

Use of Decision Support for Improved Knowledge, Values Clarification, and Informed Choice in Patients With Rheumatoid Arthritis

LIANA FRAENKEL,¹ CYNTHIA K. MATZKO,² DEBRA E. WEBB,² BRIAN OPPERMANN,³
PETER CHARPENTIER,¹ ELLEN PETERS,⁴ VALERIE REYNA,⁵ AND ERIC D. NEWMAN²

Objective. To examine the potential value of a theory-based, interactive decision support tool in clinical practice for patients with rheumatoid arthritis who are candidates for biologic agents.

Methods. We conducted an 8-week, 2-arm, parallel, single-blind pilot trial in which candidates for treatment escalation with a biologic agent were randomized to receive either a link to a web-based tool or usual care. Outcomes included changes in objective knowledge, subjective knowledge, values clarification, and satisfaction with risk communication as well as the proportion of subjects defined as making an informed choice to escalate care at 2 weeks.

Results. A total of 125 subjects were randomized. Significant between-group differences at 2 weeks favoring the intervention group were seen for changes in objective knowledge, subjective knowledge, and values clarification. No significant between-group differences were found in subjects' satisfaction with risk communication. Among those deciding to escalate care, a greater percentage met the criteria for an informed choice at 2 weeks in the intervention group compared to the control group (32% versus 13%; $P = 0.02$). Improvements in subjective knowledge and values clarification persisted at 8 weeks. There were no between-group differences in objective knowledge at 8 weeks.

Conclusion. In this study, use of a decision support tool at the time of decision-making resulted in improved objective and subjective knowledge, as well as values clarity, compared to usual care. Not all improvements were sustained, emphasizing the need to offer educational support should additional escalation of care be required over the course of the illness.

INTRODUCTION

A targeted strategy to minimize disease activity has been shown to significantly improve both short- and long-term outcomes in rheumatoid arthritis (RA), and guidelines strongly recommend that physicians monitor and escalate treatment in order to achieve this goal (1,2). Yet, despite the widespread endorsement of this approach, many patients are not effectively treated with disease-modifying antirheumatic drugs (DMARDs) (3,4). Data suggest that the undertreatment of RA patients may be due in part to inad-

equately decision support (5,6). Although the escalation of care in RA can involve many different treatment decisions, one of the more difficult decisions RA patients face is whether to initiate therapy with biologic agents after failing nonbiologic DMARDs. Currently, no proven mechanisms exist to effectively inform RA patients who are candidates for biologic agent therapy. Risk communication is particularly challenging in this situation because of the sheer number of risks to disclose, the difficulty explaining the risks of extremely rare adverse events, and

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¹Liana Fraenkel, MD, MPH, Peter Charpentier, MS: Yale University, New Haven, Connecticut; ²Cynthia K. Matzko, RN, MSN, Debra E. Webb, LPN, CCRC, Eric D. Newman, MD: Geisinger Medical Center, Danville, Pennsylvania; ³Brian Oppermann, MD: Geisinger Medical Group, State College, Pennsylvania; ⁴Ellen Peters, PhD: Ohio State University, Columbus; ⁵Valerie Reyna, PhD: Cornell University, Ithaca, New York.

Address correspondence to Liana Fraenkel, MD, MPH, Yale University School of Medicine, Section of Rheumatology, 300 Cedar Street, TAC #525, PO Box 208031, New Haven, CT 06520-8031. E-mail: liana.fraenkel@yale.edu.

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Significance & Innovations

- A web-based decision support tool was developed to effectively inform patients and promote high-quality decision-making among rheumatoid arthritis patients who are candidates for biologic disease-modifying antirheumatic drugs.
- In a proof-of-concept pretest/post-test study, viewing the tool resulted in improved knowledge, willingness to escalate care, and the likelihood of making an informed, values-concordant choice.
- This followup study confirmed the efficacy of the tool in clinical practice, at the actual time of decision-making, using a randomized, controlled trial design.

the tendency of people to discount (or underweight) future benefits.

We previously developed a theory-based decision support tool to effectively inform patients and promote high-quality decision-making in RA patients who are candidates for biologic agents (7). The tool is an interactive, web-based, computerized educational module with optional voiceovers that patients navigate through the use of a menu bar. The content and formatting of the tool were developed based on fuzzy trace theory (FTT) principles. FTT provides an evidence-based approach to help patients extract the gist (i.e., the essential “bottom line”) of available options, and retrieve and apply relevant values in order to make decisions that are concordant with personal values (8). The tool was originally developed with extensive patient input and according to the principles outlined in the International Patient Decision Aids Standards (9). Specifically, the content is presented in simple language and in sufficient detail to enable decision-making, presents probabilities in a clear and unbiased manner, uses simple graphics to facilitate understanding of probabilistic information, includes a rank ordering task to clarify values once patients are informed, and has several features to enable patients to print content in order to facilitate future discussions with their physicians (7).

In a recent proof-of-concept pretest/post-test study (7) (conducted with a convenience sample of patients with RA during a single interview unrelated to a clinical encounter), using the tool increased knowledge (Cohen’s d effect size 0.75), improved perceived knowledge and values clarity ($d = 0.88$ and 0.90 , respectively), and increased patients’ willingness to escalate care ($d = 0.50$). In this study, we conducted an 8-week, 2-arm, parallel, single-blind pilot trial in which candidates for treatment with an initial or new biologic agent were randomized to receive a link to the web-based tool or to usual care.

SUBJECTS AND METHODS

Subjects were RA patients currently being treated by 1 of 8 rheumatologists practicing in the Geisinger Rheumatolo-

gy Department in central Pennsylvania. Subjects were at least 18 years of age, able to speak and read English, and had active disease warranting the initiation, or change, of a biologic agent as determined by their treating rheumatologist. As the tool is formatted in chapters, those currently taking a biologic drug were considered eligible since they could be directed to content relevant to their decision. Subjects were excluded if they were hearing or visually impaired; were scheduled for surgery; had a current infection; had a cancer of any type diagnosed within the past 5 years (except nonmelanoma skin cancer) or a history of lymphoma, leukemia, or melanoma; had a chronic inflammatory disease (in addition to RA) requiring treatment with immunosuppressive medications; had chronic liver disease due to hepatitis C or B; were HIV positive; or had a positive screening test for tuberculosis (tuberculin skin test or interferon- γ release assay) or radiographic lesions suggestive of inactive tuberculosis and had not completed an adequate course of chemoprophylactic therapy.

We obtained Health Insurance Portability and Accountability Act and informed consent waivers to perform focused Data Warehouse searches and chart reviews each week to identify adult patients with RA, currently taking at least 1 nonbiologic DMARD, who had an appointment scheduled within the upcoming week. Two criteria were used for identifying RA patients: a diagnosis of RA, included on the patient’s problem lists (this list includes 1,718 RA patients whose charts have been reviewed to confirm the diagnosis), or patients with at least 2 visits to a rheumatologist with the International Classification of Diseases, Ninth Revision code 714.0 within the past 2 years and with at least 1 DMARD prescription (positive predictive value 89%) (10). A focused chart review was then performed to exclude subjects with the specific exclusion criteria previously listed. The research assistant notified rheumatologists before each morning and afternoon clinic when they had potentially eligible patients. She also attached a sticky label on potentially eligible patients’ face sheets to remind rheumatologists to refer eligible patients after their visits. To protect the blind, the research assistant collected baseline data after obtaining informed consent but before randomization. Random treatment assignments were placed in numbered opaque envelopes. Subjects were randomly assigned to the intervention or usual care control group in a 1:1 ratio. Subjects randomized to the intervention arm were given the option of accessing the web-based tool at home (or other convenient setting outside the clinic) or in the clinic using a laptop computer reserved for patient use. Subjects were asked to complete use of the tool within 2 weeks of the baseline visit. The tool did not have to be viewed in a single setting and there were no limits placed on the number of times it could be accessed by each participant. The tool was designed to store basic session activity in its database. Each day an automated task identified patients for whom no session activity had been recorded for at least 5 days following enrollment, and e-mailed a report to study personnel listing the study identification codes for these patients. Patients listed on these alerts were called and asked if they needed assistance accessing the tool. Once the patients successfully accessed the tool, they continued to navigate through the tool independently.

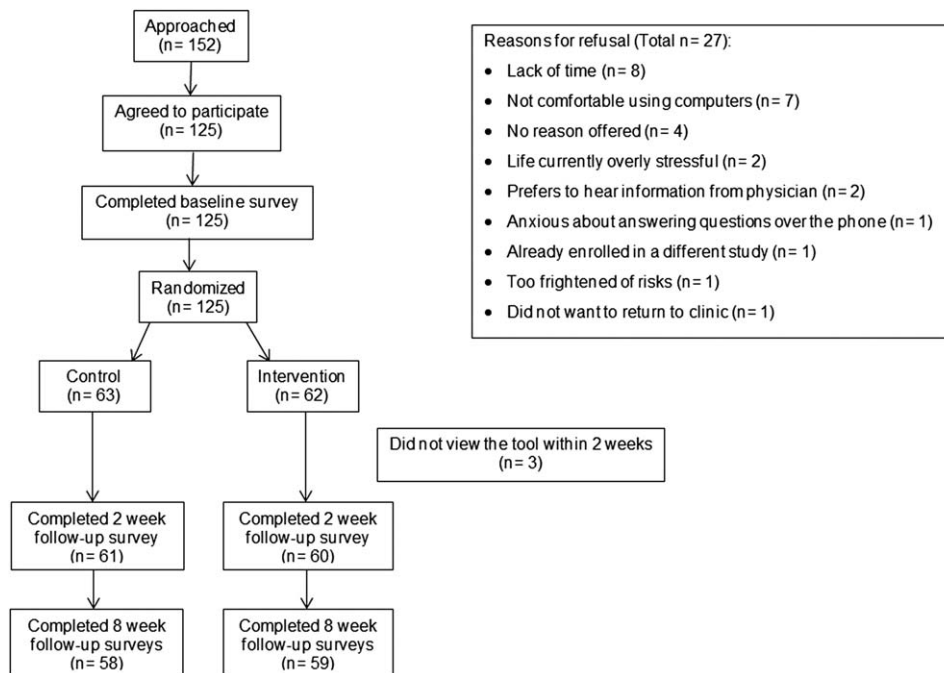


Figure 1. Flow chart of study population and reasons for refusal.

Usual care included education and counseling by an experienced nurse educator regarding the risks and benefits of biologic agents and how to administer injections (when appropriate). Because we expected most subjects to use the decision aid at home on their own time, where they did not receive additional support from clinical or research staff, we did not include an attention control arm. Followup data were collected over the telephone by trained blinded interviewers using a standardized script at 2 and 8 weeks. Subjects were reminded at the beginning of each followup call not to discuss any prior study-related procedures. We measured change in objective knowledge using a 20-item questionnaire (range 1–20), which included true or false statements related to the expected benefits, risks, and route of administration of biologic agents in the treatment of RA, previously developed for the pretest/post-test study of the tool (7). Change in perceived knowledge and clarity of values were measured using 2 subscales from the well-validated decisional conflict scale (11), which assesses subjective knowledge and perceived values clarity. These 6 items are coded on 5-point scales ranging from “strongly agree” to “strongly disagree.” The subjective knowledge items are the following: “I know which options are available to me”; “I know the benefits of each option”; and “I know the risks and side effects of each option.” The clarity of values items are the following: “I am clear about which benefits matter most to me”; “I am clear about which risks and side effects matter most to me”; and “I am clear about which is more important to me (the benefits or the risks and side effects).” Scores range from 0 to 100, with lower scores indicating higher subjective knowledge and values clarity. Decisional conflict was measured by adding both subscales. Although no instruments to measure informed choice are currently available, there is agreement that such choice is based on accurate knowledge and is concordant

with one’s values (12). Thus, we classified subjects as having made an informed choice to escalate care if they answered at least 75% of the knowledge questions correctly (7) and had low decisional conflict, as defined by a score of 25 or lower on the combined subjective knowledge and values clarity subscales. This decisional conflict score is associated with implementing decisions and has been previously used as a predefined cutoff point (13–15). The Combined Outcome Measure for Risk Communication (COMRADE; 20 items measured on a 5-point agree scale) was also administered at 2 and 8 weeks (16). The COMRADE is a patient-reported outcome that includes 2 subscales (each composed of 10 items): 1 for risk communication (a process measure) and 1 for confidence in decision (an outcome measure).

We measured both the decision to escalate care and actual escalation of care by 8 weeks by chart review. The decision to escalate care was defined as having been prescribed a biologic agent. Chart review was performed without knowledge of group assignment. Reasons for not escalating care were also recorded. Demographic characteristics were collected by self-report. Health literacy was measured using a single item: “How confident are you filling out medical forms by yourself?” coded on a 5-point scale ranging from “not at all” to “extremely” confident (17). Disease activity was measured using the Clinical Disease Activity Index.

We calculated that 110 subjects (55 subjects per group) were needed to detect a between-group difference of 25% in the proportion defined as making an informed choice with 80% power at 2 weeks, assuming $\alpha = 0.05$, the allocation ratio = 1, and $P = 1$ -tailed. We describe feasibility outcomes (the number of persons agreeing to participate and accessing the tool) and both within- (using signed rank tests) and between-group differences (using Mann-Whitney U tests). Nonparametric tests were used because distribu-

Table 1. Baseline characteristics of sample with 2-week data*

	Control (n = 61)	Intervention (n = 60)
Age, mean \pm SD	56.2 \pm 13.3	54.3 \pm 11.4
Women	44 (72)	41 (68)
White	59 (97)	59 (98)
Hispanic	3 (5)	4 (7)
Drug coverage plan	55 (90)	57 (95)
Employed	30 (49)	34 (56.7)
Married	43 (70)	36 (60)
Some college or higher level of education	24 (39)	21 (35)
Duration of RA, median (IQR)	6.0 (2.0, 19.0)	8.0 (2.0, 15.0)
CDAI score, mean \pm SD	22.5 \pm 12.6	23.6 \pm 11.3
Health literacy, median (IQR)	4.0 (4.0, 5.0)	4.0 (3.0, 5.0)
\geq 1 chronic comorbid condition	38 (62)	36 (60)
Currently taking a biologic agent	11 (18)	8 (13)
Objective knowledge, median (IQR)	16.0 (15.0, 18.0)	16.0 (14.0, 17.5)
Subjective knowledge, median (IQR) [†]	41.7 (25.0, 58.3)	50.0 (33.3, 66.7)
Values clarity, (IQR) [†]	33.3 (25.0, 50.0)	41.7 (29.2, 62.5)

* Values are the number (percentage) unless otherwise indicated. RA = rheumatoid arthritis; IQR = interquartile range; CDAI = Clinical Disease Activity Index.
[†] Lower scores indicate greater subjective knowledge and values clarity.

tions of the dependent variables were skewed. The study was approved by the Geisinger Health System and Yale University Human Research Protection Programs.

RESULTS

Study population. A total of 152 patients were referred by their rheumatologists as possible candidates for the study. Of these, 125 agreed to participate and were randomized. The most common reasons for refusal were lack of time and unwillingness to use a computer (Figure 1). Seven subjects chose to view the tool in the clinic utilizing a laptop. One hundred seventeen subjects (94%) were contacted for both followup surveys. Fifteen subjects (24%) did not access the tool after 5 days and were called. Of these, 3 subjects did not access the tool and were analyzed as part of the intervention group. Followup data were not available for 3 subjects randomized to the intervention arm and for 5 subjects randomized to the control arm. Subject baseline characteristics by group are presented in Table 1. The groups were well balanced in terms of demographic characteristics, except that a slightly greater number of subjects in the control group were married. At baseline, the control group also had greater subjective knowledge and values clarity.

Within-group differences. No improvements were seen in objective or subjective knowledge after 2 weeks among subjects randomized to the control group. In contrast, significant improvements in both were observed in the intervention group (a median difference of 1 [interquartile range (IQR) $-1.0, 2.0$]; $P = 0.003$) for objective knowledge and 8.3 (IQR $-8.3, 33.3$; $P = 0.0005$) for subjective knowledge. A significant improvement in values clarification was observed among subjects randomized to both the control group (medi-

an difference 0 [IQR 0, 16.7]; $P = 0.03$) and the intervention group (median difference 16.7 [IQR 4.2, 37.5]; $P < 0.0001$). At 8 weeks, there were no significant changes in objective knowledge within either group. Subjective knowledge, however, was significantly improved in both groups (median difference 8.3 [IQR $-8.3, 25.0$]; $P = 0.02$ and 16.7 [IQR 0, 33.3]; $P < 0.0001$ for the control and intervention groups, respectively), as was values clarity (median difference 12.5 [IQR 0, 25.0]; $P < 0.0001$ and 25.0 [IQR 8.3, 41.7]; $P < 0.0001$ for the control and intervention groups, respectively) at 8 weeks.

Between-group differences. Between-group differences are presented in Table 2. Significant differences at 2 weeks favoring the intervention group were seen for changes in objective knowledge, subjective knowledge, and values clarification. These improvements were also evident at 8 weeks; however, change in objective knowledge at 8 weeks was of borderline significance. No significant between-group differences were found in subjects' confidence with their decision or satisfaction with communication at either time point. A repeated measures analysis of variance confirmed the greater improvements of objective knowledge, subjective knowledge, and values clarification in the intervention versus control groups.

Fifty-four subjects in the control group (88%) and 53 in the intervention group (88%) had made the decision to escalate care ($P = 0.97$) by 8 weeks; of these, 44 subjects (72%) in the control group and 44 (73%) in the intervention group actually escalated care by 8 weeks. Ninety percent of treatment changes involved initiation of a biologic agent; the remaining treatment changes involved an increase in the use of synthetic DMARDs. Reasons for not escalating care are described in Table 3.

Among subjects who had decided to escalate care, a greater percentage of the intervention group met criteria for an informed choice at 2 weeks (32% versus 13%;

Table 2. Between-group differences in objective knowledge, subjective knowledge, and values clarity*			
	Control group (n = 61)	Intervention group (n = 60)	P†
At 2 weeks			
Change in objective knowledge	0 (-2.0, 1.0)	1.0 (-1.0, 2.0)	0.007
Change in subjective knowledge	0 (-16.7, 16.7)	8.3 (-8.3, 33.3)	0.002
Change in values clarity	0 (0, 16.7)	16.7 (4.2, 37.5)	0.001
Risk communication	35.0 (23.0, 42.0)	40.0 (26.5, 43.0)	0.1
At 8 weeks			
Change in objective knowledge	0 (-1.0, 1.0)	1.0 (-1.0, 2.0)	0.05
Change in subjective knowledge	8.3 (-8.3, 25.0)	16.7 (0, 33.3)	0.04
Change in values clarity	12.5 (0, 25.0)	25.0 (8.3, 41.7)	0.02
Risk communication	39.0 (25.0, 41.0)	39.5 (26.0, 42.0)	0.4
* Values are the median (interquartile range) unless otherwise indicated. † By signed rank test.			

P = 0.02), compared to the control group. This difference remained statistically significant (37% versus 11%; P = 0.001) when all individuals, whether or not they had escalated treatment, were included in the sample. No between-group differences were observed at 8 weeks (36% versus 30%; P = 0.5).

DISCUSSION

We found that patients viewing an interactive web-based tool designed to effectively inform patients about the risks and benefits associated with adding a biologic agent in order to control disease activity resulted in significant improvements in objective knowledge, subjective knowledge, and values clarity. Among those escalating care, the proportion defined as making an informed choice was significantly greater among those randomized to the intervention than the control arm. While we observed lasting effects on subjective knowledge and values clarity, improvements in objective knowledge were not as well sustained. The importance of this finding is unclear given that informed choice is most important at the moment of choice and memory for objective knowledge is always

likely to fade. In terms of feasibility, the vast majority of subjects were willing to use an online platform to learn about biologic agents, and almost all of those who were randomized to the intervention arm accessed the tool within the 2 weeks allotted to do so. Modification to enable access on a handheld personal electronic device would be important in order to meet an increasing demand to provide health-related decision support on portable and readily available platforms.

We measured both objective and subjective knowledge because they play distinct roles in decision-making. Having sufficient objective knowledge is requisite to ensure informed consent, whereas subjective knowledge, or the “feeling of knowing,” empowers people to make difficult choices (18,19). Numerous experimental studies have demonstrated that subjective knowledge has a strong impact on subjects’ choices independent of objective knowledge. Correlational studies have found that subjects who feel more informed are more willing to accept risky choices, and interventions that manipulate subjective knowledge (while holding objective knowledge constant) have the same effect (18,20–24). This body of literature strongly suggests that education is most effective when it improves both objective and subjective knowledge.

Table 3. Reasons for deciding not to escalate care or for not actually escalating care		
	Control group, no.	Intervention group, no.
Reasons for deciding not to escalate care		
Patient concerns related to toxicity	2	3
Comorbidity	1	0
Rheumatoid arthritis stable	2	1
No reason described	2	3
Total	7	7
Reasons for not actually escalating care*		
Patient concerns related to toxicity	2	0
Comorbidity	1	2
Inadequate insurance	6	6
No reason described	1	1
Total	10	9
* Among patients for whom a decision was initially made to prescribe a biologic agent.		

In contrast, we did not find any effect of the tool on patient confidence in their decision or satisfaction with communication as measured by the COMRADE. The lack of impact of decision aids on this measure has been found previously (25–29) and may reflect the limitations associated with instruments that measure satisfaction, including lack of responsiveness and scale-related bias. Moreover, patients' perceived quality of communication is influenced by numerous factors, particularly the patient–physician relationship, and may be less impacted by external factors, such as decision support tools. It should also be noted that many patients do not communicate with their physicians once a biologic agent is recommended until the subsequent followup visit. Thus, while an important goal of decision support tools is to improve communication between patients and their physicians, logistics may make this outcome difficult to assess.

The setting in which this pilot trial was conducted offered both advantages and disadvantages. First, the Geisinger Health System has widely adopted quality improvement measures, including systematic monitoring of disease activity and implementation of treat-to-target strategies, which greatly facilitated physician buy-in. Still, the use of the intervention requires only that physicians provide their patients with a link to access the web site, and thus it is likely to be acceptable to rheumatologists outside of this setting. Conversely, the high rate of adherence to best practices at our study site also proved to be a disadvantage, in that the rate of escalation was much higher than expected, which precluded our ability to examine the effects of the tool on actual decision behaviors. The premise underlying this study was that escalation rates in RA among patients with moderate or higher disease activity are low. However, this assumption did not prove to be valid at Geisinger. Only 14 patients in each group decided not to escalate care, and of these, 4 were not candidates (despite being enrolled in the trial). Thus, we were unable to examine this outcome, and whether or not decision support will actually change escalation rates remains to be tested. Future studies conducted in clinical settings with average or lower than expected escalation rates will help determine whether the benefits of the tool extend beyond improving knowledge and values clarification. Despite randomization, there was some imbalance across the 2 groups at baseline. The usual care arm had lower decision conflict scores and thus may have had less potential to improve; however, the majority (74%) had scores above 25 and were therefore eligible to make an informed choice. Lastly, while the study sample did exhibit variability by sex and education, minority patients were not represented. However, the content of the tool was previously developed and tested in both African American and Hispanic patient populations (7).

A small number of subjects in both arms were currently taking a biologic agent at the time of the study. The tool is organized in chapter format, and while we would expect the gain in knowledge to be greater among biologics-naïve patients, in clinical practice the tool serves as a valuable adjunct for all patients wishing to learn more about any of the currently Food and Drug Administration (FDA)–approved biologic agents and/or tofacitinib. However, the

decision to change biologic agents versus the decision to initiate them is likely to be much easier for most patients and thus the value of the tool in the decision to change biologic agents is primarily to increase objective and subjective knowledge and less to clarify values. In this study, the number of subjects currently taking a biologic agent was too small to examine whether this factor modified changes in knowledge or decisional conflict.

Effective risk communication is an essential component of care for RA patients. As recently discussed by patient advocates and representatives from the National Institute of Arthritis and Musculoskeletal and Skin Diseases and the FDA at the special clinical symposium at the American College of Rheumatology annual meeting “The Big Picture: Balancing Risk and Benefit from the US Food and Drug Administration, Physician and Patient Perspectives on Risk Communication,” current methods of risk communication in RA, at both the population and the individual patient levels, are inadequate. In this study, a theory-based interactive decision support tool, developed based on extensive patient and physician input, resulted in improved objective and subjective knowledge, as well as values clarity, compared to usual care. Future efforts will be required to ensure that the information is updated as needed and that the tool is easily accessible, ideally via a link through trusted web sites already familiar to rheumatologists.

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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 submitted for publication. Dr. Fraenkel had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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