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The Health Education for Lupus Patients Study: A Randomized Controlled Cognitive-Behavioral Intervention Targeting Psychosocial Adjustment and Quality of Life in Adolescent Females with Systemic Lupus Erythematosus

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Abstract

Objective—Examine in a randomized controlled feasibility clinical trial the efficacy of a cognitive-behavioral intervention designed to manage pain, enhance disease adjustment and adaptation, and improve quality of life among female adolescents with systemic lupus erythematosus (SLE).

Methods—Female adolescents (N = 53) ranging in age from 12 to 18 years were randomized to one of three groups including a cognitive-behavioral intervention, an education-only arm, and a no-contact control group. Participants were assessed at baseline, post-intervention, and at three- and six-month intervals following completion of the intervention.

Results—No significant differences were revealed among the three treatment arms for any of the dependent measures at any of the assessment points. For the mediator variables, a post-hoc secondary analysis did reveal increases in coping skills from baseline to post-intervention among the participants in the cognitive-behavioral intervention group compared to both the no-contact control group and the education-only group.

Conclusion—Although no differences were detected in the primary outcome, a possible effect on female SLE adolescent coping was detected in this feasibility study. Whether the impact of training in the area of coping was of sufficient magnitude to generalize to other areas of functioning, such as adjustment and adaptation, is unclear. Future Phase III randomized trials will be needed to assess additional coping models, and to evaluate the dose of training and its influence on pain management, adjustment, and health-related quality of life.

Keywords

lupus; cognitive-behavioral; quality of life

Systemic lupus erythematosus (SLE) is an episodic, multisystem, autoimmune disease characterized by widespread inflammation of blood vessels and connective tissue.¹ Juvenile-onset SLE represents 15% – 20% of all cases, with a median age of onset between 10–12 years. Females are affected three to five times more than males, and African American females are disproportionately affected as compared to American whites.² Clinical manifestations of SLE are extremely variable and unpredictable, and may include neuropsychiatric symptoms (anxiety and depression, cognitive deficits, and psychosis), fatigue, skin rashes, arthralgia, headache, seizures, cerebrovascular accidents, movement disorders, and neuropathy. The musculoskeletal system is frequently affected, resulting in arthritis that may be extremely painful. In fact, a high frequency of pain episodes in adolescents with SLE independently has been associated with fatigue. In addition, the presence of pain among these adolescents has been inversely related to quality of life.¹¹ The unpredictable disease course of SLE including disease exacerbations or flares as well as episodes of pain that may occur irrespective of health related behaviors may provoke feelings of learned helplessness and anxiety. The disease course in juvenile-onset SLE is typically more severe as compared to adult-onset SLE, characterized by more aggressive renal and hematologic disease and higher requirement for steroids and immunosuppressive drugs.^{3–5}

Juvenile-onset SLE most commonly presents during adolescence, a time of rapid physical, emotional, and social changes. For adolescents diagnosed with SLE, coping with a chronic illness may compromise attainment of developmentally appropriate ‘tasks’ that include increased autonomy, greater investment in social relationships and concern about peer acceptance, and perceived mastery.⁶ The unpredictable course of SLE, including disease exacerbations that may occur irrespective of health-related behaviors, may provoke feelings of learned helplessness and anxiety. Managing medical regimens and physician visits may perpetuate dependency on adults at a time when increased autonomy is desired. Symptoms

that affect appearance (e.g., skin rashes, facial swelling, hair loss, weight gain, and easy bruising) may fuel feelings of self-consciousness and social isolation. Not surprisingly, many adolescents with SLE struggle with depression.⁷ Many youth with rheumatic disorders, including SLE, also report greater concern about peer relationships and self-concept as compared to health-related matters, such as activities of daily living and general physical health.⁸ As such, maladaptive psychosocial responses to chronic illness may in turn adversely impact health care utilization and adherence to complicated medical regimens.

