

Integrating PROMIS Measures in a Treat-to-Target Approach to Standardize Patient-Centered Treatment of Rheumatoid Arthritis

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ABSTRACT. Objective. To evaluate the effect of a patient-centered rheumatoid arthritis (RA) treat-to-target (T2T) disease management approach on patient outcomes and patient satisfaction with care.

Methods. In this longitudinal, observational pilot study, rheumatologists implemented a modified T2T approach that integrated Patient Reported Outcomes Measurement Information System (PROMIS) measures for depression, fatigue, pain interference, physical function, and social function into RA care. Study participants selected 1 PROMIS domain to target treatment and completed quarterly follow-up assessments. Participants were classified as improved if their Clinical Disease Activity Index (CDAI) changed by > 5 points. Change in PROMIS *t* scores was examined for the group with improved CDAI, and then compared to those with unchanged or worsened CDAI. Satisfaction with care was assessed using multiple measures, including the Functional Assessment of Chronic Illness Therapy–Treatment Satisfaction–Patient Satisfaction Scale.

Results. The analytical sample (*n* = 119, median age 57 years, 90.8% female) was split between those with CDAI > 10 (*n* = 63) and CDAI ≤ 10 (*n* = 53). At 1 year, there was improvement in CDAI by > 5 points in 66% and 13% of individuals with baseline CDAI > 10 and baseline CDAI ≤ 10, respectively. Across all participants, improvement in CDAI by > 5 points correlated with improvements in the 5 PROMIS domains. Satisfaction with RA treatment also increased.

Conclusion. The integration of PROMIS measures into the T2T approach for RA care was associated with improvements in disease activity, and improvement in disease activity was associated with improvements in PROMIS measures.

Key indexing terms: disease management, outcome assessment, patient satisfaction, patient-centered care, rheumatoid arthritis

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The treat-to-target (T2T) approach has become the standard of care for the management of patients with rheumatoid arthritis (RA) since the publication of the principles of the T2T strategy.¹ Studies have demonstrated the benefit of this approach in achieving remission of disease activity.²⁻⁴ An integral component of the T2T approach in RA is shared decision making between patients and clinicians.¹ Initial publication of the T2T recommendations was followed by publication of a version specifically written for patients so that they could better understand and participate in treatment decisions.⁵ Although patient involvement is central to the T2T recommendations for RA therapy, clinical trials evaluating the efficacy of the T2T strategy have focused mainly on composite disease activity measures (eg, Clinical Disease Activity Index [CDAI], Disease Activity Score in 28 joints [DAS28]) and states (eg, low disease activity, remission); limited research has examined outcomes that are driven by patient perspectives and priorities.^{6,7} It is important to address patient-centered outcomes, such as ability to work, and acknowledge patient concerns, such as cost of therapy, to effectively implement and assess T2T strategies in RA clinical

care.^{8,9} Patient involvement in the decision-making process with healthcare providers has been linked to increased treatment adherence and satisfaction with medical treatment of RA.¹⁰ However, patients and clinicians may consider different aspects of disease when making treatment decisions^{11,12} and improvements in conventional measures of disease activity are not always associated with corresponding improvement in patient-reported outcomes (PROs).¹³

Few studies have examined tools that would enable rheumatologists to include patients' perspectives in disease management to ensure that the target for treatment is appropriate for the individual patient.⁷ One potential approach is the Patient Reported Outcomes Measurement Information System (PROMIS). PROMIS, a US National Institutes of Health Common Fund initiative, produced PRO measures for use across adult and pediatric diseases and health conditions. PROMIS measures assess multiple outcomes relevant to patients with RA, including depression, fatigue, pain interference, physical function, and social function,¹⁴⁻²¹ and several studies have validated its use in RA.¹⁹⁻²³ PROMIS provides a mechanism for selecting areas affected by RA disease that are important to individual patients and produces scores using a common metric.

