

**BRIEF REPORT**

# ACT for Lupus: Pilot Feasibility and Acceptability Study of a Novel Web-Based Acceptance and Commitment Therapy Program for Patients With Lupus

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**Objective.** Acceptance and commitment therapy (ACT) has demonstrated effectiveness in addressing symptoms of anxiety and depression, frequently experienced by patients with systemic lupus erythematosus (SLE). The goal of this pilot study was to develop and assess the feasibility and acceptability of a novel web-based ACT skills training program tailored for patients with lupus: ACT for Lupus. The program served as a complementary approach to support the management of symptoms and stressors during the COVID-19 pandemic.

**Methods.** This study employed a single-group pretest-posttest design. Participants with a diagnosis of SLE were primarily recruited through an institutional healthcare system between November 25, 2020 and December 17, 2020 and through an online national lupus organization listserv. Participants were invited to attend two 1-hour webinars delivered over a 2-week period. Educational ACT-based content was tailored for patients with lupus and delivered by an experienced clinical psychologist specializing in ACT. Surveys assessed patient-reported outcomes of anxiety, depression, and quality of life and evaluated program feedback, usability, and satisfaction.

**Results.** A total of 83 participants submitted the baseline survey, with 21 participants designated as study completers. The program was well received by participants, who reported feasibility and acceptability of the intervention, as reflected by high usability ratings. Participants reported favorable experiences with the program. Feedback included suggestions to include additional lupus-tailored content, increase the range and scope of sessions and activities, and improve program flexibility and availability to avoid scheduling conflicts.

**Conclusion.** This study provides preliminary evidence for an adapted, ACT-based virtual skills training program as a feasible and acceptable intervention to support the well-being of patients with lupus.

## INTRODUCTION

Systemic lupus erythematosus (SLE) is a chronic autoimmune disorder, characterized by recurrent flares of inflammation and heterogeneous clinical manifestations (1). Patients with SLE have increased rates of comorbid conditions, including

depression and anxiety, which are associated with negative impacts on quality of life (QoL) (2).

The COVID-19 pandemic resulted in additional impacts on social isolation, economic stressors, and additional barriers to healthcare and medication access for patients with SLE (3). Specifically, the adoption of hydroxychloroquine (HCQ) as a treatment

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for COVID-19 created increased interest and demand in the United States and globally (4), resulting in shortages and other reported barriers impacting patients' access to HCQ. Such shortages can lead to psychological distress and lapses in treatment, which can increase the risk of flares and hospitalization for patients relying on HCQ for treatment of their lupus (3).

Nonpharmacological interventions (eg, psychological, educational interventions) delivered remotely and in person have shown promise to improve QoL and psychological outcomes in patients with lupus (5). Acceptance and commitment therapy (ACT) is one therapeutic option that may be particularly well suited for the needs of patients with SLE. ACT has consistently demonstrated efficacy as a treatment for a wide range of symptoms commonly experienced by patients with SLE, such as depression (6), anxiety (7), and chronic pain (8). Grounded in Relational Frame Theory, ACT emphasizes the acceptance of internal and external events through the incorporation of psychological flexibility as a core component (9). There are six processes that comprise psychological flexibility: acceptance, defusion, self-as-context, flexible attention to the present moment, chosen values, and committed action (10). According to ACT principles, when these six processes are functioning together, individuals experience greater psychological flexibility and, in turn, improved psychosocial functioning and QoL. ACT-based programs can support durable commitment to behavior change consistent with personal goals and values (10).

ACT has shown support as a treatment for symptoms that are commonly experienced by patients with SLE, which may have been further compounded by pandemic-related stressors, including shortages of lupus medications (ie, HCQ). Additionally, ACT can be effectively delivered through both in-person settings and remote platforms to increase reach, accessibility, and uptake (7). Psychological support delivered through flexible, remote interventions is especially important because there are barriers to engaging in face-to-face ACT with a trained therapist, such as cost and logistical and time constraints. Remotely delivered interventions are especially important to improve accessibility to care and support for patients managing the day-to-day challenges of living with lupus in the context of the COVID-19 pandemic.

