



Scleroderma Society of Ontario
136 Kenilworth Avenue North, Hamilton, Ontario, L8H 4R8
Toll Free: 1-888-776-7776
www.sclerodermaontario.ca

Scleroderma:

A Program to Study Outcomes and Experiences Important to Patients

Principal Investigator:

Dr. Brett D. Thombs, from the McGill University / Lady Davis Institute for Medical Research, Jewish General Hospital, Montreal, Quebec, does research in behavioural health. His work in behavioural health psychology focuses on the illness experience of patients, including the etiology, assessment, and treatment of interrelated somatic and psychological symptoms that are common in medical illness, particularly cardiovascular disease and scleroderma. Dr. Thombs has authored more than 90 peer-reviewed articles, many of them in top medical journals, has served as a peer-reviewer for over 30 journals, and is on the editorial boards of 4 journals.

Study Background:

Patient-reported outcomes assess patient health, well-being, and response to treatment based on patient perspectives. Patient-reported outcomes may reflect complex constructs, such as quality of life (QOL), or narrower constructs, such as individual symptoms (e.g., pain or fatigue). Traditionally, research in scleroderma has focused on physiological markers, or other “hard outcomes,” such as survival. These outcomes are important, but it is also important to evaluate and understand experiences of patients living with the disease, including aspects, such as living with pain, fatigue, or depression, which are of great importance to patients and cannot be measured without patient input. Thus, research to improve management of outcomes that affect quality of life for people with scleroderma is urgently needed. However, no assessment tools for these important outcomes been developed and validated for use with people with scleroderma. Furthermore, there are no interventions that have been developed and tested for patients with SSc to better manage fatigue, depression, or pain, for instance, despite evidence from other chronic diseases that these symptoms can be reduced with pharmacologic and nonpharmacologic approaches.



Scleroderma Society of Ontario

136 Kenilworth Avenue North, Hamilton, Ontario, L8H 4R8

Toll Free: 1-888-776-7776

www.sclerodermaontario.ca

Study Purpose/Goals:

The objectives of this program of research are (1) to develop and evaluate assessment tools for outcomes important to patients with scleroderma (e.g., fatigue, pain, body image distress, depression, itching); (2) to assess potential causal factors; (3) to determine these symptoms are experienced over the lifespan of the disease; and (4) subsequently, to develop and test behavioural interventions to reduce distress and increase overall well-being.

Study Method:

This work will rely on data that is contributed by Canadians with scleroderma to the Canadian Scleroderma Research Group (CSRG) Registry. Patients from 15 centres across Canada complete annual assessments, at which time they undergo an extensive clinical history, physical evaluation, and laboratory investigations and complete a series of self report questionnaires (e.g., sociodemographic variables, scleroderma symptoms, comorbid conditions, disability, quality of life, pain, depression). This work will also use data from the Scleroderma Society of Canada / Canadian Scleroderma Research Group Patient Survey, for which over 600 Canadians with scleroderma, recruited through advertisements, online, and through support groups, completed a series of questions about their experiences with scleroderma and health care needs.

Study Update:

Our group has published a large number of academic manuscripts related to the work in this research program, all in high-impact, prestigious academic journals (see attached bibliography). In addition, this program has provided training for graduate students who will continue to be active in working on issues important to people with scleroderma. Finally, this work has laid the foundation for a new international collaboration, the Scleroderma Patient-centred Intervention Network (SPIN), which brings together researchers, clinicians, and patients from across the world to develop an infrastructure to provide access for people with scleroderma to programs designed to improve quality of life for people living with the disease.



Scleroderma Society of Ontario

136 Kenilworth Avenue North, Hamilton, Ontario, L8H 4R8

Toll Free: 1-888-776-7776

www.sclerodermaontario.ca

What Does This Study Mean for Persons Living With Scleroderma?

For many years, there was almost nothing published in the medical literature on the kinds of problems that affect quality of life for people living with scleroderma. Even though the nature of these problems is often obvious to people living with the disease, without means of measuring them, for instance, no research is conducted. The research that we have conducted thus far has moved this area forward quickly. We have provided researchers and clinicians who care for people with scleroderma a tangible map of the kinds of daily problems faced by people with the disease and what needs to be done to research them. As a result of this work, we have spearheaded SPIN. SPIN members from across the globe, including members of the Scleroderma Society of Canada are currently working to raise funds in order to develop and test easily accessed interventions to improve quality of life for people with scleroderma. Examples of projects that SPIN plans to undertake include, for instance, the development and dissemination of a downloadable set of instructions to provide competent physical therapy to improve hand function. Most scleroderma patients with limited hand function currently do not receive therapy or receive inappropriate therapy. Other interventions planned include peer support to improve coping and mood and online support related to body image concerns.

Bibliography¹

1. **Newton E, Thombs BD**, Groleau D. The experience of emotional distress among women with scleroderma. *Qualitative Health Research* (submitted for peer-review).
2. **Jewett LR**, Hudson M, Baron M, **Thombs BD**, Canadian Scleroderma Research Group. Correlates of body image dissatisfaction and social discomfort in systemic sclerosis: A structural equation modeling approach. *Rheumatology* (submitted for peer-review).
3. **EI-Baalbaki G, Lober J**, Hudson M, Baron M, **Thombs BD**, Canadian Scleroderma Research Group. A comparison of the McGill Pain Questionnaire and single-item pain measures in systemic sclerosis. *Rheumatology* (submitted for peer-review).

