Official Title: Investigating the Use of A Patient Navigator to Address the Social Drivers of Health in the Management of Pain: A Pilot Study

NCT06665906

IRB Approval Date: 03/28/2025

Wake Forest®
School of Medicine

Department of Internal Medicine/Rheumatology

HUMAN USE OF PATIENT NAVIGATOR TO ADDRESS THE SOCIAL DRIVERS OF HEALTH IN THE MANAGEMENT OF PAIN: A Pilot Study
Informed Consent Form to Participate in Research
Dennis, Ang, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research study is to see if patients with chronic pain can improve how they manage their pain and daily function by working with a care manager and by learning pain coping skills from an online teaching tool. You are invited to be in this study because you have chronic pain in different parts of your body. Your participation in this research will involve talking by phone once a month with a care manager and learning pain coping skills from an online teaching tool.

Participation in this study will involve completing questionnaires about your pain, fatigue, mood, and your ability to complete day-to-day activities, listening to web modules about pain management and speaking on the phone with a care manager. All research studies involve some risks. A risk to this study that you should be aware of is the potential for you to feel uncomfortable answering some of the survey questions. 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 include following up with your primary care doctor for pain management or not participating in this study. 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 [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 Atrium Health at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. Studies help researchers learn new information that may help other people in the future. You are being asked to be in this study because you have

chronic pain. 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 study team 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.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to see if working with a care manager and learning skills and strategies to manage your pain, will improve your quality of life.

WHO IS SPONSORING THIS STUDY/

This study is being sponsored by Atrium Health Wake Forest Baptist/Internal Medicine, Dept. of Rheumatology.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We expect 36 people will take part in this study.

HOW LONG WILL I BE IN THE STUDY?

Your participation in the study is planned to last about six months. Some participants will be asked to provide feedback about the study. This will involve one visit and may be several months after you have completed the study.

WHAT IS INVOLVED IN THE STUDY?

You will be asked to complete three sets of surveys throughout the study. At the beginning of the study, Week 1, at Week 12 and Week 24. The surveys will take about 20-25 minutes to complete. You can complete them online or over the phone. You will also be asked to complete a web-based pain-coping skills training called, Pain-Trainer. This is an automated web-based PCST program that includes eight 35- to 45-minute training sessions over a 12-week period, as well as daily practice sessions, to help you better manage your pain.
You will be randomly placed into one of three groups. After completing the baseline survey, 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) Group one: you will first be assigned to a care manager; you will speak with the manager at least once a month to discuss your health and create a care plan. At Week 12 you will begin web-based pain coping skills training (PainTrainer).We ask that you complete at least one session per week and take time to practice the skills shared in the trainings.
2) Group two: you will begin web-based pain coping skills training (PainTrainer).We ask that you complete at least one session per week and take time to practice the skills shared in the trainings. At Week 12, you will be assigned a care manager. You will speak with the manager at least once a month, to discuss your health and create a care plan. You will continue with the PainTrainer program and practice the skills shared in the program.

3) Group three: you will begin web-based pain coping skills training (PainTrainer).We ask that you complete at least one session per week and take time to practice the skills shared in the trainings

This study will not influence how your primary care doctor chooses to treat your pain. You may continue with whatever you are already doing to treat your pain.

WHAT ARE THE RISKS OF THE STUDY?

The risk of harm or discomfort that may happen by 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.

Taking part in this research study may involve providing information that you consider confidential or private. 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.

As part of this study, you will be asked questions about mental health and or your overall health. You do not have to answer every question you are asked. Yet, if we learn that you or someone else is in danger of harm, the study team must report that information to the proper authorities.

This study is comparing three approved methods for managing your condition. You will be randomly assigned to one of the three groups. It is possible that one group may have a better response than the other. Therefore, there is a risk that you may be assigned to a group that does not perform as well as its comparison.

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. You may experience relief of pain and improvement in quality of life. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study. You can continue to have your pain managed by your primary care doctor.

WHAT ARE THE COSTS?

All study costs, related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

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.

TEXT MESSAGE COMMUNICATION: I give permission to Advocate Health - Wake Forest University School of Medicine, and their respective affiliated entities and representatives (including third-party agents if applicable) to contact me by text message at the number I provided to send information, reminders, and to communicate with me about the research study. I understand that I am responsible for the standard text message rate of my carrier. I also understand that text messaging is not a secure form of communication, and I accept the risk that individuals not involved in the research study may be able to access the text messages. I also understand that texting is not to be used for emergency situations.

EMAIL COMMUNICATION: By providing my email address, I give permission for Advocate Health, Wake Forest University School of Medicine, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid after completing each of the surveys. $25 at Week 1, $30 at Week 12 and $45 at Week 24. If you withdraw for any reason from the study before completion, you will be paid for each survey you completed during your participation in the study.

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.

WHAT IF I AM HARMED FROM BEING IN THE STUDY?

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 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.

WHO WILL SEE MY PROTECTED HEALTH INFORMATION?

To protect the rights and safety of subjects and make sure the study information is correct, employees of Advocate Health -Wake Forest University School of Medicine, including IRB members will have access to your information.
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 remain in the main study.

Dennis Ang, 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 publications or educational purposes, all identifying information will be removed.

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.

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.

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, Dennis Ang, MD at [redacted]. Nights and Weekends, please call [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].

Signatures

- 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 Name: _____

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 **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 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