Low Literacy Decision Aid Enhances Knowledge and Reduces Decisional Conflict among Diverse Population of Adults with Rheumatoid Arthritis: Results of a Pilot Study

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Abstract

Objective—Despite innovations in treatment of rheumatoid arthritis (RA), adherence is poor and disparities persist. Shared decision making (SDM) promotes patient engagement and enhances adherence, however few tools support SDM in RA. Our objective was to pilot a low literacy medication guide and decision aid to facilitate patient-clinician conversations about RA medications.

Methods—RA patients were consecutively enrolled into one of three arms: (1) control, patients received existing medication guide prior to clinic visit; (2) adapted guide prior to visit; (3) adapted guide prior plus decision aid during visit. Outcomes were collected immediately post-visit, at 1-week, 3- and 6-month interviews. Eligible adults had to have failed at least one DMARD and fulfill one of the following: age >65, immigrant, non-English speaker, < high school education, limited health literacy, racial/ethnic minority. Primary outcomes were knowledge of RA medications, decisional conflict, and acceptability of interventions.

Results—Majority of 166 patients were immigrants (66%), non-English speakers (54%), and had limited health literacy (71%). Adequate RA knowledge post visit in arm 3 was higher (78%) than arm 1 (53%, adjusted OR 2.7, 95% CI 1.2–6.1). Among patients with a medication change,
there was lower (better) mean decisional conflict in arms 2 and 3 (p=0.03). No significant differences in acceptability.

**Conclusion**—A low literacy medication guide and decision aid was acceptable, improved knowledge, and reduced decisional conflict among vulnerable RA patients. Enhancing knowledge and patient engagement with decision support tools may lead to medication choices better aligned with patient values and preferences in RA.

In the last two decades, patients with rheumatoid arthritis (RA) have witnessed an expansion in the number and nature of treatment options available. The FDA has approved more than 10 new disease modifying anti-rheumatic drugs (DMARDs) since the late 1990s. These innovations and treat-to-target strategies have improved the likelihood of achieving remission, and, perhaps, improved survival (1).

This progress, however, has introduced high complexity for patients and clinicians with respect to deciding which agents to use. Technical approaches to the selection of DMARDs such as guidelines appear inadequate, as they may not align with patient expectations, goals, and preferences for treatment or with personal and social contexts. This may lead to poor adherence, which, like many other chronic diseases, is inadequate in RA: adherence rates for biologic DMARDs are often less than 60% (2). Such alignment of guidelines with patient goals and preferences is only possible with patient involvement in the decision making process, a national and international policy priority (3–6).

We have found that nearly one-third of adults with RA report suboptimal shared decision-making (SDM) communication with their clinicians (7), and patients with lower education, limited health literacy, lower trust in physician, and limited English language proficiency are more likely to report suboptimal SDM. Thus, lack of clear communication in these conversations may contribute to health disparities (8–9). In particular, RA patients who are non-white, immigrants, or who have limited English language proficiency have higher disease activity and poorer function despite access to effective therapies (10). Limited health literacy has also been associated with greater disability in RA (11).

SDM requires that patients and clinicians share information about safety, efficacy, and treatment burden of available options. Central to SDM is ensuring that patients have basic knowledge of RA and its treatment, which has been shown to be suboptimal in vulnerable populations (12). Clinicians are called upon to communicate this information in environments often constrained by time and competing tasks. In addition, they must make special effort to reach those with barriers to communication. Thus, efforts to improve RA outcomes may involve imparting knowledge and promoting patient engagement using efficient, low literacy approaches that reduce, rather than exacerbate, disparities in care.

Given increasing demands on patients and clinicians, evidence of suboptimal SDM, and gaps in patient knowledge, we designed a literacy appropriate medication guide and decision aid (RA Choice). RA Choice was created to facilitate conversation between patients and clinicians about RA medications (13) and support SDM with patients who experienced an inadequate response to methotrexate monotherapy. Developed in three languages, the tools are aimed at populations with barriers to communication. We then performed a pilot study to
assess feasibility and acceptability and the tools’ impact on knowledge of RA medications and decisional conflict among a diverse population in two urban rheumatology clinics.