Finally, another line of research has demonstrated that biological processes (e.g., severity of disease, functional outcome) mediate the health outcomes of various diseases, including quality of life.¹² Specifically, interventions that enhance disease adaptation and adjustment also may be affected by specific confounders or effect mediators, including disease severity and functional outcomes. For example, the effect of remediating coping strategies characterized by negative thinking, catastrophizing, and self-statements of fear in children has not been studied. The efficacy of an intervention is important in understanding whether negative cognitions may be modified and whether disease adjustment and disease adaptation may be enhanced. Finally, there is extensive evidence in the literature concerning the buffering effects of peer and family social support on adolescents' disease adaptation and adjustment.¹² The role of social support as a mediator of an intervention program on adolescents' adjustment and health quality of life remains unclear.¹²

Clearly, the chronic, debilitating course of SLE presents tremendous challenges to the individual's coping resources. However, psychosocial adjustment to SLE has been understudied and poorly understood,^{9–10} especially in juvenile-onset SLE. In a randomized controlled clinical trial, Navarrete-Navarrete¹³ examined the efficacy of a cognitive-behavioral intervention in a group of adult patients with lupus. Participants were 45 adult patients with lupus who were characterized by high levels of distress. Participants were assigned randomly to a control group or an active therapy group consisting of cognitive-behavioral therapy. Dependent measures included assessments of psychological functioning, disease severity and quality of life. Findings revealed that symptoms of depression and anxiety as well as daily stress decreased for the patients in the active cognitive therapy group relative to the control group; increased quality of life also was reported for those in participating in the active therapy condition. Based on their findings, it is concluded that cognitive therapy is an effective intervention in managing psychological distress for adult patients suffering from lupus. While the data from this investigation are especially encouraging with regard to cognitive therapy as a viable psychological treatment for adult patients with SLE, no studies have yet examined the viability of cognitive therapy for adolescents with lupus. To date, there have been no published trials of behavioral interventions specifically designed for adolescents with SLE.

This investigation represents the first known home-based delivery randomized controlled trial examining the effectiveness of cognitive-behavioral therapy (CBT) targeting pain management, enhanced psychosocial adjustment, and improved quality of life for adolescent females with SLE. In recent years there has been a burgeoning of interactive and communication technologies for the purpose of delivery of psychological treatments to children and adolescents.¹⁴ Intervention programs that are delivered by means of interactive technology have the advantage of offering youth treatments that are novel, portable and cost effective. While much research has been conducted on electronic technology with adult populations, the pediatric literature has only recently emerged. Randomized controlled trials to evaluate Internet interventions for pediatric populations have shown particular promise for various health-related conditions. In particular, cognitive-behavioral therapies delivered via the Internet also have demonstrated considerable promise for various health conditions.¹⁴ Thus, another purpose of this investigation was to examine the efficacy of a

cognitive-behavioral intervention that was administered by means of computer-based technology to adolescents with lupus and their caregivers.

It was hypothesized that participants randomized to the CBT arm would demonstrate enhanced adjustment (i.e., improved coping skills, self-efficacy, and pain management) as compared to participants randomized to the education only arm or the wait list control arm. It is also important to note that this investigation employed a novel delivery system via home-based completion of computerized modules, thereby examining the feasibility of a service delivery model that could potentially reach many underserved families.

Methods

This study began in 2003 as a multi-center, Phase III trial with an expected enrollment of 147 participants and three treatment arms—a CBT group, an education-only group, and a no-contact control group—employing a 1:1:1 randomization scheme. As time progressed, participant recruitment became problematic and the investigation was subsequently redesigned as a Phase II feasibility study. The randomization allocation was changed to 2:0:1 (CBT, education-only, no-contact control), and it was decided that the primary comparison would be between the CBT group and the no-contact control group at the seven week assessment. Comparisons to the education-only patients already recruited to the study ($n = 10$) would be considered secondary. Figure 1 illustrates the flow of patients throughout the study.

Participants

Participants were recruited from three major southeastern medical centers (Duke University, Emory University, Medical University of South Carolina) after the institutional review boards at each institution approved the study. Because of the preponderance of SLE among females, only adolescent females were included in the study. Participants ranging in age from 12 to 18 years who had an existing diagnosis of SLE as defined by American College of Rheumatology criteria¹⁶ were included in the study. The majority of the adolescents in the sample were African American. An adolescent was excluded if she attained a score less than 24 on the *Mini Mental Status Examination*¹⁷; had severe intellectual impairment as reported by their caregivers (children with mild intellectual impairments or learning disabilities and/or those receiving special education services as reported by caregivers were still eligible for participation in the investigation); had a terminal illness with a life expectancy of less than one year; had a lack of facility with the English language; or was already enrolled in another clinical trial.

Measures

The assessment battery in this study was chosen to assess participants' functioning with relation to pain severity, adjustment and adaptation, and health-related quality of life. Each psychometrically sound dependent measure was administered at each of the four data collection visits. A number of assessment instruments also were employed to assess potential confounders or effect mediators in the final analyses, including demographic variables, baseline clinical characteristics, and baseline assessment of social support and coping strategies. Table 1 summarizes demographic data for participants in each of the study groups at baseline.

