

**WOMEN EMPOWERED TO LIVE WITH LUPUS (WELL) STUDY**  
[SUB-STUDY OF THE GEORGIANS ORGANIZED AGAINST LUPUS (GOAL) COHORT STUDY]

**Full Title: A widespread self-management education program to reduce health disparities in African American women with systemic lupus erythematosus**

**Funding Source: NIH (NIMHD R01MD010455)**

**Short Title: Women Empowered to Live with Lupus (WELL) Substudy**

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## **Lay Summary**

Systemic lupus erythematosus (SLE or lupus) is a chronic disease that predominantly strikes young African American women. Because SLE can potentially affect all organs and system, it has a substantial impact on the physical and psychological functioning of patients. Consequently, people living with lupus must engage in challenging self-management tasks to promote their wellbeing. For instance, patients are burdened with managing an array of medical symptoms and often expensive medications. Patients are also challenged with the emotional sequelae of a debilitating and painful condition, and are forced to make undesirable lifestyle changes. Successful self-management of SLE requires having the skills to engage in effective daily activities, which often comes from having access to up to date health education and self-management support.

Although self-management support is crucial to help patients to take control of their disease, no SLE-specific self-management program is widely available. The Chronic Disease Self-Management Program (CDSMP) or Living Well with a chronic condition Program is a nationwide accessible community-based self-management education program that contributes to improved health in people with a variety of chronic conditions. Because the CDSMP is widely disseminated and available to the adult U.S. population through community centers, it may be a suitable and accessible option for African Americans with SLE, even though it is not specifically tailored to SLE or to African Americans. As the CDSMP has been primarily evaluated in predominantly white middle-class seniors with more common diseases (e.g. osteoarthritis, diabetes), the effectiveness of the CDSMP in helping African American women to self-manage SLE is unknown. This study will examine the effectiveness of the CDSMP to improve outcomes and reduce health care utilization in African American women with lupus.

## **BACKGROUND**

Systemic lupus erythematosus (SLE) is a chronic autoimmune disease characterized by multi-system symptoms and an unpredictable course. SLE disproportionately strikes African American (AA) women of childbearing age. AA women with SLE at any age have significantly greater morbidity and mortality compared to Whites. Notably, AA women with SLE have been underrepresented in intervention research, which may be contributing to the existing health disparities and racial gaps in effective disease management.

Because SLE impacts physical and psychological functioning, patients are burdened with managing an array of medical symptoms and often expensive medications, are challenged with the emotional sequelae of a debilitating and painful condition, and are forced to make undesirable lifestyle changes. Successful self-management of SLE requires having the skills to engage in effective daily activities, which often comes from having access to up to date health education and self-management support.

Self-management support is the provision of interventions to increase patients' skills and confidence in managing their diseases, including assessment of problems, goal-setting, action-planning, and problem-solving strategies. Although self-management support is crucial to help patients to take control of their disease, no SLE-specific self-management program is widely available.

The Chronic Disease Self-Management Program (CDSMP), also known as the Living Well Program, is an evidence-based nationwide accessible community-based self-management education program that contributes to improved health in people with a variety of chronic conditions. Because the CDSMP is widely disseminated and available to the adult U.S. population through community centers, it may be a suitable and accessible option for African Americans with SLE, even though it is not specifically tailored to SLE or to African Americans. As the CDSMP has been primarily evaluated in predominantly white middle-class seniors with more common diseases (e.g. osteoarthritis, diabetes), the effectiveness of the CDSMP in helping African American women to self-manage SLE is unknown. This study will examine the effectiveness of the CDSMP to improve outcomes and reduce health care utilization in African American women with lupus.

## **Design Overview**

A random sample selected from our GOAL cohort will be used to recruit AA women with SLE into the WELL (Women Empowered to Live with Lupus) cohort. WELL participants will attend the CDSMP classes in the community, along with people with other chronic illnesses. Measures will be completed at baseline, 6, 12, and 18 months. AA women from the GOAL cohort non-selected to be assigned to the intervention will comprise the usual care group. They will continue their routine annual assessments as part of the GOAL cohort efforts.

We will also conduct a longitudinal qualitative substudy to learn about African American women's perspectives on (a) the processes through which the CDSMP affects self-management behaviors, health-related quality of life (HQRL), and healthcare service use; and (b) identify remaining challenges to successful SLE self-management after CDSMP participation.

