Official Title: MyVoice Pilot Study : A Pilot Study to Assess Feasibility and Acceptability of MyVoice, a Family Planning Decision Aid for Women with Rheumatic Diseases – Protocol for Research Staff

Brief Title: MyVoice:Rheum Decision Aid for Women With Rheumatic Diseases

NCT Number: NCT04879745

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MyVoice Pilot Study

A Pilot Study to Assess Feasibility and Acceptability of MyVoice, a Family Planning Decision Aid for Women with Rheumatic Diseases

PittPRO ID: STUDY20060240

Full Research Protocol for Study Staff
Version II – August 23, 2021

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Contents

Statement of Compliance

The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator or Clinical Site Investigator:

Signed: _____ Date: _____

Name*: Mehret Birru Talabi

Title*: Assistant Professor of Medicine

Investigator Contact Information

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A. Study Aim

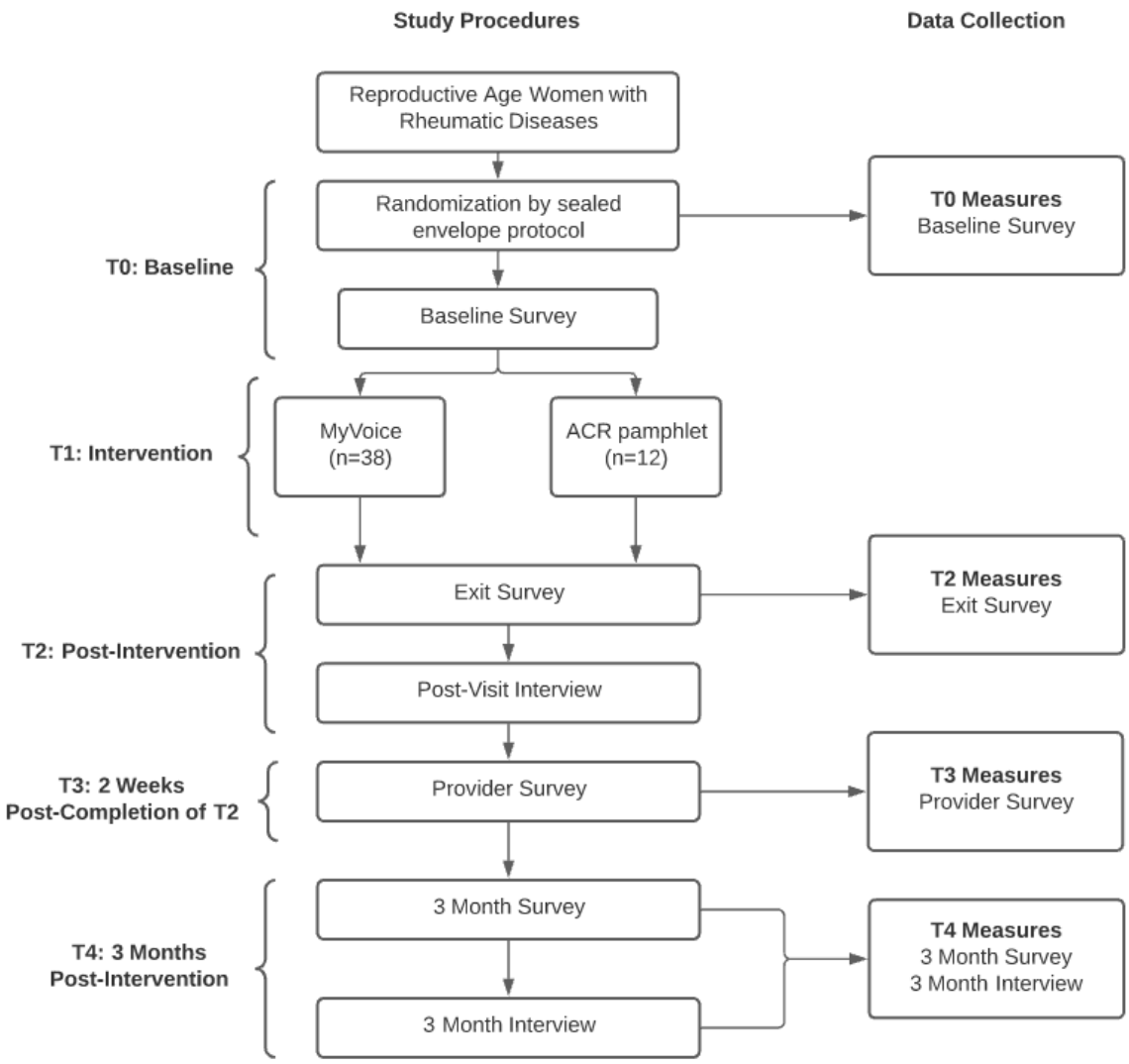
MyVoice is a web-based patient-centered decision aid developed to help women with rheumatic diseases make informed decisions about pregnancy and other family planning decisions. This pilot trial is designed to assess the extent to which MyVoice decision aid can be feasibly and acceptably implemented into the rheumatology clinical setting and will inform operational procedures for a future hybrid effectiveness-implementation trial. Women in the intervention arm will receive the MyVoice decision aid (n=38). Women in the control arm (n=12) will receive a paper-based version of the American College of Rheumatology pamphlet about pregnancy, which, similarly to MyVoice, targets women with a broad range of rheumatic diseases.

B. Protocol Summary

Title:	A Pilot Study to Assess Feasibility and Acceptability of MyVoice, a Family Planning Decision Aid for Women with Rheumatic Diseases
Grant Number:	K23 AR075057-01A1
Study Description:	This protocol describes procedures and goals for the pilot testing of MyVoice, a web-based decision aid to help women with autoimmune diseases clarify their reproductive goals and learn about if and how their autoimmune diseases and medications affect these goals. Primary hypothesis: MyVoice will be feasible and acceptable to patients who receive rheumatology care.
Objectives*:	Our aim is to conduct a pilot trial to assess feasibility and acceptability of MyVoice vs. a patient pamphlet among female patients ages 18-44 (n=55) who receive rheumatology care.
Endpoints*:	Feasibility measures: -Number of women who express interest in the study vs who are contacted -Number of women who enroll vs. decline to participate -Completion rates for MyVoice -Technical feasibility (e.g., software reliability of MyVoice) -Number of consented women who complete the study vs. number of consented women who partially complete the study or do not open or utilize the study materials Acceptability measures: -Completion rates for MyVoice -Patients' satisfaction with MyVoice or pamphlet -Patients' comprehension of instructions, scales, and surveys -Completion rates for instructions, scales, and surveys Preliminary implementation measures: -Surveys of barriers/facilitators of use -Survey of physicians' readiness to adopt the intervention in clinic -Technical issues with video visits/Epic -Number of patients who no-show for their telemedicine visits
Study Population:	We will recruit 55 women aged 18-44 who are diagnosed with rheumatoid arthritis, myositis, systemic sclerosis, or systemic lupus erythematosus who receive care at one of three UPMC rheumatology clinics. Participants cannot be pregnant and cannot be sterilized.
Phase* or Stage:	Phase II
Description of Sites/Facilities Enrolling Participants:	Participants will be recruited from the UPMC Falk Rheumatology Clinic, the Lupus Center of Excellence, and the Magee Women's Health Rheumatology Clinic.
Description of Study Intervention/Experimental Manipulation:	Interested individuals will arrive at the clinic one hour prior to their scheduled rheumatology appointment. They will be consented and randomized to either receive the intervention (the MyVoice decision aid, an interactive website) or to receive the control pamphlet. They will have approximately 40 minutes to review the tool or pamphlet prior to meeting with their rheumatologist.

