Evaluation of an Intervention to Support Patient-Rheumatologist Conversations About Escalating Treatment in Patients with Rheumatoid Arthritis: A Proof-of-Principle Study

Maria I. Danila,† Lang Chen,† Eric M. Ruderman,‡ Justin K. Owensby,† Ronan O’Beirne,† Joshua A. Melnick,† Leslie R. Harrold,§ David Curtis,¶ W. Benjamin Nowell,∥ and Jeffrey R. Curtis†

Objective. This study’s objective was to test whether an online video intervention discussing appropriate treatment escalation improves willingness to change treatment in people living with rheumatoid arthritis (RA).

Methods. We conducted a controlled, randomized trial among patients with RA enrolled in ArthritisPower, a United States patient registry. We recruited participants by email and surveyed their assessment of disease activity (patient global), satisfaction with disease control (patient acceptable symptom state), attitudes about RA medications, decisional conflict (decisional conflict scale), and willingness to modify RA treatment (choice predisposition scale, higher scores are better) if or when recommended by their rheumatologist. Intervention groups watched educational videos relevant to a treat-to-target (T2T) strategy, whereas control groups viewed vaccination-related videos as an “attention control.” We compared the between-group difference in patients’ willingness to modify RA treatment (primary outcome) and difference in decisional conflict about changing RA treatment (secondary outcome) after watching the videos using t tests.

Results. Participants with self-reported RA (n = 208) were 90% White and 90% women, with a mean (standard deviation) age of 50 (11) years, and 52% reported familiarity with the RA T2T strategy. We found a significant improvement in between-group difference in willingness to change RA treatment among intervention versus control participants (0.49 [95% confidence interval 0.09-0.88], P = 0.02). The effect size (Glass’s delta) for the intervention was 0.48. Decisional conflict about treatment change decreased, but the between-group difference was not significant.

Conclusion. This novel educational patient-directed intervention discussing appropriate treatment escalation was associated with improved willingness to change RA treatment if or when recommended by a rheumatologist. Further studies should evaluate whether this change in patients’ predisposition translates into actual treatment escalation.

INTRODUCTION

To maximize long-term health-related quality of life and prevent structural damage in affected joints in patients with rheumatoid arthritis (RA), current guidelines recommend that the goal of RA treatment is to achieve remission or low disease activity (1,2). This treatment approach has been termed treat-to-target (T2T) and relies on shared decision-making between clinicians and patients and periodic disease activity measurement and therapy adjustment based on goal attainment. Adherence to a T2T protocol varies, with some patients and clinicians well informed about the treatment options and goals, whereas others struggle with the concept or implementation. Initially, T2T focused on treating disease activity minimally, with the goal of remission or low disease activity, and adjusting medications or treatments when needed. More recently, T2T has evolved to include the treatment of patients with early-stage disease, as well as those who are not achieving the desired outcomes with their current treatment regimen (3). The T2T strategy aims to improve long-term health-related quality of life by optimizing treatment and minimizing treatment-related side effects.

This study was supported, in part, by Pfizer Independent Grants for Learning and Change (grant 20882063; principal investigator: Danila) and from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (grant P30 AR072583; principal investigator: Curtis). Maria I. Danila, MD, MSC, MSPH, Lang Chen, PhD, Justin K. Owensby, PharmD, PhD, Ronan O’Beirne, EdD, Joshua A. Melnick, MPH, Jeffrey R. Curtis, MD, MS, MPH: University of Alabama at Birmingham, Birmingham, Alabama; ‡Eric M. Ruderman, MD: Northwestern University, Chicago, Illinois; §Leslie R. Harrold, MD, MPH: University of Massachusetts Medical School, Worcester, Massachusetts; ¶David Curtis, BA, W. Benjamin Nowell, PhD, MSW: Global Healthy Living Foundation, Upper Nyack, New York.