We previously demonstrated the feasibility of integrating PRO measures in an RA clinic with limited effect on work flow, and showed that PROMIS measures are a valid and reliable way to assess patient preferences in clinical practice,²⁴ advancing the use of PROMIS in clinical practice settings.^{25,26} In this follow-on pilot study, we had 2 primary goals: (1) to evaluate any effect a patient-centered T2T approach may have had on patient outcomes as measured by CDAI, Routine Assessment of Patient Index Data 3 (RAPID3),²⁷ and PROMIS measures of depression, fatigue, pain interference, physical function, and social function; and (2) to assess patient satisfaction with care over the course of the study. We hypothesized that integration of PROMIS data into RA practice would lead to better clinical outcomes, particularly those that incorporate the patient's perspective, and would increase patient satisfaction with care.

METHODS

Our study protocol has been described in a prior publication.²⁴ Briefly, participants in this longitudinal, observational pilot study were recruited from an academic rheumatology clinic during a 16-month period from May 2014 to September 2015. Clinicians prescreened patients with RA during their clinical visit to identify potential participants and referred them to a study coordinator who screened, consented, and enrolled eligible patients into the study. We sought to recruit a sample that was evenly divided between remission or low disease activity (CDAI \leq 10) and moderate to high disease activity (CDAI > 10). Additional inclusion and exclusion criteria have been described previously.²⁴ Participants were treated with a modified T2T approach that included standard clinical assessments using the CDAI and the RAPID3, in addition to PROMIS computer adaptive tests (CATs). The RAPID3 is a patient-reported assessment of disease activity (comprising the Multidimensional Health Assessment Questionnaire [MDHAQ] RA core data set measures for physical function, pain, and patient global estimate) initially adjusted to a scale of 0-10, but later revised to use a scale of 0-30 to simplify the calculation.²⁷ Like the CDAI, it can be divided into categories of disease activity. Using the 0-30 scale, remission is \leq 3, low disease activity is > 3 to 6, moderate disease activity is > 6 to 12, and high disease activity is \geq 12.²⁸ Also using the 0-30 scale, the minimally clinically

important difference has been assessed at 3.8.²⁹ The PROMIS measures were developed using rigorous qualitative and quantitative methods²² and have demonstrated validity in RA.^{19-21,23,30} We compensated participants for their time investment. The study protocol was approved by the Northwestern University Institutional Review Board (ID STU00093803).

We included the following measures at baseline: sociodemographic survey; PROMIS CATs assessing depression, fatigue, pain interference, physical function, and social function; an item assessing satisfaction with RA treatment ("Are you satisfied with your current treatment for managing your RA?") with scores ranging from 1 (completely satisfied) to 4 (completely dissatisfied); and the Functional Assessment of Chronic Illness Therapy–Treatment Satisfaction–Patient Satisfaction (FACIT-TS-PS).³¹ The FACIT-TS-PS is a 30-item measure of patient satisfaction, with subscales for physician communication, treatment staff communication, technical competence, nurse communication, and confidence and trust. The PROMIS CATs were administered in the RA clinic using Northwestern University's web-based Assessment Center data collection platform that allows local data collection systems to administer self- and proxy-reported measures.³² Participants completed a total of 5 scheduled assessments. After the baseline study visit, they completed quarterly follow-up assessments over a 12-month period. The assessments were designed to coincide with routine clinic visits. Patients were encouraged to complete the CATs in advance of the visit to shorten time spent in clinic and to allow providers access to results for review at the start of the visit. Participants who missed clinic visits were contacted by study coordinators to give them the opportunity to complete assessments remotely by internet or telephone.

At the beginning of the study, each participant ranked the 5 PROMIS domains for their importance relative to current treatment. For the PROMIS domain selected as most important, participants further customized their assessment by selecting 5 items from the domain's full item bank that they felt best addressed their treatment goals. At each assessment, participants rated their selected PROMIS items along with a set of random, preselected PROMIS items (1 item from each of the 5 domains) that were used as control items when assessing improvement in the selected items. We included these control items to help identify whether any changes could be attributed to patient and clinician focus on the items of interest rather than just broad changes in disease activity, or simply to participation in the study. A study coordinator shared each participant's most important PROMIS domain and their 5 selected items with the treating clinician using a 2-page PRO summary report, which included a table with PROMIS CAT *t* scores and charts with PROMIS CAT *t* scores and RAPID3 scores over time (a PRO summary report with illustrative data is included as Supplementary Material to this article, available from the authors upon request). These data, along with CDAI, were tracked in subsequent visits after being manually added to a standardized flow sheet in the participant's electronic medical record. The 14 rheumatologists participating in the study were provided with information and training on PROMIS measure use and scoring, and they were able to use this information to guide conversations about whether treatment goals, both standardized and personalized, were being met. Treatment goals in each case were determined by the treating rheumatologist. We surveyed clinicians after each visit to assess whether a treatment change had been made, and whether PROMIS data had influenced this decision.