Study Duration*: Nine months
Participant Duration: Two hours.

C. Study Flow Chart and Randomization Schema



Below is a detailed description of the data in each survey [Appendix] collected at each time point.

T0: Baseline Survey

- National Survey of Family Growth Family Planning Services Question
- COLLABORATE shared decision-making scale
- Self-efficacy (Perceived Efficacy in Patient-Provider Interactions [PEPPI])
- Reproductive knowledge (ReproKnow)
- Desire to avoid pregnancy scale (DAP)
- Demographic questionnaire

T2: Exit Survey

- Acceptability and implementation measures for the MyVoice tool
- Reproductive knowledge (ReproKnow)
- Self-efficacy (Perceived Efficacy in Patient-Provider Interactions [PEPPI])
- Decision Conflict Scale (Low Literacy version)
- Interpersonal Quality of Family Planning (IQFP) Scale

T3: Provider Survey

- Providers' experiences with the study as well as information related to encounters with patients enrolled in the study

T4: 3 Month Survey

- National Survey of Family Growth Family Planning Services Question
- Self-efficacy (Perceived Efficacy in Patient-Provider Interactions [PEPPI])
- Reproductive knowledge (ReproKnow)
- London Measure of Unintended Pregnancy

D. Risk/Benefit Assessment

Known Potential Risks

- Discomfort- Study activities involve information regarding reproductive health; some individuals may be uncomfortable discussing this topic.
- Invasion of Privacy- Participants may feel uncomfortable discussing their reproductive health where other individuals may hear them.
- Breach of Confidentiality- Any possibility that de-identified information could be viewed by unauthorized parties.

Known Potential Benefits

- This pilot study will inform the procedures and practices related to a future full-scale testing of a patient-facing decision support tool for family planning. Our study team and others have demonstrated that women with rheumatic diseases do not receive adequate family planning care. We will not directly counsel patients about their particular risks, and therefore, patients will not receive a direct benefit from their participation. However, they may learn more about their family planning options in the context of their diseases.

Assessment of Potential Risks and Benefits

- Discomfort- We will minimize occurrence of discomfort by being clear about the content of the study tool and assessment measures during recruitment. All questions in study surveys and interviews will be optional, and participants will be told they can skip any question they do not wish to answer.
- Invasion of Privacy- The study will not be discussed with potential or current participants in public settings. Conversations about the study will only occur in private exam rooms or research spaces or via email or phone conversations. We will minimize risk by placing phone calls while in a private room and asking the potential participant whether they are in a private location before discussing the study.
- Multiple steps will be taken to prevent any breaches in confidentiality, including not recording patients' names or linking their names to their assessments. All study data collected from the participants will be assigned a numerical code in order to de-identify it and minimize the risk of a breach of confidentiality. will minimize the severity of the potential risks by not asking for highly personal or sensitive information in the assessment or demographic survey.
- Every step will be taken to avoid or minimize the above risks. Because this is a minimal risk study, we feel the potential benefits of the study outweigh the outlined risks. We will remind participants that they can withdraw from the study at any time.

E. Screening Procedures

C1. Eligibility Criteria

C1a. Inclusion Criteria

Participants are eligible to participate if they meet the following criteria:

- Diagnosed with at least one of four rheumatic diseases diagnosed by a rheumatologist: rheumatoid arthritis (RA), systemic sclerosis (SSc), myositis, and systemic lupus erythematosus (SLE).
- Enrolled in a disease registry for RA, SSc, myositis, or SLE
- Female sex assigned at birth
- Age 18-44 (reproductive age as described by the Centers for Disease Control and Prevention)
- Able to read and speak English
- Access to a smartphone, personal computer, or tablet

Rheumatology providers are eligible to participate if they meet the following criteria:

- Rheumatologist who sees patients in the UPMC system

C1b. Exclusion Criteria

Participants are ineligible to participate if they meet any of the following criteria:

- Prior hysterectomy or sterilization
- Currently pregnant
- Do not have access to a smartphone, personal computer, or laptop
- Do not see a rheumatologist in the UPMC system

F. Recruitment Plan

Due to the current COVID-19 pandemic, we anticipate that some potential participants will be completing their medical visits remotely via video with their rheumatologists. To ensure that all eligible potential participants are given equal access to our study and to reduce potential bias in only recruiting participants who are willing or able to come to the rheumatology clinic in person, we will offer both remote (telemedicine) and in-person (clinic) study participation and will recruit both remotely and in clinic.

Although enrollment, randomization, and all non-exploratory outcome measures are occurring in one day, we anticipate some possibility of attrition. Therefore we will recruit a maximum of 55 participants with the goal of 50 participants completing the aforementioned activities. This is a pilot study; therefore, outcomes are primarily related to feasibility and acceptability. Furthermore, we have no sample size calculations in this proposal for which we need to account for participant attrition.

D1. Recruitment Tracking

This section describes the protocol for tracking potential participants through the recruitment process.

All recruitment documentation and tracking will take place in the "Recruitment Tracking" spreadsheet in SharePoint. After screening for eligibility in the clinic schedules, research coordinators will enter all patient information into the "Approaching in Clinic" tab. The following information will be documented:

- Name
- Appointment Date
- Appointment Time
- Provider
- Age
- Disease diagnosis

Research coordinators will enter potential registry participants into the "Registry Enrollees" tab of the spreadsheet with the same information entered.

Research coordinators will enter potential participants into the recruitment spreadsheet in the "Interested" tab immediately upon expressing interest in study participation. The following information will be documented in SharePoint:

- Name
- Phone Number
- Email Address
- Mode of Contact (in person, text, email, phone)
- Date of Interest

If any information is missing or not given by a potential participant, research coordinators will leave it blank.

This interest can be expressed in person or remotely via phone, email, or text.

All participants will then be assigned a recruitment status which can be updated at any time to reflect changes in status.

Explanation and instructions for categorization of Participant Recruitment Status:

- Interested: patient has expressed interest in participating, screening not yet completed
    - If and when screening is complete, patient will be moved to appropriate recruitment status as described below
- Maximum attempts reached: study staff has reached out to interested patient three times without a response
    - Study staff will not contact interested patients again unless contacted my patient
- Ineligible: patient is ineligible to participate based on screening criteria
    - Study staff will not assign patient an ID in REDCap
- Enrolled: patient is interested in participating and decides to enroll
    - Study staff will assign patient an ID in REDCap

D2. Remote Recruitment

Existing patients who have scheduled video return visits with their rheumatologists:
Research coordinators will identify registry patients who appear to meet inclusion/exclusion criteria and have upcoming telemedicine rheumatology visits within 12 weeks. There are currently 303 eligible patients already identified within the existing rheumatology research registries (listed below) willing to be contacted for future studies.