Dependent Measures—The *McGill Pain Questionnaire – Short Form* (SF-MPQ)¹⁸ was administered to assess intensity of pain. The present study employed both the sensory and affective dimensions of pain, as well as present pain intensity.

The *Behavior Assessment System for Children* (BASC)¹⁹ was chosen as a measure of adjustment and adaptation because of its excellent psychometric characteristics²⁰ and the provision of comparable parent (BASC-PRS) and adolescent forms (BASC-SRP). The BASC measures multiple aspects of adolescent functioning and behavior, including both positive (adaptive) and pathological (clinical) dimensions. The Internalizing, Externalizing, and Adaptive Behavior Index scores were used in the analyses.

The *Positive and Negative Affect Schedule-Extended Version* (PANAS-X)²¹ is designed to measure higher and lower order factors associated with the two-factor structure of affect, positive affectivity (PA) and negative affectivity (NA). These factors were used in the analyses.

The *Self-Perception Profile for Adolescents* (SPPA)²² taps global self-worth and provides a measure of perceived self-competence. For this study, the total perceived self-confidence score was used in the analyses.

The *Multidimensional Health Locus of Control Scales* (MHLC)²³ assesses attribute of health outcomes to internal forces (i.e., oneself), powerful others (e.g., family, health-care providers), or chance occurrences (i.e., luck). The internal locus of control subscale was employed in this study as a means of operationally defining self-efficacy.

The *PedsQL*²⁴ was chosen to assess health-related quality of life in the core dimensions of physical functioning, emotional functioning, social functioning, and school functioning. The pediatric self-report form and the parent proxy-report of child *PedsQL Rheumatology Health Related Quality of Life*²⁴ also were employed for the purpose of complementing the generic core scale.

Mediator Variables—Data also were collected to assess potential confounders or effect mediators, including specific demographic variables (adolescents' chronological age, health insurance, parent/caregiver education level), specific disease characteristics, number of clinic/emergency room/inpatient contacts within the three months prior to study enrollment, and baseline assessment of social support and coping strategies.

The *Systemic Lupus Erythematosus Disease Activity Index* (SLEDAI)²⁵ was employed as a means of assessing disease activity/severity. The SLEDAI is a physician-completed rating scale that assesses signs and symptoms present in the past 10 days. Scores can range from 0 (no activity) to 105. Participants' rheumatologist completed the SLEDAI at each of the four data collection visits. The SLEDAI has demonstrated high sensitivity to clinical change in patients with juvenile-onset SLE.²⁶

Both the *Perceived Social Support-Family* (PSS-Fa) and *Perceived Social Support-Friend* (PSS-Fr)^{27–28} were employed to assess adolescents' perceived social support from family and friends. These instruments were chosen for this study as they assess functional self-support practices (e.g., coping and remaining functional in spite of symptoms). The PSS-Fa and PSS-Fr were administered to the adolescents prior to study enrollment and at the baseline assessment.

The *Coping Strategies Questionnaire* (CSQ)²⁹ was used in this study to assess adolescents' coping primarily as it is related to pain. We have chosen pain as the exemplar for coping because it is a tangible manifestation of SLE and other rheumatic disorders (e.g., juvenile idiopathic arthritis). The CSQ assesses cognitive, behavioral, and physiological strategies specifically related to pain.^{30–31} The CSQ was administered to the adolescents prior to study enrollment and at the baseline assessment.

Procedures

After having attained consent from caregivers and assent from the adolescents, participants were randomized to one of three treatment arms:

Cognitive-Behavioral Therapy (CBT) Condition—The specific ingredients of the cognitive-behavioral therapy (CBT) package included coping skills training and cognitive restructuring techniques.³² For this treatment arm, coping skills training included enhancing existing skills and teaching new skills to manage stressors associated with SLE. Efforts to teach active coping skills included training in relaxation, distraction, and problem-solving skills. The CBT arm also included cognitive restructuring exercises designed to focus on negative cognitions and evaluative responses to stressful situations in daily life, negative perceptions of physical appearance, and negative responses to pain.

