Pilot study of feasibility and acceptability of PREVAIL

NCT number NCT06706999
Document Date 05/20/2025

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: May 20, 2025
IRB Study # 24-1195
Title of Study: Pilot study of feasibility and acceptability of PREVAIL
Principal Investigator: Louise Thoma, PT, DPT, PhD
Principal Investigator Department: Division of Physical Therapy, Department of Health Sciences
Principal Investigator Phone number: (919) 843-7317
Principal Investigator Email Address: louise_thoma@med.unc.edu
Principal Investigator Address:
3041 Bondurant Hall, CB# 7135
The University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-7135

Funding Source and/or Sponsor: National Institutes of Health (NIH)

CONCISE SUMMARY

Physical therapy (PT) and exercise are widely known to improve overall health and help us participate fully in our daily activities, but are not always discussed in rheumatology care for adults with rheumatoid arthritis (RA). Our PREVAIL model of care will fill a critical gap in care by creating a system for referring RA patients to PT when appropriate and providing exercise guidance through tailored resources. This study will serve as the first step of many towards using PT and rehabilitation to help preserve function and delay disability in adults with RA.
There are three main components to the PREVAIL model of care:

1. **Screening tool.** This helps clinicians determine which patients to refer to PT. For our study, you will be asked to complete an electronic questionnaire (The Daily Activity and Participation Screen) before your routine rheumatology visit.
2. **Recommendation.** Based on your answers on the "Daily Activity and Participation Screen", your rheumatology clinician will provide you with an exercise resource and may also recommend a consultation call with a physical therapist.
3. **Exercise Resource.** For our study, you will be provided with exercise resources that are specific for adults with RA. A collection of exercise recommendations (videos, websites, documents, etc.) tailored to adults with RA will be available at a website.

For study purposes, we will collect baseline assessments prior to your routine rheumatology visit and follow-up assessments 3 months later. These assessments include questions related to RA-related pain, function, and ability to participate in physical activity, exercise, and other daily tasks.

The follow-up assessments will also include questions about your experience and perspectives with the PREVAIL model of care, and you may be asked to elaborate on your experience in an interview.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You can request to get a call from the research team to ask any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to determine the feasibility and acceptability of the PREVAIL model of care, which integrates PT and exercise recommendations into routine clinical care for adults with rheumatoid arthritis.

You are being asked to be in the study because you are over the age of 18, have a prior diagnosis of rheumatoid arthritis, and attend routine clinic visits with your rheumatology clinician at UNC.

Are there any reasons you should not be in this study?

You should not be in this study if you have a condition that restricts your ability to complete surveys and patient reported outcome measures (e.g., memory loss, dementia) or are unable to speak English. You should not participate if you are currently participating in another study related to RA, currently in PT, have been to PT or had surgery in the last 6 months, or plan to have surgery at any point during the duration of the study.

How many people will take part in this study?

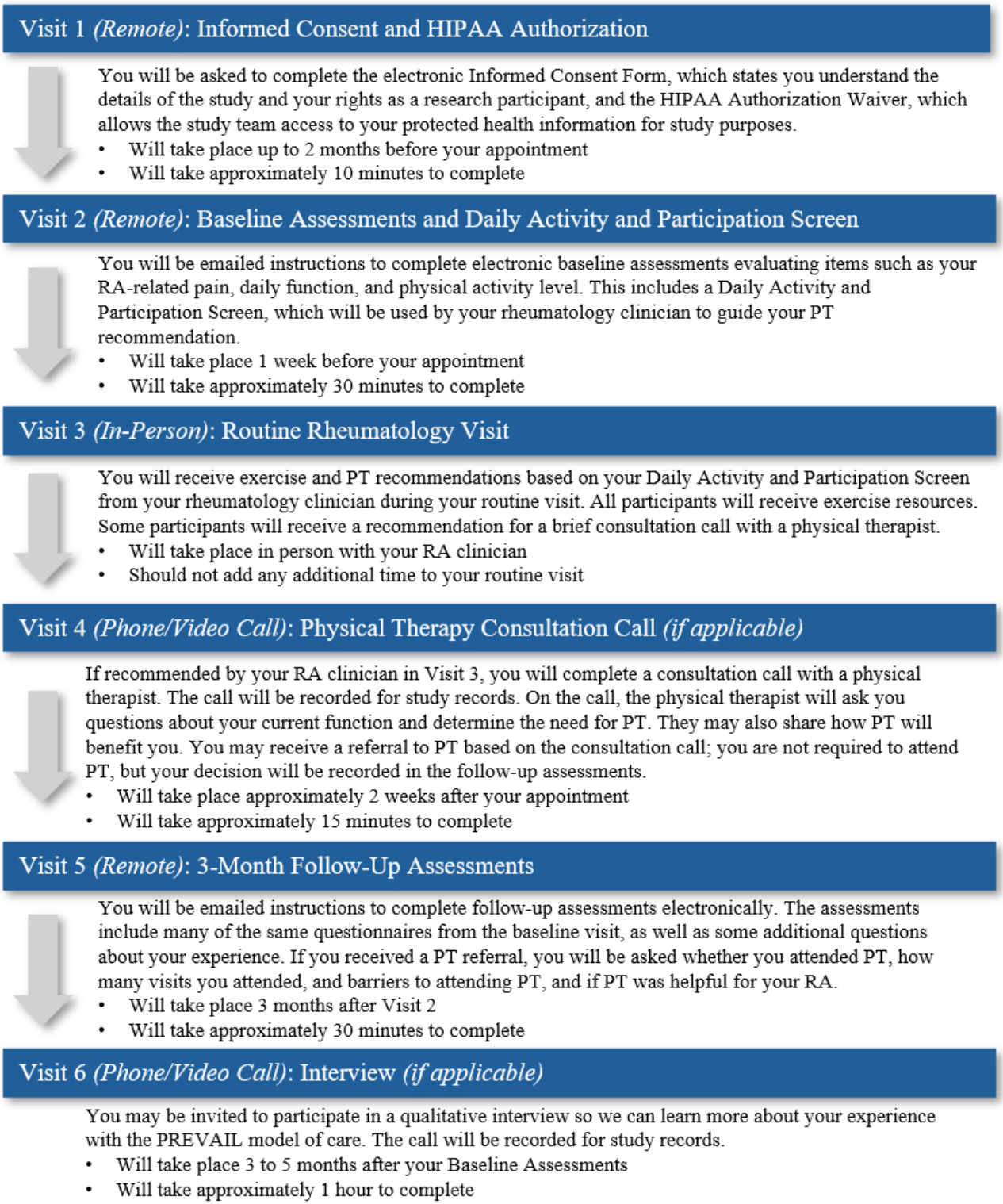
Approximately 50-75 people who receive care within UNC Rheumatology Clinics will take part in this study.