Dr. Danila has received research financial support from Pfizer, Genentech, and Boehringer and consulted with Amgen and AbbVie. Dr. Ruderman consulted with Pfizer, AbbVie, Bristol-Myers Squibb, and Lilly. Dr. O’Beirne has contracts with Takeda and Bristol-Myers Squibb. Dr. Harrold has stock options with CorEvitas, LLC, consulted with Bristol-Myers Squibb, Abb-Vie, and Roche, and is a part of the speaker’s bureau for Bristol-Myers Squibb. Dr. Nowell has received financial support from AbbVie and Lilly. Dr. J. Curtis has received financial support with AbbVie, Amgen, Bristol-Myers Squibb, CorEvitas, Eli Lilly, Janssen, Novartis, Pzifer Inc., Sanofi, Shipher, and UCB. No other disclosures relevant to this article were reported.

Author disclosures are available at https://onlinelibrary.wiley.com/action/downloadSupplement?doi=10.1002%2Facr2.11393&file=acr211393-sup-0001-Disclosureform.pdf.

Address correspondence to Maria I. Danila, MD, MSC, MSPH, University of Alabama at Birmingham, Department of Medicine-Division of Immunology and Rheumatology, FOT 838, 510 20th Street South, Birmingham, AL 35294.

Email: mdanila@uabmc.edu.

Submitted for publication May 4, 2021; accepted in revised form November 9, 2021.
approach and tight control of RA disease activity can lead to a higher likelihood of clinical remission (3–5), which has been associated with improved function and slower joint deterioration (5,6). Yet, despite the availability and efficacy of many treatment options, fewer than half of patients with RA with moderate/high disease activity enrolled in a United States physician-based registry received treatment escalation (7,8).

Many factors contribute to the observed clinical inertia about RA treatment escalation, including patient-physician therapeutic alliance (9), topics discussed at the visit, patient satisfaction with the clinical visit (10,11), knowledge about the advantages of following a T2T approach (12), and variable response to a treatment change (13). In addition, many patients with RA are concerned about the adverse effects associated with frequently prescribed medications (14,15). Thus, patients often decline treatment changes because they fear worsening symptoms and potential side effects with switching medications (ie, medication risk aversion) (12,16), a fear that outweighs their optimism for symptom improvement (17). This medication risk aversion, in particular, may contribute to RA undertreatment (18) and represents a barrier to reaching the T2T goals (12,16). Thus, to improve outcomes of patients with RA, novel interventions are needed to inform patients about the benefits of tight control of disease activity and to explain the rationale behind a T2T approach, which would potentially mitigate a patient’s perceived barriers (12,16). To address this gap in RA care, we designed a patient-directed, video-based educational intervention in English that sought to encourage patients to escalate treatment for RA when appropriate. Our intervention was tested in the Confident Treatment Decisions for Living with Rheumatoid Arthritis (CONTROL-RA) study.

MATERIALS AND METHODS

Study design and participants. The CONTROL-RA study was a parallel, controlled, randomized clinical trial, implemented online, in which participants received either a video-based educational intervention describing the T2T approach to RA care (intervention group) or an attention control (described subsequently). CONTROL-RA was nested within the ArthritisPower patient registry (19), which includes over 27,000 patients with rheumatic diseases who have consented to participate in research. The registry was created in 2015 to create a digital mechanism for the capture of real-world, patient-generated data from patients with rheumatic diseases (19–21). Human subject protocols and consent procedures for the CONTROL-RA study were reviewed and approved by the Office of the Institutional Review Board (IRB) at the University of Alabama at Birmingham (IRB-151222003).

ArthritisPower enrollees 19 years of age or older were eligible to participate if they self-reported having a physician diagnosis of RA, having a Routine Assessment of Patient Index Data 3 (RAPID3) score of >12 (range 0-30) indicating high disease activity, and (i) had been treated with disease modifying anti-rheumatic drugs (DMARDs) in the 6 months preceding study initiation or (ii) had a rheumatologist’s National Provider Identifier listed in their profile. We included participants who were aged 19 years or older because the ArthritisPower Registry has IRB approval to recruit United States participants who are at least 19 years old. Patients who, in addition to RA, reported conditions such as fibromyalgia syndrome, juvenile idiopathic arthritis, psoriatic arthritis, psoriasis, osteoarthritis, osteoporosis, ankylosing spondylitis, inflammatory bowel disease, lupus, gout, dermatomyositis, polymyositis, or scleroderma were excluded. Patients were recruited using emailed invitations between March and May 2018 and were compensated for their participation.