**PATIENTS AND METHODS**

**Study design and procedures**

We conducted a study of a literacy-appropriate medication guide and decision aid, consisting of a control group and two intervention groups. Eligible patients at two university rheumatology clinics were allocated to one of three study arms in sequence. In the control arm, patients received an existing medication guide in their preferred language prepared by Agency for Healthcare Research and Quality (AHRQ) immediately prior to their routine clinic visit. The AHRQ guide was published in English and Spanish with a reading grade level of 6; we used an official translation agency to forward and back translate it into Chinese. After completing enrollment for the control group, patients were enrolled into arm 2, in which patients received the adapted guide prior to the clinic visit, and then into arm 3, where patients received the adapted guide prior to the visit and the decision aid (used in the clinical encounter). We used this method rather than randomizing by physician to allow for the broadest possible group of physicians to participate in arm 3, to allow for additional time to complete the design and testing of materials, and to avoid contamination of the groups. The enrollment period for arms 1 and 2 was 5 months, and for arm 3, 6 months.

Subjects completed surveys in their preferred language, one in clinic immediately after the study visit, and three telephone interviews at approximately 1 week, three and six months after the visit. Patients and clinicians in arm 3 were consented to allow audio- or videotaping of their encounters in order to observe use of the decision aid.

**Patients**

Eligible patients were part of the University of California, San Francisco (UCSF) RA Cohort. Enrollment has been described previously (10). Briefly, the cohort was established in 2006, enrolling consecutive RA patients from a university-based arthritis clinic and county public hospital RA clinic, both staffed by UCSF faculty and fellows. Enrollment and follow-up are ongoing. Data are obtained from patients and physicians at each clinical visit and integrated with laboratory and radiology results. All patients are at least 18 years old at time of enrollment and meet 1987 American College of Rheumatology criteria for RA (15). During the study enrollment period there were 726 patients in the RA Cohort.

RA Cohort members attending clinic for their usual appointments were screened for study eligibility. Given that the intervention was designed to improve the RA medication decision-making process among vulnerable populations, eligible patients met at least one of the following criteria: racial/ethnic minority, immigrant, over age 65, non-English speaker (Spanish, Cantonese or Mandarin), or have limited health literacy based on the Test of Functional Health Literacy in Adults (16). Additionally, given the frequent use of methotrexate as a first-line therapy (17–19) and the design of the decision aid for use after methotrexate failure, patients must have used at least one DMARD prior to recruitment (although they were not required to be on a DMARD at time of enrollment). Lastly, in order
to best identify patients for whom a discussion about a medication change would be appropriate, a bilingual research assistant administered a self-reported measure of disease activity, the RAPID 3 (20), to patients in the waiting room. Eligibility was restricted to those with a score > 6, equivalent to moderate disease activity or higher (21). Because the study did not require much time commitment from participants, very few patients postponed enrollment to a later visit. However, if patients had been ineligible at a prior visit due to low disease activity, they could be eligible at a subsequent visit. Only 13 patients were enrolled at a later point due to prior low disease activity. Patients without access to a telephone or who did not speak English, Spanish, Cantonese, or Mandarin were excluded. The study was approved by the UCSF Committee on Human Research; all participants provided written informed consent.

Development of a low literacy, multi-lingual medication guide and decision aid

Both an adapted medication guide and decision aid were created as part of the study, following principles for developing materials for low literacy populations with larger font, photographs, short sentences, and plain language (22). The process of tool development is described in detail elsewhere (13) and involved extensive input from an RA patient advisory board as well as clinicians, designers, decision aid and health literacy experts. Briefly, the existing AHRQ guide was discussed in patient and clinician focus groups; transcripts and field notes were analyzed and informed content of the adapted guide which included chapters on: “What is RA?”, “What can RA medicines do for you?” The design and development process for RA Choice was based on a tool created for diabetes medications for use in the clinic to facilitate a conversation between clinician and patient (23, 24). Tool development involved field-testing low-fidelity prototypes (drafts or incomplete versions) in real clinical encounters followed by modifications and iterative field testing. The final tool (Figure 1) presents 12 synthetic and biologic DMARDs across 5 issues (one issue per card): frequency of administration, time to onset, cost, side effects, and contraindications.