### Recruitment and Informed Consent

A random sample of SLE patients already recruited into the population-based GOAL study will be offered the opportunity to participate in the WELL Sub-study. Target enrollment will be 150 African American women who are resident of one of the metropolitan Atlanta counties where community-based CDSMP classes are provided. [Enrollment number increased to 168 to accommodate participants on a waiting list due to workshop cancellations and participants' rescheduling needs (e.g., illness, hospitalizations, and family emergencies)]. Each woman will have the same probability of being chosen at any stage of the sampling process. Thus, we will ensure

<b>Table 1. Summary of Study Measures</b>		
<b>Category</b>	<b>Measure</b>	<b>Tool</b>
Self-management Behaviors	Communication with Physicians	3-item scale
	Medication Adherence	MMAS-8
Health-related Quality of Life	Global Health	PROMIS
	Physical Function	PROMIS
	Pain Interference	PROMIS
	Fatigue	PROMIS
	Sleep	PROMIS
	Anxiety	PROMIS
	Social Function	PROMIS
Disease Severity	Disease Activity	SLAQ
	Organ Damage	SA-BILD
	Multimorbidity	CCHP
	Depression	PROMIS
Demographics	Age	Ad-hoc
	Education	Ad-hoc
	Employment	Ad-hoc
	Social Support	Ad-hoc
Health Service Utilization	ED visits	GA HDDB
	Hospitalizations	GA HDDB

MMAS: Morisky Medication Adherence Scale; PROMIS: Patient-Reported Outcome Measurement Information System; SLAQ: Systemic Lupus Activity Questionnaire; SA-BILD: Self-administered Brief Index Lupus Damage; ED: emergency department; GA HDDB: Georgia Hospital Discharge Database

representation of the AA female population in the CDSMP. The only exclusion criteria will be participation in the CDSMP in the past 5 years.

Women randomly selected will be mailed a flyer about the study and will receive a phone call by the Project Coordinator (PC) within the following week. During the phone call, the PC will assess the entry and exclusion criteria and will explain the study and level of participants' commitment needed to ensure study integrity. Interested participants will receive a packet with the consent, information of the CDSMP workshops schedule and location, a list of measures and study staff contact information. The PC will follow up with a phone call within 1 week to answer any questions and finalize the recruitment and CDSMP registration. Since this study entails minimal risk, interested GOAL participants will be consented via mail, e-mail, in person or telephone.

The PC will coordinate CDSMP schedules and locations with CDSMP leaders, in order to facilitate the registration of WELL participants in CDSMP workshops at convenient locations and schedules. Participants of the WELL Substudy will receive monetary compensation for the research tasks (gift cards of \$35 \$40, \$45 and \$50 for the baseline, 6-, 12- and 18-month assessments, respectively, and a round-trip MARTA card, \$10.00 gas card, or shuttle/taxi services for transportation costs.

## **Data Collection**

*Self-reported data.* Baseline assessment for WELL participants will take place within the 4 weeks that precede the start of the CDSMP classes. Post-intervention assessments will be scheduled at 6-, 12- and 18-month after baseline. All patient-reported measures will be collected online using the RedCap database. WELL participants will have a 2-week window to respond to the online surveys. Participants without computer access or those who do not complete the online survey within 2 weeks will be phone-interviewed.

All self-reported measures collected for WELL participants are included in the GOAL survey and summarized in Table 1. The time needed to complete the self-reported data survey will be between 20 and 40 minutes.

*Data on Health Service Utilization (HSU).* These data will be obtained by a well-established linkage procedure that links the GOAL cohort data with the GA Hospital Discharge Database (IRB#55041). This database contains claims data on emergency department (ED) visits and hospital admissions, including causes of admissions and ED visits.

## **CDSMP Implementation**

The CDSMP consists of six weekly sessions, each lasting 2.5 hours, led by two peer leaders and conducted in a small group workshop format with 10 -16 participants. CDSMP clients are community adult men and women of all races and ages with a variety of chronic conditions (e.g., diabetes, heart disease, arthritis) who all are interested in learning self-management skills. WELL participants will be referred to CDSMP at community centers in Atlanta. Participants will have the flexibility to register for workshops based on the convenience of the location and CDSMP schedule. The importance of attending all CDSMP classes will be emphasized during recruitment. Attendance at 4 or more classes will be considered “program completion” for purposes of analyses. The PC will check in with each participant about the last week’s class attendance at the reminder phone call for the next class. Reasons for missing classes will be collected.