Randomization. Participants were randomized 1:1 to the intervention or the control group using a computer-generated list of random numbers. Randomization occurred when the invitation to participate was sent. Participant randomization to each group was made by a research coordinator (JM) who did not have knowledge of the participants’ details. Study investigators were blinded to the intervention assignment.

Intervention and attention control. Based on the results of our qualitative study, which aimed to understand the barriers to T2T from patient and rheumatologist perspectives (12), we designed an educational intervention for patients to overcome barriers to escalating treatment and bolster patient participation in decisions about their RA treatment. The intervention comprised an animation-based video program that focused on providing answers to the following questions: “What is treat-to-target in RA?” “What questions should I ask when choosing a medication for RA?” “Are my RA medications helping to meet my goals?” “What risks should I consider when choosing RA medications?” “Should I consider changing my RA medications?” and “What is the difference between joint inflammation and joint damage?” These questions were generated in response to patient- and rheumatologist-identified barriers to T2T in RA (12) and were designed to showcase the benefits of a T2T strategy, as well as address potential patient concerns such as worsening symptoms and the medication side effects some experience when making a medication change. Videos had a mean duration of 2 minutes. Participants in the intervention group were required to watch the two videos “What is treat-to-target in RA?” and “Should I consider changing my RA medications?” that addressed the decision about treatment escalation and when/why it is important and appropriate to consider a change in medication. The rest of the video program was optional (ie, participants were allowed to skip content). Upon completing the video program, key information summarizing the content was displayed with instructions for patients to print and use during future rheumatology visits. This summary included a quick response (QR) code linked to a Continuing Medical Education (CME) activity for rheumatologists (22) on how to...
encourage patient participation in decisions about escalating treatment when RA was not controlled.

The participants randomized to the control group were invited to watch an attention control video program. The attention control was also animation-based and addressed issues regarding vaccinations and RA. The following topics were included: “Living with RA: why get vaccinated?” and “Living with RA: which vaccines should I get?” The videos comprising the attention control had a mean duration of approximately 1 minute and 30 seconds.

Participants were invited to watch the video program in their assigned group immediately after completing the baseline survey. In both groups after viewing each video, the participants were invited to rate on a 5-point Likert-type scale (1 representing “poor” to 5 representing “excellent”) the length, helpfulness, clarity, and interest in the material they just viewed. They were also asked to answer a comprehension question to determine the participant’s ability to understand the main points of each video.

Data collection. A baseline questionnaire evaluated patient global assessment of disease activity (23), subjective general health (possible choices were excellent, very good, good, fair, and poor), health literacy using a one-item measure asking about confidence in filling out medical forms (possible choices were extremely, quite a bit, a little bit, and not at all) (24), and whether goals of RA treatment were discussed in the prior year. Participants were asked to provide the name and location of their rheumatologist and the expected date of their next rheumatology clinic visit. Patient satisfaction with RA treatment was measured using the patient acceptable symptom state, which asks for a “yes” or “no” answer to the question “Considering all the different ways your arthritis affects you, if you were to stay in this state for the next few months, do you consider that your current health state is satisfactory?” (25). Participants’ attitude toward RA medications was inferred by surveying participants’ agreement with five positive and five negative statements about use of medications in RA, with a higher score representing a more favorable attitude toward medications (26). Participants’ willingness to change RA treatment if/when recommended by their rheumatologist was determined using the validated decision/choice predisposition scale (27). Participants were asked, “If at your next visit, your rheumatologist recommends that you change RA medication(s), would you be willing to do so?” and invited to choose answers on an 11-point scale anchored by “0 not willing at all” and “10 extremely willing” (26). Decisional conflict about changing RA treatment was measured using the validated 16-item Decisional Conflict Scale (DCS) assessing personal perception of uncertainty about changing RA treatment (28). Each item is coded on a 5-point scale from “strongly agree” to “strongly disagree.” DCS scores range from 0, representing no decisional conflict, to 100, representing extremely high decisional conflict. DCS scores lower than 25 are associated with implementing decisions, and scores exceeding 37.5 are associated with decision delay or feeling unsure about the decision (29). Participants’ responses on the surveys were linked to demographic and clinical data (eg, age, sex, rheumatoid factor and cyclic citrullinated peptide antibody status, RA duration, and DMARD use) available from the ArthritisPower registry.

