confirming ophthalmologic safety, patients are randomized (1:1) to receive HCQ or placebo for 24 months. Visits at 3 month intervals assess clinical and laboratory features and record SLICC criteria. Any participant who is found to meet SLICC classification criteria for SLE is required to exit from the trial. Biosamples are collected at each visit for measurement of autoantibody and cytokine arrays; other samples are banked for later studies.

Results Enrollment started at the beginning of 2018 and ended on July 28, 2022. At that time 256 patients had been screened and 185 enrolled into the randomized phase, slightly less than the planned enrollment of 192. The randomized participants are more than 90% female, and the average age is 33 years. The study population is predominantly White, and only 15% are Black or more than one race. A small number (5/256) screen-failed due to ophthalmologic findings. Greater than 45% of enrollees have added SLICC criteria during followup, including approximately 15% who have exited the study after achieving 4 or more SLICC criteria and thus classifying as SLE. No drug-related SAEs have been reported and treatment has not been unblinded for any participant. The last enrollee is predicted to exit the trial in mid-2024.

Conclusions The ILE definition used in SMILE targets a population in which accumulation of additional SLE criteria and transition to classifiable disease is observable within a 2 year study period. The enrolled population has a lower percentage of Black patients than anticipated, and whether this is due to a lower prevalence of the ILE stage of disease in these patients is of interest for further investigation. SMILE is generating a valuable biobank of samples for future mechanistic studies.

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Clinical Research in SLE

611 EFFICACY AND SAFETY OF NIPOCALIMAB IN ADULT PATIENTS WITH ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS: DESIGN OF A PHASE 2 STUDY

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Background Autoantibody-mediated diseases, such as systemic lupus erythematosus (SLE), are caused by pathogenic antibodies that can damage tissues or organs. Approved treatments are few and associated with limitations including suboptimal response. Nipocalimab is a novel high affinity, fully human, aglycosylated, effectorless IgG1 monoclonal antibody that selectively blocks the neonatal Fc receptor (FcRn). Clinical studies conducted with nipocalimab in healthy volunteers (NCT02828046) and in adult generalized myasthenia gravis patients (NCT03896295) demonstrated rapid and durable serum IgG and pathogenic autoantibody reductions. Here we describe the protocol of a Phase 2 study evaluating the efficacy and safety of nipocalimab in patients with active SLE (NCT04882878).

Methods A phase 2, multicenter, randomized, placebo-controlled, double-blind, parallel-group study enrolling adults with active, autoantibody-positive SLE with an inadequate response to one or more standard of care treatments. The study consists of a ≤6-week screening period, a 52-week double-blind treatment period, and a 6-week follow-up period. A target of approximately 225 participants will be enrolled. Participants will be randomized in a 1:1:1 ratio to receive nipocalimab dose 1, dose 2 or placebo intravenously every 2 weeks through Week 50.

Results The primary efficacy endpoint is the percentage of participants achieving an SLE Responder Index (SRI)-4 composite response at Week 24. Secondary efficacy endpoints assessed at Week 24 include the percentage of participants achieving: ≥50% reduction in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity score (CLASI), ≥50% reduction in active joints, ≥4 points improvement in SLE Disease Activity Index 2000 (SLEDAI 2K), and British Isles Lupus Assessment Group Composite Lupus Assessment response (BICLA); time to first disease flare; and reduction in corticosteroid use. Percentage of participants achieving an SRI-4 composite response at Week 52 will also be assessed. Safety endpoints include adverse events (AEs), serious AEs, AEs of special interest (severe infections, grade ≥3 hypoalbuminemia), and AEs leading to treatment discontinuation through Week 58. Additional assessments include pharmacokinetic, pharmacodynamic, and immunogenicity evaluations.

Conclusions This ongoing phase 2 study will evaluate the safety and efficacy of nipocalimab in adults with active SLE, using multiple clinical outcome measures.

612 SOCIAL COGNITIVE CORRELATES OF ACCELEROMETER-MEASURED AND SELF-REPORTED PHYSICAL ACTIVITY IN PERSONS WITH SYSTEMIC LUPUS ERYTHEMATOSUS

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Background/Purpose Evidence suggests that physical activity is a modifiable lifestyle behavior that helps manage the manifestations of systemic lupus erythematosus (SLE). However, persons with SLE are often physically inactive. There is a need to identify variables grounded in a well-developed theory associated with physical activity in persons with SLE, to identify correlates, targets, and behavior change strategies. This study

examines the social cognitive theory (SCT) correlates of physical activity in persons with SLE.