Upon enrollment, but before the clinic visit, patients in arm 1 were given the AHRQ guide, and patients in arms 2 and 3 were given the adapted guide in their preferred language. In arm 3, clinicians received a set of RA Choice cards to be used during the visit. Use of RA Choice was left to the clinician’s discretion. All participating clinicians received brief (5 minutes), in-person training about RA Choice prior to arm 3 enrollment, and a short script on how to introduce the tool: “Ms./Mr. _____, your rheumatoid arthritis is very active today and we need to discuss your medication. We can increase your ___________________ (current medicine, if applicable) or add or switch to a new medicine. These cards will help us talk about the options for a new medicine. What aspect of a medicine would you like to talk about first?”

Measures

Primary outcomes—Patient-reported quality of the decision about a medication change was assessed with the low literacy version of the Decisional Conflict Scale (DCS) (25, 26). Across all three arms, only patients with a medication change completed the DCS. Patients’ general knowledge about RA medications was measured through a series of eight questions assessing basic understanding designed for this study. Because the questions were
designed to capture very rudimentary knowledge (Appendix A), scores of 7 out of 8 correct answers were considered adequate RA knowledge. Both the DCS and the RA knowledge measure were completed immediately after the clinic visit.

**Secondary outcomes**—The Trust in Physician (TIP) scale (27) and the Interpersonal Processes of Care measure (which includes a 2-item decision-making subscale) (28–29) were collected during the one-week interview. Following the practice in the literature, TIP scores were grouped above and below the median (7). The 2-item validated decision-making subscale of the IPC is calculated as the mean score for 2 items, “How often did you and your doctors work out a treatment plan together?” and, “If there were treatment choices, how often did doctors ask if you would like to help decide your treatment?” The 5-item response ranged from 1 (“never”) to 5 (“always”). We created a summary score from the average of the 2 items. Mean scores < 4 (corresponding to never/rarely/sometimes) were categorized as suboptimal communication, as has been done in prior studies (30–31). In addition to these proximal outcomes measures, patient-reported medication adherence was assessed at three months, using a validated single-item measure, “How many times do you think you may have missed taking your pills in the last week?” (32–35). A response of 1 or greater was considered non-adherent. Change in disease activity over three months from the study visit was assessed using the Clinical Disease Activity Index (CDAI) (36). We used data collected as part of the clinical visit closest to the three-month telephone interview. Change in functional status over six months was assessed with the Health Assessment Questionnaire (HAQ) (37), collected at 1-week and 6-month telephone interviews.

Other measures included in the surveys assessed the acceptability of the interventions using a questionnaire adapted from a previously validated scale (35). Clinicians were surveyed at study end about the impact of the tool on their discussion of RA medications, their preference for using the tool in the future, impact of the tool on patient knowledge, satisfaction, adherence; and usefulness of each RA Choice issue card. All patient survey measures were translated into Spanish and Chinese.

**Statistical analysis**

Subjects in the three study arms were compared by demographic and health characteristics and all outcome measures, using chi-square tests for categorical measures and ANOVA for continuous measures. For continuous outcomes -- DCS, change in CDAI and change in HAQ -- adjusted mean differences were calculated for each of the two intervention groups in comparison to the control group, from a linear regression model adjusting for gender and clinic. For the categorical outcomes -- adequate RA knowledge, adherence, adequate trust in physician and shared decision-making communication -- odds ratios were calculated for each intervention group in comparison to control, from logistic regression models also adjusting for gender and clinic. All analyses were conducted as intention to treat. To reliably detect a minimally important difference in CDAI with 80% power and 95% confidence would require a sample size of 120, and to detect a difference in DCS, would have required 160 respondents.
Outcomes for patients with a medication change. Although the study was designed to capture patients with moderate to high disease activity which would prompt a discussion of medications, in only 65 of the 166 study visits (39%) did the clinician report a medication change. The decision aid would not have been appropriate for all patients, and was not used for all arm 3 patients. Therefore, a sub-group analysis was conducted to evaluate the impact of the decision aid on decisional conflict and knowledge which included patients from any arm who had a medication change. Confirmation of decision aid use in arm 3 was made by research assistant review of physician-completed questionnaires and available audio/videotapes. We then compared patients in arm 3 in whom a medication change was made to patients in arms 1 and 2 who reported a medication change.