The CBT arm was administered over the course of six weeks. Because of the extant psychosocial intervention literature underscoring the importance of time-limited and focused interventions that may be delivered over a period of several weeks, and also due to the numerous medical appointments and ongoing follow-up for these adolescents, we opted for a treatment period that was relatively short-term. Short-term therapies have been fairly typical in the cognitive therapy literature with pediatric populations.¹⁵ In addition, shorter interventions are typically associated with fewer compliance problems.³⁶

The participants were provided with laptop computers to take home for use during the intervention. The computer had three separate manualized modules preinstalled that were password protected. In weeks one, three, and five, the participants worked on a separate module containing several lessons. Participants were required to complete each of the lessons during the week following completion of a module. A member of the research team telephoned the participants in the week between sessions one and two, sessions two and three, and during the week immediately following the third session to monitor treatment adherence, answer any questions about the module, and ensure compliance with treatment homework. Each lesson took approximately 45 minutes to complete. Primary caregivers also were provided with written materials about the intervention and tips regarding ways to support and encourage their adolescent in the acquisition and practice of the skills taught during each module.

The first session focused on established rapport with the adolescent, explaining the rationale for the cognitive-behavioral intervention, and teaching self-monitoring of mood and activity level. The second session focused on coping skills. This included training in relaxation (e.g., progressive muscle relaxation, diaphragmatic breathing), and distraction (e.g., focusing on one thing in the physical environment, mental counting techniques). In addition, an important component addressed problem-solving skills (e.g., appropriate pacing of daily activities). These relaxation, distraction, and problem-solving skills were discussed during the session and the adolescents were asked to practice and apply skills as homework between sessions. Obstacles to practicing skills at home were discussed as a means of relapse prevention.

Finally, the third session focused on calming self-statements and cognitive restructuring, that were designed to diminish negative affectivity and alter perceptions of pain. Cognitive restructuring also was employed for the purpose of altering distorted perceptions of physical appearance and social competence. Again, strategies were described, presented on a CD-ROM, and practiced with the adolescents. In this session, additional training was provided in the area of relapse prevention. Adolescents were required to complete a record of their practice. Self-monitoring was employed as a means of ensuring compliance. The therapists also conducted two 10–15 minute telephone contacts in the week between sessions and in

the week immediately following the third session to review their homework assignment and assure compliance with treatment. For any participant who experienced an acute flare of lupus symptoms, the intervention sessions were postponed until the adolescent was designated stable by the site rheumatologist.

Booster sessions (sessions four and five) were held with each adolescent two and five months after they began the study. These sessions focused on continued cognitive skill development, application, refinement, and relapse prevention beginning with a discussion of the patient's current status and use of coping skills. While a complete description of the intervention is not possible within the space constraints of this article, the complete instructional manual and modules are available from the senior author by request.

Education-Only Condition—An education-only intervention was administered in a similar format to the intervention arm outlined above. Participants in this condition who were recruited from each of the three sites were provided with the rationale that understanding their disease would help them manage the disease more appropriately. As in the active-intervention arm, sessions in both the active and maintenance phases of this intervention were presented as 45-minute long modules on a laptop computer. The first session focused on the impact of SLE on daily functioning at home and at school. The second session, held during the third week, focused on issues pertaining to healthy living (e.g., maintaining a balanced diet, exercise, and appropriate sleep hygiene). The third session, conducted during the fifth week, reviewed the material that had been taught up to that point. In addition, the therapist also conducted two 10–15 minute telephone contacts during the week between the first and second sessions, the second and third sessions, and the week immediately following the third session to review the instructional materials.

No-Contact Control Condition—A no-contact control group recruited equally from the three sites was included in this study for the purpose of eliminating possible secular effects over time on the dependent variables. Any differences in participants' characteristics at baseline (i.e., years since SLE diagnosis, inpatient hospital visits, emergency department visits, insurance coverage) were covaried in the final analysis.

For each of the three treatment conditions, the assessment battery was administered immediately prior to the intervention (baseline), immediately following the intervention (i.e., post-test), seven weeks after the commencement of the intervention, and finally at three and six months following the intervention program. For each study visit, participants were offered a nominal monetary incentive to defray the cost of gasoline or other travel expense.

Statistical Analyses

Because some attrition was expected, the primary data analyses were conducted using an intention-to-treat approach, including all participants who were randomized in the analyses. For missing data, we used a worst-case-scenario approach,³³ which involved assigning values for outcomes equal to the worst outcome among participants in their treatment group at the time point of interest.

