Institutional Review Board
Informed Consent Document for Research
MASTER INFORMATION SHEET

Study Title: RESOLVE
Version Date: 12/28/2022

Part 1 of 2: MASTER INFORMATION SHEET

You are being invited to take part in a research study. This study will take place at several different locations. Therefore, this information sheet includes two parts. Part 1 is the Master Information Sheet and includes information that applies to all study sites. Part 2 is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are part of the informed consent process and must be provided to you. You can complete the informed consent process online or over the phone with a study team member. You will have the opportunity to ask questions on the phone. If you are completing the informed consent process online, you can call the study to ask questions. You will be asked to give your consent after you have had the opportunity to ask questions.

Researchers
This study is led by Lynn DeBar, PhD, Kaiser Permanente Northwest

Funder
The RESOLVE study is funded by the National Institute on Aging.

Key information about this study:

RESOLVE is a research study that will compare three different services to help patients learn skills to manage pain. These services include a printed resource guide, access to an online training program, or access to a training program with a live coach who would meet with you by phone or video. The skills taught in the online and telephone programs are based on Cognitive Behavioral Therapy, or "CBT," a type of therapy that helps people think about and respond to challenging situations, like having chronic pain. If you join the RESOLVE study, you will be assigned randomly to get one of these three services. There will be no cost to you to receive the services. We will collect some information from your medical record about care provided to you. We will also ask you to complete five surveys and up to two interviews over the next year. You will be in the study for 12 months. While you are in the study, you can use any treatments or services recommended by your doctor. About 2,400 people will take part in this research study.

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Being in this study is up to you. If you decide not to be in this research study, or drop out later, it won't affect the health care you receive or benefits you are entitled to. If you join, you can stop being in this study at any time.

Risks that you can expect if you take part in this study:

You might feel uncomfortable answering some study questions. You may skip any questions you don't want to answer.

You might feel uncomfortable practicing new pain management skills. For example, it might be challenging to change your thoughts or behaviors related to your pain; or, it might be hard to change physical activity patterns.

It is possible that someone other than the researchers could find out you were in the study or see your private study information. The steps we take to keep this from happening are described in Part 2 of this information sheet.

Positive effects that might result from this study:

We cannot promise any direct benefits to you or others by taking part in this research. However, some people who received the pain management tools used in this study experienced improvements in their pain.

Procedures to be followed:

If you are interested in being in this study, we will ask you to answer a few questions over the phone or online to find out if you are eligible. Some of the questions are on sensitive topics such as substance use. You don't have to answer any questions you don't want to. However, without your answers we won't know if you are eligible to join the study.

If you join the study, we will ask you to:

- **Complete a baseline survey** that will last about 30-45 minutes (survey #1). You will do the survey as soon as you join the study. You can choose to complete it over the phone or online. The survey will ask questions about your pain and how it affects your life. Some of the questions are on sensitive topics such as mental health and substance use. You can skip any question you do not want to answer.

Be randomly assigned to get 1 type of service over the course of 8-12 weeks. After you complete the baseline survey, a computer will randomly assign you to 1 of 3 study "groups" – like a coin toss or like drawing straws. Each group gets only 1 of the 3 services for pain management offered in the study. You have an equal chance of being placed in any 1 of these 3 groups. You cannot choose which group you will be in. We will mail you a packet about a week after the baseline survey to tell you which group you are in. You also cannot change the group after you've been assigned.

- **Group 1** will be mailed a printed resource guide on managing chronic pain. If you are assigned to this group, you would read and use the guide on your own.

- **Group 2** will receive access to an online training program. The skills taught in the web-based program are based on Cognitive Behavioral Therapy, or "CBT," a type of therapy that helps people think about and respond to challenging situations, like chronic pain. There are 8 sessions in the online program and each session takes about 45-60 minutes. If you are assigned to this group, you would complete one session each week and have 12 weeks to complete all 8 sessions.
    - In addition, you would need to register on the program website with an email address and accept the Terms and Conditions and Privacy Policy. The website will track your online activity and record when you log in. If your internet or mobile phone service requires you to pay for the data you use, using the online program may result in data usage fees from your service provider. The program uses a minimal amount of data.

- **Group 3** will receive access to a telephone training program with a live coach who teaches CBT skills. There are 8 sessions in this training program and each session would take about 60 minutes. If you are assigned to this group, you would complete on session each week and have 12 weeks to complete all 8 sessions. You can choose to use video with the telephone calls or use only voice with the telephone calls.
    - In addition, we will ask for your permission to audio record the telephone-only sessions or video record the video sessions. The recordings will be used for quality and training purposes. You can still participate in the sessions even if you do not agree to have the

conversation recorded. If your internet or mobile phone service requires you to pay for the data you use, joining the video calls may result in data usage fees from your service provider.