**RESULTS**

Of 345 consecutive patients approached, 111 were ineligible due to low disease activity by RAPID3, 64 declined, and 4 did not complete the initial assessment. A total of 166 were enrolled (58 in arm 1, 48 arm 2, 60 in arm 3). Figure 1 outlines enrollment and retention. A majority of patients were immigrants (66%), non-English speakers (36% Spanish, 18% Chinese), had limited health literacy (71%), and high school or less education (52%). Mean age was 58 (SD 12) years, 88% female with mean disease duration of 11 (SD 9) years (Table 1). There were no significant differences in characteristics across the three study arms with the exception of gender (more women in arms 1 and 3, p=.02) and clinic site (78% in arm 1 were from the county hospital compared to 60% each in arms 2 and 3). Mean HAQ at the week 1 interview was 1.6 (SD 0.7) which reflects moderate disability. Mean RAPID-3 was 16 (SD 5), indicating high disease activity.

**Primary outcomes: knowledge and decisional conflict (Table 2)**

The percentage of patients with adequate RA knowledge immediately post-visit as defined by a score of ≥7 out of 8 in arms 2 and 3 was higher (63% and 78% respectively) than in the control group (53%). This difference was significant after adjustment for gender and clinic site for arm 3 compared to arm 1 (adjusted odds ratio 2.7, 95% CI 1.2–6.1). Among patients with a medication change (n=65), there was a lower mean decisional conflict score immediately post-visit in the intervention arms compared to the control (17 and 11 respectively for arm 2 and 3 compared to 24 for arm 1; p=0.09). After accounting for gender and clinic site, the adjusted mean difference in the decisional conflict scale for arm 3 compared to arm 1 was −12.6 (p=0.03). In addition, the proportion of patients who achieved a DCS <25 (associated with implementing decision) was 79% in arm 3, 68% arm 2, and 63% in arm 1 (p=0.18 for test of trend). Secondary outcomes of trust in physician and shared decision-making communication did not differ by arm in unadjusted and adjusted analysis with the exception of arm 2, in which subjects reported poorer trust in physician compared to arm 1.

**Acceptability and feasibility**

The acceptability scale completed by patients immediately post-visit did not differ significantly across the three trial arms (p=.24). Rheumatologists who participated in the study completed a survey after study end to assess acceptability of the decision aid.
Clinician responses were overwhelmingly positive with 78% reporting that the decision aid “moderately” to “greatly helped” their discussion of RA medications with patients. One third preferred to use the decision aid with most patients and 56% preferred to use it in some common instances (e.g., methotrexate failure). All clinicians agreed that the decision aid is best used when a patient has expressed interest in participating in medical decisions and 56% felt it best used when a patient speaks a language other than their (the physician’s) primary language. Nearly 90% of clinicians predicted that the decision aid would have a positive impact on patient knowledge about medication choices and satisfaction with their decision, while 56% predicted the decision aid would positively impact adherence. All clinicians reported they were satisfied with the training to use the decision aid.

Longer term outcomes of adherence and change in disease activity at 3 months, change in function at 6 months

Table 3 demonstrates the unadjusted and adjusted results of self-reported adherence at 3 months which was significantly worse in arm 2 compared to arm 1 but no different between arms 1 and 3. Both intervention arms had a reduction (improvement) in mean disease activity score as captured by the CDAI. However, this was not statistically significant nor did it reflect a clinically meaningful change (MCID for CDAI is 6) (38). Change in function at 6 months compared to baseline for the intervention arms compared to control was also not statistically significant.