**CDSMP Certified Leaders:** CDSMP lay leaders are trained and certified according to the Stanford Patient Education Center Protocol, updated in 2012. Leaders will be selected and overseen by the community organizations offering the classes and will not receive any specific training from the research team on SLE.

## **Analytic Methods**

Data will be organized and cleaned following quality control procedures after each wave, involving identifying outliers and inappropriate patterns of missing data. Psychometric properties of known measures will be compared with reported properties. For multi-item scales and indices, we will use methods such as reliability and factor analyses for data reduction and formation of composite summary variables. Confirmatory factor analyses will be conducted to evaluate the consistency and fit of individual items to a combined construct. We will make every attempt to avoid missing data by discouraging omissions, e.g., by ensuring confidentiality of responses in the

study description and encouraging participants to respond to each question.

For patient-reported and health services utilization outcomes, analysis of repeated measures data is needed that properly accounts for the correlation between multiple observations from the same participant. Two commonly used models to analyze such data will be employed: the mixed-effects model and the generalized estimating equations (GEE) approach.<sup>60</sup> Both approaches allow for covariate adjustment. The results will be summarized with adjusted means and 95% confidence intervals for continuous outcomes. GEE can also be used to analyze count data (e.g., ED visits), ordinal data, and to perform a logistic regression of repeated binary responses within participants. Low classes attendance may attenuate outcome change and have a negative impact on study integrity. Longitudinal analyses will allow us to estimate the effect of CDSMP attendance (# of classes attended) on outcome change.

### **Qualitative component**

A longitudinal qualitative substudy will be conducted to learn about WELL participants' perspectives on (a) the processes through which the CDSMP affects self-management behaviors, HQRL, and healthcare service use; and (b) identify remaining challenges to successful SLE self-management after CDSMP participation.

*a) Recruitment.* We will use a form of purposive sampling to generate a subsample of 25 women from the WELL Substudy that is varied with respect to 4 characteristics that are relevant to the research question: depression, disease activity, age and educational attainment. Participants will be randomly drawn from the WELL Substudy prior to beginning the CDSMP. Responses from the most recent GOAL survey will be used to stratify the WELL Substudy at enrollment by pre-intervention measures of depression, disease activity, age, and education. Eligible women from each of these strata will be called and recruited for the interview.

*b) Interviews.* Wave 1 interview will be conducted after the baseline survey and before the start of the CDSMP. Wave 2 interview will be conducted one month after completion of the CDSMP. Each in-person interview will be conducted by a graduate research assistant (GRA) student, and will take 60-90 minutes. With participant's permission, interviews will be audiotaped and transcribed verbatim, which strengthen the validity of the qualitative analysis. Participants will be able to choose among several interview locations at the Rollins School of Public Health or Emory School of Medicine Grady campus, located in downtown Atlanta. Each participant will receive a round-trip MARTA card (or \$10 gas card) for transportation, and \$35 and \$40 for taking part in the two interviews, respectively. Providing slightly increasing amounts for data collection has been used in other studies as a successful retention strategy.

*c) Outcomes.* We will develop a semi-structured interview guide to explore women's definitions of "successful SLE self-management," "HRQL," and "successful health services utilization," and their efforts and challenges in managing SLE and improving their HRQL and health services utilization. After the intervention, domains will include their current definitions of "successful SLE self-management," "HRQL," and "successful health services utilization." As is common in qualitative research, we will analyze data as we gather it. Ongoing analyses allow altering the guide in response to emerging findings.

*d) Analytic Methods.* We will use a longitudinal qualitative design to learn about

women's perspectives of the challenges to successful SLE self-management; women's efforts and remaining challenges after participating in the CDSMP; and women's views of the processes through which participating in CDSMP affected women's self-management behaviors, HRQL and healthcare service use. We will use thematic methods to analyze interviews' transcripts.

We plan to work with an independent transcription service, Transcript Divas, to transcribe qualitative interviews. The transcribers who work for this company will sign a confidentiality agreement to assure the privacy of interview respondents and any identifying information. Each participant's audiofile will be uploaded to a secure encrypted website owned by Transcript Divas. Audiofiles will be transcribed, transcripts will be returned to the researchers via this same encrypted website, and audiofiles (both at transcript divas and at Emory) will be destroyed after transcription.

Qualitative findings will generate a deeper understanding of how AA women with SLE define successful "SLE self-management", "health-related quality of life" and "health service utilization" before taking part in CDSMP; and of how these definitions change after participating in CDSMP. It will also help identify challenges that AA women perceived to successful self-management of SLE before and after participating in CDSMP. This aim will also explore variations of women's definitions and experiences across participants' characteristics.

