Official Title: Initial Testing of a Mobile App Pain Coping Intervention for Outpatient Oncology Settings (PainPac)

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Please read the following information carefully. Please do not skip any sections. If you agree to participate in the research study, you will be asked to indicate this at the end of the document. In order to participate, you as the study participant must give consent. A legally authorized representative or legal guardian may not consent on your behalf.

If you have any questions, please call [study staff] at [study staff phone number].

Consent to Participate in a Research Study
Initial Testing of a Mobile App Pain Coping Intervention for Outpatient Oncology Settings

CONCISE SUMMARY

This study is being done to examine the feasibility (ease and convenience), burden, engagement, and acceptability of a behavioral cancer pain mobile application intervention (PainPac) compared to a therapist-led videoconference-delivered behavioral cancer pain intervention (PCST-Video) in adults with colorectal cancer.

This study will recruit patients from the Duke Cancer Institute (DCI) and be delivered by mobile application (Pattern Health) or videoconference in the participants' home. Participants will complete a baseline questionnaire online, using a mobile application or paper/pencil. Once the initial assessment is complete, participants will be randomized (like a flip of a coin) to receive PainPac or PCST-Video. PainPac will include 4 modules delivered on a mobile application. In each module, participants will learn coping skills that are efficacious for reducing pain in patients with cancer. The mobile application will also include audio and video resources, a place to track symptoms, and will send personalized feedback. PCST-Video will include 4 videoconferencing sessions (45-60 minutes each) with an expert pain therapist that match the content and skills taught in PainPac. Both groups will also complete two additional questionnaires.

The greatest risks of this study include the possibility of loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you have been diagnosed with colorectal cancer. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

If you are interested in learning more about this study, please proceed to the next page.

☐ I have read the concise summary and I wish to continue reading the consent form.
☐ I have read the concise summary and I DO NOT wish to participate in the study.

If the person chooses not to participate, provide a message that says: "Thank you for your time. You have chosen not to participate in this research study. If you have any questions, please contact the research study team by phone at [study staff phone number] or email [study staff email]."

Please tell the study doctor or study staff if you are taking part in another research study.

Sarah Kelleher, PhD will conduct the study and it is funded by the National Institutes of Health. They have paid for the study team to perform this research and these funds may reimburse part of Dr. Kelleher's salary.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, you will not have a different medical doctor. Your regular doctor will continue to be your doctor throughout the time that you are in the study. A member of the study team may be in contact with your doctor throughout the time you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to examine the feasibility of a mobile application intervention (PainPac), when compared to a therapist-led videoconference-delivered behavioral pain intervention (PCSTVideo), for reducing pain and pain-related symptoms in adult patients with colorectal cancer. The PainPac and PCST-Video programs are designed to teach patients coping strategies to help them effectively cope with symptoms of pain.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 60-75 people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form.

You will then complete questionnaires online, using a mobile application, or paper/pencil. The questions will ask about your symptoms (pain), health and well-being, and how you think and feel about your symptom and cancer experience. We expect these questions to take about 15-20 minutes to complete. There are three assessments in total. The first assessment is completed at study enrollment, the second assessment is completed approximately 4 weeks later immediately following your final study intervention session or mobile app module, and the last follow-up assessment is one month after that.

In addition, you will be randomized (like flipping a coin) into one of two groups.

Group 1. PainPac. Participants randomized into this group will receive a message through MyChart, email, and/or text to download a mobile application by Pattern Health designed solely for this study. Participants will self-guide through 4 weekly modules that will teach skills to cope with pain and improve self-efficacy for managing pain. The app also uses real-time data to send personalized messages to participants.

Group 2. PCST-Video. Participants randomized into this group will receive 4 weekly videoconferencing sessions with an expert pain therapist, each lasting about 45-60 minutes. Videoconference sessions will take place from a location convenient to you (e.g., home, work). Each session will match the content in PainPac and teach skills to cope with pain and improve self-efficacy for managing pain. Your sessions will be audio-recorded only and reviewed by Dr. Kelleher and her research staff to better help development of the program. The audio-recording will occur through a local program at Duke and the videoconferencing platform will not have access to the audio-recording.

All participants will continue to receive standard care from their medical team. No participant will be asked to change pain management strategies. Participants will receive instructions for PainPac or PCSTVideo technology, handouts with FAQs and troubleshooting strategies, and contact information for the study team and tech support. Therapists and staff will check in with participants regarding technology usability and tech assistance will be available within 24 hours.

