Patient-Reported Outcomes Measurement Information System (PROMIS) Integration into Rheumatology Clinical Practice

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Pilot Trial

1.0. Background

Chronic medical conditions, such as rheumatic diseases (RD), have a detrimental effect on self-reported physical, mental, and social health, i.e., health-related quality of life (HRQOL) [1, 2]. RDs are diverse with variable impact on HRQOL, can fluctuate over time, and may mirror disease flares [3-5]. A patient-reported outcome (PRO) is any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else [6]. PROs can supplement clinical decision making by aiding assessment and management of these conditions. There is increased enthusiasm within the rheumatology research community to integrate PRO measures with clinical assessments [7-9].

The National Institutes of Health Patient-Reported Outcomes Measurement Information System (PROMIS®) Roadmap initiative (available at http://www.nihpromisorg) is a cooperative research program designed to develop, evaluate, and standardize item banks to measure PROs across patients with varying medical conditions and in a cross section of the US population [10]. PROMIS ® aims to use item response theory (IRT) to develop reliable and valid item banks that can be administered as short forms and computerized adaptive tests (CAT) [11, 12]. As it improves measurement precision, it lessens burden on the patient. PROMIS short forms are available for incorporation in the electronic medical records [13].

The overarching aim of our project is to lay the groundwork for a well powered randomized controlled trial to assess the impact of incorporating PROs – specifically PROMIS questionnaires – at the point of care in clinical rheumatology practice. This IRB application is for a pilot study to assess the feasibility of a future randomized controlled trial (RCT) of strategies to promote review and discussion of PROs during rheumatology consultations. The current pilot trial will yield important preliminary results to help us design a future RCT, including assessment of the following:

- Recruitment and retention
- Data collection procedures
- Required resources and management capacity
- Intervention acceptability and feasibility
- Expected intervention effect and variability
- Provide data to assess sample size for definitive trial

We will also qualitatively assess health care provider (HCP) and patient perspectives on the barriers and facilitators of integrating PRO use into rheumatology care

2.0. Preliminary Work

There are a number of requirements of integrating PRO assessment into a clinical practice to make it feasible and easily acceptable amongst providers – (a) PRO data should be collected completely and accurately with little effort, (b) the scoring of the data should be automated and happen in real time during the clinic visit, (c) the PRO data should be longitudinally stored in patient's electronic medical record and should be easily retrievable to allow monitoring, and (d) the scores should be represented in a format that is easy to understand for both the provider and patient [14-16].

We conducted a multi-phase study at MM titled Patient Reported Outcomes Measurement Information System (PROMIS) in Rheumatology - HUM00076269. In this study, we iteratively collected data to 1) identify the PROMIS health domains most relevant to the care of patients with RDs; 2) identify clinically meaningful cut-points for PROMIS domains with input from patients and HCPs using real patient data collected at MM, and 3) incorporate PROMIS domains in the MM EMR.

Completed Preliminary Work Phase 1: Consensus from rheumatology care providers

We conducted focus group discussions with practicing rheumatologists at MM to identify PROMIS domains that are clinically relevant and actionable at the point of care. They identified four domains—physical function, pain interference, sleep disturbance, and depression—as important in patients with rheumatic diseases and actionable in clinical practice [7]. There was also consensus among HCPs to incorporate PROMIS domains in the EMR along with guidance where appropriate action needs consideration.

Completed Preliminary Work Phase 2: Identify clinically meaningful cut-points for chosen domains

Initially, data on T-scores across different domains - physical function, pain interference, sleep disturbance, and depression – were collected in a convenience sample of patients with RDs at MM. Subjects were enrolled, and data was collected using the Assessment Center® (a free, online data collection tool that enables researchers to create study-specific websites for capturing PROMIS). The scores in PROMIS measures are computed to a T-score metric, where 50 represents the mean for US general population, and 10 is the standard deviation. A higher PROMIS T-score represents more of the concept being measured (except physical function where a lower T-score indicates increased impairment). The team adapted the bookmark standard-setting procedure for creating clinical vignettes at different cut-points. This method is routinely used in educational and psychological testing and was recently used to develop vignettes in multiple sclerosis, juvenile inflammatory arthritis, and in oncology settings [17-19].