Outcomes and follow-up. Two follow-up surveys were deployed, the first immediately after the participants watched the videos (ie, post-video) to assess the primary and secondary outcomes, and the second after the participants reported that they saw their rheumatologist (ie, post-rheumatology visit) for additional secondary outcomes. The follow-up surveys collected data on willingness to make a change in RA treatment and decisional conflict about changing RA treatment. The primary outcome of the study was the observed difference in the participants’ willingness to modify their RA treatment if recommended by their rheumatologist, calculated as the difference between post-video and baseline answers on the decision/choice predisposition scale. The secondary study outcomes were the difference in the decisional conflict between baseline and post-video, the difference in decisional conflict between baseline and post-rheumatology visit, and the difference in willingness to change treatment between baseline and post-rheumatology visit.

Statistical analysis. We determined that a sample size of 103 per group would provide greater than 80% power to detect a significant difference with a hypothesized effect size of at least a 10% pre-post difference (comparing intervention vs. control) in participants’ willingness to change RA treatment. Alpha was set at 0.05 and was evaluated using a one-sided test, given little or no expectation that the intervention would make participants less willing to change RA therapy. We compared outcomes between the randomized groups immediately after the video program was viewed, as well as after the participant’s subsequent visit with their rheumatologist.

We used means and standard deviations (SDs) to summarize data for continuous variables and frequency and proportions for categorical variables. A t test was used to examine pre-post difference in willingness to change RA treatment assessed using the decision/choice predisposition scale on the baseline and post-video surveys (primary outcome) comparing within-person variability in the control and intervention groups. Similarly, t tests were used to evaluate secondary outcomes. We performed a subgroup analysis for the primary outcome among the participants who stated that they were not familiar with the T2T treatment paradigm. Sensitivity analyses for the primary outcome were conducted, one excluding baseline decision/choice predisposition scores >8 (ie, high willingness to change RA treatment) and another excluding baseline decision/choice predisposition scores <2 and >8 (ie, very low and very high willingness to change...
RA treatment). All analyses were conducted in SAS (version 9.3, Enterprise Guide version 4.3, Cary, NC).

RESULTS

The study Consolidated Standards of Reporting Trials diagram is presented in Figure 1. We sent 1,264 email invitations to ArthritisPower registry participants who met our eligibility criteria between March and April 2018. A total of 234 participants were randomized, and 208 completed the post-video follow-up survey deployed immediately after viewing the video materials and were analyzed for the primary outcome. A total of 132 participants (64% overall) completed the second follow-up survey after they had a rheumatologist visit between June 2018 and February 2019.

Among the 208 participants included in the CONTROL-RA study (104 per arm), 90% were White, and 90% were women with a mean (SD) age of 50 (11) years, consistent with the characteristics of patients in the ArthritisPower registry (19). Over 90% of participants had used conventional or biologic DMARDs, and for 35 participants (17 intervention and 18 control), DMARD data were missing. A total of 51% of participants self-reported good or better health, and a majority (89%) reported a more favorable attitude about the use of RA medications (see Materials and Methods). Although the majority of participants reported discussions with their rheumatologist about disease activity and goal of RA treatment, only half reported being familiar with the T2T strategy for RA treatment in both arms. At baseline, participants in both intervention and control groups appeared to be willing to change RA medications if recommended by their rheumatologist, with a mean (SD) score on the decision/choice predisposition scale (0 = not willing at all, 5 = unsure, 10 = extremely willing) of 6.7 (2.44) in the intervention and 7.3 (2.24) in the control group. The decisional conflict about making a change in RA treatment was high, with participants in the intervention arm scoring 32.6 (16.8) and participants in the control arm scoring 32.7 (18.8) on the DCS, which ranges between 0 and 100 and on which scores greater than 37.5 are associated with decision delay or feeling unsure about the decision. At baseline, we observed no differences between groups in participants’ sociodemographic characteristics, patient global assessment of disease activity, willingness to change RA treatment, or decisional conflict about changing RA treatment (Table 1).