Sub-group analysis

For this analysis, we examined the impact of the decision aid on knowledge, decisional conflict, and change in disease activity among 65 patients who had a medication change, as it is those instances in which the decision aid would be most relevant. Arm 1 and arm 2 groups who had no exposure to the decision aid (n=42) were grouped and compared to arm 3 patients (n=23 with confirmed use of decision aid). In this sub-group, all patients in arm 3 had adequate RA knowledge (100%) vs. 60% in arms 1 and 2 (p<0.01; Table 4). Arm 3 patients also had a significantly lower DCS (14 point lower score, p=0.01), and greater reduction in disease activity at 3 months (CDAI −7.6 vs. −1.1 in arms 1 and 2). Although this latter difference did not reach statistical significance (p=0.10) it was a change larger than the minimal important difference of 6 for CDAI.

DISCUSSION

The use of a multi-lingual, literacy-appropriate medication guide and decision aid tool was acceptable and feasible to vulnerable populations with RA and their clinicians, and increased knowledge. In a subgroup analysis of patients in whom a medication change was reported, patients exposed to the decision aid had significantly reduced decisional conflict as well. In this subgroup, patients exposed to the decision aid had a reduction in disease activity which exceeded the minimal important difference, but was not statistically significant at 6-month follow-up compared to patients not exposed to the decision aid. The interventions did not impact secondary outcomes of trust, SDM communication, adherence, or change in function at 6 months. A major finding (and limitation) of this practice-based, real world study was that even in patients reporting moderate or high disease activity, a medication change did not...
take place. This may reflect an inherent problem with the self-reported disease activity measure in that it may capture other factors (problems with mood, sleep or fatigue) or that clinicians’ and patients’ readiness or willingness to change treatment may be low (39).

If we are to promote patient knowledge and engagement in care as a mechanism by which persistent disparities in RA outcomes are addressed, communication barriers and time constraints faced by patients and providers in daily practice must be acknowledged. In our study, we intentionally did not dictate the use of the decision aid to clinicians. The decision aid was placed in the clinic room and then the visit proceeded in a natural manner. Some clinicians elected not to use the decision aid, while others consistently utilized it, indicating that our approach was feasible for most clinicians and most medication decisions.

Use of decision aids among patients with limited health literacy is a growing field of study. The design of our tool was such that its overarching purpose was to facilitate a conversation between patient and clinician. The decision aid was not intended to be comprehensive but to be a tool to initiate and facilitate meaningful dialogue. Our results indicate that the tools were successful in imparting knowledge and improving decision quality for patients with communication barriers. The adapted medication summary guide alone (arm 2) did not generate significant improvements in the primary outcomes which leads one to conclude that the combination of adapted guide plus decision aid had a synergistic effect on improving outcomes. The other possibility, which the study was not designed to test, was that the decision aid alone had the greatest effect on the outcomes.

There are several strengths to this work. Most important among them is that we demonstrated the feasibility of engaging patients and clinicians in the development of decision support tools and in enhancing patient knowledge during routine RA care. Because we could not use a randomized trial design, we do not know the extent to which our results are affected by selection bias, although we selected those most likely to have difficulties with communication and more likely to benefit from interventions to improve knowledge. Limitations of sequential enrollment include the possibility that patients enrolled in arm 1 may have differed in characteristics from those in arm 2 or 3, however the only significant differences were in gender and clinic site. Those patients approached initially may have been more willing to participate than those later on. Another potential source of bias may be that only patients and providers in arm 3 who provided consent were audio or videotaped. This may have introduced bias into the nature of the encounter or survey responses, however, it has been demonstrated in a number of other point-of-care decision aid trials that recording of the encounter does not interact with outcomes of decisional conflict or knowledge (40). While a decrease in disease activity was observed for those patients who received the decision aid, the lack of statistical significance for this clinically meaningful change may be due to sample size limitations. Another limitation is the number lost to follow up at the 6-month phone interview interval across all three arms (n=16, n=9, n=15; respectively). However, it should be noted that the primary outcomes of knowledge and decisional conflict were captured on all participants during the immediate post-visit survey.