To our knowledge, only one study to date has evaluated ACT therapy for SLE in a small sample ( $n = 24$ ) of patients in Iran; the authors found that ACT sessions delivered in a group format reduced psychological distress and anxiety (11). As the generalizability of these findings may be limited, additional studies are needed to evaluate ACT as a therapy for SLE. Our work aims to address this knowledge gap through the development and evaluation of a pilot ACT-based virtual intervention to improve psychological and QoL outcomes: ACT for Lupus. We aimed to assess the feasibility and acceptability of a novel ACT for Lupus program to support the health and well-being of patients with lupus. Because of additional COVID-19 pandemic-specific concerns related to medication access, namely HCQ (4), we sought to assess whether our patients had been impacted by these disruptions and shortages.

## MATERIALS AND METHODS

### Participants and study design

In November 2020, patients with a diagnosis of SLE were identified through the University of North Carolina (UNC) Healthcare System if they had a visit to the UNC General Rheumatology Clinic or Lupus Specialty Clinic in the past 2 years. Additional recruitment was conducted at a national level through a national lupus advocacy organization's email registry. To be eligible for the study, participants had to have a reported lupus diagnosis, be aged 18 years or older, have computer/internet accessibility, and have English proficiency. The UNC Chapel Hill Institutional Review Board approved this study (No. 20-1085).

Participants were emailed an online Qualtrics survey (<https://software.sites.unc.edu/qualtrics/>) link to review study information, provide informed consent, and submit baseline self-assessments once enrolled. Follow-up reminders were sent before the sessions to remind participants to complete surveys. Post-intervention surveys were sent to participants who attended at least one session. Participation in this study was not compensated.

**Table 1.** Description of the ACT for Lupus session topics and activities

Session 1: December 10th, 2020 3:00-4:00 pm (EST)	Session 2: December 17th, 2020 3:00-4:00 pm (EST)
Topic: Finding Well-Being During COVID-19 and Rolling With Pain and Anxiety	Topic: Values in Action and Wellness for Life
Introduction to ACT for Lupus (introducing the concept of psychological flexibility and the rationale for ACT)	Living a Fulfilling Life (identifying values and daily activities that create a fulfilling life)
Living with Lupus (engaging in self-care activities from a place of acceptance of discomfort and defusion from beliefs about lupus and its limitations)	Taking Action (identifying barriers to living a fulfilling life and committing to taking action in the face of barriers)
Living in the Present (developing a present moment awareness through mindfulness practice and a sense of self that occurs in the context of lupus but that is not defined by lupus)	Moving Forward (putting these skills into an actionable plan that can be carried forward)
Activities: <ul style="list-style-type: none"> <li>• Getting present (mindfulness exercise)</li> <li>• Finding your place of peace (mindfulness exercise)</li> <li>• Self-care action plan</li> </ul>	Activities: <ul style="list-style-type: none"> <li>• Loving kindness meditation</li> <li>• Putting values into action</li> <li>• SMART (Specific, Measurable, Achievable, Relevant and Time-based) goal setting</li> <li>• SEAT (Situation, Emotion, Ask, Thank) tool for communicating needs</li> </ul>

Abbreviations: ACT, acceptance and commitment therapy.

## Patient involvement

ACT for Lupus was developed because of the urgent need expressed by patients with lupus for support during the COVID-19 pandemic, in response to feedback from patients at the UNC Rheumatology Lupus Clinic. Due to the critical need to deliver a timely intervention, we were unable to involve patient partners in the development of this pilot study. However, we solicited feedback from program participants and have since established a lupus patient stakeholder advisory board to provide guidance on dissemination of plans and inform future refinement of the program.

## Intervention

The intervention used in this study consisted of two 1-hour webinars that took place over two consecutive weeks in December 2020. The content for the ACT-based sessions was developed and delivered by an experienced clinical psychologist who specializes in ACT and was tailored specifically to patients with lupus in consultation with a rheumatologist/lupus specialist. Both experts served as session panelists. Each session consisted of 40 minutes of ACT-based education followed by a 20-minute question and answer session with the panelists. The ACT specialist (CS), rheumatologist and allergist/immunologist (SS), and session moderators (EM and TE) were present on the virtual stage to field and answer questions that were noted in the chat function of the platform. Participants

were provided with the support team's information if any technological issues arose.

