PainTRAINER Spanish

NCT05917171

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Wake Forest School of Medicine
Research Study Informed Consent Document

Study Title:

Developing and Implementing a Culturally Appropriate Non-Opioid Pain Coping Skills Training Intervention for Spanish-Speaking Hispanic/Latinx Patients with Cancer Pain

Principal Investigator:
Donald Penzien, PhD
[redacted]

Informed Consent Form to Participate in Research for Patients

Summary

You are invited to participate in a research study. The purpose of this research is to see if an internet-based approach (8 sessions of the Internet-based program with education) helps to reduce pain and/or discomfort that are related to chemotherapy treatment. You are invited to be in this study because you are Spanish speaking, identify as Hispanic/Latinx and you have a history of cancer that was treated with chemotherapy and have reported experiencing on-going pain and/or discomfort that is related to your chemotherapy. Your participation in this research will involve 8 visits and last about 10 weeks.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. You will not lose any services, benefits, or rights you would normally have if you chose 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. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the **Principal Investigator, Dr. Donald Penzien 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 Wake Forest University Health Sciences Research Subject Advocate at [redacted]

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer. We are asking you to take part in this research study because you have a history of cancer and have reported experiencing on-going pain and/or discomfort that is related to your cancer or treatment.

This study in being conducted in partnership between Wake Forest School of Medicine, Wake Forest University, and Duke University.

Taking part in this study is your choice.

You may choose to take part in this study, or you may choose not to take part in this study. You also can change your mind at any time and leave the study for any reason. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Please take time to read it. You may talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all of your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

What is this the purpose of this study ?

This study is being done to test an Internet-based Spanish-language pain coping skills training program. This study will help us better understand how this program can help reduce pain and improve how pain impacts the daily lives of cancer survivors.

You have received a cancer diagnosis and have received treatment for cancer treatment, but you still have a persistent pain that is related to your cancer and/or treatment. The purpose of this study is to test a new Spanish-language pain program and to determine if this 8-session Internet-based pain management program can help you better manage your cancer-related pain and/or discomfort.

We don't know if this Internet-based pain management improves pain and/or discomfort in Spanish-speaking cancer survivors with pain, but it has been helpful for reducing pain and/or discomfort in English-speaking patients.

There will be about 40 people taking part in this study.

What is the usual approach for cancer-related pain?

The usual approach for patients who are not in a study is treatment with medications for cancer-related pain that have been approved by the Food and Drug Administration (FDA), one-on-one or group counseling, and/or any other recommendations from your doctor.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.
- You may choose not to be treated for cancer-related pain.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will be asked to complete an Internet-based pain program (PainTRAINER en Español) in addition to your usual care plan for pain. This internet-based program will last for about 8-10 weeks.

You may choose to complete this research study remotely without ever coming to an in-person appointment, though you are invited and encouraged to attend your first study visit in-person. If you choose to complete the program remotely, all study visits will be held on-line over via computer or smart-phone. If you choose to attend the first visit in-person, this visit will be held at a community location (the Clinical Research Unit at Wake Forest University). During the first study visit, you will enroll into the study and complete some surveys about your pain and health. Your next study visit will be after you have completed the 8-10-week Internet-based program. One final visit will be two months after you complete the program. You will complete questionnaires during each visit. Each visit will last about 2 hours. For each visit you complete, you will receive a $25 gift card. After you have completed the 8-10-week Internet-based program, a member of the research team will then contact you to complete a phone interview to talk about your experiences with the program. This interview will be approximately 30 minutes and you will receive $25 for completing this interview.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

If you choose to take part in this study, there is a risk that the Internet-based pain program may not be as good as the usual approach at reducing your pain and improving your pain's impact on daily activities.

There may be some risks that the study doctors do not yet know about.

Benefits

There is evidence that this Internet-based pain program is effective in helping patients cope with pain. It is not possible to know now if this Internet-based pain program will reduce your pain and improve your pain's impact on daily activities compared to the usual approach. This study will help the study doctors learn things that will help people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. If you stop, you can decide if you want to keep letting the study doctor know how you are doing. If you stop, you will be contacted by a member of the research team to participate in an optional phone interview to learn more about your experiences with the Internet-based program and your reasons for stopping the study. This interview will be approximately 30 minutes long and you will receive $25 for completing this interview.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study are no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- The study is stopped by the Institutional Review Board (IRB) at Wake Forest School of Medicine.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What are the study groups?

This study has 1 study group.

If you choose to join this study, in addition to your usual care, you will be provided access to the 8-session Internet-based pain program plus pain education. You will need to complete your sessions within 10 weeks of being provided your log-in code. You will be allowed to revisit sessions that you have completed during this 10-weeks. After completion of the study, you will be provided with on-going access to the 8-session Internet-based pain program.

What exams, tests, and procedures are involved in this study?

If you choose to join this study, you will be expected to complete 8 weekly sessions (40 minutes each) within 10 weeks of being provided access to the Internet-based program. If you do not begin this program within 7 days of getting access, you will be contacted by a member of the research team to see how they can help. Similarly, if you delay more than 10 days between weekly sessions, you will receive a call to check on your progress. You will be given the opportunity to add your cell phone number to the Internet-based program to receive "text" reminders to do your weekly session on your phone. This is optional and can be turned off at any time during the study.

Finally, you will be asked to provide a working email address to ensure you can receive the electronic study forms and gift cards, as well as access to the Internet-based pain program. You will also be asked to provide a phone number in case the research team needs to contact you.

If you choose to take part in this study, you will be asked to fill out forms with questions about your pain, health problems, Internet usage, medication and tobacco use, physical and memory function, emotions and sleep patterns. You will also be asked to complete an evaluation on your experience using the Internet-based pain program. Researchers will use this information to determine if this Internet-based pain program helps cancer patients better manage pain and/or discomfort related to their cancer treatment.