Because there were multiple correlated outcome measures, we used a global statistical test (GST)³⁴ statistic as the dependent variable in an analysis of covariance (ANCOVA) model to compare outcomes between treatment groups. To compute the GST, each participant's relative rankings on individual outcomes (domains) were computed, summed, and averaged by the number of outcomes, which gave each participant a single summary score. For each treatment group, the mean rank differences, associated 95% confidence intervals, and p-values comparing the treatment groups were reported. Aside from not making any

assumptions about the underlying distribution of the outcome measures, one benefit of using ranks for reporting across such a varied list is the inherent standardization that occurs. The domains that were included in the GST were (1) personal adjustment index (BASC-SRP-adolescent form), (2) affectivity (PANAS-X), (3) perceptions of physical appearance and social competence (SPPA), (4) pain intensity (SF-MPQ), (5) quality of life (PEDS-QL, PEDS-QL Rheumatology), and (6) self-efficacy (MHLC). The GST represents sums of the participants' rankings of their changes from baseline to follow-up assessment for each of the various outcomes.

In the ANCOVA model, the treatment arm served as the independent variable of interest, with covariate adjustment as needed. Separate ANCOVA models were created to perform primary and secondary comparisons for each domain included in the GST. The three- and six-month outcomes were included in the secondary analyses to determine the durability/sustainability of treatment. Our study was designed to provide 90% power for detecting a moderate effect size (Cohen's $d = 0.64$) for the primary comparison between the CBT group and no-contact control group, assuming an alpha of 0.25 and one-sided hypothesis testing, a strategy used for pilot studies of this type.³⁵ Although the education-only group was originally part of the design as an additional control, recruitment difficulties required us to focus on the other two groups. Thus, the power to detect a moderate effect size between the education-only group and the other groups was somewhat lower (intervention group: 85%; no-contact control group: 82%), with alpha = 0.25 and one-sided hypothesis testing.

Finally, post-hoc analyses (Wilcoxon rank sum tests) were performed to test whether there were any significant differences by treatment group in the changes in the subscores of the CSQ. The CSQ subscores served as process measures, and their analyses helped to determine whether participants were, in fact, altering their coping strategies in response to the intervention.

Results

Participants' demographic and baseline characteristics are summarized in Table 1. Each of the groups was similar with respect to race, age, parents' education level, years since diagnosis of SLE, baseline disease activity, recent health-care services, social support, and most coping strategies. Compared to participants in the no-contact control condition, participants in the active intervention arm were more likely to have health-insurance coverage (93% vs. 75%, $p < 0.15$), fewer visits to the emergency department during the three months prior to randomization (8% versus 38%, $p < 0.15$), and higher ($p < 0.15$) catastrophizing and lower coping self-statement scores. Finally, compared to the participants in the no-contact control group, participants in the education-only arm were younger (15.0 years vs. 15.9 years, $p < 0.15$), more likely to have health insurance (100% vs. 75%, $p < 0.15$), diagnosed with lupus for a longer period of time (3.3 vs. 2.0 years, $p < 0.15$), and had fewer visits to the emergency department during the three months prior to randomization (10% vs. 38%, $p < 0.15$).

A summary of participant and caregiver report at baseline on the outcome measures for each of the three groups is presented in Table 2.

Results of the primary analysis of the GST that compared the CBT group and the no-contact control group at post-testing revealed that the CBT group did not exhibit significant overall improvement compared to the no-contact control group ($T = -0.34$, $p = 0.63$) (see Table 3). Secondary analyses revealed that the performance of the education-only arm was somewhat better than the no-contact control group at the three-month follow-up ($T = 1.24$, $p = 0.11$), and at the six-month follow-up ($T = 0.92$, $p = 0.19$), where the levels of statistical

significance fell below the 0.25 threshold, which had been the alpha level prespecified for the primary analyses.

The analyses of changes from baseline to post-testing on the CSQ suggest that the patterns of change in coping behaviors were significantly different among the three treatment arms (see Table 4). Specifically, increases in the “coping self-statements” and “increased behavioral activities” subscores were significantly ($p < 0.05$) greater among the participants in the CBT group compared to the no-contact control group. Increases in the “coping self-statements” and “diverting attention” subscores were significantly ($p < .05$) greater among participants in the CBT group compared to the education-only group.