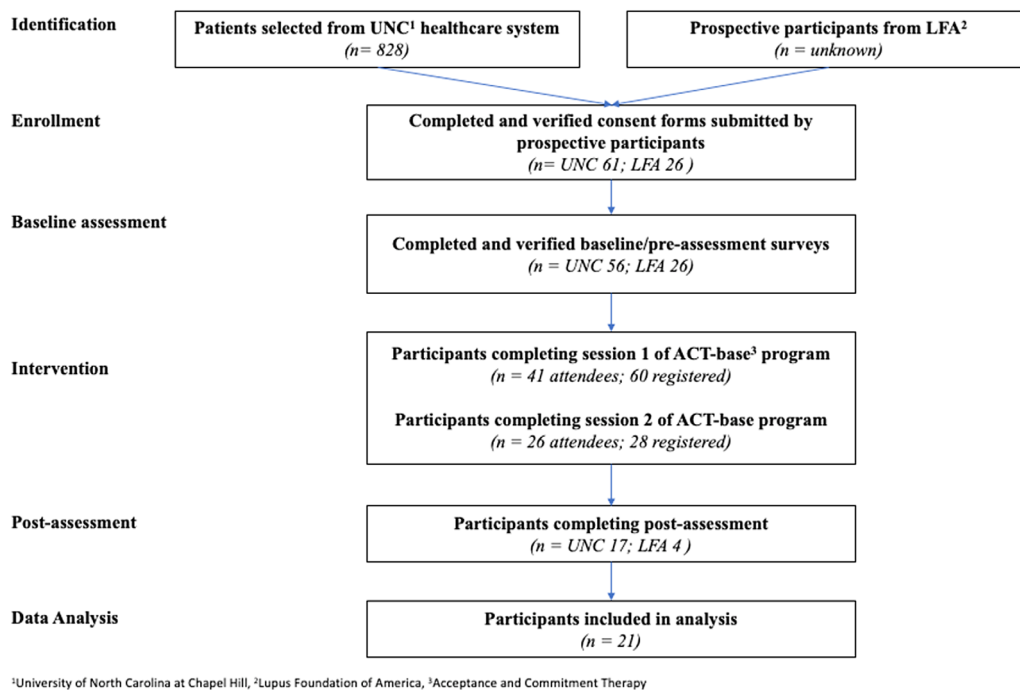
The web-based ACT for Lupus program consisted of an online event platform, Hopin ([www.hopin.com](http://www.hopin.com)). Prior to each session, automated email reminders were sent notifying participants of upcoming events. Participants could then use their personal login to access the platform.

The virtual platform allowed for live presentation by panelists with a participant-enabled chat box to enter questions and comments. Participants and presenters were provided a link to the event following completion of the surveys and session registration.

Session topics included mindfulness, distress tolerance, self-care, advocacy, goal setting, and action planning. ACT topics were presented in a manner that considered the fluctuations in disease activity and the range of comorbid conditions that patients with lupus can experience. Lupus-tailored content primarily focused on acceptance of lupus symptoms, improving sense of self and awareness in the context of lupus, and committing to taking action when facing disease-related barriers. Further descriptions of the session topics and activities are outlined in Table 1.

## Measures

**Acceptability and usability measures.** Program feedback was assessed through Likert style and open-ended questions asking participants about their perceptions of the program and suggestions for future programs. The overall usability of the



**Figure 1.** Study participant flow chart. ACT, acceptance and commitment therapy; LFA, Lupus Foundation of America; UNC, University of North Carolina.

program was assessed using the System Usability Scale adjective rating scale, which asks participants to rate the overall “user-friendliness” of the program on a 7-point scale, from a value of 1 assigned to “Worst Imaginable” to 7 assigned to “Best Imaginable” (12).

**Medication access measures.** Due to emerging reports of disruptions in availability of HCQ for patients with SLE during the COVID-19 pandemic (3), we secondarily developed survey questions to assess medication accessibility during the pandemic.

