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Evaluating Peer-Provided Clinical Trial Education to Increase Trial Participation

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Background

Clinical trials (CTs) in the United States (US) have struggled to adequately enroll minority racial and ethnic groups to participate in drug efficacy studies. Lack of representation in CTs makes it harder to assess the associated risks and benefits of a new treatment among minority patients. Without accurate assessments of a drug's effects on minority patients, the US Food and Drug Administration (FDA) is limited in their ability to approve new treatments for use among minority populations.[1; 2]

This problem is demonstrated among Black patients diagnosed with systemic lupus erythematosus (SLE), a chronic inflammatory disease. Black patients encounter three times the prevalence of SLE as White patients,[3] and experience disproportionately higher morbidity and mortality related to SLE.[4] Despite the disproportionate affliction, Black patients make up only 14% of participants in SLE related CTs.[4; 5]

Black patients have the greatest risk of developing SLE and frequently experience more severe manifestations of SLE compared to other groups, therefore increasing Black representation in CTs is an important health equity initiative.

Various models of patient advocacy in other fields have proven effective at increasing patient participation and patient retention in medical studies.[7-12] A patient advocate may be defined as a person brought onto a healthcare team specifically to assist patients in navigating and engaging the healthcare system.[8]

Patient advocates empower patients to make informed decisions about their care by supporting their knowledge of relevant resources. Patient advocates are less formal compared to providers and are often chosen to serve communities they also represent, which may lead to a smaller social and power differential when connecting and communicating with patients. By using more relatable patient peers as advocates, the divide is narrowed even further. Patient peers are experts from personal experience who share a similar condition/disease as the patient and are therefore uniquely able to offer invaluable insights.

The Lupus Research Alliance (LRA)/Lupus Therapeutics (LT) developed a patient peer advocate program to educate minority SLE patients about relevant CTs with the ultimate goal of increasing minority representation in lupus CTs. LT's Patient Advocates for Lupus Studies program (LT-PALS) aims to help minority SLE patients better comprehend how CTs work. LT-PALS trained SLE patient peers (Pals) to educate minority SLE patients about scope and common content of lupus CTs, the potential risks/benefits associated with participation, and how participation of underrepresented groups supports the advancement and approval of safe and promising new treatments.

Pals and patients discussed key topics during individual education sessions. On average, Pals took 15 weeks to complete five to six education sessions with each patient participant. LT-PALS software enabled text, video, and voice communications; however, most Pals communicated via cell phone.

KDH Research & Communication conducted an impact evaluation of the LT-PALS program to assess the extent that LT-PALS program exposure was associated with significant gains in cognitive outcomes theoretically related to behavior change: Knowledge about, attitudes toward, self-efficacy toward, and intentions to participate in a lupus CT.

Methods

Design: We used a randomized, two-group, pretest/posttest/follow-up design to evaluate the impact of the LT-PALS intervention. After receiving approval from KDH Research & Communication's Institutional Review Board (IRB) and the local IRBs from respective sites, the study team recruited participants at five university sites in LRA's Lupus Clinical Investigators Network (LuCIN) that each serve a particularly high proportion of minority patients.

Patient eligibility criteria: To participate in the study, participants were required to: 1) be 18 or older; 2) speak English; 3) meet the Revised American College of Rheumatology Criteria and/or Systemic Lupus International Collaborating Clinics Criteria for SLE; 4) have access to reliable internet, and 5) not have prior participation in any drug CT.

Pal eligibility criteria: Pals were selected and recruited primarily by the principal investigators (P/Is) at each university site. Pals had the same eligibility criteria as participants, except Pals were required to have had prior experience participating in clinical research, with a strong preference for having participated in a CT. Pals underwent in person and remote trainings to help them discuss the clinical research process with patients, explore patient concerns about CTs, and highlight the importance of clinical research.

Dependent variables: Knowledge, positive attitudes, self-efficacy, and intentions to participate in lupus CTs. Each cognitive outcome had a series of adapted validated questions covering topics in the LT-PALS intervention.

Measures: We used five multiple choice questions to assess knowledge. We used five Likert-type questions to explore attitudes, and six Likert-type questions to assess self-efficacy and intentions. 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 ten Likert-type questions about their satisfaction with the LT-PALS intervention after program completion.

Exposure variable: We created a dummy variable for whether providers experienced the LT-PALS 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 and follow-up. Due to multiple comparisons, we used Bonferroni's correction to establish a significance level of $p \leq 0.025$. We conducted regression analyses to explore the impact of LT-PALS on cognitive outcomes while controlling for participant characteristics. Finally, we assessed correlations between CT engagement at one-year follow-up and participant characteristics. We defined CT engagement as initiating conversation with a healthcare provider about an LCT, following up on an LCT referral, contacting an LCT site, participating in screening for an LCT, and/or enrolling in an LCT.

Findings

Participants: We recruited 235 participants, of which 136 finished both pretest and posttest. The intervention group consisted of 64 patients while 72 were in the control group. The majority of participants were Black (68%), The average age of participants was 40 years old (sd=11.86). Participants had a large range of time since being diagnosed with SLE from less than a month to 43 years. The most common reason given for never having participated in a CT was never being offered the opportunity (34%).

Pals: Eight of the 10 Pals who completed the program identified as Black. Pals worked with 13 participants on average and spent about 13 weeks on average to complete all education sessions with each participant.

The age of the intervention group was significantly higher than the control group and the length of SLE diagnosis was significantly longer among the control group.

Results

Knowledge: The intervention group was associated with significantly higher posttest scores for knowledge ($p<0.01$) and significantly higher gains from pretest to posttest ($p<0.01$) compared to the control group. The intervention group gained significantly in knowledge scores from pretest to posttest ($p<0.001$).

Attitudes: The intervention group was associated with significantly higher posttest scores for attitudes compared to the control group ($p=0.02$).

Self-efficacy: From pretest to 3-month follow-up, the intervention group gained significantly in self-efficacy scores ($p<0.01$).

Intentions: The intervention group was associated with higher posttest scores for intentions compared to the control group, yet this did not reach the corrected significance level ($p=0.04$). The intervention group decreased in intentions scores from posttest to 3-month follow-up, returning to baseline levels.

Satisfaction: The intervention group had an average satisfaction score of 7.55 (sd=1.55) showing a favorable experience with the LT-PALS implementation.

Regression analyses: When controlling for participant characteristics, exposure to the LT-PALS intervention was associated with increased posttest scores for knowledge ($p<0.001$) and intentions ($p=0.04$).

One year follow-up: Of the 49 intervention group participants who participated in the one-year follow-up survey, 23 (46.94%) self-reported broad engagement in a CT.

Discussion

The LT-PALS educational intervention is a hopeful strategy for engaging minority patients with lupus in CTs. At one-year follow-up nearly half of the intervention group self-reported broad engagement with a lupus CT.

The LT-PALS intervention received encouraging satisfaction scores from the intervention group, and interviews with Pals also highlighted a sense of importance in regard to supporting other lupus patients.

This study occurred during the onset of the COVID-19 pandemic and as such many changes were made to study protocols including from in person to virtual interactions. Such changes may have had effects on the intervention's efficacy or validity of findings. We were limited in our ability to make causal inferences about follow-up data due to lack of a control group at later timepoints. Furthermore, results may be subject to bias due to use of self-reported measures and necessary adaptations of study protocols. Nevertheless, the findings from this study are encouraging. The use of patient peers with lupus to connect and support other patients with lupus in making informed choices about their healthcare is an exciting new strategy for decreasing disparities in CT enrollment.

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