- **Complete a brief paper survey** that will take about 5 minutes (survey #2). It will come with the mailed packet you get telling you which group you are in. This survey should be completed right away and mailed back in the pre-paid envelope provided.

- **Complete 3 follow-up surveys** about 3 months, 6 months, and 12 months after you join the study that will take about 30 minutes each (surveys #3, 4 and 5). You can choose to do the surveys over the phone, on paper, or online. The surveys will ask questions about your pain and how it affects your life. Some of the questions are on sensitive topics such as mental health and substance use. You can skip any question you do not want to answer.

- **Let us collect some information from your medical record about health care provided to you for the past year and for the 12 months that you are in the study.** This will help us better understand how well the program works and the costs of health care services you use. We won't look at the notes your doctor writes or any bills sent to you or payments you've made. Instead, we will use a computer to collect information on the health services you use and calculate the typical costs of those services. We will collect information about all doctor visits, trips to the hospital, medications (including opioid and other pain medications) and diagnoses (including behavioral health diagnoses.) We will also collect information about you, including your age and ethnic background. Your medical record information will be linked with your survey answers.

- About 120 of the 2,400 people who participate in the study will be selected to complete up to two, optional, **hour-long telephone interviews** about their experiences with pain management and being in the study. You may not be selected, and if you are, you don't have to be interviewed.

You will receive Amazon gift cards to thank you for the surveys and interviews you do. These are the amounts you can receive.

- **Baseline survey:** $25
- **3-month survey**: $30 if done by phone or paper; $35 if done online

- **6-month survey**: $35 if done by phone or paper; $40 if done online
- **12-month survey:** $40 if done by phone or paper; $45 if done online
- **Interviews**: $30 per interview (up to two interviews)

Clinical Trials Registry

A description of this clinical trial is available on 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 website at any time. [ClinicalTrials.gov Identifier: NCT04523714]

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STUDY SITE INFORMATION- EH

Part 2 of 2: STUDY SITE INFORMATION

Site Name:	Essentia Health
Site Principal Investigator:	Irina Haller, PhD, MS
Site Principal Investigator Contact:	218-786-8185
Site Study Coordinator	Krystal Klicka, MPH
Site Study Coordinator Contact	218-576-0082

This part of the consent form includes information about the site that is asking you to participate in this study and is specific to participation at your site only. Before making your decision, both the site-specific information and the general study information should be reviewed with you.

Who to call for any questions:

Please call the study coordinator at Essentia Health, Krystal Klicka, at (218) 576-0082.

For questions about your rights as a research participant, please contact the Human Protections Administrator for Essentia Health at (218) 786-2540.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Medical Center Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

If you have questions about your rights as a study patient, refer to the "Bill of Rights for Study Patients" document included with this Part 2 of 2: Study Site Information form.

Protecting your confidentiality

This study is led by researchers at KP Washington, KP Northwest, KP Georgia, and Essentia Health. They are listed on Part 1 of this information sheet. This study also includes researchers at Northwestern University who manage the online coaching program and researchers at the University of Utah who manage the study database These researchers each signed a pledge at their institution that requires them to keep your information private.

The researchers and their staff will use your study information for research only. All identifiable information will be stored in password-protected systems behind security firewalls, and only approved study staff will receive access to the information.

The researchers are involved in different parts of the study. So, your study information will be stored in different places.

- Research staff at KP Washington or KP Northwest will have **your contact information**. They will communicate with you if you are placed in the online coaching group or the telephone coaching group. They will also communicate with you to complete surveys and interviews.
- **Your survey answers** will be entered into a secure website and stored on secure servers at KP Northwest and the University of Utah.
- **Your medical record information** will be linked with your survey answers and stored on secure servers at KP Northwest and the University of Utah.
- **Audio and video recordings** will be stored on secure servers at KP Northwest and KP Washington.
- **Interview transcripts** will be stored on secure servers at KP Northwest.
- If you are placed in the online coaching group, information about **your activity on the website** will be stored on secure servers at Northwestern University, KP Northwest, and the University of Utah.

We won't use your name in study reports or write it on your survey answers or audio and video recordings. Instead, we will label everything with a code number only.

We will not tell your doctor whether or not you join this study or add information to your medical record. If you would like to tell your doctor that you are in the study, we encourage you to do so.

We plan to keep your study information as described in this form until August 31, 2027. At that time, we will destroy any study records with identifiable information.

Your information may be used or distributed for future research studies without your additional informed consent. To protect your privacy, identifiers will be removed.

Certificate of confidentiality
We have a Certificate of Confidentiality from the National Institute on Aging. This helps us protect your privacy. The certificate means that we do not have to give out identifying information about you, even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

In certain situations, we would not be able to keep your information confidential. The law requires us to report in cases of a medical emergency or serious threats of harm to you or others.