**Table 2.** Participant characteristics for baseline respondents, completers, and non-completers

Participant characteristics	Baseline N = 83	Baseline, completers n = 21	Baseline, non-completers n = 62	Fischer's exact P value
Age, y, mean ± SD	44.0 (12.4)	47.6 (14.1)	42.8 (11.7)	
Female, n (%)	76 (91.6)	18 (85.7)	58 (93.5)	0.3618
Race/ethnicity, n (%)				
White	48 (57.8)	15 (71.4)	33 (53.2)	0.6503
Black/African American	16 (19.3)	3 (14.3)	13 (21.0)	
Hispanic/Latino	10 (12.0)	2 (9.5)	8 (12.9)	
Asian	4 (4.8)	1 (4.8)	3 (4.8)	
Other	5 (6.0)		5 (8.1)	
Education, n (%)				
High school degree	5 (6.0)	3 (14.3)	5 (8.1)	0.1113
Some college, no degree	15 (18.1)	12 (57.1)	12 (19.4)	
Associate degree	8 (9.6)	6 (28.6)	8 (12.9)	
Bachelor's degree	30 (36.1)		18 (29.0)	
Graduate degree or above	25 (30.1)		19 (30.6)	
Employment status, n (%)				
Full-time	35 (42.2)	7 (33.3)	28 (45.2)	0.5814
Part-time	6 (7.2)	2 (9.5)	4 (6.5)	
Unemployed	9 (10.8)	2 (9.5)	7 (11.3)	
Retired	6 (7.2)	3 (14.3)	3 (4.8)	
Medically disabled/unable to work	19 (22.9)	6 (28.6)	13 (21.0)	
Other	8 (9.6)	1 (4.8)	7 (11.3)	
Recruitment source, n (%)				
North Carolina	58 (69.9)	17 (81.0)	41 (66.1)	0.2744
Nationally	25 (30.1)	4 (19.0)	21 (33.9)	
Psychotherapy use <sup>a</sup> , n (%)	20 (24.1)	6 (28.6)	14 (22.6)	0.5685
Anxiety medication use <sup>a</sup> , n (%)	45 (54.2)	13 (61.9)	32 (51.6)	0.4570
Hydroxychloroquine use (current), n (%)	69 (83.1)	16 (76.2)	53 (85.5)	0.3296
Reported difficulties with hydroxychloroquine prescription, n (%)				
None	35 (42.2)	9 (42.9)	26 (41.9)	1.0000
Received a reduced supply	11 (13.3)	4 (19.0)	7 (11.3)	0.4575
Medication refill was delayed	21 (25.3)	4 (19.0)	17 (27.4)	0.5676
The cost of the prescription increased	10 (12.0)	5 (23.8)	5 (8.1)	0.1128
I had to find a different pharmacy	6 (7.2)	2 (9.5)	4 (6.5)	0.6400
Unable to fill medication at all	2 (2.4)		2 (3.2)	1.0000
Decided not to take during this time	6 (7.2)	1 (4.8)	5 (8.1)	1.0000
Other	10 (12.0)	3 (14.3)	7 (11.3)	0.7081
Patient-reported outcomes, mean (SD)				
Anxiety GAD-7 <sup>b</sup> (n = 80)	8.7 (5.62)	10.1 (6.2)	8.2 (5.35)	
Depression PHQ-9 <sup>c</sup> (n = 81)	9.4 (6.01)	10.1 (5.1)	9.2 (6.32)	
LupusQoL domains <sup>d</sup> (n = 73)				
Pain	60.8 (27.4)	60.7 (27.0)	60.9 (27.8)	
Physical health	63.6 (26.7)	62.5 (27.5)	64.1 (26.6)	
Planning	61.5 (34.4)	66.7 (29.7)	59.5 (36.2)	
Intimate relationships	62.7 (36.7)	67.9 (34.6)	60.6 (37.7)	
Burden to others	51.6 (34.9)	56.0 (32.6)	49.8 (36.0)	
Emotional health	69.3 (23.6)	72.8 (18.0)	67.9 (25.6)	
Body image	68.2 (25.5)	77.0 (20.3)	64.6 (26.6)	
Fatigue	49.0 (30.2)	49.4 (29.0)	48.8 (31.0)	