A total of 80 (77%) participants in the intervention group watched 80% or more of each of the six videos. We found that, immediately after viewing the videos, there was a significant improvement in the willingness to change RA treatment in
Sensitivity analyses demonstrated a consistent trend in improvement in the willingness to change RA treatment among those with a baseline willingness score of <8 and those with baseline willingness scores that excluded very low (<2) or very high (>8) values (Figure 2). For the secondary outcome of change in decision conflict, although the DCS scores regarding RA treatment decreased in both groups post-video viewing, no significant pre-post differences in decisional conflict between groups were observed (0.06 [95% CI –2.51 to 2.63], P = 0.9) (Table 2). A total of 67 participants in the intervention group and 65 participants in the control group completed the post-rheumatologist visit follow-up survey. We found that the QR code embedded in the

Table 1. Sociodemographic and clinical characteristics of Confident Treatment Decisions for Living with Rheumatoid Arthritis (CONTROL-RA) clinical trial study participants included in per-protocol analyses

| Variable                                           | Intervention (n = 104) | Control (n = 104) | P value |
|----------------------------------------------------|------------------------|------------------|---------|
| Age, years, mean (SD)                              | 49.3 (10.8)            | 49.8 (11.2)      | 0.8     |
| Race, White, n (%)                                | 92 (88.5)              | 96 (92.3)        | 0.6     |
| Sex, female, n (%)                                | 92 (88.5)              | 94 (91.3)        | 0.5     |
| Biologic DMARD use, ever, n (%)a                  | 62 (71.3)              | 56 (65.1)        | 0.4     |
| Conventional DMARD use, ever, n (%)a              | 69 (79.3)              | 70 (81.4)        | 0.1     |
| Biologic or conventional DMARD use, ever, n (%)a  | 80 (82.0)              | 82 (95.4)        | 0.4     |
| General health, good or better, n (%)b            | 53 (51.0)              | 54 (51.9)        | 0.9     |
| Health literacy, n (%)c                           | 0.7                    |                  |         |
| Extremely confident                                | 71 (68.3)              | 74 (71.2)        |         |
| Quite a bit confident                              | 26 (25)                | 24 (23.1)        |         |
| Familiar with T2T, n (%)                          | 54 (51.9)              | 54 (51.9)        | 1       |
| Patient global assessment of disease activityd    | 5.44 (2.3)             | 5.68 (2.3)       | 0.4     |
| Patient acceptable symptom state, yes, n (%)      | 42 (40.4)              | 39 (37.5)        | 0.7     |
| Reported values that favored RA medication use, yes, n (%) | 91 (87.5) | 95 (91.3)        | 0.4     |
| Prior year discussion with rheumatologist about active RA, yes, n (%) | 89 (85.6) | 91 (87.5) | 0.7 |
| Prior year discussion with rheumatologist about goals of RA treatment, yes, n (%) | 77 (74.0) | 81 (77.9) | 0.5 |
| Decisional conflict about RA treatment change, mean (SD)e | 32.6 (16.8) | 32.7 (18.8) | 1 |
| Willingness to change RA treatment, mean (SD)f    | 6.7 (2.4)              | 7.3 (2.2)        | 0.2     |

aSeven participants from the intervention and eight from the control did not report ever taking either a biologic or a conventional DMARD and seventeen intervention and eighteen control participants had no medication data.
bSubjective General Health (range: Excellent to Poor).
cHealth Literacy (range: Extremely confident to Not at all confident).
dPatient Global Assessment (range: 0 [Very well] to 10 [Very poorly]).
eDecisional Conflict Scale (range: 0 to 100).
fChoice Predisposition Scale (range: 0 representing not willing at all and 10 representing extremely willing).
Abbreviations: —, no data; DMARD, disease modifying anti-rheumatic drug; RA, rheumatoid arthritis; SD, standard deviation; T2T, treat-to-target.