Finally, effect sizes were computed between the CBT group and the no-contact control group at the post-test (seven weeks) follow-up assessment. For each of the effect sizes computed for the dependent variables, only one effect size (self-efficacy, doctor’s influence) exceeded 1.00 and this was a negative effect size, indicating that the control group evidenced more of an increase than the intervention group. Moreover, only one effect size (affective dimension of pain) exceeded one-half of a standard deviation (.54), suggesting a trend for greater self-efficacy and less affective dimensions of pain for the CBT group relative to the no-contact control group. A number of other effect sizes exceeded one-third of a standard deviation, including parents’ reports of their adolescents’ externalizing behavior problems (.42), self-efficacy (.37), and self-worth (.35), which suggests worse externalizing behavior problems as reported by the parents, but better self-efficacy and self-worth for the CBT group relative to the no-contact control group. Parents of adolescents in the CBT group also reported higher frequencies of quality of life for their adolescents (.46) relative to the no-contact control group. The effect sizes for adolescents’ negative affectivity (–.32) and physical appearance (–.39) were in the negative direction, indicating that the control group evidenced a greater increase than the intervention group. All other effect sizes were less than one-third of a standard deviation.

Discussion

The purpose of this study was to examine the efficacy of a cognitive-behavioral intervention designed to manage pain, enhance adjustment and adaptation, and increase quality of life among adolescents with systemic lupus erythematosus (SLE). This particular study is unique because, to date, it is the first known randomized controlled clinical trial designed to enhance adjustment among adolescent females with SLE delivered by means of a home-based completion of computer modules. Our study employed three treatment arms where it was hypothesized that participants in the cognitive-behavioral therapy (CBT) arm would evidence greater improvement in adjustment relative to those in the education-only and no-contact control arms. We also hypothesized that social class, disease severity, coping style, and the adolescents’ perceived peer and family support would mediate the success of the CBT intervention.

For the primary analysis, no significant greater overall improvement was detected for the CBT group compared to the no-contact control group. Likewise, the secondary analyses showed no significantly greater overall improvement for the CBT group relative to the no-contact control group at the three- or six-month follow-ups. The performance of the education-only arm was somewhat better across measures than the no-contact control group at the three- and six-month follow-ups. Finally, when the CBT group and education-only group were combined, they did not exhibit overall improvement compared to the no-contact control group at any of the time points.

That the primary analyses failed to confirm our initial hypothesis is disappointing. A “floor effect” may account for the failure to detect significant overall improvement in outcome variables, as both adolescent participants and their caregivers reported non-significant levels of maladjustment at baseline. It is also possible that the small sample size was responsible for the failure to demonstrate an effect (i.e., Type II error). It is encouraging that effect sizes ranged from large to moderate, which suggests that the intervention demonstrated some efficacy, albeit insignificant, in the areas of pain management, adaptive behavior, and quality of life. Future clinical trials using larger samples may yield more encouraging results.

Despite the absence of significant differences on the dependent measures as a function of group placement, analyses of change from baseline to post-testing in the area of coping revealed significant differences among the three treatment arms. Effect sizes that were computed between the CBT group and the no-contact control group at the post-test assessment suggested generally larger effect sizes for self-efficacy and less affective dimensions of pain, with means in favor of the CBT group. Data also revealed increases in coping self-statements, diverting attention, and increased behavioral activity for the CBT group compared to the no-contact control group. Thus, the training in relaxation and distraction, as well as problem-solving skills (e.g., appropriate pacing of daily activities), may have enhanced coping (as evidenced by the adolescents’ reports).

The findings of this particular study must be interpreted within the context of the study limitations. First, the difficulties associated with participant recruitment resulted in a relatively small number of participants in each of the treatment arms. The small sample size likely mitigated significant effects that may have been observed in a larger sample. Clearly, recruitment of children and adolescents with a low incidence disorder in a clinical trial that requires ongoing contact with the investigative team is a major challenge. Despite the fact that this study was a multisite clinical trial, the study did not escape the problem of enrolling a sufficient number of participants. Any future study would require a much larger number of sites so as to obtain a greater number of participants to participate in the clinical trial.

Another limitation of this study may be associated with the intensity or dose of the intervention, which may not have been sufficiently large in length or intensity to produce the hypothesized changes in the dependent measures. It is recommended that future research efforts focus on comparing intervention programs that differ in dose or intensity of intervention. In addition, which aspect of the CBT intervention resulted in improved coping cannot be determined from this multi-push intervention. Future studies will need to focus on dismantling the various components of treatment employed in this study to determine the specific ingredients that actually produced change in the area of coping. Finally, consistent with the majority of clinical trials that typically recruit the highest functioning individuals with a particular disease, the participants in this study were certainly no exception. Thus, it is possible that the participants in this study may have been too high functioning in the various domains evaluated, and thereby evidenced little improvement from the intervention.