For analyses of the patient-selected and the random, preselected PROMIS items, we averaged the 5 items, rated on a 1-5 scale, such that higher scores represented better outcomes. PROMIS measures have a mean of 50 and SD of 10, referenced to a general population, and higher scores represent more of the measured domain (eg, more pain, better physical function). Average change from baseline was estimated for CDAI, RAPID3, and PROMIS scores, stratified by baseline disease activity group and, separately, by priority domain. We classified participants as improved at 1 year if their CDAI changed by > 5 points. Although some have suggested the use of different cut points for assessing change depending on starting CDAI value,³³ we opted for a consistent 5-unit change in this analysis based

on patient characteristics in our rheumatology practice and the observation that most patients in our sample (79.3%) had starting CDAI values in the low to moderate range (CDAI < 10: 49/116 = 42.2%; CDAI 10-22: 43/116 = 37.1%; CDAI > 22: 24/116 = 20.7%). Use of this metric in our pilot study was novel, yet sensitive to prior research,³³⁻³⁵ and aimed to help establish the feasibility of using PRO data to enhance clinical decision making and patient outcomes. Change in PROMIS *t* scores was examined for the group with improved CDAI, and then compared to those with unchanged or worsened CDAI. The FACIT-TS-PS subscale items, rated on a 0-3 scale ("Not at all" to "Yes, and as much as I wanted"), were summed such that higher scores represented higher satisfaction, and changes in mean scores were assessed between baseline and year 1 using a mixed model for repeated measures.

RESULTS

We enrolled 121 patients with RA into the pilot study; 119 provided complete PROMIS data at their baseline visit and formed the analysis sample. Of these, 102 (85.7%) completed the 3-month visit and 99 (83.2%), 87 (73.1%), and 91 (76.5%) completed the 6-, 9-, and 12-month visits, respectively. At each of these visits, PROMIS data were available for 97.5-99% of participants, CDAI for 71.3-97.5%, and RAPID3 for 67.8-93.4%. Representative of the population of patients with RA, the study sample had a median age of 57 (range 21-77) years and most participants were female (90.8%; Table). Over two-thirds (69.7%) of participants had a college or advanced degree, and 59.7% were employed at the baseline assessment. The sample was split between those with CDAI > 10 (*n* = 63) and CDAI ≤ 10 (*n* = 53). Although baseline PROMIS *t* scores for depression and social function were not substantially different from the general population mean of 50, patients in this sample reported worse pain interference, fatigue, and physical function (Table). Detailed baseline demographics are presented in the Table, and a table with baseline demographics by CDAI group is included as Supplementary Material to this article (available from the authors upon request). Participant-selected priority PROMIS domains have been reported previously, with physical function, pain, and fatigue being selected most frequently as most important (38.7%, 37%, and 16% of the full sample, respectively).²⁴

Improvement in disease activity was largely seen in participants with moderate or high disease activity at baseline (Figure 1). At 1 year, we saw improvement in CDAI by > 5 points in 27/41 (66%) individuals with baseline CDAI > 10; 15 (37%) of these individuals had a CDAI improvement of > 10 points. For those with baseline CDAI ≤ 10, 6/47 (13%) had an improvement of > 5 points; 38 (81%) were unchanged over the course of the year (CDAI change ± 5 points or less). Improvement in CDAI by > 5 points correlated with mean changes in the 5 PROMIS domains across the entire sample (Figure 2). The change in CDAI was greatest in those participants who selected pain as their priority domain; participants who selected physical function and fatigue had similar changes in CDAI at year 1 (Figure 3). RAPID3 improvements mirrored the CDAI response, as the mean improvement in those with baseline CDAI ≤ 10 was 1.7, whereas the improvement in those with baseline CDAI > 10 was 9.5.