Nine patients and 10 HCPs participated in a 2-day expert panel meeting at MM. Eight of the nine patients were women. There was large variability in patients classified as having severe impairment in physical function (24% by patients and 2% by HCPs).

Table 1: Clinically Meaningful Scores for Different Severity of Physical Function

Clinically Meaningful Scores for Different Severity of Physical Function				
Clinical vignettes **Category**	Cut scores*		Severity level when applied to UM cohort (N=233)	
	Patient classification	HCP classification	Patient classification	HCP classification
			%	%
No problem	>65	>60	0.4	1
Mild problem	45-65	45-60	27	26
Moderate problem	35-45	25-45	48	70
Severe problem	<35	<25	24	2
***Mean for US population is 50 with higher score is better physical function**				

Table 1 shows cut points reached separately by patients and HCPs for the physical function domain. In the patient classification, across physical function domains, the categories tended to have a T-score distribution that was within 0.5-1 SD of HCPs, except for moderate and severe problems where the difference was 1 SD. Based on these, a majority of the patients [75-96%] would be classified as having none to mild to moderate problems with physical function.

Completed Preliminary Work Phase 3: Incorporate PROMIS short forms in MM EMR

The PROMIS item banks for physical function, pain intensity, and sleep disturbance have now been integrated into MiChart (EPIC EMR at MM). The PROMIS data is collected in selected MM rheumatology clinic locations and by selected HCPs as part of standard of care. The PROMIS questionnaires are completed by patients either via online portal or on tablet at check-in before the clinic appointment with the HCP). Currently, two rheumatology clinic locations are equipped with portable tablets for collecting PROMIS questionnaire data. Rheumatology HCPs currently participate in this set-up where in, all their patients are given these tablets to complete the questionnaire while in the waiting room. The scores from these PROMIS questionnaires are available for display in two formats (Figures 1-2) on MiChart (electronic medical record used at MM). The box labeled 'PROMIS score interpretation' denotes the interpretation of the physical function score and also provides an actionable cut point (chosen as 30 [Table 1]—the average between patients' and HCPs' cut-scores for severe physical limitations in Table 1) and recommendations. While the tabular format (Figure 1) is importable into the encounter note, the graphical format is not importable. HCPs can generate the graphical format with numerical scores (Figure 2) for discussions with the patients during the encounter. Figure 2 shows incorporation of the PROMIS item bank (physical function and pain intensity are shown as examples) in the MM EMR. Also, HCPs can track changes in PROMIS scores over time (red arrow). The pre-visit PROMIS questionnaires are administered as standard of care to patients across all MM Rheumatology clinics.

Figure 1: Tabular display of PROMIS physical function, pain intensity, and sleep disturbance imported into the EMR note