Registries:

1. UPMC Lupus Center of Excellence Patient Registry (STUDY19060329)
2. Rheumatoid Arthritis Comparative Effectiveness Research (RACER) registry (STUDY19090282)
3. Banking of Biological Samples and Collection of Clinical Data for Connective Tissue Disease Research (STUDY19090054)

We will start recruitment with these patients. All patients who are able to conduct video visits for UPMC are assumed to have access to smartphones or tablets/laptops/PCs.

Patients will be contacted via phone, email, or by mail to inquire if they would be amenable to discussing our study with a research coordinator. Patients who are amenable will contact one of the research coordinators, Olivia Stransky or Alison Decker, at their office phone numbers (voice mail checked daily) or via email. Research coordinators will discuss the study with patients prior to their rheumatology visits, and screen for eligibility and interest. The coordinator will also provide a link for the written informed consent form, which patients can review while she is on the phone call with them or at a later time. They will be asked to sign the form electronically if they consent to participation. If they desire more time to think about the study and review the consent document before committing, they will be given the research coordinator's information to contact her if they wish to enroll in the study. Verbal consent may also be provided to patients based on their preference or ability to electronically sign a consent document. Participants will also sign a HIPAA authorization allowing study personnel to access their medical records. This form will be discussed over the phone, and an electronic version will be sent via DocuSign to the participant's email. DocuSign will send out automated reminder emails to participants to remind them to complete the consent form. Once completed, DocuSign automatically uploads the completed document to the DocuSign site and notifies the research study staff of form completion.

D3. Clinic Recruitment

Recruitment will occur among patients who receive care at three UPMC rheumatology clinics that are located within a three-mile radius of each other:

UPMC Falk Clinic
3601 Fifth Ave.
Suite 2B
Pittsburgh, PA 15213
412-647-6700

UPMC Mercy
1350 Locust St.
Suite G102
Pittsburgh, PA 15219
412-647-6700

Lupus Center of Excellence
580 South Aiken Ave.
Suite 430
Pittsburgh, PA 15232
412-586-3550

Research coordinators will identify registry patients who have upcoming in-person clinic visits within 12 weeks, screen for eligibility and interest as above, and ask them to come to their next clinic visits one hour early to provide consent and engage in study procedures. They will also sign a HIPAA authorization allowing study personnel to access their medical records.

D4. Provider Recruitment

Rheumatologists within the UPMC healthcare system will be notified via email when the study begins recruitment. Drafted language for recruitment notification sent to rheumatology providers (distributed by Dr. Birru-Talabi):

"Dear Colleagues,

I am principal investigator of a research study that is testing the benefit of a web-based family planning decision aid for women with rheumatic diseases that will begin soon. The study will be recruiting. The purpose of this email is simply informational—no action is required on your part. Women enrolled in the study who use the decision aid will get a printout summary sheet generated by the decision aid and some patients may wish to share this with you, their care providers. Please treat this summary sheet similarly to any other information patients bring to their appointments. Please feel free to reach out if any questions or concerns arise."

Note: Edits to this language should include only site-specific changes to the clinic name.

Rheumatology providers with enrolled patients will be asked to complete a survey at T3 (described in study procedures section). The registry database indicates the rheumatologist that the patient sees, which will be confirmed using Epic Hyperspace. If one or more of their patients completed the study, rheumatologists will be encouraged, via email, to complete an anonymous REDCap survey about their experiences with the study and related patient encounters. This will occur 2 weeks after the final patient participant completes the study. Rheumatologists will not be informed by study personnel which of their patients participated in the study.

D5. Additional Recruitment Methods

D5a. Pitt+Me

We do not anticipate difficulty recruiting 55 women using our remote and in clinic recruitment methods. However, if we are not recruiting 2-3 patients per week after 2 months, we will begin recruitment with Pitt+Me.

A description of the study will be posted on CTSI's Pitt+Me research registry website for women to self-refer. Pitt+Me also distributes emails that will advertise the study to women who may be

eligible based upon demographics and/or participant-chosen health areas of interest. Pitt+Me advertises over multiple social media avenues such as Twitter and Facebook.

Because our remote and in clinic recruitment stems from a registry of UPMC rheumatology patients and EPIC schedules for rheumatology providers within UPMC, we will need to confirm that all interested patients referred through Pitt+Me meet the same criteria as those recruited remotely or in clinic. Pitt+Me patients must therefore be screened to ensure that they meet the following inclusion criteria:

- Under the current care of a UPMC rheumatologist
- An upcoming scheduled appointment with their UPMC rheumatologist within the next 3-4 months

To confirm patient answers to the prescreening questions and to confirm eligibility, research coordinators will ask for verbal approval to access the patient's EPIC medical records. Patients will be reassured that their medical information will remain confidential and will not be used for anything other than to confirm eligibility. If verbal approval is given, coordinators will then check the patient's medical records to confirm the patient's responses. If the patient is eligible, they will be further screened based on inclusion criteria described in the Screening Procedures section. If the patient is found to be ineligible after the prescreen, she will be informed that she cannot complete the study.

G. Materials List

The following is a list of items that need to be brought to the clinics with research staff for in-person study visits:

- Paper printouts of baseline and exit surveys
- Stylus
- iPad
- iPad charger
- iPad keyboard
- Disinfecting wipes
- Audio recorder
- Audio recorder batteries (AAA)
- Pens
- Smartphone with voice recording technology (for backup)
- Vincent payment cards
- Vincent payment brochures
- Ear plugs
- REINA Registry consent forms

All materials will be located in a study kit for easy transport to and from clinic visits. At least two study kits will be made available to allow for both research coordinators to complete study visits simultaneously, if needed.

H. Data Collection and Entry

F1. REDCap Instructions

Accessing REDCap Database

Pitt Log in Page https://www.ctsiredcap.pitt.edu/redcap/

REDCap Account Request Form (Pitt)
https://www.ctsiredcap.pitt.edu/redcap/surveys/?s=injPIG

REDCap Introductory/Training Videos – general overview information of how to use REDCap

- https://projectredcap.org/resources/videos/
- https://redcapinfo.ucdenver.edu/redcap-videos.html

F1a. Form Completion Instructions

To enter participant data:

- Click "Add/Edit Records"
- For a participant with an existing ID, choose appropriate participant ID from the drop down menu
- For a new participant without an existing ID, click "Add new record"
- Choose appropriate form corresponding to the time point of the participant to enter data or administer survey

F1b. Order of Form Completion

- Time point T0: MyVoice RD Baseline Survey
- Time point T2: MyVoice RD Exit Survey
- Time point T3: MyVoice RD Provider Survey
- Time point T4: MyVoice RD 3 Month Survey
- Withdrawal Form: MyVoice RD Withdrawal Form

Throughout time points T0-T4 (delineated in "Study Procedures"), participants will be asked to complete a series of surveys to gather study information. Clinic patients will complete all surveys on an iPad provided by the research team. Telemedicine participants will be required to complete all surveys on their own smartphone, personal computer, or tablet. All surveys are located in REDCap within the "MyVoice RD Pilot" study page.