At baseline, PROMIS scores for depression, fatigue, pain, physical function, and social function, were all significantly

Table. Participant characteristics, CDAI, and PROMIS scores at baseline and 1-year follow-up (*n* = 119).

	Value
Age, yrs	57 (21-77)
Gender	
Female	108 (90.8)
Male	11 (9.2)
Hispanic ethnicity	14 (11.8)
Race	
White	84 (70.6)
Black	17 (14.3)
Asian	2 (1.7)
American Indian/Alaska Native	1 (0.8)
Other	15 (12.6)
Education	
Some high school	2 (1.7)
High school graduate/GED	11 (9.2)
Some college/technical degree/AA	23 (19.3)
College degree (BA/BS)	47 (39.5)
Advanced degree (MA/PhD/MD)	36 (30.2)
Marital status	
Never married	21 (17.6)
Married/in committed relationship	78 (65.5)
Separated/divorced	16 (13.4)
Widowed	4 (3.4)
Employment status	
Employed/self-employed	71 (59.7)
Unable to work	8 (6.7)
Out of work	5 (4.2)
Homemaker	5 (4.2)
Student	2 (1.7)
Smoker	7 (5.9)
CDAI (baseline ^a ; 1-yr follow-up ^c)	
CDAI > 10	63 (54.3); 26 (29.6)
CDAI value, mean (SD)	14.0 (12.1); 8.6 (8.4)
RAPID3 (baseline ^b ; 1-yr follow-up ^c), mean (SD)	9.7 (6.2); 7.9 (6.6)
PROMIS <i>t</i> scores (baseline ^a ; 1-yr follow-up ^c), mean (SD)	
Depression	51.6 (8.4); 49.0 (9.7)
Fatigue	56.4 (9.1); 53.4 (9.1)
Pain interference	57.7 (7.5); 54.6 (9.4)
Physical function	42.4 (5.9); 44.6 (7.9)
Social function	47.3 (7.2); 49.8 (8.3)

Values in table are *n* (%) or median (range), unless otherwise specified.

^a Three participants with missing baseline data. ^b Twelve participants with missing baseline RAPID3. ^c *n* = 88 participants with 1-year follow-up data for CDAI, *n* = 85 for RAPID3, *n* = 90 for PROMIS *t* scores. AA: Associate in Arts; CDAI: Clinical Disease Activity Index; GED: General Educational Development; PROMIS: Patient Reported Outcomes Measurement Information System; RAPID3: Routine Assessment of Patient Index Data 3.

worse for participants with CDAI > 10. When changes in the 5 PROMIS domains were considered, there was overall improvement in all domains for all participants (ie, those with baseline CDAI ≤ 10 and those with CDAI > 10). The improvement in depression was more prominent for those with baseline CDAI ≤ 10. For other domains, improvement was independent of baseline disease activity (Figure 4). The participant-selected PROMIS items showed improvement in both those with

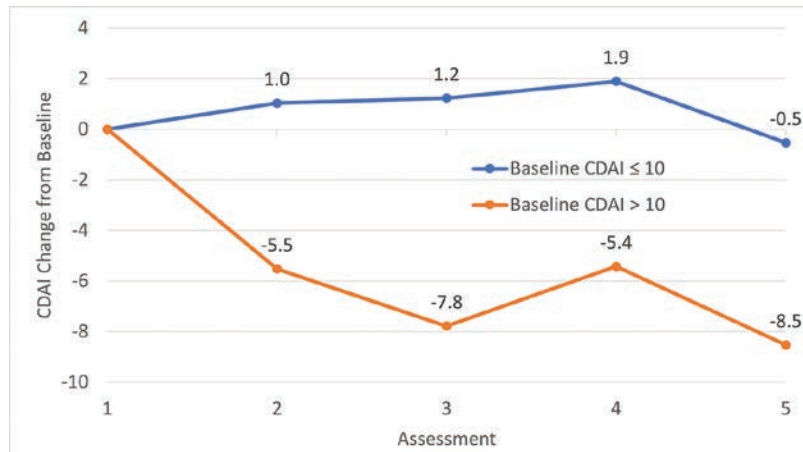


Figure 1. Change in CDAI by baseline disease activity. CDAI: Clinical Disease Activity Index.