Others have demonstrated that SDM tools are more helpful in those who arrive at the encounter with more disadvantage, such as older age or lower levels of education (41).
did not see a change in self-reported measure of adherence, which may prompt one to speculate over the true mechanism by which disease activity was lower in the decision aid group in the subgroup analysis. One hypothesis is that increased self-management or self-efficacy through increased patient engagement led to overall symptom improvement. Adherence and other measures were imprecisely estimated in this pilot which, along with our findings of acceptability and promising estimates of impact on disease activity, support the conduct of a large, multicenter trial to precisely estimate the effectiveness of RA Choice.

In summary, our literacy-appropriate, multi-lingual medication guide and decision aid was acceptable, improved knowledge and reduced decisional conflict among vulnerable patients with moderate to severe RA. The use of decision support tools to facilitate exchange of evidence and patient preferences and values may increase knowledge and patient engagement leading to less variation in care and improve outcomes in a patient-centered fashion for all RA patients.

Acknowledgments

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References


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Appendix A. Rheumatoid arthritis medication knowledge questions

Once you have rheumatoid arthritis, how long does it last?

• a. For 6 months
• b. For 3 weeks
• c. For a few days
• d. For life

Mark the following sentences as true (T) or false (F):

2 Medicines can cure rheumatoid arthritis.
3 Medicines are the main treatment for rheumatoid arthritis.
4 Rheumatoid arthritis can affect the eyes.
5 RA medicines can be taken as a pill, a shot or in the vein.
6 RA medicines can never be combined.
7 RA medicines decrease swelling in joints and relieve pain.
8 Most people only need RA medicines for a couple of days.
Significance and Innovations

- This is the first study to test a medication summary guide and decision aid designed with low literacy principles in three languages to facilitate a conversation between patients and clinicians about RA medication choice.
- These results show that tools developed for vulnerable populations with RA improve knowledge and reduce decisional conflict around medication choice.
- Enhancement of patient engagement using literacy and language appropriate tools in RA treatment discussions is central to improving care and has the potential to reduce disparities in RA.
Figure 1. Study enrollment and follow-up
*demographic criteria were to meet one or more of the following: racial/ethnic minority, immigrant, over age 65, non-English speaker (Spanish, Cantonese or Mandarin), or have limited health literacy based on the Test of Functional Health Literacy in Adults (TOFHLA)
Figure 1.
RA Choice decision aid tool (English version)
Table 1

