

3. **Sophie Hu¹**, Marie-Eve Carrier¹, Meira Golberg¹, Marie-Claude Geoffroy²⁻⁴, Linda Kwakkenbos^{5,6}, Susan J. Bartlett^{7,8}, Catherine Fortuné⁹, Amy Gietzen¹⁰, Karen Gottesman¹¹, Amanda Lawrie-Jones^{12,13}, Vanessa L. Malcarne^{14,15}, Michelle Richard¹⁶, Maureen Sauvé^{17,18}, Luc Mouthon^{19,20}, Andrea Benedetti^{2,8,21}, Brett D. Thombs^{1,2,4,7} on behalf of the SPIN Investigators¹.

¹Lady Davis Institute for Medical Research, Jewish General Hospital, Montreal, QC, Canada; ²Department of Epidemiology, Biostatistics, and Occupational Health, McGill University, Montreal, QC, Canada; ³Douglas Mental Health University Institute, Montreal, QC, Canada; ⁴Department of Psychiatry, McGill University, Montreal, QC, Canada; ⁵Department of Clinical Psychology, Behavioural Science Institute, Radboud University, Nijmegen, the Netherlands; ⁶Radboudumc Center for Mindfulness, Department of Psychiatry, Radboud University Medical Center, Nijmegen, the Netherlands; ⁷Department of Medicine, McGill University, Montreal, QC, Canada; ⁸Research Institute of the McGill University Health Centre, Montreal, QC, Canada; ⁹Ottawa Scleroderma Support Group, Ottawa, ON, Canada; ¹⁰Steffens Scleroderma Foundation, Albany, NY, USA; ¹¹National Scleroderma Foundation, Los Angeles, CA, USA; ¹²Scleroderma Australia, Melbourne, Victoria, Australia; ¹³Scleroderma Victoria, Melbourne, Victoria, Australia; ¹⁴Department of Psychology, San Diego State University, CA, USA; ¹⁵San Diego State University/University of California, San Diego Joint Doctoral Program in Clinical Psychology, San Diego, CA, USA; ¹⁶Scleroderma Atlantic, Halifax, NS, Canada; ¹⁷Scleroderma Society of Ontario, Hamilton, ON, Canada; ¹⁸Scleroderma Canada, Hamilton, ON, Canada; ¹⁹Service de Médecine Interne, Centre de Référence Maladies Autoimmunes et Autoinflammatoires Systémiques Rares d'Ile de France, de l'Est et de l'Ouest, Hôpital Cochin, Paris, France; ²⁰Assistance Publique Hôpitaux de Paris-Centre, Hôpital Cochin, Université Paris Cité, Paris, France; ²¹Respiratory Epidemiology and Clinical Research Unit, McGill University Health Centre, Montreal, QC, Canada.

Evaluating Context Effects on PHQ-8 Somatic Item Scores among People with Systemic Sclerosis: A Scleroderma Patient-centered Intervention Network (SPIN) Randomized Experiment.

Systemic sclerosis (SSc; scleroderma) is a chronic, autoimmune rheumatic disease characterised by fibrosis of the skin and other organs. Some symptoms commonly experienced by SSc patients overlap with somatic symptoms of depression, potentially introducing bias in depression symptom assessment. We previously found, however, that people with SSc scored similarly on somatic items of depression across subtypes despite having different disease presentations and symptom severity. Similar results have been found in other chronic illnesses, and the reason for these surprising findings is unknown. Our primary objective was to evaluate differences in mean sum scores of Patient Health Questionnaire-8 (PHQ-8) somatic symptom items in people with SSc when the items were administered outside the context of a depression questionnaire versus as part of the PHQ-8. Secondary objectives were to evaluate individual somatic item scores. We hypothesised that people who completed somatic items outside of the PHQ-8 would have significantly higher scores than those who completed items as part of the PHQ-8.

We conducted a randomised controlled experiment within the Scleroderma Patient-centered Intervention Network (SPIN) Cohort, a multinational cohort of people with SSc. SPIN Cohort participants were randomly allocated to complete the PHQ-8 with somatic items (sleep disturbances, fatigue, appetite changes) presented separately from psychological items and without any indication they were part of a depression questionnaire (Reordered Items arm) or in standard format (Standard PHQ-8 arm). Participants were automatically randomised when they logged into the SPIN Cohort platform to complete routine assessments. The primary outcome was the mean sum score of PHQ-8 somatic items. Secondary outcomes were mean scores of individual somatic items. Differences were assessed using between-groups t-tests.

In total, 851 participants were included (N = 428 in Reordered Items arm, N = 423 in Standard PHQ-8 arm). Mean (SD) PHQ-8 score was 6.0 (5.3) for all participants. We found no statistically significant differences in PHQ-8 somatic item sum scores (0.05 points; 95% confidence interval [CI] -0.29 to 0.38) or in mean scores for item 3 (sleep disturbances; 0.04 points; 95% CI -0.09 to 0.19), item 4 (fatigue; 0.03 points; 95% CI -0.11 to 0.16), and item 5 (appetite changes; -0.03 points; 95% CI -0.15 to 0.10).

We did not find evidence that responses to PHQ-8 somatic items were influenced by whether participants were aware they were responding to items about depression. This finding supports the validity of self-reported questionnaires for depression symptom assessment in people with SSc.