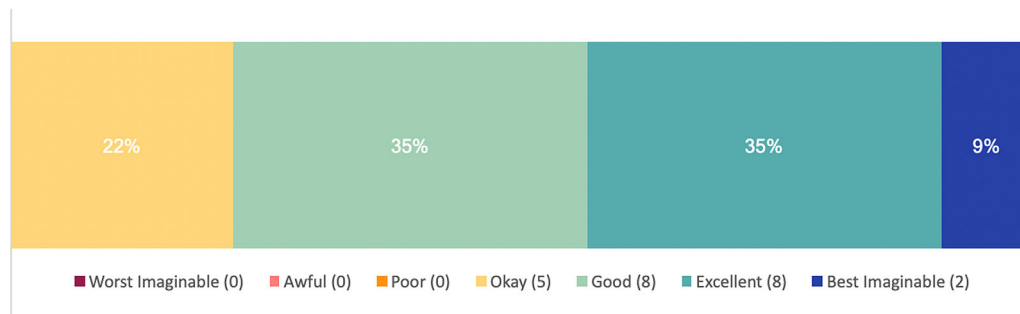
Abbreviations: GAD-7, General anxiety disorder-7; LupusQoL, Lupus quality of life; PHQ-9, Patient health questionnaire-9.

<sup>a</sup>Past 30 days.

<sup>b</sup>GAD-7 scores range 0-21, higher scores represent worse symptoms.

<sup>c</sup>PHQ-9 scores range 0-27, higher scores represent worse symptoms.

<sup>d</sup>LupusQoL domain scores range 0-100, higher scores represent better health-related QoL.



**Figure 2.** System usability scale overall ratings.

**Outcome measures.** Patient-reported outcomes (PROs) were assessed at baseline and post intervention using validated measures for anxiety (General Anxiety Disorder-7 [GAD-7]) (13), depression (Patient Health Questionnaire [PHQ-9]) (14), and health-related QoL domains (LupusQoL) (15).

### Statistical analysis

Descriptive statistics were calculated for covariates and PROs at baseline and follow-up, using means and standard deviations for continuous variables and frequencies and percentages

for categorical variables. Individuals who attended at least one program session and participated in baseline and post-intervention surveys were designated as study completers and are the set of participants on whom the analyses are based.

We calculated paired *t*-tests for changes in baseline and 6-week follow-up scores to assess pre-test and post-test differences. Mean changes between baseline and 6-week follow-up scores were calculated using multivariate linear regression models while controlling for baseline outcome score, age, and sex. Effect sizes, expressed as Cohen's *d*, were estimated by comparing the mean change scores from baseline to 6 weeks divided by