Using email
We will ask you for your email address. You do not have to give us your email address. However, if you are placed in the online coaching group, you will need to use your email address to register for the website. Information shared by email is not considered secure. We cannot guarantee the privacy of email, and we will be careful to limit the amount of personal information included in messages we send you. These are the kinds of information we will send you by email:

- Schedule study appointments
- Send reminders for study appointments and surveys
- Send electronic gift cards for completing surveys and interviews
- If you are placed in the online coaching group, links to the website
- If you are placed in the telephone coaching group and want to do a video call, links to video calls

Texting

- If you are placed in the telephone coaching group, research staff may use a study cell phone to text you if they have not been able to reach you using other methods (phone call, email or letter).

Authorization to use/disclose protected health information
The Health Insurance Portability and Accountability Act (HIPAA) requires protection of your health and medical information so that it is kept as private and confidential as possible. Protected Health Information (PHI) is any health information that identifies you. It includes information collected about you as part of this study and health information that is stored in your medical record.

How HIPAA applies to this study
KP Washington, KP Northwest, KP Georgia, Essentia Health, Northwestern University, and the University of Utah must follow this privacy law. According to HIPAA, the information collected by the researchers for this study is part of that protected health information.

The HIPAA privacy law does not always apply to those who are given protected health information. Once Essentia Health and/or KP Washington has given out health information, the person who receives it may re-disclose it. Privacy laws may no longer protect the information.

Individual Health Information to be Used or Disclosed
By agreeing to participate in this study, you are giving KP Washington, KP Northwest, KP Georgia, Essentia Health, Northwestern University, and the University of Utah permission to allow the researchers to collect, use, and share the following information about you for this study:

1. Your survey and interview answers
2. Your medical record information as described in Part 1 of this information sheet
3. If you are placed in the online coaching group, your activity on the website

It is possible that staff from KP Washington, KP Northwest, KP Georgia, Essentia Health, Northwestern University, University of Utah, and the funding agency may look at our study records for oversight. We will not share the information we collect for this study with anyone else except as allowed by law.

In order to be in the study, you must agree to this use of your health information. This permission for the researchers to obtain your health information for this study ends on August 31, 2027.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits.

Purposes for using and/or sharing your health information
Your health information may be used and/or shared to:

- Confirm that you are eligible to enroll in a study.
- Conduct the study and make certain that the study is being carried out properly.
- Ensure that the information collected during the study is accurate and complete.
- Analyze the study results.
- Protect your safety and rights as a research subject.
  Bill responsible parties for services or procedures related to your participation in the study (if applicable).

Right to refuse to give authorization (permission)
You do not have to agree to participate in this study. If you decide not to give your authorization, you will not be able to take part in this research study or receive any research-related treatment provided through the study. Your decision will not affect any other treatment, payment, health plans, or eligibility for benefits.

Right to revoke your authorization (permission)
You can change your mind and revoke (withdraw) your authorization at any time. If you revoke your authorization in the future:

- The researcher may use and disclose the protected health information already collected for this research study, but no more information will be added to the research records.
- You will not be allowed to continue to participate in the study.

To withdraw your authorization, you must notify the researcher in writing to inform him or her of your decision. If you wish to revoke your authorization, send a letter to the researcher at the address below:

Irina Haller, PhD, MS
502 East Second Street
Duluth, MN 55805
P: (218) 786-8185

When access to your information may be limited

You have the right to see and copy your medical records and PHI related to this study for as long as the study team or institution holds this information. But to ensure the scientific integrity of the study, you may not be able to see or copy some of the study information until after the study has been completed. (When the study is over, you will have the right to access the information again.) The Notice of Privacy Practices available in the hospital, clinic, or office where the research is being conducted provides general information on your rights to review, copy, and correct your health information.

Expiration

This authorization to use and share your PHI in connection with this study ends August 31, 2027.

Bill of Rights for Research Participants

As a participant in a research study, you have the following rights:

- To have enough time to decide whether or not to be in the research study.
- To make your decision without any pressure from the people who are conducting the research.
- To refuse to be in the study at all and to stop taking part at any time after you begin the study.
- To be told what the study is trying to find out, what will happen to you and what you will be asked to do if you are in the study.
- To be told about the reasonably foreseeable risks or discomforts of being in the study.
- To be told about the possible benefits of being in the study.
- To be told whether there are any costs associated with being in the study and whether you will be compensated for participating in the study.
- To be told who will have access to information collected about you, how the information will be used, and how your confidentiality will be protected.
- To be told who can answer questions about the research, about research-related injuries, and your rights as a research subject.

<u>If the study involves treatment or therapy</u>:

- To be told about the other non-research treatment choices you have.
- To be told where treatment is available if you have a research-related injury and who will pay for the research-related treatment.

You will receive a copy of this form.