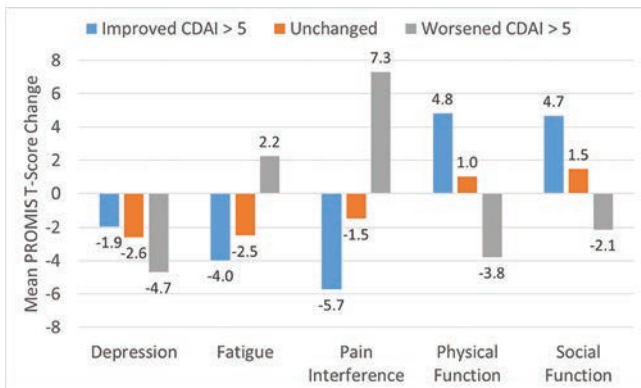


Figure 2. Change in PROMIS *t* scores by change in CDAI from baseline to 1 year. Note: group differences and changes ≥ 2 points may be clinically meaningful. CDAI: Clinical Disease Activity Index; PROMIS: Patient Reported Outcomes Measurement Information System.

CDAI ≤ 10 (mean 0.71 [standard error (SE) 0.13]) and CDAI > 10 (mean 0.89 [SE 0.14]) at baseline. Mean improvements in the random, preselected items were only 0.34 (SE 0.08) in participants with baseline CDAI ≤ 10 and 0.12 (SE 0.10) in those with baseline CDAI > 10 .

We surveyed clinicians about whether PROMIS data influenced their RA treatment decisions. There were 12 care visits during which treatment was changed even though CDAI was ≤ 10 ; in 2 of these cases, the clinician reported that the PROMIS data influenced that decision (Figure 5). By contrast, 68/109 (62.4%) care visits with CDAI > 10 did not result in a change in treatment. In 15 (22.1%) of these visits, clinicians indicated that the PROMIS data had influenced this decision.

We also asked participants to rate satisfaction with their disease management. At baseline, 46.2% of participants reported that they were completely satisfied with their current treatment for managing their RA (64% of those with CDAI ≤ 10 , 31% of those with CDAI > 10). At 1 year, 58% of participants were completely satisfied with their current treatment (68% with CDAI ≤ 10 , 47% with CDAI > 10). However, FACIT-TS-PS subscale scores declined over time. These declines were numerically small but statistically significant. Specifically, mean change from baseline to year 1 was -2.08 (SE 0.40, $P < 0.001$) for physician communication, -0.80 (SE 0.44, $P = 0.07$) for treatment staff communication, -0.28 (SE 0.10, $P = 0.004$) for technical competence, -0.49 (SE 0.21, $P = 0.02$) for nurse communication, and -0.53 (SE 0.14, $P < 0.001$) for confidence and trust.

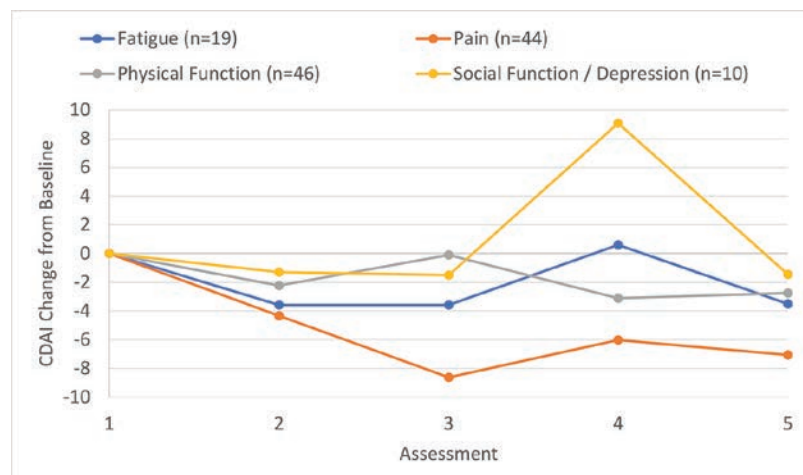


Figure 3. Change in CDAI by participants' highest priority PROMIS domains. CDAI: Clinical Disease Activity Index; PROMIS: Patient Reported Outcomes Measurement Information System.