### **RISKS TO PARTICIPATION**

Potential risks to participants are considered minimal. This study involves primarily attending an evidence-based community-based education program to learn about chronic disease self-management, and answering questions. Some people find answering questions frustrating. We will choose questions carefully to be sure that we will collect only necessary information. Demands on participants will be minimized; time required to fill out surveys will not exceed 45 minutes. Letters and written information will be at the 8<sup>th</sup>-grade level. Additionally, participants will have the option to complete the surveys by telephone, mail, face-to-face, or web according to their needs and/or preferences.

### **SOURCES OF MATERIALS**

Involvement of human subjects for this study includes the completion of surveys, participation in the Chronic Disease Self-Management Program (CDSMP) and optional semi-structured interviews among those participants enrolled into the WELL cohort. Surveys will be done at four intervals (baseline, 6-month, 12-month, and 18-month post baseline) by computer or by telephone. WELL participants will attend the CDSMP workshop at a convenient location. Through quota-sampling, a purposive sample of 25 CDSMP participants will be enrolled in a qualitative substudy to participate in semi-structured interviews. Interviews will be conducted in-person at two intervals (pre- and post- CDSMP workshop completion).

As previously discussed, the types of data that will be obtained from WELL (CDSMP) participants are self-reported data from questionnaires and semi-structured interviews. Validated instruments will be used to examine self-management behaviors and health-related quality of life. NIH-PROMIS measures will be used to assess the specific health-related quality of life domains. Self-administered data will be collected

through online surveys using the Research Electronic Data Capture (REDCap), which is a mature, HIPPA compliant secure web application for building and managing online surveys and databases. Participants may also request to have the questionnaire interviewer-administered via telephone.

Qualitative semi-structured interviews will be designed to explore personal definitions of successful self-management, health-related quality of life, health service utilization and challenges to the successful management of SLE. Interviews will be audio recorded and transcribed verbatim. Audio recordings and transcripts will be stored on an encrypted password-protected computer. Any printed transcripts will be stored in locked cabinets.

De-identified data routinely collected from those GOAL participants receiving usual care, who meet the same inclusion and exclusion criteria than WELL participants (CDSMP group), will be used to enable the comparison of study outcomes between the CDSMP group and the usual care group.

Health services utilization data will be obtained under the auspices of the Georgia Department of Public through a well-established procedure that links the GOAL cohort data with the GA Hospital Discharge Database. Thus, for both the CDSMP and usual care groups, administrative claims data regarding emergency department visits and hospitalizations will be captured from the GA Hospital Discharge Database. This includes the number and characteristics of visits to the emergency department and the number and characteristics of hospital admissions. These data will be stored on an encrypted password-protected computer. Emory University and GA Department of Public Health have provided the IRB approval needed to conduct the databases linkage necessary to obtain health services utilization data for the GOAL population-based cohort.

### **POTENTIAL BENEFITS**

Participants may benefit from having direct access to an education program that may help them self-manage their SLE. They may gain an increased knowledge of their behaviors and their health, and enhance the skills they use to manage their disease. Results from this study may provide another option for SLE patients to improve health education and the skills needed to better self-manage the symptoms of their disease. Results from this study may also be relevant to efforts to improve health outcomes and health care utilization among African American women with SLE, by potentially disseminating the findings on the effectiveness of the CDSMP in the lupus community, including patients, providers, payers and policymakers. Findings may also inform broader public health policies by drawing attention to SLE in African American communities, for which there is a paucity of existing research; and may also highlight self-management activities in this population. Accordingly, findings from this study have the potential to benefit the broader population of African American women with SLE, and may generate results that can be used to design strategies to manage SLE. Participants will be kept informed about the study progress through annual newsletters

### **TRAINING**

The Research Coordinator and Graduate Research Assistants will be trained in all components of this study: Consenting, Data Collection, Data Entry. They will be trained to address participants' questions/concerns and explain study purpose and

importance. They will also be training on the importance of appropriate telephone etiquette and prompt replies.