**Table 3.** Illustrative quotes of participant feedback on the ACT for Lupus program

Program feedback	Illustrative quotes
General comments	<p>"Very relaxing and validating. I enjoyed it."</p> <p>"Enjoyed both sessions immensely. Hope to put them into practice regularly if not daily."</p>
Timing and accessibility	<p>"I wish the sessions were recorded so that patients could have a chance to watch them when they are able to. I was always having to work when they were being shown."</p> <p>"Could use more sessions!"</p>
Mindfulness activities	<p>"The body scan and five senses exercises were great. Really relaxed my body and helped ease the achiness."</p> <p>"Both Imagery exercises and practical application of values exercise...worked well for me and inspired further self-evaluation."</p> <p>"I liked the color guided finding the present moment resetting exercise."</p> <p>"Guided meditation was boring."</p> <p>"Meditations were not helpful for me."</p>
Communication skills and values-based activities	<p>"I liked the activity in the second session where we focused on our values and thought of barriers and goals for making those values prominent in our lives. I also liked the SEAT tool even though it seems difficult to have those conversations."</p> <p>"Both imagery exercises and practical application of values exercise. They worked well for me and inspired further self evaluation."</p>
Session scope and pacing	<p>"I realized some have done counseling before and some haven't, so this was too elementary for me."</p> <p>"Could be contextualized for people who do not have experience with or are newer to therapy/CBT. A lot of the exercises felt redundant to the work I do with my therapist weekly."</p> <p>"I don't really feel as though it was centered around some who doesn't feel the symptoms of lupus!"</p> <p>"...It was geared to people who don't get the symptoms [of lupus]."</p>
Suggestions for additional topics	<p>"How to deal with others and their lack of understanding of what it is like to manage a long-term illness."</p> <p>"Differentiating between mental and physical pain. How to set expectations with family/friends over the holidays."</p> <p>"Further resources for coaching? The values &amp; goals process is one I would like to [ensure] I'm on the right track."</p> <p>"How to manage without support network."</p> <p>"Support groups for Lupus patients?"</p> <p>"Mind exercises [for] when you can't sleep or for when you're in pain."</p> <p>"Expand on mindfulness."</p>
Participant engagement	<p>"How can you leverage the chat to add value for people who are not auditory learners?"</p> <p>"Some of the questions from the audience seemed really left-field to me. But everybody needs a chance to be heard."</p>

Abbreviations: CBT, Cognitive behavioral therapy; SEAT, Situation, Emotion, Ask, Thank.



**Table 4.** Means (SD) and effect sizes<sup>a</sup> for changes in outcomes from baseline to end of study (N = 21)

Outcome measures	Baseline mean (SD)	End of study mean (SD)	Effect size unadjusted (95% CI)	Effect size adjusted <sup>b</sup> (95% CI)
Anxiety GAD-7 <sup>c</sup>	10.1 (6.2)	7.9 (4.5)	-0.40 (-1.03 to 0.22)	-0.43 (-1.05 to 0.20)
Depression PHQ-9 <sup>d</sup>	10.1 (5.1)	9.6 (5.3)	-0.10 (-0.72 to 0.52)	-0.11 (-0.73 to 0.51)
LupusQoL domains <sup>e</sup>				
Pain	60.7 (27.0)	68.3 (20.5)	0.16 (-0.43 to 0.75)	0.30 (-0.32 to 0.93)
Physical health	62.5 (27.5)	67.4 (19.8)	0.20 (-0.42 to 0.83)	0.20 (-0.42 to 0.82)
Planning	66.7 (29.7)	70.6 (22.8)	0.15 (-0.47 to 0.77)	0.15 (-0.47 to 0.78)
Intimate relationships	67.9 (34.6)	75.6 (27.2)	0.25 (-0.37 to 0.87)	0.25 (-0.37 to 0.87)
Burden to others	56.0 (32.6)	61.1 (24.1)	0.18 (-0.44 to 0.80)	0.18 (-0.44 to 0.80)
Emotional health	72.8 (18.0)	72.0 (15.7)	-0.05 (-0.67 to 0.57)	-0.05 (-0.67 to 0.57)
Body image	77.0 (20.3)	76.3 (19.8)	-0.04 (-0.66 to 0.58)	-0.04 (-0.66 to 0.58)
Fatigue	49.4 (29.0)	56.3 (20.6)	0.27 (-0.35 to 0.90)	0.26 (-0.36 to 0.89)

Abbreviations: CI, Confidence interval; GAD-7, General anxiety disorder-7; LupusQoL, Lupus quality of life; PHQ-9, Patient health questionnaire-9.

<sup>a</sup>Effect sizes for normally distributed outcomes computed using Cohen's *d*.

<sup>b</sup>Effect sizes adjusted for baseline score, age, and sex.

<sup>c</sup>GAD-7 scores range 0-21, higher scores represent worse symptoms.

<sup>d</sup>PHQ-9 scores range 0-27, higher scores represent worse symptoms.

<sup>e</sup>LupusQoL domain scores range 0-100, higher scores represent better health-related QoL.

the pooled standard deviation. All tests were two-sided and considered statistically significant at the  $P = 0.05$  level. Analyses were carried out using SAS software version 9.4 (SAS Institute Inc).