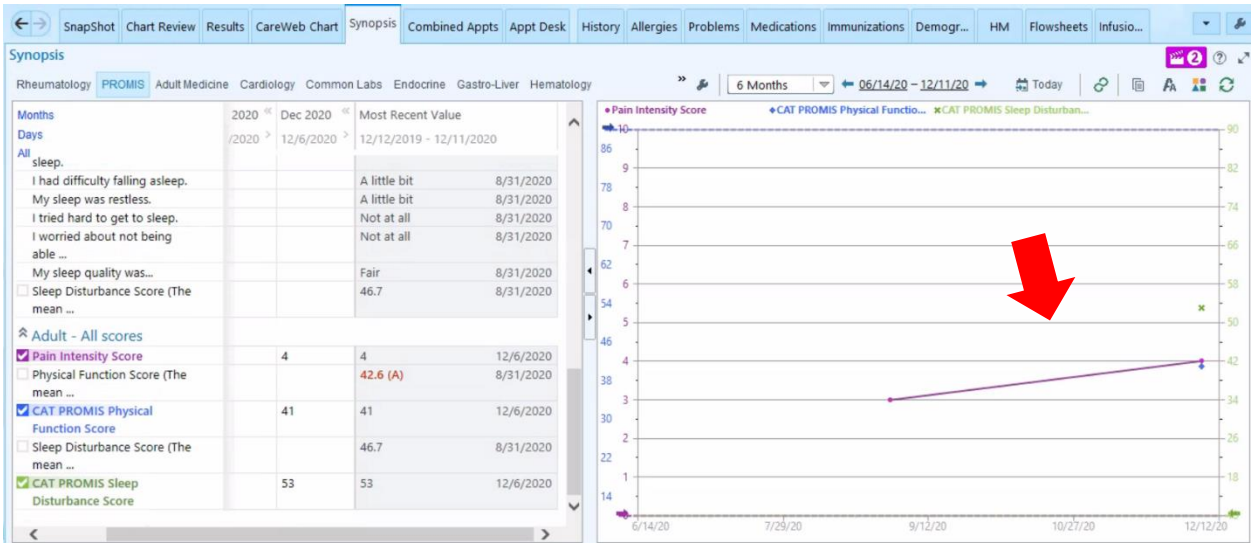
PROMIS Scores

AMB PROMIS CAT RHEUM	10/29/2018	3/25/2019	9/23/2019	12/7/2020
Pain Intensity Score	1	1	0	1
PROMIS Physical Function T-Score	-	-	-	53 (within normal limits)
PROMIS Sleep Disturbance T-Score	-	-	-	41 (within normal limits)

PROMIS Score interpretation

Domain	Interpretation
Pain Intensity	A higher score denotes more pain intensity. A score of greater than or equal to 5 is suggestive of moderate-to-severe pain. Consider evaluating the cause(s) of the ongoing pain and management of pain (including pharmacologic and non-pharmacologic management and appropriate referral).
Physical Function	The mean score for the US general population is 50. A higher score denotes a better physical function. A score of less than or equal to 40 is suggestive of moderate-to-severe limitation in physical function. Consider optimizing therapy (such as PT or change in medication) or reevaluation at follow up visit.
Sleep disturbance	The mean score for the US general population is 50. A higher score denotes worse sleep disturbance. A score of greater than or equal to 60 is suggestive of moderate-to-severe impact in their sleep quality. Consider optimizing therapy (such as referral to sleep medicine), counseling about sleep hygiene, or reevaluation at follow up visit.)

Figure 2: Screenshot of PROMIS physical function, pain intensity, and sleep disturbance on MiChart



2.1. Phase I (HUM00145286)

Part A: The feasibility of administering the PROMIS questionnaire to patients using a tablet in multi-HCP rheumatology clinics at Michigan Medicine was assessed between July 1, 2016 and March 31, 2018 [20]. Of all patients seen in clinic, 87.2% completed the PROMIS® questionnaires, of which 82.4% used tablets at check-in, 14.1% completed at home (portal), and 3.4% were assisted on a clinic desktop computer to complete the questionnaire. Around 13% of patients did not complete questionnaires due to various reasons – lack of portal access, limited tablet availability at check-in, time constraints for MAs in a busy clinic, and rarely, patient refusal to complete.

Part B: Seven rheumatology HCPs were invited to participate in a study from January 2019-January 2020 to assess the feasibility and impact of training on use of the PROMIS scores. Participating HCPs were educated in a session on how to import the PROMIS scores into the encounter note. Of 5041 clinical encounters reviewed, patients had not completed PROMIS® questionnaires in 1072 (21%) of the encounters. Of the remaining 3969 encounters, PROMIS® scores were imported to the note in 2745 encounters (69.2%). In these encounters, providers had documented their interpretation of the PROMIS® scores in 2261 (82.3%) notes. In feedback sessions over the course of the year, HCPs shared challenges they encountered with using PROs in practice. The most frequent reason for not importing the scores to the note was a new workflow pattern for the providers to remember during their office encounters. Another less common reason for not importing PRO scores into the note was the presence of a trainee participating in the visit and doing the initial documentation. Overall, the providers felt it was easy to import the scores using the dot phrase and to complete the subsequent documentation.

3.0. The Proposed Study: PROMIS Integration into Clinical Rheumatology Practice (Pilot trial)

3.1. Specific Aims

The goals identified for this study are centered on appraising HCP documentation and referrals as well as patient-provider communication.

Aim 1: To assess the HCP documentation of PROs in the electronic medical record (EMR) as a result of PROMIS report card availability at the point-of-care.

Aim 2: To determine the presence or absence of appropriate HCP referrals in the electronic medical record (EMR) as a result of PROMIS report card availability at point-of-care.