F2. Telemedicine Participants

To access study forms and surveys for telemedicine participants, research coordinators must send a REDCap link to participants via email as described in the REDCap Instructions section. Study participants will then enter their own data using the REDCap link. During the remote study visit, research coordinators will call the participant on the phone to assist with any issues or to answer any questions that participants may have and will remain on the phone until study activities are completed.

F3. Clinic Participants

To access study forms and surveys for clinic participants, research coordinators must log in to their REDCap account to administer the surveys. During the in-person clinic study visit, research coordinators will log in to their REDCap accounts, open the appropriate surveys for each specific time point, and administer the survey to participants by allowing participants access to the iPad to answer the questions confidentially. Coordinators will be present for the duration of the survey completion to assist with any iPad issues or to answer any questions that participants may have.

F4. Troubleshooting

F4a. REDCap Issues

Should there be an unforeseeable issue with REDCap during a telemedicine or clinic study visit that prevents REDCap log in, research coordinators will be prepared with paper copies of all study forms and surveys located in their study kits.

For telemedicine participants, research coordinators will administer all surveys over the phone to participants and record their responses on a paper form. For clinic participants, research coordinators will allow participants to complete paper copies of the surveys themselves. Once REDCap is accessible again, the coordinator who administered the surveys will then record participant responses in REDCap manually and retain all paper copies.

If REDCap experiences issues while participants are logged in and completing surveys, the research coordinator will contact the REDCap support administrator at Pitt_Biomedical_Informatics_Support@pitt.edu to attempt to restore any survey responses already recorded. If REDCap is still experiencing issues, the study will continue with paper form protocol as described above.

F4b. Internet Connection Issues

Should telemedicine participants experience an issue with their own internet connectivity/WiFi that prevents them from logging in to REDCap, the research coordinator will administer the surveys over the phone while logged in to REDCap and will enter all responses in real time.

For clinic participants, any issues with internet connectivity/WiFi within the clinics will follow paper form protocol by having participants complete the surveys on a paper copy of the surveys. Once access to an internet connection/WiFi is regained, the coordinator who administered the surveys will then record participant responses in REDCap manually and retain all paper copies.

I. Study Procedures

After eligible participants are screened and enrolled, participation in the study can begin. While it is preferred that participants answer as many questions on the surveys and complete as much of the study activities as they can, participants will be reminded that all questions and activities throughout the study are completely voluntary, and they do not need to answer any questions they do not wish to answer. In this case, there is a "prefer not to answer" response for all survey questions.

G1. Randomization

Research coordinators will randomize patients using sealed envelope protocol. In this protocol, a series of unmarked envelopes will be prepared at the onset of the study. In each envelope, a piece of paper will assign the patient to the control arm or to the intervention arm. When a patient gives consent, the coordinator will select the next envelope in the pile, open the envelope, and assign the patient to the intervention or control arm.

Women in the intervention arm will receive the MyVoice decision aid (n=38). Women in the control arm (n=12) will receive a paper-based version of the American College of Rheumatology pamphlet about pregnancy [Appendix], which, similarly to MyVoice, targets women with a broad range of rheumatic diseases.

G2. Telemedicine Participants

Telemedicine participants will be asked to engage in T0 and T1 study activities between 1 week and 1 hour prior to their remote clinic visit.

G2a. Consent

Consent will occur prior to performing any of the research interventions/interactions and before the participant goes to their clinic appointment. Research coordinators will discuss the study with patients prior to their rheumatology visits, and screen for eligibility and interest. The coordinator will also provide a link for the written informed consent form, which patients can review while she is on the phone call with them or at a later time. They will be asked to sign the form electronically if they consent to participation. If they desire more time to think about the study and review the consent document before committing, they will be given the research coordinator's information to contact her if they wish to enroll in the study.

Verbal consent may also be provided to patients based on their preference or ability to electronically sign a consent document. Participants will also sign a HIPAA authorization

allowing study personnel to access their medical records. This form will be discussed over the phone, and an electronic version will be sent via DocuSign.

If a patient wishes to participate, they will sign the document electronically in DocuSign, which creates an encrypted identifiable signature. The electronic consent process will also ask the participant to provide their mother's maiden name, the location of their birth, and the name of their high school.

G2b. T0: Baseline

For telemedicine participants, T0 forms will be completed prior to their remote clinic visit.

The following forms are to be completed at T0:

- Baseline Survey: This survey collects demographic information and asks participants about their medical visits, knowledge on their rheumatic disease as related to pregnancy and risk, as well as their experiences with birth control, pregnancy, and healthcare services for women.

G2c. T1: Intervention

For telemedicine participants, T1 will be completed prior to their remote clinic visit.

Participants randomized at enrollment to the intervention arm will access the MyVoice intervention tool. Those randomized to the control arm will access the American College of Rheumatology online pamphlet. This access will be given prior to their clinic visit. Participants randomized to the intervention arm will have approximately 20 minutes to navigate through the MyVoice decision tool.

For telemedicine participants, patients who have not completed their forms will receive one text (using Google Voice) or email every day to remind them to complete the forms prior to their rheumatology appointment. The final reminder will occur 3 hours before their clinic visit. If forms are still not completed before their clinic visit patients will be contacted to inform them that they are withdrawn from the study. If these patients have an additional rheumatology appointment within the recruitment period and are still interested in participating, they will be given the option to reschedule their study visit and will not be considered withdrawn.

Patients randomized to the intervention arm will have the option to print out a summary of the questions they have asked and decisions they have made using the tool (i.e., the MyVoice summary sheet) to bring to their appointment if they have access to a printer.

G2d. T2: Up to 48 Hours Post-Intervention

For telemedicine participants, T2 forms will be completed up to 48 hours post-intervention after their rheumatology visit.

The following forms are to be completed at T2:

- Exit Survey: This survey asks participants questions regarding acceptability and implementation measures for the MyVoice tool.

After completion of the exit survey, women will also engage the research coordinator in a post-visit phone interview to discuss their perceptions and reactions to the MyVoice tool and their experience using it. This interview will take approximately 20 minutes.

Ideally, the exit survey and interview will be completed immediately after the patient leaves her rheumatologist visit. However, if participants are unable to complete the study activities at that time, research coordinators will schedule a time to complete them over the phone between 24-48 hours after the visit.

Research coordinators will collect the following PHI from electronic health records of participants within 24 hours of their rheumatology visit, and again 90 days later at T4:

- Orders for pregnancy tests (urine, serum)
- Orders for emergency contraception
- Billing code for family planning or contraception counseling
- Order for non-emergency contraception method
- Order/Referral for obstetrics-gynecology or maternal-fetal medicine consultation
- Order/Referral for PCP consultation for family planning indication
- Prescription for prenatal vitamin
- Change from fetotoxic/teratogenic disease-modifying anti-rheumatic drug or small molecule medication to a pregnancy-compatible anti-rheumatic drug
- Documentation of pregnancy

G2e. T3: 2 Weeks Post-Recruitment Completion (Providers)

T3 is a time point only relevant to rheumatology providers. No action is needed from participants at T3.