## RESULTS

**Participant characteristics.** A total of 235 individuals accessed the study consent form, and of those, 35.3% ( $n = 83$ ) completed the baseline assessment. Of those who completed the baseline assessment, there were 60 registrants and 41 attendees for the first session and 28 registrants and 26 attendees for the second session. Of the cohort of study completers ( $n = 21$ ), all attended the first session and 19 participants attended the second session. The final sample consisted of 21 participants (25.3% of individuals who completed the baseline assessment), referred to as "Completers," who attended at least one session and completed the end of study survey (Figure 1).

Baseline participants ( $n = 83$ ) mostly identified as female (91.6%) and white (57.8%). A total of 69 participants (83.1%) reported current use of HCQ. When asked about difficulties accessing HCQ during the pandemic, a majority of participants reported that they experienced barriers to access (57.8%). No significant differences in demographic characteristics were detected between completers and non-completers (Table 2).

**Acceptability and usability outcomes.** Overall mean and standard deviations for the program's usability score were  $5.30 \pm 0.91$  (out of 7 possible points), with the majority of scores (70%) marked as good or excellent (Figure 2).

Generally, participants had positive views of the program and had a range of views on individual components; selected quotes are outlined by main themes/topics in Table 3. When asked what worked well in the sessions, many participants highlighted the mindfulness and goal-setting activities as valuable components.

Participants reported mixed views on the utility of mindfulness activities in this setting. A few respondents who had received prior external counseling services expressed a desire for a more advanced version of the program. Participants suggested a variety of additional areas to expand on in the future, including setting expectations and communicating with family and friends, finding support within or out of a social context, and additional instruction and mindfulness exercises. Examples of feedback are outlined in Table 3.

**Outcome measures.** Table 4 displays the means and effect sizes for changes in primary outcome measures from baseline to post-intervention. Nonsignificant, small to medium effect sizes were observed in all variables except emotional health and body image QoL domains.

## DISCUSSION

This study is the first to adapt and evaluate an online ACT-based program for patients with lupus. Results demonstrated favorable participant experiences and high acceptability ratings. Participant feedback emphasized the need for lupus-centered mindfulness programs and included valuable suggestions for program improvements. Overall, the ACT for Lupus program was a safe, feasible, and acceptable online intervention to implement and use during the COVID-19 pandemic.

Our study had several limitations. This was an exploratory single-group feasibility study, which was not powered to detect significant changes in outcomes. Additional studies with larger sample sizes are needed to further explore the effects of ACT on improving PROs for patients with lupus. Additionally, the small sample size may limit generalizability of these findings. The low recruitment and retention rates in this study are likely to be driven by a variety of factors. First, the program took place over the

holiday season, with sessions held in early December, which may have contributed to the limitations in recruitment and retention. Sessions also took place in the afternoon during standard working hours (3:00-4:00 pm EST), with no other time options provided, which was highlighted as a barrier to participation in feedback surveys. Additionally, we believe that the virtual nature of this study may have restricted participation for those with limited digital literacy or access.

The ACT for Lupus program will be modified based on participants' feedback from this study, and there is planned patient stakeholder engagement to guide recruitment and retention procedures and refine the intervention before progressing to evaluation in a randomized trial. Future iterations will include more session offerings, additional tailoring to lupus-specific topics, and improved accessibility of sessions by adapting it to a self-paced format with pre-recorded sessions and exercises, available at any time. Based on findings from this study, we believe that providing an ACT-based program in this accessible and flexible format will better meet the individual needs of participants and improve participation and satisfaction in future editions of ACT for Lupus.

In conclusion, our evaluation found that an adapted ACT-based program was a feasible intervention to support patients with lupus during the COVID-19 pandemic. Results from this study will be used to enhance the ACT for Lupus program and establish an evidence base for ACT as a nonpharmacological approach to support the health and QoL of patients with lupus.

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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 published. Dr. Sheikh 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.

**Study conception and design.** McCormick, Englund, Schiller, Sheikh.

**Acquisition of data.** McCormick, Englund, Dickson, Sheikh.

**Analysis and interpretation of data.** McCormick, Englund, Cleveland, Dickson, Sheikh.

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