Sample characteristics at time 1 clinic visit, by study arm

<table>
<thead>
<tr>
<th></th>
<th>Total (n=166)</th>
<th>Arm 1: Control (original guide) (n=58)</th>
<th>Arm 2: Low literacy guide (n=48)</th>
<th>Arm 3: Low literacy guide &amp; decision aid (n=60)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient at county hospital clinic</td>
<td>110 (66)</td>
<td>45 (78)</td>
<td>29 (60)</td>
<td>36 (60)</td>
<td>0.08</td>
</tr>
<tr>
<td>Female</td>
<td>146 (88)</td>
<td>53 (91)</td>
<td>37 (77)</td>
<td>56 (93)</td>
<td>0.02</td>
</tr>
<tr>
<td>Age, (mean (sd), range)</td>
<td>58 (12) (24–85)</td>
<td>60 (13) (24–85)</td>
<td>56 (12) (32–81)</td>
<td>57 (12) (32–83)</td>
<td>0.19</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.39</td>
</tr>
<tr>
<td>White</td>
<td>21 (13)</td>
<td>8 (14)</td>
<td>7 (15)</td>
<td>6 (10)</td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>23 (14)</td>
<td>9 (16)</td>
<td>5 (10)</td>
<td>9 (15)</td>
<td></td>
</tr>
<tr>
<td>Latino</td>
<td>74 (45)</td>
<td>24 (41)</td>
<td>20 (42)</td>
<td>30 (50)</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>43 (26)</td>
<td>16 (28)</td>
<td>12 (25)</td>
<td>15 (25)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>5 (3)</td>
<td>1 (2)</td>
<td>4 (8)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Immigrant</td>
<td>114 (69)</td>
<td>44 (76)</td>
<td>32 (67)</td>
<td>38 (63)</td>
<td>0.32</td>
</tr>
<tr>
<td>Language</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.52</td>
</tr>
<tr>
<td>English</td>
<td>76 (46)</td>
<td>22 (38)</td>
<td>25 (52)</td>
<td>29 (48)</td>
<td></td>
</tr>
<tr>
<td>Spanish</td>
<td>60 (36)</td>
<td>22 (38)</td>
<td>16 (33)</td>
<td>22 (37)</td>
<td></td>
</tr>
<tr>
<td>Chinese</td>
<td>30 (18)</td>
<td>14 (24)</td>
<td>7 (15)</td>
<td>9 (15)</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.34</td>
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<tr>
<td>HS or less</td>
<td>80 (52)</td>
<td>30 (57)</td>
<td>27 (60)</td>
<td>23 (41)</td>
<td></td>
</tr>
<tr>
<td>Some college, AA, trade</td>
<td>42 (27)</td>
<td>14 (26)</td>
<td>10 (22)</td>
<td>18 (32)</td>
<td></td>
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<td>College graduate</td>
<td>32 (21)</td>
<td>9 (17)</td>
<td>8 (18)</td>
<td>15 (27)</td>
<td></td>
</tr>
<tr>
<td>Low health literacy</td>
<td>110 (71)</td>
<td>43 (80)</td>
<td>31 (71)</td>
<td>36 (64)</td>
<td>0.20</td>
</tr>
<tr>
<td>Disease duration (mean (sd), range)</td>
<td>11(9) (0–46)</td>
<td>12(10) (0–46)</td>
<td>10(9) (1–38)</td>
<td>12(8) (0–28)</td>
<td>0.74</td>
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<tr>
<td>HAQ (mean (sd), range)</td>
<td>1.6(0.7) (0–3)</td>
<td>1.8(0.7) (0–3)</td>
<td>1.6(0.7) (0–3)</td>
<td>1.6(0.8) (0–3)</td>
<td>0.16</td>
</tr>
<tr>
<td>CDAI (mean (sd), range)</td>
<td>18(11) (1–56)</td>
<td>18(10) (1–42)</td>
<td>19(11) (3–45)</td>
<td>18(12) (3–56)</td>
<td>0.93</td>
</tr>
<tr>
<td>RAPID-3 disease activity (mean (sd), range)</td>
<td>16(5) (6–27)</td>
<td>16(5) (7–26)</td>
<td>15(6) (6–27)</td>
<td>15(5) (6–27)</td>
<td>0.64</td>
</tr>
<tr>
<td>PHQ-9 depression score (mean (sd), range)</td>
<td>8(6) (0–27)</td>
<td>7(6) (0–27)</td>
<td>8(7) (0–23)</td>
<td>8(6) (0–22)</td>
<td>0.65</td>
</tr>
</tbody>
</table>

Notes:

p-value for differences by study arm, from chi square or ANOVA tests.
Low health literacy based on 3-item questionnaire in telephone survey (n=154). Report of 'always, often, sometimes' has difficulty or needs help reading medical information, or 'somewhat, a little bit, not at all' confident in filling out medical forms.

RAPID-3 ≥6 was part of study inclusion criteria
Table 2

Post-visit outcomes of a pilot trial of an RA medication summary guide and decision aid tool, with and without adjustment