The following forms will be completed at T3:

- Provider Survey: This survey will be given to rheumatology providers with one or more patients enrolled in the research study. This survey asks providers about their

experience with the study as well as information related to encounters with patients enrolled in the study.

Providers will be emailed this survey to complete through a REDCap link. Emails with the REDCap link to the survey will be sent out 2 weeks after our final participant completes their T2 survey. Providers will **NOT** be informed of which of their patients participated in the study. Study personnel will follow up with providers once a week via email to complete the survey a maximum of three times.

G2f. T4: 3 Months Post-Intervention

T4 will begin for participants 3 months post-intervention.

The following forms will be completed at T4:

- 3 Month Survey: This survey asks participants about any potential pregnancies post-intervention, their current birth control habits, and their knowledge on pregnancy risks in the context of rheumatic disease.

Participants will be emailed this survey via a REDCap link (as described in REDCap instructions section). Prior to emailing, study personnel will call participants to remind them of their upcoming survey. Study personnel will follow up with participants once a week via email to complete the survey for a maximum of three times.

Participants will also complete a follow-up interview at the T4 time point. Research coordinators will reach out to participants 3 months post-intervention to schedule the interview. Coordinators will reach out to schedule interview once a week via email and phone to complete the survey for a maximum of three times.

Research coordinators will collect the following PHI from electronic health records at T4:

- Orders for pregnancy tests (urine, serum)
- Orders for emergency contraception
- Billing code for family planning or contraception counseling
- Order for non-emergency contraception method
- Order/Referral for obstetrics-gynecology or maternal-fetal medicine consultation
- Order/Referral for PCP consultation for family planning indication
- Prescription for prenatal vitamin
- Change from fetotoxic/teratogenic disease-modifying anti-rheumatic drug or small molecule medication to a pregnancy-compatible anti-rheumatic drug
- Documentation of pregnancy

G3. Clinic Participants

Clinic participants will be asked to arrive to their rheumatology clinic visits 1 hour early to complete required study activities. Research coordinators will meet with participants in an available space in the clinic. If space is not available, study activities will be completed outside (weather permitting) or in a neutral space inside.

G3a. Consent

Consent will occur prior to performing any of the research interventions/interactions and before the participant goes to their clinic appointment. At consent, a research coordinator will walk through the informed consent document with participants and answer any questions that arise. If the participant agrees to participate, both the participant and the research coordinator will sign the informed consent document. They will also sign a HIPAA authorization allowing study personnel to access their medical records.

G3b. T0: Baseline

The following forms are to be completed at T0:

- Baseline Survey: This survey collects demographic information and asks participants about their medical visits, knowledge on their diseases as related to pregnancy, as well as their experiences with birth control, pregnancy, and healthcare services for women.

G3c. T1: Intervention

For clinic participants, T1 will be completed prior to their clinic visit.

Participants randomized at enrollment to the intervention arm will be administered MyVoice on a computer tablet provided by the research coordinator. Those randomized to the control arm will be given a paper version of the American College of Rheumatology online pamphlet. Participants randomized to the intervention arm will have approximately 20 minutes to navigate through the MyVoice decision tool.

To comply with social distancing in the clinic, the location in which the patients complete the survey will be delineated prior to their appointment. We will work with UPMC clinic management to see if there is an available room in which the patients can complete the surveys and tool or assess if they should be met at their cars and given the study materials.

Patients randomized to the intervention arm will be given a copy of the summary sheet (printed by a research coodinator) with questions they have asked and decisions they have made using the tool to bring to their appointment.

G3d. T2: Up to 48 Hours Post-Intervention

For clinic participants, T2 forms will be completed up to 48 hours post-intervention after their rheumatology visit. Ideally, clinic patients will complete this immediately after their rheumatology visit.

The following forms are to be completed at T2:

- Exit Survey: This survey asks participants questions regarding acceptability and implementation measures for the MyVoice tool.

After completion of the exit survey, women will also engage the research coordinator in a post-visit interview to discuss their perceptions and reactions to the MyVoice tool and their experience using it. This interview will take approximately 20 minutes and will be completed either in person in an open space at the clinic or via phone, depending on the participants' preference.

Ideally, the exit survey and interview will be completed immediately after the patient leaves her rheumatologist visit. However, if participants are unable to complete the study activities at that time, research coordinators will schedule a time to complete them over the phone between 24-48 hours after the visit.

Research coordinators will collect the following PHI from electronic health records of participants within 24 hours of their rheumatology visit, and again 90 days later at T4:

- Orders for pregnancy tests (urine, serum)
- Orders for emergency contraception
- Billing code for family planning or contraception counseling
- Order for non-emergency contraception method
- Order/Referral for obstetrics-gynecology or maternal-fetal medicine consultation
- Order/Referral for PCP consultation for family planning indication
- Prescription for prenatal vitamin
- Change from fetotoxic/teratogenic disease-modifying anti-rheumatic drug or small molecule medication to a pregnancy-compatible anti-rheumatic drug
- Documentation of pregnancy

G3e. T3: 2 Weeks Post-Recruitment Completion (Providers)

T3 is a time point only relevant to rheumatology providers. No action is needed from participants at T3.

The following forms will be completed at T3:

- Provider Survey: This survey will be given to rheumatology providers with one or more patients enrolled in the research study. This survey asks providers about their experience with the study as well as information related to encounters with patients enrolled in the study.

Providers will be emailed this survey to complete through a REDCap link. Emails with the REDCap link to the survey will be sent out 2 weeks after our final participant completes their T2 survey. Providers will **NOT** be informed of which of their patients participated in the study. Study personnel will follow up with providers once a week via email to complete the survey a maximum of three times.

G3f. T4: 3 Months Post-Intervention

T4 will begin for participants 3 months post-intervention.

The following forms will be completed at T4:

- 3 Month Survey: This survey asks participants about any potential pregnancies post-intervention, their current birth control habits, and their knowledge on pregnancy risks in the context of rheumatic disease.

Participants will be emailed this survey via a REDCap link (as described in REDCap instructions section). Prior to emailing, study personnel will call participants to remind them of their upcoming survey. Study personnel will follow up with participants once a week via email and phone to complete the survey for a maximum of three times.

Participants will also complete a follow-up interview at the T4 time point. Research coordinators will reach out to participants 3 months post-intervention to schedule the interview. Coordinators will reach out to schedule interview once a week via email and phone to complete the survey for a maximum of three times.