Methods The Lupus Intervention Fatigue Trial (LIFT) is a Phase II ongoing study designed to mitigate fatigue by increasing physical activity. Data for the analysis presented here are from LIFT's baseline visit. All participants satisfied American College of Rheumatology or Systemic Lupus International Collaborating Clinics classification criteria for SLE. Participants completed questionnaires to assess physical activity and SCT variables: exercise self-efficacy (EXSE), outcome expectations, exercise goal-setting (EGS), and physical function. Participants wore an ActiGraph GT3X accelerometer for 7 days, and Troiano cutpoints were used for moderate-to-vigorous physical activity (MVPA). Estimated associations between MVPA, Godin Leisure-Time Exercise Questionnaire Health Contribution Score (GLTEQ HCS), and SCT variables were derived using Spearman correlations (r). For regression analyses, we conducted univariate analyses to identify SCT variables for inclusion in multiple regression models of each outcome (selection criterion: $p \leq 0.2$). We then used multivariable regression models to examine associations between selected SCT variables and physical activity outcomes: 1) due to skewness of MVPA, we used log(base10) transformed weekly MVPA minutes in the regression models; 2) logistic regression models were used for analysis of the Sufficiently Active outcome, defined as GLTEQ HCS $\geq$ 24.

Abstract 612 Table 1 Descriptive and clinical characteristics for the sample with SLE.

Variables	SLE Sample (n=83)
Age (years) (mean, SD)	44 (12)
Sex (n,% female)	74 (89%)
Race (self-reported)	
Asian	6 (7%)
Black or African American	28 (34%)
White	44 (53%)
Unknown	5 (6%)
Ethnicity	
Hispanic or Latino	11 (13%)
Not Hispanic or Latino	69 (83%)
Unknown	5 (4%)
Education Level	
High School Diploma/GED	6 (7%)
Some College	10 (12%)
2-Year College Degree	7 (8%)
4-Year College Degree	25 (30%)
Masters' Degree	26 (31%)
Doctoral Degree	4 (5%)
Professional Degree	5 (6%)
SLICC SDI Score (mean, SD)	1.17 (1.45)
SLEDAI Score	
< 6	67 (81%)
>= 6	16 (19%)

Note: SLE = Systemic lupus erythematosus; SD = Standard Deviation; SLICC SDI = Systemic Lupus International Collaborating Clinics Standard Damage Index; SLEDAI = Systemic Lupus Erythematosus Disease Activity Index.

Abstract 612 Table 2 Descriptive statistics for physical activity and social cognitive theory variables for the sample with SLE.

Variables	Mean (SD)	Median (IQR)
GLTEQ HCS	15 (20)	5 (0,27)
MVPA	21 (23)	14 (6,28)
EXSE	70 (27)	78 (50,100)
MOEES Total	60 (9)	61 (56, 67)
EGS	20 (10)	20 (14, 32)
PROMIS physical function	50 (8)	49 (44, 56)

Note: SD = Standard Deviation; IQR = Interquartile Range; GLTEQ = Godin Leisure-Time Exercise Questionnaire; HCS = Health Contribution Score (0-13 = Insufficiently Active/Sedentary, 14-23 = Moderately Active, $\geq$24 = Sufficiently Active); MVPA = average daily minutes, moderate-to-vigorous physical activity; EXSE = Exercise Self-Efficacy Scale; MOEES = Multidimensional Outcome Expectations for Exercise Scale; EGS = Exercise Goal-Setting Scale; PROMIS = Patient Reported Outcomes Measurement Information System.

Abstract 612 Table 3 Correlations between physical activity and social cognitive theory scores for the sample with SLE.

Variables	Spearman Correlations	
	GLTEQ HCS (n=82)	MVPA (n=83)
GLTEQ HCS	1	0.35*
MVPA	0.35*	1
EXSE (0-100)	0.45*	0.22
MOEES total (15-75)	0.11	0.09
EGS (10-50)	0.51*	0.34*
PROMIS physical function (15-75)	0.32*	0.35*

Note: GLTEQ HCS = Godin Leisure-Time Exercise Questionnaire Health Contribution Score; MVPA = moderate-to-vigorous physical activity; EXSE = Exercise Self-Efficacy Scale; MOEES = Multidimensional Outcome Expectations for Exercise Scale; EGS = Exercise Goal-Setting Scale; PROMIS = Patient Reported Outcomes Measurement Information System; *p-value of <0.01.

Results Participant characteristics (n=83) are summarized in table 1. The median (Interquartile range) for average daily accelerometer-measured MVPA was 14 (6, 28) (table 2). According to the self-reported GLTEQ HCS, 28% of participants were classified as Sufficiently Active, 15% Moderately Active, and 57% Insufficiently Active/Sedentary. MVPA was significantly correlated with EXSE (r =0.22), EGS (r =0.34) and physical function (r =0.35). GLTEQ HCS was significantly correlated with EXSE (r =0.45), EGS (r =0.51), and physical function (r=0.32) (table 3). Outcome expectations were not significantly correlated with either accelerometer-measured MVPA or GLTEQ HCS. Adjusting for race and age had limited influence on associations between physical activity and SCT variables. In multivariable models, levels of accelerometer-measured MVPA were positively associated with EGS (p<0.01) and physical function (p<0.001). Being classified as Sufficiently Active was positively associated with EGS (p<0.01).

Conclusion These results suggest that researchers may consider applying intervention strategies that address exercise goal setting and self-perceived levels of physical function for improving MVPA participation among persons with SLE.

613 UNDERREPRESENTATION OF MINORITY PATIENTS IN AN OBSERVATIONAL COHORT STUDY

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Background Underrepresentation of ethnic minorities in lupus clinical trials has been identified as an important disparity. We