¹ Names of supervised trainees are underlined and in bold.



Scleroderma Society of Ontario

136 Kenilworth Avenue North, Hamilton, Ontario, L8H 4R8

Toll Free: 1-888-776-7776

www.sclerodermaontario.ca

4. **Knafo R**, Haythorthwaite JA, Heinberg L, Wigley F, **Thombs BD**. The association of body image distress and pain with sexual impairment in women with systemic sclerosis. *Rheumatology* (in press).
5. **Milette K**, **Razykov I**, Pope J, Hudson M, Baron M, **Thombs BD**. Clinical correlates of sleep problems in systemic sclerosis. *Rheumatology* (in press).
6. **Milette K**, **Roseman M**, **Thombs BD**. Transparency of outcome reporting and trial registration of randomized controlled trials in psychosomatic and behavioural health research: A systematic review. *Journal of Psychosomatic Research* (in press).
7. **Bassel M**, Hudson M, Taillefer S, Schieir O, Baron M, **Thombs BD**. Frequency and impact of symptoms experienced by patients with systemic sclerosis: Results from a Canadian national survey. *Rheumatology* (in press).
8. **Jewett LR**, Hudson M, Haythornthwaite JA, Heinberg L, Wigley F, Baron M, **Thombs BD**, Canadian Scleroderma Research Group. Development and validation of the Brief-Satisfaction with Appearance Scale (Brief-SWAP) for systemic sclerosis. *Arthritis Care & Research*. 2010;62(12):1779-1786.
9. **El-Baalbaki G**, **Razykov I**, Hudson M, **Bassel M**, Baron M, **Thombs BD**, Canadian Scleroderma Research Group. The association of pruritus with quality of life and disability in systemic sclerosis. *Arthritis Care & Research*. 2010;62(10):1489-1495.
10. **Thombs BD**, van Lankveld W, **Bassel M**, Baron M, Buzza R, Haslam S, Haythornthwaite JA, Hudson M, **Jewett LR**, **Knafo R**, Kwakkenbos L, Malcarne V, **Milette K**, Motivala S, **Newton EG**, Nielson W, Pacy M, **Razykov I**, **Schieir O**, Worrion-Sauve M, Taillefer S. Psychological health and well-being in systemic sclerosis: State of the science and consensus research agenda. *Arthritis Care & Research*. 2010;62(8):1181-1189.
11. **Milette K**, Hudson M, Baron M, **Thombs BD**, Canadian Scleroderma Research Group. Comparison of the PHQ-9 and CES-D depression scales in systemic sclerosis: Internal consistency reliability, convergent validity, and clinical correlates. *Rheumatology*. 2010;49(4):789-796.



Scleroderma Society of Ontario

136 Kenilworth Avenue North, Hamilton, Ontario, L8H 4R8

Toll Free: 1-888-776-7776

www.sclerodermaontario.ca

12. **Schieir O, Thombs BD**, Hudson M, Boivin JF, Steele R, Bernatsky S, Hanley J, Baron M, Canadian Scleroderma Research Group. Prevalence, severity, and clinical correlates of pain in patients with systemic sclerosis. *Arthritis Care & Research*. 2010;62(3):409-417.
13. **Razykov I, Thombs BD**, Hudson M, **Bassel M**, Baron M, Canadian Scleroderma Research Group. Prevalence and clinical correlates of pruritus in patients with systemic sclerosis. *Arthritis Care & Research*. 2009;61(12):1765-1770.
14. **Knafo R, Thombs BD, Jewett LR**, Hudson M, Wigley F, Haythornthwaite JA. (Not) talking about sex. A systematic comparison of sexual impairment in women with systematic sclerosis and other chronic disease samples. *Rheumatology*. 2009;48(10):1300-1303.
15. **Thombs BD**, Hudson M, **Bassel M**, Taillefer SS, Baron M, Canadian Scleroderma Research Group. Sociodemographic, disease, and symptom correlates of fatigue in systemic sclerosis. *Arthritis Care & Research*. 2009;61(7):966-973.
16. **Thombs BD, Bassel M**, McGuire L, Smith MT, Hudson M, Haythornthwaite JA. Fatigue in systemic sclerosis: A systematic comparison with other chronic illnesses. *Rheumatology*. 2008;47(10):1559-1563.
17. **Thombs BD**, Hudson M, Taillefer SS, Baron M, Canadian Scleroderma Research Group. Prevalence and clinical correlates of symptoms of depression in patients with systemic sclerosis. *Arthritis Care & Research*. 2008;59(4):504-509.
18. **Thombs BD**, Hudson M, **Schieir O**, Taillefer SS, Baron M, Canadian Scleroderma Research Group. Reliability and validity of the Center for Epidemiological Studies Depression Scale in patients with systemic sclerosis. *Arthritis Care & Research*. 2008;59(3):438-443.
19. **Thombs BD, Fuss S**, Hudson M, **Schieir O**, Taillefer SS, Fogel J, Ford DE, Baron M, Canadian Scleroderma Research Group. High rates of depressive symptoms among patients with systemic sclerosis are not explained by differential reporting of somatic symptoms. *Arthritis Care & Research*. 2008;59(3):431-437.
20. **Thombs BD**, Taillefer SS, Hudson M, Baron M. Depression in patients with scleroderma. A systematic review of the evidence. *Arthritis Care & Research*. 2007;57(6):1089-1097.