Research coordinators will collect the following PHI from electronic health records at T4:

- Orders for pregnancy tests (urine, serum)
- Orders for emergency contraception
- Billing code for family planning or contraception counseling
- Order for non-emergency contraception method

- Order/Referral for obstetrics-gynecology or maternal-fetal medicine consultation
- Order/Referral for PCP consultation for family planning indication
- Prescription for prenatal vitamin
- Change from fetotoxic/teratogenic disease-modifying anti-rheumatic drug or small molecule medication to a pregnancy-compatible anti-rheumatic drug
- Documentation of pregnancy

G4. Troubleshooting

For telemedicine and clinic participants, T0 (baseline) is completed before their scheduled rheumatology appointments. While participants will be asked to arrive one hour early to their appointments to complete study activities, we suspect that everything can be completed in 45 minutes. If participants arrive more than 20 minutes late to their scheduled study appointment, research coordinators will inform them that they cannot complete the first part of the study that day. If the participant has another upcoming rheumatology appointment within one month, they can be rescheduled. If they do not, they will be withdrawn from participation.

J. Payment Protocol

H1. Full Study Completion

Participants who complete all study activities in time points T0-T3 will receive $40 payable by a university-issued payment card (Vincent). This payment card will be loaded and issued to the participant by the research coordinator and will be reloaded with additional funds if and when the participant completes follow up visits. For telemedicine participants, Vincent cards will be mailed to them. Participants will be asked to contact the study team upon receipt of their card for the study team to activate it. Clinic participants will be given their loaded Vincent cards at the time of their study visits. Participants will be instructed to keep their Vincent cards until the completion of the study (3 months post-intervention).

Participants who complete the study remotely (telemedicine) will receive an additional $10 on their payment card to compensate for data usage and cell phone minutes, regardless of how much of the study they complete. Those who complete the study in-person (clinic) will receive a parking voucher, worth $8-10.

Participants who complete the interview at T4 (3 months post-intervention) will receive an additional $20 on their Vincent cards.

H2. Partial Study Completion

Because the study is voluntary and participants have the option to withdraw at any time, there is potential for partial payment depending on how much of the study is completed. Partial payment guidelines are listed below, described as how much a participant would receive if withdrawing after completing the listed study activity.

- Consent: $0
- Baseline survey/Intervention (MyVoice/pamphlet): $5

Telemedicine participants that only complete a portion of the study will still be compensated an additional $10 for data usage and cell phone minutes, regardless of how much of the study they complete.

I. Communication Protocol

Participants will be asked how they would prefer to be contacted for study reminders and communication (call, email, text, or any combination of these options).

For those who request text message communication or reminders, texts will be sent by the study team using Google Voice to remind participants about upcoming appointments. Google Voice generates a unique phone number (412-419-1563) and allows research staff to communicate with participants via phone and text anonymously without needing to provide personal phone numbers to participants.

Phone numbers for texting are also included on recruitment materials. Participants will be able to contact the study team via Google Voice texting with study related questions. Messages and contact information will not be stored on or downloaded to any devices. Research staff will delete text message chains on a regular monthly basis. The content of the messaging is limited to appointment reminder and study related information questions.

A study specific email address was created for communication with participants during recruitment and for scheduling/appointment reminder purposes. This study email address is: myvoice@pitt.edu.

J. Protocol for Withdrawal/Lost to Follow Up

J1. Withdrawal

Participants are able to withdraw from study participation at any time for any reason. To withdraw, a participant must either provide verbal or written notification that they want to withdraw from the study and discontinue any ongoing study activities. Any information and data collected prior to withdrawal will be retained and can be used for research-related purposes, unless specified by participant at withdrawal.

At the time of participant withdrawal, research coordinators will load a Vincent card for the withdrawn participant with the appropriate payment amount as delineated in the Payment Protocol section. Coordinators will then complete the Withdrawal Form in REDCap.

J2. Lost to Follow Up

Participants will be deemed lost to follow up if they participate in the intervention but are unable to be reached for future study activities (time point T2). To clarify, if participants do not complete the exit survey/interview after their rheumatology appointment, research coordinators will attempt to schedule study activities 24-48 hours after their visits (described in Study Procedures section). If study staff is unable to reach them to schedule and they do not hear from the participant to complete the study activities, participants will then be considered lost to follow up. Coordinators will then complete a Lost to Follow Up form in REDCap.

Note: Because T4 study activities are supplemental to the main study data, participants that cannot be reached to complete the final 3-month survey will not be considered lost to follow up.

K. SAFETY ASSESSMENTS

1. Study oversight is being conducted by an internally-appointed Safety Officer, Dr. Elizabeth Krans, Assistant Professor in the Department of Obstetrics, Gynecology & Reproductive Sciences at the University of Pittsburgh.

2. ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

i. **DEFINITION OF ADVERSE EVENTS**

Adverse event**:** An unfavorable medical occurrence, which may include abnormal signs (for example, abnormal physical exam or laboratory finding), symptoms, or disease, temporally associated with, but not necessarily considered related to, the subject's participation in the research study. Not all adverse events meet IRB reporting guidelines.

Possible adverse events for this study include discomfort, invasion of privacy, and breach of confidentiality. See the DSM for greater detail.

ii. **DEFINITION OF SERIOUS ADVERSE EVENTS**

An adverse event or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: Death, a life threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/ birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

We do not anticipate any serious adverse events for this study.

iii. **DEFINITION OF UNANTICIPATED PROBLEM**

Any accident, experience, or outcome that meets all of the following criteria:

1. Unexpected in terms of nature, severity, or frequency;
2. Related, or possibly related, to a subject's participation in the research;
3. Places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Possible unanticipated problems might include changes to the clinic structure based on the Covid-19 pandemic or a complaint from the subject about content of study materials.

iv. **DEFINITION OF PROTOCOL DEVIATION**

Non-compliance: Failure on the part of the investigator or any member of the study team to follow the terms of University of Pittsburgh IRB approved protocol or to abide by applicable

laws or regulations, or University of Pittsburgh IRB policies. This includes protocol deviations.

Incidents of non-compliance *on the part of research participants which do not involve risk* need not be reported to the IRB.

Possible protocol deviations include:

- Enrollment of an ineligible participant
- Failure to obtain consent prior to the start of study activities
- Participant interview and exit survey conducted outside of follow-up window

3. Reporting

i. General IRB Reporting Timelines for Adverse Events

Adverse Events that meet the University IRB's reporting requirements must be reported to the IRB office as follows:

- Adverse Events which are unexpected, fatal or life-threatening, and related or possibly Related to the Research Intervention will reported to the IRB within 24 hours of learning of the event.
- All other Adverse Events will be reported to the IRB within 10 working days of the investigator learning of the event.

All non-serious adverse events will be reported in aggregate to the Internal S.O. and the NIAMS as part of the routine safety report.

We do not anticipate any Serious Adverse Events such as death during this study; however, all Serious Adverse Events will be reported to the Internal S.O. and NIAMS within 48 hours of the investigator becoming aware of the event. The Internal S.O.'s feedback will be shared with NIAMS once received by the study team.

ii. Unanticipated Problems Involving Risk to Subjects or Others and Non-compliance

Unanticipated problems which meet the following definition of "any accident, experience or outcome" that meets ***all three* of the following criteria must be reported:**

- unexpected in terms of nature, severity, or frequency;
- related, or possibly related, to a subject's participation in the research;
- places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized;

Incidents of non-compliance, which meet the following must be reported:

- Failure on the part of the investigator or any member of the study team to follow the terms of University of Pittsburgh IRB approved protocol or to abide by applicable laws or regulations, or University of Pittsburgh IRB policies that:
    - adversely affect that rights and welfare of human subjects, or
    - significantly compromises the quality of the research data

3. **Incidents of protocol deviations impacting participant safety:**

All incidents of protocol deviation which impact participant safety will be reported to NIAMS and the Internal S.O. within 48 hours of the investigator becoming aware of the event; all other protocol deviations which do not impact participant safety can be reported as part of the routine safety report.