### **PROTECTIONS AGAINST RISKS**

Surveys and workshop settings are designed to minimize risks. Demands on participants will be minimized; time required to fill out quantitative measures will not exceed 40 minutes. Moreover, we have developed safeguards for protecting against the loss of confidential data. Personal identification information used for contacting participants and tracking their participation in the CDSMP will be stored in a separate secure database that is encrypted and password protected. This data will only be accessible to the investigators and project coordinators in order to contact participants for recruitment, scheduling, and data collection reminders. Participants will be assigned a unique identification number that will be linked to analytical data. Participants who opt to complete a web-based questionnaire must have access to a stable Internet connection. Participants will be given a unique identifier to login to the web page. Once authenticated, the participant will be prompted to complete the survey. The web-based system will be firewall protected and SSL certified. For those who request to complete annual surveys via telephone, upon verifying the identity of the participant, the Research Coordinator will be trained to enter responses directly into the computer via the web-based system.

In order to minimize the potential that some subjects may feel coerced to participate and to protect the rights and welfare of all subjects, study staff will take precautions: (1) during the informed consent process, subjects will be informed that participation is voluntary and that they may withdraw at any time without penalty and (2) subjects will be given printed copies of the informed consent form including contact information for the principal investigator and the IRB.

Participants may also experience psychological discomfort from sensitive items on the questionnaire. However, the majority of questions are from standard instruments that have been previously used in the target population of the study. Participants will also be told that they may refuse to answer any question.

Hard copies of informed consent forms in addition to all personal identifying information will be stored in a locked file cabinet in a locked office, which will be attached to a unique identifier to connect the different types of data that are being collected. Hard copy interest reply cards that ask for participants' contact information will be destroyed within one year of receipt. Personally identifying information that will be used for tracking and locating participants, including names and addresses, will be held in a separate, secure file that is encrypted and password protected. This information will only be accessible to the principal investigators and project coordinator in order to contact participants for recruitment and scheduling. All analytic data will be de-identified. Individually identifiable information will not be linked to survey data. Rather, we will use unique participant identifiers to link types data within study wave components and across data waves.

Computers storing data will be password protected. The anonymity of all study data will be assured by the appearance of their identity linked to their Study ID only on a single log to be maintained and stored in locked files. Accounts and passwords will be issued only to staff involved with the direct processing of the data, and only these individuals will have access to any of the files.

Research Electronic Data Capture (REDCap) is the program that will be used to collect survey data via the computer and Internet. This is a secure and web-based program that is HIPAA compliant. Security is based on Emory Net IDs and there are many levels of user rights that enable the investigators to control who has access to identifiable data. All data are stored at Emory in a secure, HIPAA compliant zone and are backed up by University Technology Services (UTS) regularly.

### **CONFIDENTIALITY**

All facts about participants will be kept private. Participants' identifiers will be used for contact purposes and to track CDSMP workshops attendance. Identifiers will not be linked to the research database. All surveys will display record numbers instead of personal identifiers. All research data will be stored on a HIPPA compliant server. Only team members based on assigned role limitations will be able to access the data.

### **RECRUITMENT AND INFORMED CONSENT**

The randomized sample will be mailed a packet including detailed instructions regarding the requirements for this study and a copy of the consent form. This provides potential participants with an opportunity to closely review documents and ask questions before determining their interest and availability. If interested, a research coordinator will discuss the study further and start the telephone consent process. Potential study participants will be enrolled after a full understanding of the purpose, rationale and procedures of the study is reached. Informed consent will be obtained during this telephone discussion. In some circumstances, informed consents may be also obtained by written, or online-based methods (RedCap). Written consent will occur during face-to-face visits of selected participants to their clinic appointments. During telephone recruitment process, participants will also be given the opportunity to finalize the consent process through the RedCap online system, once all questions are answered and concerns addressed by the RC. All informed consent conversations will be documented and stored with consent.

The information in the consent form will be reviewed in detail and a verbal agreement to participate in this study will be obtained. Similarly, the graduate research assistant (GRA) will call participants randomly selected for the qualitative substudy. During a face-to-face interview with the GRA, potential qualitative substudy participants will be enrolled after a full understanding of the purpose, rationale, and procedures of the study is reached.

### **NEW FINDINGS**

This study will add to knowledge, on multiple system levels including patient, health care system and public health. This knowledge will contribute to filling a longstanding void in self-management needs for SLE patients. By addressing this unmet need, this knowledge could lead to a reduction in the overall disease burden and health disparities in SLE.

### **DATA SAFETY AND MONITORING PLAN**

The PI will be responsible for the oversight and monitoring of the study activities to ensure the safety of participants and validity and integrity of the data.