Aim 3: To evaluate the patient-provider communication due to PROMIS score availability at point-of-care.

3.2. Hypotheses

Providing PROMIS scores to patients and HCPs at point-of-care will give both patients and HCPs an objective tool to track symptoms' progression over time. Patients will be empowered to discuss symptoms and issues of concern with their HCPs, and can be actively involved in decisions about medications and other treatments. We hypothesize that, compared to not, providing PROMIS scores to patients and HCPs at the point-of-care will be associated with:

1. Improved documentation of PRO scores in the EMR (primary outcome)
2. Incorporation of the interpreted data in medical decision-making about treatments or referrals (secondary outcome)
3. Improved patient-provider communication (secondary outcome)
4. Improved PROMIS symptoms (secondary outcome)
5. Improvements in health outcomes as measured by PROs (exploratory)
6. Improved patient satisfaction with treatment (exploratory outcome)
7. Improved patient satisfaction with care (exploratory outcome)

A comprehensive integration of PROs into clinical care involves not only patients, but also HCPs, and may be even more effective than providing PRO scores to patients alone. In addition, we will use qualitative research approaches to explore the effects of PRO implementation as well as patient and HCP expectations and doubts regarding PRO implementation.

Table 2. Primary, Secondary, and Exploratory Endpoints

Assessment	Description	Timeframe
PRIMARY ENDPOINTS		
Percent of appointments at which PROMIS scores are documented in the EMR note by the participating HCP	Documentation in EMR notes will be categorized as either 'yes' or 'no' and identified through EMR data pulls.	Each appointment with the HCP during the trial period
SECONDARY ENDPOINTS		
Percent of appointments at which referrals/recommendations related to PROMIS scores are documented in the EMR note by the participating HCP	Documentation in EMR notes will be either 'yes' or 'no' and identified through EMR data pulls.	Each appointment with the HCP during the trial period
Quality of patient-provider communication	Patient-reported assessment of different aspects of patient-provider communication using the **Interpersonal Processes of Care** (IPC) Survey (29 items), which measures 7 subscales: hurried communication, elicited concerns/responded, explained results/medications, patient-centered decision making, compassion, discrimination, and disrespectful office staff (score for each subscale ranges from 1-5; a higher score indicates better IPC) [24].	Up to 2 weeks after baseline appointment
Change in score of the most bothersome PROMIS domain from baseline to 3 months	Change in the T-score of the most bothersome PROMIS domain at baseline for sleep disturbance and physical function domains, and change in actual score on a scale 0-10 for pain intensity domain.	3 months post-baseline appointment
EXPLORATORY ENDPOINTS		
Percent of participants reporting discussion of PROs with their rheumatology provider during appointments	Patient report of whether or not PROs were discussed during appointment (assessed via survey).	Up to 2 weeks after baseline appointment

Patient satisfaction with treatment	Patient reported satisfaction with treatment, assessed with the Treatment Satisfaction Questionnaire for Medication 1.4 (TSQM) [25]. (Measures 4 domains, including Effectiveness, Side Effects, Convenience, and one global scale item, Global Satisfaction; each domain score ranges from 0-100, with higher score indicating greater satisfaction).	Up to 2 weeks after baseline appointment
Patient satisfaction with care	Patient reported satisfaction with rheumatology care, assessed with the Leeds Satisfaction with Care Questionnaire (score ranges from 1-5, with higher value indicating greater satisfaction) [26].	Up to 2 weeks after baseline appointment
Percent of participants achieving a clinically meaningful improvement at 3 months in the most bothersome PROMIS domain at baseline	Percent of participants achieving a clinically significant improvement in the most bothersome PROMIS domain T-score in sleep disturbance and physical function domains and actual score on 0-10 scale for pain intensity domain from baseline to 3 month's post-baseline.	3 months post-baseline appointment
Change in PROMIS pain intensity between Arms 1 and 2 among participants for whom pain is the most bothersome domain at baseline	Among those for whom pain is the most bothersome domain at baseline, we will compare the change in PROMIS pain intensity scores in Arm 2 vs. Arm 1.	3 months post-baseline appointment
Change in PROMIS physical function between Arms 1 and 2 among participants for whom physical function is the most bothersome domain at baseline	Among those for whom physical function is the most bothersome domain at baseline, we will compare the change in PROMIS physical function scores in Arm 2 vs. Arm 1.	3 months post-baseline appointment
Change in PROMIS sleep disturbance between Arms 1 and 2 among participants for whom physical function is the most bothersome domain at baseline	Among those for whom sleep disturbance is the most bothersome domain at baseline, we will compare the change in PROMIS sleep disturbance scores in Arm 2 vs. Arm 1.	3 months post-baseline appointment