Examples of non-compliance that are not reportable but should be documented in a log:

- Obtaining consent using an outdated consent form when there were no substantive differences between the consent form that was used and the consent form that should have been used (i.e., dates in the footer)
- Protocol deviations that do NOT adversely affect the rights and welfare of human subjects or significantly compromise the quality of the research data
- Subject non-compliance that doesn't involve risk or alter the data
- Performing non-safety related research procedures outside the protocol specified window, i.e., involuntarily administering a questionnaire outside of the protocol specified window.

General Reporting Requirements for Unanticipated Problems Involving Risk to Human Subjects or Others and Non-Compliance:

Investigators are to submit all Unanticipated Problems Involving Risks to Human Subjects or Others that are Possibly or Definitely Related to the research and incidents of reportable Non-compliance within 10 working days of the investigator becoming aware of the reportable event/reportable new information.

L. Publication and Data Sharing Policy

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers one year after the completion of the primary endpoint by contacting Dr. Mehret Birru Talabi. Only de-identified data will be shared and will not be traceable back to individual participants.

M. Appendix

Screening Script

Hi Ms (_____),

Thank you again for participating in the Pitt (disease) registry. We have a new research study we wanted to tell you about. This research study is being conducted by University of Pittsburgh Division of Rheumatology and is funded by a grant from the National Institutes of Health.

The purpose of the research study is to explore whether a web-based tool called MyVoice or a pamphlet from the American College of Rheumatology helps women with autoimmune diseases to get the information and support they need to make informed decisions about if and when to have a child, and gives them information about birth control, fertility options, and how their diseases and medications might affect a pregnancy.

Does this sound like it might be of interest to you?

If No, thank the patient and hang up.

If Yes, continue

Let me tell you a little more about the research study to help you to make up your mind.

This research study will be conducted remotely. You'd need to have access to the Internet to complete this study.

Do you have access to Internet? (probe: smart phone, laptop, personal computer, tablet, etc)

If No, thank the patient and hang up.

If Yes, continue

Great. Two weeks before your next appointment with your rheumatologist, we would email or text you a link with some surveys to complete, along with either the web-based tool or a link to the pamphlet from the American College of Rheumatology. We will send you some email or text reminders to complete the study.

Overall, we think the surveys will take about 30 or 40 minutes to complete, and the tool will take about 20 minutes or so to navigate through.

Then, you'd have your visit with your rheumatologist. We'd like to interview you within a week of the visit to see how the visit with your rheumatologist went, and to give you some additional

surveys. This step would probably take an additional 30 minutes or so. We'd need to be able to talk with you over the phone. Our research coordinator will also look in your chart immediately after the visit, and 90 days after your visit.

We think altogether, you might expect to spend about two hours on the study. We would compensate you with $40 for completing the study and $10 to go towards your use of your cell phone minutes or data.

I should mention that your rheumatologist will not be told that you are participating in the study, and all of your survey and interview content will be kept confidential.

Might you be interested in participating in the research study? If so, I have a consent form that I will send you. If you are interested, I can go over this document with you verbally and you can consent for the study now over the phone.

If No, thank the patient and hang up.

If Yes, continue with the verbal consent.

Interview Guide

Note: Consent for participation in the study will have previously been obtained.

INTRODUCTION: (OPTIONAL)

Hello. My name is XXX. I am very appreciative that you are taking the time to talk with me today. The purpose of this research study is to hear about your thoughts and opinions related to the MyVoice:RD decision aid as well as your experiences and perspectives regarding reproductive health discussions you may have had with your rheumatologist. What we learn from talking with women like you will help us improve the tool and this aspect of care for women with rheumatic diseases.

I am going to use an audio recorder to tape our conversation. Our conversation will be entirely anonymous, which means that I won't share this recording with anyone but our study team. We will not use your name or the name of anyone else you mention in this interview.

I really want to make sure that you feel comfortable sharing your experiences and opinions with me. All questions are voluntary, so you don't have to answer any that you don't want to. You can stop participating at any time. If there are any comments or thoughts that you'd like to add, I'd love to hear them.

There are no risks or benefits to participating in this interview. I expect that the interview will take around 20-30 minutes to finish.

Do you have any additional questions about the information we just reviewed together?

If any questions do arise, please don't hesitate to ask. I'll also give you my information at the end of the interview so you can follow up with me if you wish.

Do you have any questions for me at this point?

I will turn on the recorder now.

I. MyVoice:RD Feedback

- Please tell me your thoughts about MyVoice:RD.

[Prompt] What did you like about it? What did you dislike?

[Prompt] Did you learn anything about pregnancy, parenthood, or birth control related to women with rheumatic diseases from the decision aid?

[Prompt] Has MyVoice:RD been helpful to you? Did it help you to have a conversation with your rheumatologist related to your reproductive health? Did MyVoice:RD help you make decisions related to your reproductive goals (parenthood, pregnancy, or choice of contraception)? If yes, tell me about that.

[Prompt] What can we do to make the tool better?

- Is MyVoice:RD appropriate for women with rheumatic diseases? Is it valuable?
- How usable is MyVoice:RD?

[Prompt] What features were easy to use? What features were too complex?

[Prompt] Do you need help using MyVoice:RD?

[Prompt] Were the different parts of MyVoice:RD well-integrated?

- What are the barriers to using MyVoice:RD?

[Prompt] Did using MyVoice:RD require an excessive amount of time?

- What are the facilitators to using MyVoice:RD?

[Prompt] Did anything help you to use MyVoice:RD

- Are there any situations where you think MyVoice:RD would be particularly helpful? Are there any situations or practices where you think MyVoice:RD would not be helpful?

II. Reproductive Health Discussions with your rheumatologist

- Did you discuss your reproductive goals or plans (including parenthood, pregnancy, or choice of birth control) with your rheumatologist during your last visit? If yes, how did that discussion go? If no, why not?

[Prompt] Who initiated the conversation? Who was in the room?

[Prompt] Did you feel heard? Did your provider help you understand your reproductive decisions?

[Prompt] Did your provider listen to the things that matter most to you about your reproductive decisions?

[Prompt] How much effort was made to include what matters most to you in choosing what to do next?

- Did MyVoice:RD influence your discussions with your rheumatologist? If yes, how?

- Did you have reproductive health discussions with your rheumatologist before you used MyVoice:RD?

[Prompt] Were those conversations different at all after using MyVoice:RD?

- Do you feel confident in your ability to get answers to your reproductive health question? Seek out reproductive health care?

[Prompt] Did MyVoice:RD help at all?