What will happen if you take part in the study?

The steps of participating in the study are outlined in the figure below. Visits listed as ‘Remote’ will be completed electronically on your personal device (phone, tablet, computer). The only visit in person will be your routine rheumatology visit as previously scheduled. Visits listed as

'Phone/Video Call' will take place either on the phone or over Zoom during a designated time. Both 'Phone/Video Call' visits will be recorded for study purposes.

Figure 1. Study Flow Diagram



How long will your part in this study last?

If you decide to participate, you will be enrolled in this study for approximately 4-6 months. You are considered "enrolled" after the completion of this Informed Consent Form and the HIPAA Authorization. Your active participation includes the baseline assessments 1 week before your routine RA appointment, the in-person appointment with your rheumatology clinician, and the 3-month follow-up assessments. Study duration may be longer depending on how soon before your RA appointment you were contacted and whether you are invited to participate in an interview after completing your follow-up assessments. All study visits will take place either in your UNC Rheumatology clinic or electronically on your personal device (phone, tablet, computer).

What are the possible benefits from being in this study?

Participants may experience improvements in pain, physical function, or other symptoms related to RA from following through with exercise and/or PT recommendations. It is possible that this study may not benefit you directly, but participation may lead to information that can benefit other patients with RA and their clinicians.

What are the possible risks or discomforts involved from being in this study?

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

i. **Physical risks.** You will be provided with an exercise resource and potentially a PT referral. Both recommendations will be tailored to people with RA and how you utilize these resources is up to you. However, exercise may be associated with risk of injury, muscle soreness, and temporary joint pain. In general, the risk of these events with moderate physical activity is very low.
ii. **Psychological, social, or cultural risks.** We do not anticipate any psychological, social or cultural risks associated with participation in this study. Study assessments include patient-reported measures of pain, function, fatigue, activity, as well as other demographic and clinical characteristics. It is possible that some participants may feel uncomfortable answering some of these questions. You may refuse to answer any questions and remain involved in the study. You may stop your participation in the study at any time. We will only ask you questions that are necessary for the study.
iii. **Financial or legal risks**. There are no financial or legal risks associated with this study.
iv. **Risk to privacy and/or confidentiality.** We will be collecting some elements of personal health information (PHI) necessary for the study. To minimize breaches of confidentiality, all data will be stored on a secure UNC server or a UNC Institutional Review Board (IRB) approved platform for sharing PHI. Only approved study personnel will have access to this data. PHI will only be shared with approved study team members; any information shared among study team members will be done by phone, encrypted email, or UNC IRB approved platform for sharing PHI.

If you choose not to be in the study, what other treatment options do you have?

Your decision to be in this study does not impact your routine RA care. You do not have to be in this research study to receive treatment.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect

your willingness to continue your participation.

How will information about you be protected?

We will only collect protected health information (PHI) to be used for study purposes. Certain data will be pulled from electronic medical records during baseline assessments to minimize the number of questionnaires for participants. All data will be stored electronically on REDCap, a secure web application for managing online surveys, and not on individual devices. Data will only be accessible to IRB-approved key personnel that require access to the data to perform study functions. Data will be de-identified for storage. There will be one key file that links the study identification with the personal identifier; this file will only be accessible to IRB-approved key personnel that require access to the data to perform study functions.

Participants will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent. A description of this clinical trial will be 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.

Audio and video recordings will be collected during the PT consultation call (Visit 4) and qualitative interview (Visit 6). This is to provide the study team with as much information as possible on the usefulness of the PREVAIL model of care. These recordings will be kept on a secure UNC server, only accessible to the IRB-approved key personnel, and labeled only by your study identifier. You have the option to opt out of these recordings. If you opt out of being recorded during this study, you will not be invited to participate in the qualitative interview.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety. You will be asked to sign a separate form ("HIPAA Authorization") to allow researchers to review your medical records.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt or become sick, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries/illnesses, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will receive a $25 gift card after the baseline assessment and a $25 gift card after the follow-up assessments. If you are selected for an interview, you will receive a $50 gift card after the interview is complete.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by the Institutional Review Board (IRB), a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the IRB at 919-966-3113 or by email to IRB_subjects@unc.edu.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form. If you would like to discuss the informed consent process, or are unsure if you understand everything stated above, you have the option to request a call with the study team to complete the consent process instead.

(After reviewing this form, please return to REDCap and complete the 'Informed Consent Form Review'. You will be asked if you would like to proceed, are no longer interested, or would like to request a call with the study team before continuing. If you choose to proceed, you will be directed to a short assessment of the key points of this document.)