The aforementioned limitations notwithstanding, it also should be noted that this was one of the few clinical trials that has been conducted primarily by means of computer technology, thereby requiring less transportation to and from the medical setting. There is a critical need for novel and effective intervention programs that target psychosocial adjustment among youth with chronic illness. Moreover, interventions that overcome the barriers of underserved areas are in critical shortage. The computerized presentation of the intervention provided in this clinical trial is easily administered in the home setting, thereby making it cost effective. Although participant recruitment was challenging, once enrolled, no

participants were lost to follow-up, lending further support for the feasibility of this service delivery model.

Although the present study fell short of demonstrating efficacy across various areas of functioning, we anticipate that future research efforts in this area will be productive in documenting the efficacy of such interventions for enhancing the quality of life of adolescents with SLE. Replication of the present clinical trial with a greater number of participants will be important in determining the veracity of the present findings so as to establish the empirical evidence for cognitive-therapy among female adolescents with SLE and ultimately establish it as an empirically-based intervention for adolescents with SLE.

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Figure 1.
Flow of participants through the various phases of the study.

Table 1

Participant characteristics for each of the three groups at baseline.

	Cognitive- Behavioral Intervention (<i>n</i> = 27)	Education- Only (<i>n</i> = 10)	No-Contact Control (<i>n</i> = 16)
Race (% African American)	74	90	81
Age: mean (SD)	15.4 (3.0)	15.0 (3.3) *	15.9 (2.0)
Parent's education			
High school	33	30	56
Some college	37	20	19
College graduate	30	50	25
Health insurance coverage (% yes)	93 *	100 *	75
Years since diagnosis of SLE:			
mean (SD)	3.0 (2.6)	3.3 (2.2) *	2.0 (1.9)
Baseline SLEDAI disease activity score:			
mean (SD)	4.7 (4.2)	3.4 (2.8)	6.1 (9.6)
6 (%)	37	20	38
In 3 months prior to baseline visit			
Inpatient hospital visit (% yes)	8 *	0 *	38
Emergency department visit (% yes)	8 *	10 *	38
Outpatient clinic visits: median (IQR)	1.5 (0–3)	1.5 (1–4)	1.5 (1–3.5)
SLE flare events: median (IQR)	0 (0–1)	0 (0–0)	0 (0–1)
SLE flare event (% yes)	35	20	38
Perceived Social Support Scale			
Family score	15 (9–19)	17 (14–19)	14 (11–18)
Friend score	15 (10–18)	16 (14–18)	14 (13–18)
Coping Strategies Questionnaire			
Catastrophizing: median (IQR)	14 (10–20) *	12 (5–17)	9 (8–29)
Coping self statements: median (IQR)	20 (14–26) *	26 (19–36)	26 (21–33)
Diverting attention: median (IQR)	17 (14–20)	19 (8–34)	20 (12–23)
Increase behavioral activities: median (IQR)	16 (12–22)	23 (11–34)	17 (12–24)
Ignoring sensations: median (IQR)	13 (8–18)	17 (9–36)	18 (4–25)
Praying/hoping: median (IQR)	28 (20–30)	27 (19–35)	29 (26–33)
Reinterpreting pain sensations: median (IQR)	10 (4–17)	10 (3–24)	12 (2–18)

* $p < 0.15$ compared to No-Contact control group by chi-square test, Fisher's exact test, or Wilcoxon rank sum test and thus included as a covariate in the relevant multivariable analyses.

Table 2

Baseline data for the primary outcome measures.