If you do not have one or wish not to use your own, you will be loaned a smartphone. A study team member will instruct you on how to use and care for the smartphone. You will also be provided with written instructions and given a number that you can call for assistance with your smartphone. The smartphone will be programmed with a mobile application designed solely for this study. The mobile application, developed by the study team and Pattern Health, will provide you with access to session content information and other study materials. You will be asked about your use of the coping skills, and to use the study mobile application on the smartphone between sessions to report information about your symptoms and your coping skills practice experience. You will be asked to provide your name, date of birth and e-mail address when creating your personal account for the study app. We ask that you use the smartphone for study related purposes only. You will be asked to complete a post-treatment assessment immediately following your final study intervention session and a follow-up assessment one month later. You will be asked to return the smartphone after completing the study procedures. This will be the last thing you will be asked to do for this study.

HOW LONG WILL I BE IN THIS STUDY?

You will be in the study for approximately 11 weeks. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

WHAT ARE THE RISKS OF THE STUDY?

The risks associated with this study are minimal. There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make

you feel uncomfortable. You may refuse to answer any of the questions. Discussing stressors associated with your symptoms may be upsetting. You also have the option of not discussing concerns you find upsetting.

If you are loaned a Duke smartphone for use during this study and you use it for non-study related reasons, this could add your personal information onto the device and potentially result in it being sent to unauthorized persons. The device will be preset with security settings. Please do not alter these during the course of the study. When you return the device at the end of the study, the device will be cleaned to remove any of your personal information. If the device is lost or stolen during the course of the study, please contact the study team immediately. There is some risk of loss of confidentiality due to the use of videoconferencing to conduct the intervention sessions. A cloud for video and audio conferencing that will be used for the Zoom is not a secure form of communication. Zoom is a third-party provider, and no contract exists between Duke and Zoom for its use in this study. The security of any information communicated via Zoom cannot be assured. You may stop your participation in this study at any time.

Risks Specific to Mobile Apps: Information collected by mobile applications or 'apps', including Pattern Health, is subject to their terms of use, which you should read carefully. Many apps claim that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Duke. You are encouraged to limit personal identifiers you enter into mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to those that you wish to voluntarily share with others. These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Facebook). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully.

It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (e.g., battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. At the conclusion of the study, we will provide you instructions on how to remove the mobile app from your device.
We are not asking you to make any health decisions based on the use of these mobile apps. You should discuss health decisions directly with your healthcare provider.

As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct benefits to you. You may find that your participation in the study intervention improves your symptoms of pain and your overall quality of life. We also hope the information learned from this study will benefit other patients with cancer.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. Kelleher's office located at [redacted]. All audio-recordings will be stored on an encrypted laptop and will be available only to authorized study personnel as necessary to review the content of the sessions. All audio-recordings will be destroyed at the end of the study.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include the Duke Office of Audit, Risk and Compliance, Duke University Health System Institutional Review Board, and Duke Cancer Institute. If your research record is reviewed by this group, they may also need to review your entire medical record. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1. there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2. you have consented to the disclosure, including for your medical treatment; or
3. the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

As part of this study, Dr. Kelleher and her study team will ask you to complete assessments. Results of the assessments are done solely for this research study and not as part of your regular care will not be included in your medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?

There will be no costs to you as a result of being in this study.

WILL I BE PAID TO BE IN THE STUDY?
You will receive $30 for completing each of the three major study assessments. Total compensation may be up to $90. If you choose to withdraw from the study, you only will receive compensation for the parts of the study that you completed. In order to issue your payment, Duke University may need to collect your name, mailing address, and social security number for tax reporting purposes. If you do not want to provide this information, you cannot be paid but you can still take part in the research study.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center or your local community hospital emergency room in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury. For questions about the study or research-related injury, contact Dr. Kelleher at [redacted] during regular business hours or by page at [redacted].

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes except to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Kelleher in writing and let her know that you are withdrawing from the study. Her mailing address is Sarah Kelleher, PhD, [redacted].

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

If you choose to withdraw from the study, your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law. This Web site 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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Kelleher at [redacted] during regular business hours and at [redacted] after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

- □ I have read the consent document and I wish to participate in the study.
- □ I have read the consent document and I DO NOT wish to participate in the study.

If the person chooses to participate, provide a message that says "You have indicated that you will participate in this research study. Please confirm by entering the information requested below." *(asked to provide first name, last name, date of birth, signature, date of consent, email address).*

Click here to download a copy of the consent form.

If you have any questions or concerns about the study, please contact the research study team by phone at [study staff phone number] or email [study staff email].