3.3. Study Period

The study intervention will be active for a period of at least 12 months or until the adequate sample size is recruited.

3.4. Study Population

The study will include participation of patients with rheumatic diseases.

1. Patients: New and established patients seeking care at Michigan Medicine rheumatology clinics.
    a. Eligibility criteria:
        i. Age ≥ 18 years
        ii. Patients should be able to read and write English
        iii. Patients should have access to the MyUofMHealth patient portal
        iv. Patients should have access to the internet to be able to complete the PROMIS PRO measures and study surveys online
    b. Trial inclusion criteria:
        i. Patients should have completed PROMIS pain, physical function, and sleep disturbance measures at least one day before their baseline appointment
        ii. At least one of the PROMIS PRO scores should be in the concerning zone (pain intensity ≥ 5 (0-10), physical function ≤ 40 (on a T-score), or sleep disturbance ≥ 60 (on a T-score)).
2. Providers: Rheumatology HCPs, including clinicians and advanced practice providers at Michigan Medicine
    a. Eligibility criteria:
        i. Currently treating rheumatology patients

3.5. Recruitment

We will inform HCPs in the Division of Rheumatology about the study and what it will entail for patients who decide to participate. To ensure that non-participating HCPs will not be surprised by patients' questions about interventions in the study, we will also inform the rheumatology HCPs about where they can view PROMIS scores in the EMR and about the information that will be shared with patient participants.

We will approach eligible patients with upcoming appointments scheduled with an initial recruitment email, with follow-up contact via email, phone call, or text. Patients will be able to opt out of further communications regarding this study at any time. We will also approach rheumatology HCPs at University of Michigan clinics interested in participating.

Interested patients and HCPs will be contacted and informed about the details of the study. All interested patients and HCPs will be given an informed consent. Patients will be given the choice to opt in to participating in the qualitative portions of the study if interested.

3.6. Study Activities

This study will have two components: a controlled trial to assess the impact of integrating PROs into clinical practice, and qualitative interviewing (optional for patients and HCP's) to identify barriers to and facilitators of effective integration. This protocol is for the controlled trial.

Figure 3 (Study Flowchart) and Figure 4 (Study Schedule of Events) show how the different parts of the study will fit together.