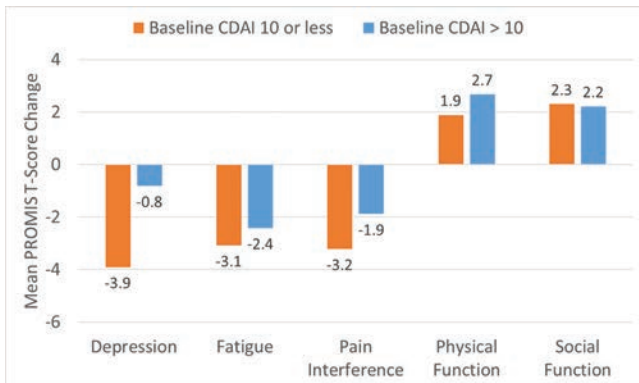


Figure 4. Change in PROMIS *t* scores from baseline to 1 year by baseline CDAI. Note: group differences and changes ≥ 2 points may be clinically meaningful. CDAI: Clinical Disease Activity Index; PROMIS: Patient Reported Outcomes Measurement Information System.

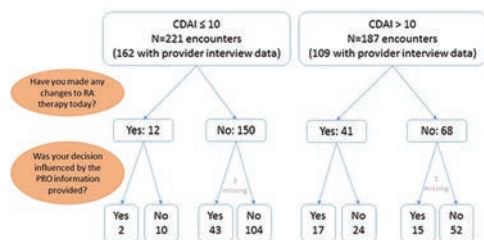


Figure 5. Clinician-reported effect of PROMIS data on treatment decisions. CDAI: Clinical Disease Activity Index; PRO: patient-reported outcome; PROMIS: Patient Reported Outcomes Measurement Information System; RA: rheumatoid arthritis.

At the conclusion of the study, when participants were asked whether they had noticed changes in their physician's behavior, 73/90 responding (81%) said no. When provided an opportunity to comment, most responded that they were already satisfied with their clinician's care. However, when surveyed if sharing the things most important to them had improved the care that they had received, 64 (71%) agreed (43% reported to some degree, 28% reported to a great degree).

DISCUSSION

Our previous research demonstrated that PROMIS measures can be integrated into the routine clinical care of a sample of patients with RA, and rheumatologists indicated that integration occurred without significant disruption of clinic flow.²⁴ The present study, which incorporated these measures, showed that changes (improved and worsened) in disease activity at 1 year were related to baseline disease activity. Improvements in disease activity were seen primarily in those participants entering the study with a CDAI > 10 , indicating active disease. Interestingly, changes in PROMIS measures were less related to baseline disease activity. Modest mean improvements in PROMIS scores for all 5 measured domains, including physical function and fatigue, which were top priority domains for 75.7% of the sample, were seen in participants with and without active disease at baseline. Depression was not perceived as a significant issue for most

participants in our sample; 60.5% indicated that depression was the PRO domain that was least important for them. Importantly, this study demonstrated the responsiveness of PROMIS data in RA in the directions of improvement and worsening using a clinical anchor, thus highlighting that PROMIS self-reported health measures correspond with disease activity measures and provide unique information not identified by CDAI or RAPID3. For example, our approach using PROMIS adds fatigue, depression, and anxiety to the physical function, pain, and patient global estimate domains identified by RAPID3.

Pain was frequently selected by participants as the PRO domain most important to them. We found it interesting that those selecting pain as their priority domain were more likely to have improvement in CDAI scores over the year. Further research should explore whether this resulted from a higher likelihood of escalating therapy when indicated because the presence of pain led the patient or the rheumatologist to be more accepting of a change. In an analysis of the Dutch Rheumatoid Arthritis Monitoring (DREAM) cohort, clinical improvement was not always associated with patient perceptions of perceived health improvement.⁶ Pain and fatigue were the 2 factors most likely to be associated with patient perceptions of nonimprovement in the DREAM cohort, suggesting that the intersection between pain and patient perceptions of response would be an intriguing area to explore.

