



2026 PILOT GRANT

Ghaith Noaiseh, MD

Associate Professor

Division of Allergy, Clinical Immunology, and Rheumatology

University of Kansas Medical Center

Longitudinal Concordance Between ESSDAI Disease Activity and Psychiatric Patient-Reported Outcomes in Sjögren's Disease

Abstract: Depression and anxiety, along with sleep disturbance, are common in Sjögren's disease (SjD) and contribute substantially to disease burden, yet it remains unclear whether within-person fluctuations in systemic disease activity track with within-person changes in these outcomes over time. Longitudinal SjD cohorts demonstrate substantial individual-level variability in ESSDAI, including frequent transitions across low vs. moderate/high activity thresholds, underscoring the need for analytic approaches that distinguish within-person dynamics from between-person differences. We will conduct a prospective, clinic-based observational cohort of adults with SjD meeting 2016 ACR/EULAR classification criteria, assessed at three routine-care-aligned time-points over 12–18 months (baseline, 6–9 months, 12–18 months). At each visit, the Project Lead will score systemic disease activity (ESSDAI) and collect ESSPRI, while participants complete validated patient-reported measures of depression (PHQ 9; primary outcome), anxiety (GAD 7), and insomnia severity (ISI). A resident-led workflow will support e-consent at baseline, structured psychiatric history, standardized safety screening, and REDCap-based data capture with automated reminders to optimize retention without participant compensation. The primary analysis will use pre-specified mixed-effects models with person-mean centering to estimate the association between within-person ESSDAI change and within-person change in psychiatric and sleep outcomes, while separating between-person effects. Sensitivity analyses will address medication changes (confounding by indication), symptom overlap (PHQ 9 cognitive/affective vs somatic subscales), and domain-level ESSDAI patterns, including an internal validity check using an ESSDAI domain not expected to relate to mood outcomes. This study will provide foundational evidence on whether systemic activity dynamics co-vary with depression, anxiety, and insomnia trajectories.

©2026 Sjögren's Foundation. All rights reserved. This abstract is provided for informational purposes only and may not be reproduced, distributed, published, or transmitted, in whole or in part, without the prior written permission of the Sjögren's Foundation and the author(s).

For more information, please contact the Sjögren's Foundation at research@sjogrens.org.