Since these forms are being used for research, the responses you provide will not be shared with your study doctor. If you have any serious health issues or other concerns, please talk with your doctor or nurse right away.

What risks can I expect from taking part in this study?

General Risks

If you choose to take part in this study, there is a risk that the Internet-based pain program may not be as good as the usual approach at reducing your pain and improving your pain's impact on daily activities.

You also may have the following discomforts:

- Being asked sensitive or private questions about things you normally do not discuss.
- You may find completing the surveys about your health or other personal information to be uncomfortable, embarrassing, and/or stressful.
- You may find the 8 sessions of the Internet-based pain program to be uncomfortable and stressful.

The likelihood that any of these discomforts will be encountered is small. The surveys were designed to avoid creating any discomfort, embarrassment, or stress, and most people complete them without having these experiences. Likewise, very few people have said that any part of this Internet-based pain program is uncomfortable or stressful. In nearly every instance, you

will have the option to not provide information you consider confidential or private without it having an impact on your participation in this study.

What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Keep your study appointments or phone calls.
- Tell the research team about:
  - all medications and supplements you are taking
  - any doctors' visits or hospital stays outside of this study
  - if you have been or are currently in another research study

What are the costs of taking part in this study?
There is no financial cost to participate in this study. You and/or your insurance plan will need to pay for the costs of your regular medical care, just as you would if you did not participate in this study. Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical trial. Also, find out if you need approval from your insurance plan before you can take part in the study.

Taking part in this study may mean that you need to make visits to meet with the study team. You may:

- Have more travel costs.
- Need to take more time off work.
- Have other additional personal costs.

The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment. You will get compensation in the form of a gift card for participation as seen below:

- $25 gift card at completion of the initial visit
- $25 gift card at completion of the 10-week visit
- $25 gift card at completion of the 2-month visit
- $25 gift card at completion of the phone interview

Depending on your personal data provider and plan, there may be additional costs to your data plan when using a personal smartphone or tablet device to complete any surveys or Internet-based pain program sessions. The study is not responsible for costs to access or use the Internet for completing study surveys or Internet-based pain program sessions.

What happens if I am injured because I took part in this study?

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-

related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

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: your response to cancer treatment, results of study tests, and medicines you take.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

We will take steps 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 Atrium Health Facilities; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries. The study sponsor and any company supporting the study now or in the future, the NCI and the groups it works with to review research, The National Institutes of Health (NIH) and any researchers and groups it works with now or in the future, including the NIH HEAL Initiative, the study investigator from Wake Forest School of Medicine and his study staff or designees. People Designs, the company that maintains and supports users of the Internet-based pain program, will only have access to information within the program, owners of the Internet-based pain program and designees will only have access to information obtained within the program.

None 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, videotapes, audiotapes, or other recorded media which identify you unless we you're your written authorization.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database or at sites NIH selects for this study. Your data will be stored indefinitely. We will do our best to protect your personal information. Your name and other personally identifying information will be kept with the data during the study, so that we can contact you for study-related activities. Access to your personal health information will be limited to the study PI and designees. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- The study sponsor and any company supporting the study now or in the future.
- The NCI and the groups it works with to review research.
- The National Institutes of Health (NIH) and any researchers and groups it works with now or in the future, including the NIH HEAL Initiative.
- The study investigator from Wake Forest School of Medicine and his study staff or designees.
- People Designs, the company that maintains and supports users of the Internet-based pain program, will only have access to information within the program.
- Owners of the Internet-based pain program and designees will only have access to information obtained within the program.

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

Research gives us the best information and progresses more quickly when data is available from many studies and many individuals, and when many researchers can work with the data and analyze them in different ways. Your stored data will also be made widely available to other researchers. The shared data may be used indefinitely for research not related to this study or the NIH, without asking you for additional consent.

If you withdraw from this research study before it is done, we will keep and continue to use data that have already been collected.

Potential benefits of sharing of data
There is no direct benefit to you from the storage and sharing of your data, but sharing may help researchers learn more about reducing your pain and improving your pain's impact on daily activities and other diseases, which may help you or others in the future.

Risks of sharing data
Even though we will protect your privacy as much as possible, there is a very small chance that the data could be identified as yours. The risk of this happening is very small but may increase in the future as technology changes.

Research using data from this study may lead to new tests, drugs, or devices with commercial value. You will not receive any payment for any product developed from research using your data.

If you do not want your data used for other research, you should not participate in this study.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: [redacted]

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.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact information for the study doctor is below:

At Wake Forest School of Medicine:
Dr. Donald Penzien
[redacted]

[redacted] **Interview**

If you choose to take part in this optional phone interview, you will be asked questions about your experience with the Internet-based pain program and any suggestions you have on improvements. You don't have to answer any question that makes you feel uncomfortable. Researchers will use this information to improve the program by implementing your suggestions. The phone interview will be digitally recorded and transcribed. Transcriptions of the recordings will not include any identifying information. Recordings will be deleted after transcriptions are completed.

Since this interview is being used for research, the responses you provide may not be shared with your doctor. If you have any serious health issues or other concerns, please talk with your doctor or nurse right away.

You will be asked to do a phone interview once after your 10-week visit.

Each interview takes approximately 30 minutes and will take place at a time that is convenient for you. There is a compensation of a $25 gift card for completing the interview. The gift cards will be sent electronically, but an option of mailing will be provided if electronic delivery is not possible.

Please circle your answer: I am willing to take part in the recorded telephone interview if I am selected.

YES NO

My signature agreeing to take part in the study.

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies where I circled "Yes".

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 (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm