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Lupus Clinical Trials: Reaching Patients through Targeted Healthcare Provider Training

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Background

Systemic lupus erythematosus (SLE) is an autoimmune disorder that disproportionately affects women and minorities.[1,2] Estimates report up to 90% of lupus patients are women.[3] Black and Latino individuals experience up to three-times the lupus incidence rate,[4,5,6] more severe disease symptoms, a higher frequency of lupus-related complications, and a sharply higher mortality rate compared to non-Latino White individuals.[7,8,9]

However, despite their disproportionate lupus prevalence, large disparities exist in Black and Latino clinical trial (CT) involvement compared to White patients.[10] This is a cyclical problem that increases health disparities among patients with lupus because clinical trial representation is required in order for new efficacious treatments to become FDA-approved.[10] Because there is no cure for lupus, participation in lupus CTs is an imperative component of current treatment and improving treatment over time, especially for minority groups who experience more severe manifestations of the disease.

There are various barriers to participation in lupus CTs that occur at different levels. Provider-level barriers may be the least explored yet are critical to consider and are imminently addressable.[11-14] Provider-level barriers are diverse and affect the likelihood that patients learn about the existence of CTs. Providers may be unaware or unfamiliar with CT sites and studies, specific protocols, or their patient's eligibility to participate in a lupus CT.[14] Providers may hold negative attitudes about CTs safety or coerciveness, personal biases about minority patients' abilities to engage and adhere to scientific study protocols, [15,16] or hold concerns that if their patient participated in a CT it could affect the professional relationship they have with their patient.[16] Finally, providers often face logistical barriers to have adequate time to inform and educate patients about CTs.[14]

Equipping healthcare providers with better tools to engage patients in discussions about CTs is a potential strategy for increasing minority engagement with CTs. The American College of Rheumatology (ACR), assisted by a multi-disciplinary advisory committee of experts in the field and patients living with lupus created the Materials to Increase Minority Involvement in Clinical Trials (MIMICT) to help address such provider-level barriers. MIMICT is an online educational module that aims to enhance providers' knowledge about, attitudes toward, self-efficacy towards, and intentions to refer Black and Latino patients to lupus CTs by teaching providers about CTs and how to facilitate discussions with patients about CTs. Linguistically and culturally appropriate materials for minority patients support this intervention. KDH Research & Communication conducted an impact evaluation to assess the efficacy of MIMICT by examining cognitive outcomes theoretically related to behavior change among exposed providers in comparison to an unexposed control group.

Methods

Design: We used a randomized, two-group, pretest/posttest study design to evaluate the impact of ACR's MIMICT intervention. After receiving approval from KDH Research & Communication's Institutional Review Board, we recruited providers from across the United States through partnered organizations.

Eligibility criteria: To be accepted into the study providers were required to 1) speak English, 2) have treated a patient with lupus previously, 3) practice specifically in general health or family medicine, general internal medicine, pediatrics, gynecology, obstetrics, nephrology, or dermatology, 4) or be a non-physician provider including clinical nurse specialists, nurse practitioners, registered nurses, physician assistants, licensed practical nurses, and other allied health professionals.

Dependent variables: Knowledge, positive attitudes, self-efficacy, and intentions to refer Black and Latino patients to lupus CTs. Each cognitive outcome had a series of adapted validated questions covering topics in the MIMICT intervention.

Measures: We used five multiple choice questions to assess knowledge, and for the other three outcomes we used seven Likert-type attitudes questions, six Likert-type self-efficacy questions, and four Likert-type intentions questions. Each Likert-type scale ranged from zero (strongly disagree) to 10 (strongly agree). We averaged scores across each outcome to create composite scores ranging from zero to 100 for knowledge and from zero to 10 for attitudes, self-efficacy, and intentions. We also asked only the intervention group a series of eight Likert-type questions about their satisfaction with the MIMICT intervention after program completion.

Exposure variable: We created a dummy variable for whether providers experienced the MIMICT educational intervention or instead were in the control group who received no intervention.

Analyses: We performed between and within groups t-tests to explore changes in cognitive outcomes from pretest to posttest.

Findings

Participants: We recruited 712 provider participants, of which 344 finished both pretest and posttest. The intervention group consisted of 160 providers while 184 were in the control group. The majority of participants were White (70.36%), physicians (46.51%), had medical training (65.99%), and had specialized in dermatology (27.62%). The average age of participants was 48 years old (sd=10.26).

We characterized participants in each group based on whether they had been educated via the medical model, including Medical Doctors (MDs) and Physician Assistants (Pas) (n=227); or educated via the nursing model including Registered Nurses (RNs) and Nurse Practitioners (NPs) (n=107). We also categorized providers by specialty into family care, including general and family medicine (n=72); dermatology (n=95); internal medicine, which included participants who listed internal medicine, nephrology, rheumatology, cardiology, oncology, gastroenterology, endocrinology, and geriatrics (n=99); and "other" for all other specialties such as surgery OB/GYN, pediatrics, and neurology (n=78).

Results

Participation in the intervention group was associated with significantly positive gains across most of the cognitive outcomes.

Knowledge: The intervention group was associated with significantly higher posttest scores ($p<0.01$) for knowledge and higher gains from pretest to posttest ($p<0.01$) compared to the control group. By specialty, both the Family Care and Other categories of the intervention group had significantly higher posttest scores for knowledge compared to the same categories in the control group ($p<0.05$). The Other category had significantly higher gains from pretest to posttest ($p<0.01$) compared to the Other category in the control group. By education type, intervention group participants with both medical and nursing backgrounds had significantly higher composite knowledge posttest scores compared to their respective backgrounds in the control group ($p<0.01$).

Intervention group participants with a nursing background also had significantly higher gains from pretest to posttest compared to those with a nursing background in the control group ($p<0.01$).

Attitudes: We observed no significant differences relating to attitudes posttest scores or gains from pretest to posttest between or within the intervention and control groups.

Self-efficacy: The intervention group was associated with significantly higher posttest scores for self-efficacy than the control group ($p<0.01$). By specialty, the Family Care and Other categories had significantly higher gains in self-efficacy compared to the Family Care and Other categories in the control group, both with ($p<0.05$). By education type, intervention group participants with a nursing background had significantly higher composite posttest scores and gains from pretest to posttest for self-efficacy, both with ($p<0.01$).

Intentions: The intervention group was associated with significantly higher posttest scores for intentions and higher gains from pretest to posttest compared to the control group, both with ($p<0.001$). All specialty categories had significantly higher posttest scores ($p<0.01$) and gains ($p<0.05$) in intentions from pretest to posttest compared to their respective categories in the control group. By education type, intervention group participants with both medical and nursing backgrounds had significantly higher composite intentions posttest scores compared to their respective backgrounds in the control group ($p<0.05$). Intervention group participants with both medical ($p<0.001$) and nursing ($p<0.05$) backgrounds had significantly higher gains from pretest to posttest compared to their respective backgrounds in the control group.

Satisfaction: The average composite score for satisfaction score was 7.59, revealing that intervention group participants held a favorable opinion towards the MIMICT educational intervention. We conducted Spearman's rank correlation analyses and found satisfaction was weakly and positively associated with attitudes posttest scores ($R_s[148] = 0.31, P < 0.001$), and self-efficacy posttest scores ($R_s[150] = 0.31, P < 0.001$), and was strongly and positively associated with posttest scores for intentions ($R_s[150] = 0.62, P < 0.001$).

Regression analyses: We explored multiple linear regressions using each of the posttest cognitive outcome scores as the dependent variables. We controlled for age, race (using White as the reference), number of patients previously referred to lupus CTs (0 as the reference), specialty type (Other as the reference), and type of degree (MD as the reference).

Even when controlling for participant characteristics, we found that exposure to the MIMICT educational course was positively and significantly associated with posttest scores for knowledge ($p<0.001$), self-efficacy ($p<0.05$), and intentions to refer Black and Latino patients to lupus CTs ($p<0.001$).

Participants who had previously referred patients to lupus CTs scored higher on composite posttest scores for self-efficacy ($p<0.05$), intentions ($p<0.001$), and satisfaction ($p<0.05$), compared to participants who had never referred a patient to a lupus CT before.

Participants who held degrees classified as Other had significantly higher posttest scores for intentions ($p<0.05$) compared to participants who held MD degrees. Participants with RN degrees had significantly higher posttest scores for self-efficacy ($p<0.001$) and intentions ($p<0.01$) compared to participants who held MD degrees. Participants with NP degrees had significantly higher posttest scores for attitudes ($p<0.001$) compared to participants who held MD degrees.

By specialty, dermatologists had higher posttest scores for knowledge ($p<0.01$) and satisfaction ($p<0.05$) compared to participants whose specialty was classified as Other. Family practitioners and internal medicine providers both had significantly higher posttest scores for intentions compared to participants whose specialty was classified as Other, with ($p<0.001$) and ($p<0.01$), respectively.

Discussion

The MIMICT educational course is an efficacious tool for addressing provider-level barriers to lupus CT referrals by enhancing knowledge about, self-efficacy towards, and intentions to refer Black and Latino patients to lupus CTs. The MIMICT course received relatively high satisfaction scores from the intervention group, which had a strong, positive association with posttest scores for intentions to refer diverse patients to lupus CTs.

Minority patients may experience better access to and more opportunities to participate in lupus CTs if healthcare providers are better informed on how to facilitate conversations with patients about lupus CT engagement. By educating healthcare providers, providers themselves can help their patients make more informed decisions about participation in lupus CTs.

Healthcare providers are in direct contact with their patients and serve as an important liaison between patients and potential CT opportunities. By increasing provider knowledge and awareness regarding lupus, related health disparities, and lupus CTs providers are better enabled to support their patients and potentially increase the number of referrals in hopes of ultimately increasing the representation of Black and Latino patients within lupus CTs.

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