Measures	Cognitive-Behavioral Intervention (n = 27)						Education-Only (n = 10)		No-Contact Control (n = 16)	
	M	SD	M	SD	M	SD	M	SD	M	SD
SF-MPQ										
Sensory Dimension	4.84	5.50	5.50	6.19	5.88				5.88	8.52
Affective Dimension	2.30	2.37	1.90	2.77	1.25				1.25	1.34
Present Pain Intensity (PPI)	9.52	9.25	8.60	9.19	9.94				9.94	12.01
BASC-PRS										
Internalizing Problems Index	57.81	8.67	52.00	8.19	58.25				58.25	14.13
Externalizing Problems Index	48.07	11.32	45.80	5.45	44.75				44.75	10.34
Adaptive Behavior Index	47.63	10.18	53.30	7.75	51.69				51.69	11.33
BASC-SRP										
Emotional Symptoms Index	49.33	10.39	45.60	8.53	46.94				46.94	7.17
Clinical Maladjustment Index	49.37	6.90	47.40	7.29	46.94				46.94	7.71
School Maladjustment Index	42.70	7.26	45.10	4.51	46.38				46.38	7.86
Personal Adjustment Index	50.56	12.42	52.10	10.08	50.81				50.81	7.34
PANAS-X										
Positive Affectivity	31.78	9.97	33.30	11.93	31.63				31.63	8.81
Negative Affectivity	13.63	3.59	12.20	3.08	12.00				12.00	3.06
SPPA										
Physical Appearance	13.48	4.52	13.50	4.50	15.06				15.06	3.66
Self-worth	16.26	3.48	15.20	3.91	17.63				17.63	1.82
Social Acceptance	14.40	4.72	16.15	3.08	15.81				15.81	3.33
MHLC										
Internal Locus of Control, Form B	22.31	6.79	27.60	2.84	22.44				22.44	6.26
Internal Locus of Control, Form C	16.88	6.51	22.90	2.92	17.98				17.98	6.59
PedsQL Teen Self-Report Total Score	62.65	18.54	69.21	16.40	68.53				68.53	15.51
Peds QL Parent Report Total Score	61.42	9.87	77.76	10.05	63.74				63.74	21.06
Peds QL Rheumatology Teen Self-Report										
Daily Activities	77.04	23.34	89.00	13.50	81.25				81.25	21.17

Measures	Cognitive- Behavioral Intervention (n = 27)		Education- Only (n = 10)		No-Contact Control (n = 16)	
	M	SD	M	SD	M	SD
Communication	58.95	29.14	54.17	25.53	69.27	21.02
Pain and Hurt	48.38	26.89	74.38	21.74	53.52	40.70
Treatment	71.30	26.07	82.50	16.53	73.21	15.15
Worry	50.93	31.38	55.83	30.69	57.29	27.20
Peds QL Rheumatology Parent Report						
Daily Activities	80.10	24.57	90.00	14.42	78.78	28.36
Communication	69.38	28.58	83.33	20.41	69.05	35.87
Pain and Hurt	45.35	20.35	70.63	31.74	51.53	28.98
Treatment	72.99	22.36	91.14	18.62	76.81	20.70
Worry	64.50	25.55	84.26	24.45	66.96	33.03

SF-MPQ = McGill Pain Questionnaire – Short Form; BASC = Behavior Assessment System for Children, PRS = Parent Rating Scale and SRP = Self-Report of Personality; PANAS-X = Positive and Negative Affect Schedule-Extended Version; SPPA = Harter Self-Perception Profile for Adolescents; MHLC = Multidimensional Health Locus of Control Scales; PedsQL = Pediatric Health Related Quality of Life, Pediatric Self Report and Parent Report; Peds QL Rheumatology = Pediatric Rheumatology Health Related Quality of Life

Table 3

Summary of primary and secondary analyses.

Comparison of Interest	t	df	p*
Primary Analysis			
Cognitive-Behavioral Intervention ($n=27$) vs. No-Contact Control ($n = 16$), post-test	-0.34	36	0.63
Secondary Analyses			
Cognitive-Behavioral Intervention ($n = 27$) vs. No- Contact Control ($n = 16$), 3-month follow-up	-0.39	36	0.65
Cognitive-Behavioral Intervention ($n = 27$) vs. No- Contact Control ($n = 16$), 6-month follow-up	-0.74	36	0.77
Education-Only ($n = 10$) vs. No-Contact Control ($n = 16$), post-test	-0.80	19	0.78
Education-Only ($n = 10$) vs. No-Contact Control ($n = 16$), 3- month follow-up	1.24	19	0.11
Education-Only ($n = 10$) vs. No-Contact Control ($n = 16$), 6-month follow-up	0.92	19	0.19
Cognitive-Behavioral Intervention & Education-Only combined ($n = 37$) vs. No-Contact Control ($n = 16$), post- test	-0.48	46	0.68
Cognitive-Behavioral Intervention & Education-Only combined ($n = 37$) vs. No-Contact Control ($n = 16$), week 12	-0.15	46	0.56
Cognitive-Behavioral Intervention & Education-Only combined ($n = 37$) vs. No-Contact Control ($n = 16$), 6- month follow-up	-0.38	46	0.65

* The p-value reported comes from a 1-sided test of the null hypothesis that the intervention is no better than the control, using an analysis of covariance model with the global statistical test as the dependent variable and treatment-group assignment as the independent variable, adjusting for baseline covariates that were significantly ($p < 0.15$) different between comparison groups.