Table 2. Comparisons between pre-post differences in preference for changing RA treatment (primary outcome) and decisional conflict about changing RA treatment (secondary outcome) in the Confident Treatment Decisions for Living with Rheumatoid Arthritis (CONTROL-RA) clinical trial study

| Outcome                                           | Intervention (n = 104) | Control (n = 104) | P value |
|----------------------------------------------------|------------------------|------------------|---------|
| Willingness to change RA treatmenta                | 6.7 (2.44)             | 7.2 (2.20)       | 0.5 (0.17) | 0.02 |
| Decisional conflictb about changing RA treatment  | 32.6 (16.81)           | 29.7 (16.62)     | –2.9 (0.98) | 0.01 |

aChoice Predisposition Scale (range: 0 representing not willing at all and 10 representing extremely willing).
bDecisional Conflict Scale (range: 0 to 100). Scores range from 0, representing no decisional conflict, to 100, representing extremely high decisional conflict.
Abbreviations: RA, rheumatoid arthritis; SD, standard deviation; SE, standard error.
study summary provided to the participants was downloaded only once during the study period. Thus, it is unlikely that the treating rheumatologist participated in the CME activity we developed. No statistically significant difference between intervention and control group was observed for the secondary outcomes of difference in willingness to change RA treatment (−0.36 [95% CI −1.33 to 0.61], \( P = 0.5 \)) and change in decisional conflict (1.63 [95% CI −3.81 to 7.06], \( P = 0.6 \)) between responses on the baseline and post-rheumatology visit surveys. We found that the average scores on the decision/choice predisposition scale in the post-rheumatology visit survey were lower than those on the baseline and post-video surveys in both groups, suggesting decay of the intervention effect.

DISCUSSION

We report that a patient-directed video intervention to support patient–rheumatologist conversation about escalating treatment resulted in significant improvement in the willingness to change RA treatment as measured by the decision/choice predisposition scale in the short term, although it did not significantly decrease the decisional conflict experienced by these patients in making such a change. Our study presents a novel method for proof-of-principle evaluation of an educational intervention to support patients with RA in making informed decisions about treatment escalation. We recruited patients directly through email, implemented our intervention online, and collected data through online surveys. We observed a high retention rate in the study, with 132 (63%) of the participants who completed post-video surveys also completing post-rheumatology visit surveys. This finding is remarkable given the lack of contact with the study team between surveys and may be explained by the implementation of the CONTROL-RA study within the ArthritisPower registry. As such, the participants had already expressed an interest in participating in research and therefore could have been more motivated to complete study procedures. In addition, the study provided modest compensation for completing surveys.

Given the benefit of the T2T strategy for RA outcomes (31–35), there has been a growing interest in developing approaches for improving T2T adherence. Trials testing physician-directed interventions to improve adherence to guideline-recommended care have had mixed results. A cluster-randomized quality-improvement trial in the United States found that a 9-month group-based rheumatologist learning collaborative resulted in a somewhat higher proportion of patients being treated using a T2T approach compared with the control group (57% vs. 25%) (36). In another cluster-randomized clinical trial, rates of treatment acceleration and achievement of low disease activity were relatively low and were similar among patients randomized to receive care from rheumatologists who participated in a T2T educational program versus usual care (9). However, in that study the rheumatologists participating in the intervention arm were not required to follow a T2T approach to RA treatment (9). Similar to a previous study (36), we also aimed to engage rheumatologists and other rheumatology providers in participating in a CME module focused on how to motivate patients with RA to escalate treatment. Our pragmatic approach relied on
the patient soliciting their rheumatologist to participate using a study summary with an embedded QR code, but the uptake of the CME module using QR code was very low.

