injured as a direct result of your participation in the study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists, or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information. The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date