

Title: Web-based Pain Self-Management: Nurse-Guided  
NCT03927846  
Date: 2/20/2020

**Web-based Pain Self-Management: Nurse-Guided**  
Informed Consent Form to Participate in Research  
Dennis C Ang, M.D., M.S, Principal Investigator

## Summary

You are invited to participate in a research study. The purpose of this research is to determine if phone-delivered nurse support can improve the use of pain coping skills to manage chronic musculoskeletal pain. You are invited to be in this study because you have chronic pain. Your participation in this research will involve 3 visits and each one will last about an hour.

Participation in this study will involve questionnaires, web modules, and documentation of your medical history. All research studies involve some risks. A risk to this study that you should be aware of is you may feel uncomfortable talking to us over the phone or answering the paper study questions. There is the possibility that you may benefit from participation in this study.

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. Some other choices may include follow up with your primary care doctor for pain management. 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 Dennis Ang, M.D. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: Dennis Ang at [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].

## INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have chronic pain, a condition that affects multiple body parts. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

## WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine if phone-delivered nurse support can improve the use of pain coping skills to manage chronic musculoskeletal pain.

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

There will be 60 subjects taking part in this study which will take place at Wake Forest Baptist Medical Center.

## WHAT IS INVOLVED IN THE STUDY?

If you take part in this study, you will complete the following:

If you agree to participate in the study, you will complete a pre-screening questionnaire to determine if you meet the required criteria for this study. If you qualify, you will be asked to come for a baseline visit to our Clinical Research Unit (CRU) here at Wake Forest Baptist Medical Center. Below is a list of all the things that happen during the study:

### **Baseline visit:** (approximately 1 hour)

- Demographics: date of birth, age, sex, race, ethnicity and will include providing your e-mail address
- Review medical history
- Health Questionnaires: To help the study doctor assess your condition during the study you will be asked to complete questionnaires about your overall health, your pain and how your condition is affecting your health and quality of life. During your visit to the CRU you will:
  - Rate your fatigue and pain
  - Rate your physical function
  - Assess your pain condition and treatment
  - Assess your sleeping pattern

In addition to providing your personal e-mail (that will not be used), you will use an assigned email account to log into the learning modules but will not have access to receive direct messages. You will receive reminders from the WFBH study staff to your personal email address. This reminder will remind you to log into the website to complete your participation. Your personal email address will not be disclosed to third parties and will only be used by the study staff for purposes of the study.

You will also be given the link to begin the web-based pain self-management program called “PainTrainer.” You will be assigned into a group who will receive six telephone contacts over an 8-week period by a trained clinical nurse, or a group who will not receive any calls. You cannot choose your study group. You will be put into a study group by chance like a coin toss. All subjects will receive a weekly e-mail reminder to complete the learning modules (PainTrainer).

### **Web-based Pain Self-management Program**

The web-based pain self-management program (PainTrainer) consists of eight online lessons to

teach you how to better manage your pain. You have to complete one lesson each week for 8 weeks. Lesson content is focused on (1) understanding pain and relaxation, (2) brief relaxation with mini practices, (3) activity/rest cycles, (4) pleasant activity scheduling, (5) coping thoughts, (6) pleasant imagery, (7) problem solving, and (8) looking back and moving forward. This web based program will allow you to have access to downloadable lesson summaries with practical homework exercises, related educational videos, relaxation audio files, and an “at home” exercise program.

### **Visit 8**

This visit will take place at the CRU (same place as your baseline visit). During this visit:

- Medications will be reviewed
- Health Questionnaires: On your overall health, your pain and how your condition is affecting your health and quality of life. You will (same as baseline):
  - Rate your fatigue and pain
  - Rate your physical function
  - Assess your pain condition and treatment
  - Assess your sleeping pattern

### **Visit 16**

This visit will take place at the CRU (same place as your baseline visit). During this visit:

- Medications will be reviewed
- Health Questionnaires: On your overall health, your pain and how your condition is affecting your health and quality of life. You will (same as baseline):
  - Rate your fatigue and pain
  - Rate your physical function
  - Assess your pain condition and treatment
  - Assess your sleeping pattern

As part of this research study, you will be audiotaped. This is being done for training and quality assurance reasons. You understand that you may request the recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the audiotape before it is used. You should also understand that you will not be able to inspect, review, or approve the audiotapes or other media (including articles containing such) before they are used in this study.

Please choose one of the following regarding the use and disclosure of the audiotape used in this research study:

\_\_\_\_\_ I would like the audiotapes of me to be destroyed once their use in this study is finished.

\_\_\_\_ The audiotapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

## HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 16 weeks.

You can stop participating at any time. 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.

## WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to this study include:

- You may feel uncomfortable talking to us over the phone or answering the paper study questions.
- Completing the homework exercises may increase your risk of injuries to the muscles, ligaments, tendons and joints of the body.
- In addition, there is a slight risk of a breach of confidentiality (surveys and group therapy). We will do our best to protect your confidential information.
- A subject that is actively suicidal or who scores equal to or greater than 20 on the PHQ8 questionnaire will be advised to go to the nearest ER and be given contact information to the nearest mental health professional.

To minimize the above risks, you can take the following measures:

- Tell the study team about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects and other risks.
- Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be maintained to keep your information safe. All study participants and team members participating in group therapy will be reminded that any information shared should be kept confidential.

## Reproductive Risks and other Issues to Participating in Research

Pregnant women are excluded from participation in this study. Pregnancy can affect their pain sensitivity and pain reporting.

Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, OrthoEvra patch, NuvaRing, intrauterine devices (IUD), Nexplanon implant, DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous

relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a diaphragm with spermicide with Plan B used for any noticed condom or diaphragm failures. We encourage you to discuss this issue further with your physicians if you have any questions.

### WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such 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. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of \$25,000 coverage for each claim and is limited to a total of \$250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [REDACTED].

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.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Dennis Ang at [REDACTED] during normal business hours and [REDACTED].

### 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 information learned from this study will benefit other people in the future. The possible benefits of participating in this study include reduction of pain, and improvement in physical function and quality of life. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

### WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options:

1. Participate in physical exercise program on your own.
2. Follow up with a primary care provider for management of your pain. You could be treated with the standard treatments even if you do not take part in the study.

### WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from

your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: Contact information, demographic information, medical history, and responses to questions about health activity.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you (“your health information”) may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state law.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished

You can tell Dennis Ang MD that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dennis Ang, MD



However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

### **WHAT ARE THE COSTS?**

There are no costs to you for taking part in this study. The use of the Clinical Research Unit (CRU) and the parking space is free for the required visits.

### **WILL YOU BE PAID FOR PARTICIPATING?**

You will be receiving \$15 for every visit you complete in the CRU for a total of \$45 for all 3 study visits (i.e., baseline, week 8, and week 16). If you withdraw for any reason from the study before completion, you will receive \$15.00 for each study visit that you completed. Costs for your regular medical care, which are not related to this study, will be your own responsibility.



To receive payment, you must provide your social security number, name, and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study, but you will not be paid.

### WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest School of Medicine (Department of Internal Medicine and Rheumatology Section). The sponsors are providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the intervention being studied.

### WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant 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 if this study falls within its jurisdiction.

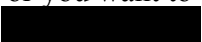
### WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

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, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Your relationship with your healthcare provider will not be affected by whether or not you decide to participate in this study.

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

### WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the researcher Dennis C. Ang   


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 the Chairman of the IRB at .

You will be given a copy of this signed consent form.

## SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed): \_\_\_\_\_

Subject Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_ am pm

Person Obtaining Consent: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_ am pm