*Monitoring the Progress of Research and Participants' Safety*

Study staff will receive extensive training on data collection protocols, including methods for presenting the study and responding to questions. All study staff will be certified to conduct research on human beings and will sign a confidentiality agreement. The Project Coordinator will be trained not to deviate from any standardized techniques when completing surveys by telephone. He/her will receive training about research ethics with a focus on the importance of confidentiality and safety. The Project Coordinator and graduate research assistant staff will also be trained to recognize and document any unusual circumstances that they observe while collecting data.

Observations will be recorded on comment cards that the Project Coordinator reviews. Should a major, sensitive issue be arising in the process of data collection (e.g., suicidal thoughts), research personnel collecting the information will: 1) Provide the participant with referral to the Georgia Crisis and Access Line [GCAL]; phone number: 1-800-715-4225), if the participant is capable of calling on her own. The GCAL is a resource provided by the Georgia Department of Behavioral Health and Developmental Disabilities. GCAL is staffed with professional social workers and counselors 24 hours, 7 days per week and will ensure that the participant receives a mental health referral that is local for the participant. 2) In the case of immediate emergency (e.g. imminent danger to self or others), research personnel will directly contact GCAL or local authorities on behalf of the participant.

#### *Reporting adverse events*

The proposed research will examine the CDSMP, an evidence-based self-management education program that has been implemented for over 20 years in the community across the country, in a population with SLE. Participating in the proposed research does not involve more than minimal risk. Adverse events are not anticipated, but should an unanticipated adverse event occur, the principal investigator will report the event immediately to the Emory University Institutional Review Board. Should the unanticipated adverse event be research related, it will be reported to the Office of Human Research Protections and the NIH project officer, along with a description of the event. The NIH project officer will be informed of any IRB action taken concerning unanticipated adverse events. All project personnel will adhere to state laws regarding the reporting of these events. Limitations of confidentiality are discussed during the informed consent process.

Cumulative adverse events and study progress summary will be communicated to the IRBs at the time of continuing review.

#### *Data accuracy and protocol compliance*

The principal investigator will be responsible for reviewing protocol compliance, data collection and verification. Protocols for data collection (Case Report Form Design), data back-up, routine data management, and data quality audits will be in place before the enrollment of the first participant into the study and through the data collection. Monthly data summary reports and data tracking reports will be generated by the data analyst to assure data quality and procedural adherence. Reports will include data on screening and recruitment, the status of case report form completion, queries regarding data edit checks for data accuracy, baseline demographic and covariate data, CDSMP workshop attendance, a longitudinal

summary of patient-reported outcomes and missing data, and cohort retention. Quality control will be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.

#### **NIH DATA AND SAFETY MONITORING BOARD**

The proposed study is exempted from the NIH Data and Safety Monitoring Board requirement because the research will be conducted in community delivered, commonly accepted educational settings, involving an evidence-based self-management educational program for people with chronic conditions. Participating in the proposed research does not involve more than minimal risk.

#### **CLINICALTRIALS.GOV REQUIREMENTS**

This research will examine the effectiveness of the CDSMP, an evidence-based community-based self-management education program, on patient reported outcomes and health care utilization among African American (AA) women with SLE. A random sample selected from our parent GOAL cohort will be used to recruit AA women with SLE into the WELL (Women Empowered to Live with Lupus) cohort. WELL participants will attend the CDSMP classes in the community, along with people with other chronic illnesses. Measures will be completed at baseline, 6, 12, and 18 months. AA women from the GOAL cohort non-selected to be assigned to the intervention will comprise the usual care group. They will continue their routine annual assessments as part of the GOAL cohort efforts.

This research meets the NIH definition of a clinical trial because it entails the prospective assignment of SLE patients to the CDSMP to evaluate the effect of the intervention on health-related outcomes. Our research will be conducted in commonly accepted educational settings, involving an evidence-based self-managing educational program to gather information on the effect of the intervention in a population of SLE patients.

**This study is exempted from the Public Law 110-85 for mandate registration and results reporting of “applicable clinical trials” in ClinicalTrials.gov because the study does not include 1) Trials of Drugs or Biologics; or 2) Trials of Devices.** However, following NIH recommendations for all clinical trials, the PI will register the research at the ClinicalTrials.gov Protocol Registration System Information Website (<http://prsinfo.clinicaltrials.gov/>) before starting the recruitment of the first participant. Upon the receipt of the NCT ClinicalTrials.gov registry number, we will submit results under the voluntary submission provision.

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