N. Statistical Analysis Plan

Measures

We collected baseline information about participants' demographic and personal characteristics. Questions about contraception use, reproductive histories, and healthcare utilization were adapted from the National Survey of Growth. The Desire to Avoid Pregnancy scale was used to assess patients' preferences around a future pregnancy.

Feasibility, usability, and acceptability of MyVoice:Rheum and the control pamphlet were assessed using qualitative and quantitative measures. The validated Intervention Appropriateness Measure (IAM) and Acceptability of Intervention Measure (AIM) consist of Likert scales ranging from 1-5; we assigned a feasibility threshold of ≥ 3.5 of 5 for AIM and IAM scores, for which higher scores indicate more positive responses. Usability was assessed via summary scores from the System Usability Scale (SUS), which consists of a 10-item Likert scale with scores ranging from 0-100; we set a threshold of scores >80.3 as 'A'/excellent and 68-80.3 as 'B'/very good, consistent with standard rating for the SUS. To assess the perceived value of MyVoice:Rheum and the pamphlet, we developed a five-item Likert scale with responses ranging from 1-5 (1: strongly disagree, 5: strongly agree).

While pilot studies are not designed to test hypotheses, we preliminarily assessed the effectiveness of MyVoice:Rheum in prompting family planning discussions by comparing the incidence in which these discussions occurred across the study arms. We also evaluated self-efficacy and knowledge scores within each arm before and after the intervention. Self-reported efficacy in communicating with providers was assessed using a modified version of the validated five-item Perceived Efficacy in Patient-Provider Interactions (PEPPI) scale. Rheumatology-specific reproductive health knowledge was assessed via ReproKnow, a measure developed and preliminarily validated by our team that covers domains of contraception safety and efficacy, pregnancy management, pre-conception planning, medication safety, fertility; a score of nine indicates the highest level of reproductive knowledge. Overall knowledge scores as well as scores related to specific domains of reproductive knowledge were calculated across individuals in each study arm. Among MyVoice:Rheum users only, knowledge was assessed again three months after the intervention.

Analysis

Quantitative. Quantitative measures of demographics, feasibility, and acceptability were assessed via descriptive statistics. Among MyVoice:Rheum users and controls, we conducted paired comparisons pre- and post-intervention regarding self-efficacy and reproductive health knowledge, using McNemar's test for proportions and Wilcoxon's signed rank test for means. Calculations were performed using Stata 17.0.

Qualitative. A deductive approach was used to prepare the preliminary codebook, which was organized by the following domains: feasibility and acceptability; family planning discussed at rheumatology visit (yes/no), and reasons why or why not; barriers and facilitators to discussing family planning at the rheumatology visit; ideal timepoints and contexts to use the tool; and suggested modifications. Interview transcripts were entered into NVivo software to

facilitate coding and thematic analysis. Transcripts were reviewed by two experienced qualitative analysts with master's degrees in public health and sociology, respectively (O.S., L.P.). O.S. and L.P. used an open coding approach to identify themes that arose inductively, and subsequently refined the codebook based on the most frequent and important codes. G.L., a trained research assistant, also independently coded the transcripts. As a form of investigator triangulation, the analysts and P.I. (M.B.T.) used a consensus approach to reconcile coding and create new codes. Focus coding was used to re-review all transcripts and synthesize themes.

RESULTS

Sample Characteristics

Fifty-five patients consented to participate in the study, among whom 46 patients were randomized to a study arm. Forty patients completed the study, among whom 31 patients were randomized to the MyVoice:Rheum intervention and 9 were randomized to the control arm. The most common rheumatic disease diagnoses were SLE, RA, and myositis. Most participants identified as heterosexual, and nearly half of all participants were married. More than half of participants had at least a college degree. Over 40% of participants identified their rheumatologist as their main health provider. Most participants had never been pregnant, and approximately 10% had a diagnosis of infertility. Over two-thirds of participants used a method of contraception.

Quantitative Outcomes

MyVoice:Rheum and the control pamphlet were both rated as feasible, acceptable, usable, and valuable by study participants. The minimum threshold score of 3.5 for the Acceptability of Intervention Measure (AIM) was met or exceeded by 96.8% of MyVoice:Rheum users and 88.9% of controls; average AIM scores for MyVoice:Rheum and controls were 4.4 (S.D. 0.58) and 3.97 (S.D. 0.65), respectively. The minimum threshold score of 3.5 for the Intervention Appropriateness Measure (IAM) was met or exceeded by 96.8% of MyVoice:Rheum users and 88.% of controls; average IAM scores among MyVoice:Rheum and controls were 4.48 (S.D. 0.60) and 4.11 (S.D. 0.85), respectively. System Usability Scale scores for MyVoice:Rheum users were rated in the range of "excellent", whereas scores for pamphlet users were rated in the range of "very good" (83.0 vs. 79.3, respectively).

Approximately 55% of MyVoice:Rheum users vs. 44% of control participants discussed any family planning issues, plans, or questions with their rheumatologists during their clinic visit. Among these participants, 55% of MyVoice:Rheum users indicated that the tool influenced their decision to discuss family planning with their rheumatologists as compared to 44% of controls. Among MyVoice:Rheum users, self-efficacy scores on the PEPPI scale rose from a pre-test mean of 3.47 (S.D. 1.19) to a post-test mean 4.07 (S.D. 0.82) (mean difference: 0.59 (S.D. 0.91)).

Overall reproductive knowledge scores on ReproKnow rose from a pre-test mean of 5.77 (S.D. 1.76) to a post-test mean of 7.27 (S.D. 1.17) (mean difference: 1.50 (S.D. 1.93)). Reproductive knowledge appeared to increase across the ReproKnow domains of birth outcomes, fertility, contraception, pre-pregnancy planning, and pregnancy management.

Qualitative Outcomes. The following themes emerged from interviews with MyVoice:Rheum users: 1) MyVoice:Rheum was feasible, informative, usable, and customizable to the user; 2)

MyVoice:Rheum users felt prepared to initiate and engage in family planning conversations with their rheumatologists; 3) MyVoice:Rheum optimally should be provided for patients to review immediately prior to the rheumatology encounter, around the time of the initially RMD diagnosis and periodically afterwards; 4) Family planning conversations at the rheumatology visit were facilitated by respectful and trusting relationships with the rheumatologist, whereas distrustful relationships and rushed visits were a barrier to family planning conversations; 5) Suggested modifications to MyVoice:Rheum included tools directed towards clinicians to facilitate patient-centered care, and information modules for partners or family members. Representative quotations are presented in.

Three-month outcomes. Most MyVoice:Rheum users engaged in interviews three months following the intervention (N=30). Some MyVoice:Rheum users indicated receipt of family planning services after the intervention, including: 1) initiation of a new birth control method (N=7); 2) counseling about birth control or pregnancy planning from a clinician (N=4); and/or 3) a clinic visit or medical test related to birth control or pregnancy planning (N=3). When reproductive knowledge was re-evaluated again three months, overall scores remained significantly higher than pre-intervention scores (pre-intervention mean 5.77 (SD 1.76) vs. post-intervention 7.27 (1.17), mean difference 1.50 (1.93)).