Although clinicians in our practice generally follow a T2T approach to RA management (though this is not explicitly mandated by practice guidelines), we found that treatment was not always modified as indicated by T2T recommendations. During the course of our study, treatment changes were made at only 37.6% of the visits at which the CDAI score was > 10 . This lack of treatment acceleration when indicated has been shown in previous T2T clinical trials.^{4,36,37} For example, in a cluster-randomized trial of T2T in US rheumatology practices, treatment acceleration at the T2T sites ($n = 246$), as a percentage of visits where it was indicated, fell from 73% at enrollment to 31% at 9+ months.³⁷ In that study, the primary reasons indicated for nonacceleration were both patient-related (patient preference and comorbid conditions) and physician-related (concern for lag time of medication response and disagreement with the CDAI score).

There is also evidence that treatment is not being modified in accordance with T2T recommendations in clinical practice.^{7,38,39} As reported by both rheumatologists and patients with RA, barriers to implementing T2T include treatment-related costs and medication risk aversion.³⁹ Patients also identified comorbidities associated with RA, inadequate medication effectiveness, and RA prognosis as additional barriers, whereas clinicians reported administrative issues (eg, prior authorization requirements) and concerns about clinical tools to reliably measure RA disease activity as barriers to controlling disease activity.³⁹ In our study, we did not identify specific reasons why RA treatment was not changed when indicated. However, in 22.1% of study visits, the rheumatologist reported that PROMIS data had influenced this decision, indicating that PROMIS measures may have provided information about the participant that was

not obtained from routine history and clinical examination. As with prior research,²⁵ our data indicate that regular collection of PRO data may provide a mechanism by which patient self-assessment and goals can influence treatment recommendations. Moreover, research has shown that when patients participate in shared treatment goal discussions with their rheumatologists, they are more likely to be satisfied with their treatment plans, have improved disease activity levels, and reach remission.⁴⁰

Finally, results for satisfaction with care in this study were mixed. Based on our single-item measure, participants reported improvement in satisfaction with RA care, despite being largely satisfied with their care at baseline. We administered this item because the FACIT-TS-PS is not structured to provide an overall measure of patient satisfaction.³¹ The individual subscales of the FACIT-TS-PS reflected small but statistically significant decreases in scores, perhaps reflecting regression to the mean, given how high baseline scores were. Participants in our study expressed the importance of being able to focus on aspects of disease impact that were particularly important to them; this potentially contributed to satisfaction with care. Patient-related reasons remain important factors when treatments are not modified as indicated by T2T guidelines, supporting the focus on patient involvement espoused in the T2T recommendations. Future studies should focus on whether the integration of individualized PROMIS data, and resultant improvement in satisfaction with care, can lead to both improved adherence to T2T guidelines and improved outcomes.

There were some limitations to our pilot study. Although rheumatologists in our practice generally approach RA management according to T2T recommendations, this research was observational, and they were not explicitly instructed to modify therapy in patients not in remission or in low disease activity. Although we asked clinicians whether PROMIS data influenced treatment decisions, we did not identify specific reasons for decisions that were made. These are areas that could be explored in future research. As an observational study, we did not include a control group in this research. A future study could randomize patients into 2 groups, with PROMIS data provided to clinicians at the time of the patient visit for only 1 of the groups. In our analysis, we classified participants as improved if their CDAI changed by more than 5 points; future research with larger, more diverse patient samples could examine appropriate values for classifying CDAI improvement, based on baseline values, that would be generalizable to rheumatology practices with a wide range of patients. We did not make analytical adjustments for participant baseline characteristics (eg, comorbidities), which may have influenced disease activity because sample sizes in most subgroups were insufficient to allow for stratified analyses. Finally, we faced some logistical challenges collecting and scoring PROMIS data from patients in a timely fashion so that clinicians were able to integrate this information into their decision making with patients. Ideally, patients would complete PROMIS CATs before each visit, and scores would be entered directly into the electronic medical record to allow clinicians to see them during the visit. Future research in this area might also

examine shared decision making when clinicians and patients both have access to PRO data to inform treatment decisions.

This pilot study suggests a link between an individualized PRO-based augmentation of a T2T approach and the management of RA and clinical outcomes. Without a control group, we cannot confirm that the intervention approach itself caused the improved outcomes. However, participants did report greater improvement in their specific, selected PROMIS items of interest, as compared to the random, preselected items, which would seem to indicate that the focus on items of interest may have affected care. Finally, on the RA-specific measure of satisfaction with care, participants reported that the use of these PROMIS measures led to greater satisfaction with care they received.

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