Figure 3. Study Flowchart

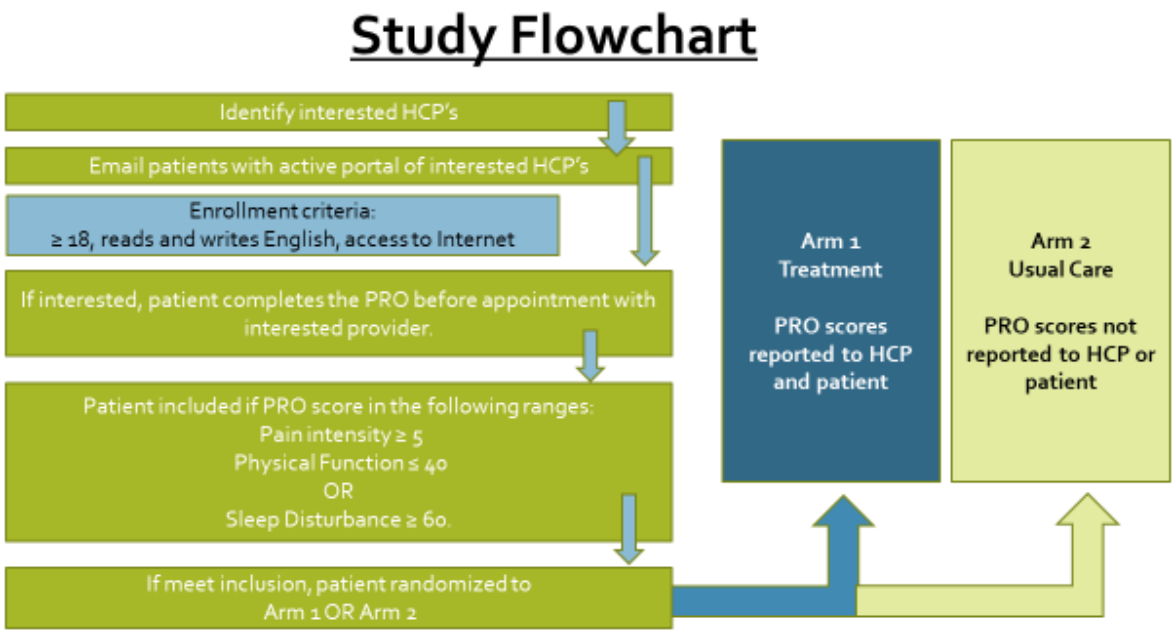


Figure 4. Study Schedule of Events

	Screening*	Baseline/ enrollment**	3 months after baseline appointment	End of study
***For patients**:*				
Informed consent	X			
Patient background survey	X			
PROMIS questionnaires *** (pain intensity, physical function, and sleep disturbance)	X		X	
Email with PRO scores to patients in Arm 1****		X		
Post-appointment survey		X		
3 month follow-up survey			X	
Patient interview (Optional)				X
***For HCPs**:*				
Informed consent	X			
Email Arm 1 enrolled patient PRO score summaries to HCP1		X		
Post-study interview				X

*Patients will be in the screening phase from time of consent to first reported concerning PROMIS score.
**Patients are enrolled only after reporting a concerning PROMIS score.
***Patients are asked to complete PROMIS questionnaires prior to visits as part of standard of care; only PROMIS scores from patients who opt in for screening will be reviewed for eligibility.
****Only Arm 1 receives scores

Patients will have up to 2 weeks to complete surveys/questionnaires.

3.6.1. Pre-trial Period

Once consented to the study, patients will be asked to complete PRO questionnaires online (which includes PROMIS pain intensity, physical function, and sleep disturbance) that are integrated in the MiChart before their next rheumatology appointment (within 3 weeks prior to their scheduled appointment), as part of the current standard of care for UM rheumatology patients. To promote completion of the PRO questionnaires, we will send email and/or text reminders to all consented patients.

Patients will be enrolled in the trial the first time that they report a concerning level of symptoms (pain intensity ≥ 5, physical function ≤ 40, or sleep disturbance ≥ 60). Enrolled patients will be randomized to Arm 1 or Arm 2 in 1:1 fashion. Patients who do not have concerning scores will not be enrolled and excluded from the trial.

3.6.2. Controlled Trial

3.6.2.1. Trial Study Design

There will be two arms (1: 1 randomization) of the trial to assess PRO integration into care (Figure 3).

- Arm 1: PRO Integration into Clinical Practice Intervention Group
- Arm 2: Usual Care Control Group

3.6.2.2. Interventions

PRO Integration into Clinical Practice Treatment Group

For Arm 1, PRO scores will be shared with patients and HCPs via an emailed report card in order to facilitate discussion of the PRO scores during consultation. HCPs will document their discussion and recommendations/referrals using the dot phrase in MiChart (Epic EMR).

Usual Care Control Group

For Arm 2, patients and HCPs will not receive an emailed PROMIS score report. PROMIS scores, however, will be available in the EMR as usual. This arm will receive *usual care*.

3.6.2.3 Stratification, Randomization, and Blinding/masking

Patients eligible for randomization to Arm 1 or Arm 2 will be first stratified based on their concerning PRO domain.

- If the patient has only one concerning PRO domain:
    - Patients will be placed into one of 3 groups: “Concerning pain”, “Concerning sleep” or “Concerning physical function”
- If the patient has more than one concerning PRO domain:

- Patient will be asked to complete a single-item survey to rank the PRO domains in order of importance.
- Depending on what domain patients indicate is the most concerning to them, patients will be placed into one of 3 groups: “Concerning pain”, “Concerning sleep”, or “Concerning physical function”.