<table>
<thead>
<tr>
<th></th>
<th>1: Usual care</th>
<th>2: Adapted Guide</th>
<th>3: Guide + DA</th>
<th>p-value</th>
<th>Adjusted mean difference (95% CI)</th>
<th>Adjusted mean difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Decisional Conflict Scale</strong></td>
<td>24 (14,34) (n=24)</td>
<td>17 (9, 25) (n=28)</td>
<td>11 (4,18) (n=29)</td>
<td>0.09</td>
<td>-6.1 (-19.8, 7.6)</td>
<td>-12.6 (-23.7, -1.4)</td>
</tr>
<tr>
<td>(range 0–100)</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td><strong>Adequate RA Knowledge (score ≥ 7 out of 8)</strong></td>
<td>53 (41,66) (n=58)</td>
<td>63 (49,76) (n=48)</td>
<td>78 (68,89) (n=60)</td>
<td>0.02</td>
<td>1.3 (0.6, 3.0)</td>
<td>2.7 (1.2, 6.1)</td>
</tr>
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<tr>
<td><strong>Adequate trust in physician (above median score)</strong></td>
<td>58 (45,72) (n=53)</td>
<td>37 (22,52) (n=43)</td>
<td>57 (44,71) (n=56)</td>
<td>0.08</td>
<td>0.4 (0.1, 0.9)</td>
<td>1.0 (0.5,2.2)</td>
</tr>
<tr>
<td><strong>Adequate Shared Decision Making (mean score equivalent to “usually” or “always”)</strong></td>
<td>20 (9,31) (n=54)</td>
<td>12 (2,22) (n=43)</td>
<td>13 (4,21) (n=56)</td>
<td>0.40</td>
<td>0.4 (0.1, 1.4)</td>
<td>0.6 (0.2,1.7)</td>
</tr>
</tbody>
</table>

DA = Decision Aid; CI = confidence interval

P-value for difference by study arm, from linear regression for DCS, logistic regression for RA knowledge

Adjusted models control for clinic site and sex.

Odds ratio >1 and adjusted mean difference <0 favor treatment arms.

* p <0.05

1 Sample for Decisional Conflict Scale limited to patients reporting a decision at the clinic visit.

2 Adjusted mean difference for continuous measures (negative values favor treatment arms).

3 Adjusted odds ratio for dichotomous measures (values < 1 favor treatment arms).
## Table 3
Long-term outcomes of a pilot trial of an RA medication summary guide and decision aid tool, with and without adjustment

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted results, by study arm</th>
<th>Adjusted results, vs. Arm 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-reported adherence at 3 months</td>
<td>% (95% CI)</td>
<td>% (95% CI)</td>
</tr>
<tr>
<td>Did not miss dose in past week</td>
<td>73 (59.87) (n=41)</td>
<td>50 (34.66) (n=40)</td>
</tr>
<tr>
<td>Disease activity measured in clinic</td>
<td>Mean (95% CI)</td>
<td>Mean (95% CI)</td>
</tr>
<tr>
<td>Change in CDAI at 3 months</td>
<td>0.8 (−2.7, 4.4) (n=34)</td>
<td>−1.0 (−5.6, 3.6) (n=25)</td>
</tr>
<tr>
<td>Self-reported functional status</td>
<td>−0.1 (−0.2, 0.1) (n=42)</td>
<td>0.0 (−0.1, 0.1) (n=38)</td>
</tr>
<tr>
<td>Change in HAQ at 6 months</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DA = decision aid; CI = confidence interval; HAQ = Health Assessment Questionnaire

CDAI = Clinical Disease Activity Index, measured at time 1 visit and at clinic visit nearest 3 month follow-up.

P-value for difference by study arm from logistic regression for adherence, linear regression for CDAI and HAQ change.

Adjusted models control for clinic site and sex

Odds ratio >1 and adjusted mean difference <0 favor treatment arms.

* p<0.05
Table 4

Sub-group analysis: Comparing RA knowledge, decisional conflict and change in disease activity among patients with a medication change in DA arm and non-DA arms

<table>
<thead>
<tr>
<th></th>
<th>No DA (arms 1 &amp; 2) (n=42)</th>
<th>DA (arm 3) (n=23)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate RA Knowledge</td>
<td>60 (45,75)</td>
<td>100 (--)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Decisional Conflict Scale</td>
<td>21 (13,29)</td>
<td>7 (2, 12)</td>
<td>0.01</td>
</tr>
<tr>
<td>Change in CDAI at 3 months</td>
<td>−1.1 (−5.7,3.6)</td>
<td>−7.6 (−13.7, −1.5)</td>
<td>0.10</td>
</tr>
</tbody>
</table>

DA = Decision Aid; CI = confidence interval

CDAI = Clinical Disease Activity Index, measured at time 1 visit and at clinic visit nearest 3 month follow-up.