Patient knowledge of the disease and satisfaction with disease control have been associated with adherence to treatment in RA (10,37). Thus, efforts to improve patient knowledge about RA treatment are critical for improving shared decision-making about escalating treatment when needed and for optimizing outcomes in RA. There have been only few studies evaluating the benefit of providing patient education regarding the T2T principles (38,39). A nurse-led educational program (40) discussing the T2T treatment strategy in RA resulted in improvements in disease activity, fatigue, and quality of life in Korean patients with moderate to severe RA. In another study, the implementation of a nurse telephone education program for patients with recently diagnosed RA promoting shared decision-making and a T2T approach resulted in improved adherence to follow-up visits at one institution (38). Similar to previous studies, our intervention informed patients about the importance of changing treatment when treatment goals were not met. However, in contrast to previous studies, our intervention was directly delivered to patients utilizing online videos and was less resource intensive, because it did not rely on ancillary staff to provide the education but rather used an online video program. Thus, given the low burden on clinical staff, our intervention is attractive for use in routine rheumatology practice because it can easily and inexpensively be scaled-up. Such an approach would be particularly useful during times when access to lengthy office visits are limited, such as during the ongoing COVID-19 pandemic, because links to these videos can be sent to patients for them to watch the materials remotely.

Because achieving low disease activity and remission hinges on accelerating RA treatment when indicated, which we could not measure using our study design, we chose to measure the extent to which our educational program catalyzed the decision-making process that precedes the action of RA treatment escalation, namely, willingness to make a change in RA treatment. A measure of patients’ inclination to favor RA treatment change is represented by a higher score on the decision/choice predisposition scale, a tool that has been extensively used to measure effects of decision aids for clinical applications (26,29,41–43). For example, a previous study that included patients with RA found that a decision aid designed to effectively communicate the risks and benefits associated with biologic therapy in RA increased the likelihood that the patients will make an informed choice and patient willingness to escalate care (26). A previous study in patients with hepatitis C found that the choice predisposition score is the strongest predictor of treatment initiation independent of disease severity (41), but this has not been evaluated in RA. However, the minimal clinically important difference for the decision/choice predisposition scale has not been published.

Our study has some limitations. Our population excluded non-English speakers, was predominantly White, and had high health literacy, and therefore our findings are not generalizable to a more diverse population with more heterogeneous levels of health literacy. In addition, we excluded patients with concomitant osteoarthritis and osteoporosis, who are likely to be older, thus limiting the generalizability of the findings to older people living with RA. Because this was a proof-of-principle study, this was done in order to focus the patients’ attention toward concerns about RA treatment. We recognize that patient history of treatment escalation and prior adverse events experience may influence willingness to change RA treatment and thus the effectiveness of our intervention. However, we thought that specifically asking these questions immediately before delivering the intervention may elicit availability bias among our participants.

Although we show that the patients in the intervention group expressed a higher preference for changing RA treatment, given the design of this study, we were not able to collect measures of disease activity to determine whether they were more likely to achieve low disease activity or remission compared with the participants assigned to the attention control group. In this proof-of-principle study, we evaluated our intervention among people with RA with high disease activity measured by RAPID3 because of the higher concordance between RAPID3 and the Clinical Disease Activity Index among this group (44), a subgroup of patients most vulnerable to poor outcomes owing to uncontrolled RA. Whether the intervention would improve willingness to change medications among those with moderate disease activity is the subject of future investigation. We observed a decay of the intervention effect for those participants who completed the post-rheumatologist survey. This was unsurprising because the interval of time between the viewing of the intervention and the rheumatologist visit was variable, suggesting that the highest opportunity for treatment change is in close proximity to the delivery of the education program.

In summary, our novel, patient-directed intervention educating patients about treatment escalation was associated with improved willingness to change RA treatment if/when recommended by the rheumatologist. Educational interventions, such as the one we developed and tested, could be part of behavioral intervention programs that include counselling about shared decision-making on RA management. Further studies are needed to evaluate whether this change in patients’ willingness translates into actual behavior modification, namely, RA treatment escalation at the appropriate time.
ACKNOWLEDGMENTS

The authors thank the patients participating this study without whose research would not have been possible.

AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published.

Study conception and design. Danila, J. Curtis.

Acquisition of data. Melnick, D. Curtis, O’Beirne.

Analysis and interpretation of data. Danila, Chen, Owensby, O’Beirne, Harrold, Nowell, Ruderman, Curtis.

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