A permuted block randomization scheme stratified by most concerning PRO domain (pain, sleep, physical function) will be created before enrollment begins. Once a participant has completed the screening and evaluation for inclusion/exclusion criteria, the participant will enter the randomization process. Participants will be randomized to Arm 1 and Arm 2 with equal probability (1:1) in RedCap. At time of randomization, the investigator or study coordinator will use the randomization sheet to obtain the assigned randomization number and intervention assignment. In this study, participants and physicians will know the assigned treatment group.

3.6.2.4. Outcome Assessment

Health outcomes (PROMIS pain intensity, physical function and sleep disturbance) will be assessed before appointments and at three (3) months post appointment with an online patient-reported survey.

Patient-provider communication, the patient’s experience with the PRO scores, and satisfaction with disease management will be assessed with a patient-reported survey after the appointment.

Process of care measures (documentation and interpretation of PRO scores, clinical decisions) will be assessed for each appointment using data from the EMR (notes, medication changes, and referrals). We will utilize the Data Direct tool to assist with exporting quantitative data from the EMR, and the EMERSE tool to assist with reviewing textual data from the EMR (https://research.medicine.umich.edu/our-units/data-office-clinical-translational-research/data-access/self-serve-data-tools).

Study Measures/outcome Variables

Table 3 below summarizes the measures and outcomes to be used to compare health outcomes and processes of care for the different study arms.

Patient-provider communication will be measured using the Interpersonal Process of Care Survey (IPCS) with a 12-item communication subscale and an 8-item patient-centered decision making subscale [24]. It has been used to predict patient satisfaction [30].

Satisfaction with treatment will be measured using the Treatment Satisfaction Questionnaire for Medication (TSQM version 1.4) [25].

Satisfaction with care will be measured using the Leeds Satisfaction with Care Questionnaire, which was developed for patients to assess quality of rheumatology care [26].

Table 3. Study Measures/outcome Variables

Measure/variable name	Description	Type
PROMIS Numeric Rating Scale v1.0 – Pain Intensity 1a	Patient reported rating of average pain intensity over the last 7 days (instrument, 1 item)	Continuous. Ranges from 0 (no pain) to 10 (worst pain you can think of)
PROMIS Physical Function Computer Adaptive Test (CAT)	Patient reported ability to do activities of daily living (computer adaptive test instrument)	Continuous. T-score ranges from approximately 20 (extreme impairment)-80 (no impairment)
PROMIS Sleep Disturbance CAT	Patient reported sleep quality (computer adaptive test instrument)	Continuous. T-score ranges from approximately 20 (no problems with sleep)-80 (severe problems with sleep)
Interpersonal Processes of Care Survey	Patient reported quality of patient-provider communication (instrument, 29 items) [24]	Continuous scores for 7 domains: hurried communication, elicited concerns/responded, explained results/medications, patient-centered decision making, compassion, discrimination, and disrespectful office staff. Scores range from 1-5 for each domain.
Discussion of PRO scores with patient during the appointment	Patient report of whether the physician discussed the PRO scores during the appointment (post-appointment survey question).	Binary
Satisfaction with rheumatology care	Leeds Satisfaction with Care Questionnaire (post-appointment survey) [26]	Continuous. Score ranges from 1-5, with higher value indicating greater satisfaction.
Satisfaction with treatment	Treatment Satisfaction Questionnaire for Medication 1.4 (post-appointment survey) [25]	Continuous. Measures 4 domains, including Effectiveness, Side Effects, Convenience, and one global scale item, Global Satisfaction; each domain score ranges from 0-100, with higher score indicating greater satisfaction.
Documentation of PRO scores in the EMR note	Whether the HCP imported the PRO scores into the EMR note (outcome)	Binary

Interpretation of PRO scores	Whether the HCP interpreted the PRO scores (outcome)	Binary
Clinical decision	What decision was taken at the appointment to address the patient's issues (outcome).	Categorical. Possible decisions include: medication change, referral to another provider, and no action taken.

3.6.2.5. Qualitative Assessment of the PRO Integration Process

We will use a combination of qualitative interviews with patients and HCPs participating in the study, and open-ended survey questions to identify the barriers and facilitators to integrating PROs into the clinical workflow, as well as the reasons these barriers and facilitators are arising, and how they may be addressed in the future. Using varied sources of information collected from different stakeholders (patients and HCPs) and at different times will allow us to develop a more objective and richer picture of how the PROs fit into the clinical workflow and how to facilitate increased uptake and more effective usage in the future.

The RE-AIM model will [31] be used to guide investigation of specific aspects of implementation, including recruitment and retention of patient and HCP participants, the impact of interventions on study outcomes, adaptations made to the interventions during the study, factors influencing use of PROs during the study, intention to continue using PROs after the study, and long-term sustainability of the interventions and behaviors.

3.6.2.5.1. Qualitative Interviews with Patients and HCPs

We will conduct semi-structured interviews with up to 10 patients from Arm 1 to understand patients' perspectives on how the PRO information was discussed and used during their appointments, and how PROs fit into their overall care. Interviews will take place after completion of the three (3) month PROMIS questionnaire. During interviews, patients will be asked to discuss their rheumatic disease status, their needs and expectations for the appointment, how the PRO information was discussed or used during the appointment, what decisions were made to address their needs, and their satisfaction with the appointment.

We will also conduct semi-structured interviews with up to 5 HCPs who have patients in Arm 1. During the interview, HCPs will be asked to discuss their experience using PROs in clinical practice, what went well/not well, why, and what changes could help facilitate integration of PROs into practice. HCP interviews will take place toward the end of the study.

Interviews for both patients and HCPs will be conducted via telephone or Zoom Health, and will be recorded and transcribed. Transcripts will be deidentified before analysis to protect interviewees' privacy.

3.6.2.5.2. Open-ended Survey Questions

Open-ended survey questions will be included in the post-appointment survey for patients and the 3-month follow-up surveys for patients.

These questions will allow patients and to communicate anything they think is relevant about their experience which cannot be otherwise conveyed through the remaining survey questions.

3.7. Study Analyses

Our data sources for this study will be electronic medical records (EMR), survey responses collected through REDCap, and qualitative data collected through semi-structured interviews. We will utilize the Data Direct tool to assist with exporting quantitative data from the EMR, and the EMERSE tool to assist with reviewing textual data from the EMR (https://research.medicine.umich.edu/our-units/data-office-clinical-translational-research/data-access/self-serve-data-tools).

3.7.1. Statistical Analysis

Sample Size Calculation:

Up to 300 patients will be randomized. Based on our preliminary review, we believe that 70% of the consented patients will meet the inclusion criteria with concerning zone. We expect to screen up to 1,000 patients to meet the randomization goals.

The current study is a convenience sample size since we don't have a priori data to calculate sample size. We believe that approximately 300 patients randomized in 1:1 fashion will give robust point estimates to design a Phase 3 trial.

Planned Analyses:

Characteristics of patients will be summarized descriptively, by treatment group and overall, using numerical and graphical methods. We will compare Intervention groups on baseline characteristics, including demographics and PRO measurements, using descriptive statistics. Fisher's exact test and ANOVA/Kruskal-Wallis will be used to comparing the three treatment arms.

For categorical outcomes, count and proportion and 95% confidence interval will be reported. For continuous outcomes, mean, standard deviation, median, and inter-quartile range will be reported. P value < 0.05 will be considered statistically significant.

T-scores for the physical function, sleep disturbance and actual score on 0-10 scale for pain intensityat baseline and 3 month follow-up will be calculated based on the guidelines provided by http://www.healthmeasures.net/media/kunena/attachments/257/PROMIS29_Scoring_08082018.pdf.

The planned statistical analyses will enable us to assess the feasibility of the study and assess the potential effects of the interventions. The information gained from this project will help us design the

next trial to formally test the effect of PRO integration on communication, decision making, and health outcomes.

3.7.2. Analysis of Qualitative Data

The qualitative data gathered will include transcriptions of interviews and free text comments from post-appointment surveys. Analysts will code the deidentified data using CAQDAS software such as NVIVO. The analysts will perform inter-rater reliability checks periodically to ensure coding is reconciled. Coded concepts will be organized into themes describing barriers and facilitators to PRO integration into clinical practice, and ways to facilitate more effective PRO integration and uptake in the future.

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