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Testing whether patients and researchers presenting side-by-side improves communication of scleroderma research to patients

Submission date 30/07/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol
Registration date 04/08/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 04/08/2025	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Research ethics policies and funding agencies emphasize or require that researchers involve patients as research partners across all stages of research, including the sharing of research findings. Many researchers find it difficult to simplify complex findings, and many patients find it hard to understand the purpose or results of studies. To help make research more accessible, our Scleroderma Patient-centered Intervention Network (SPIN) piloted a new approach called “co-presentation,” where researchers and patients present study results together to other patients. This study will test whether co-presentation helps patients better understand research compared to when researchers present alone.

The study, called the SPIN – Patients Alongside Investigators in Research-Sharing (SPIN-PAIRS) Trial, will compare these two ways of sharing results during an online, patient-oriented event for people with scleroderma. It will examine how participants perceive the completeness, understandability, relevance, and trustworthiness of the information presented.

Who can participate?
Adults with scleroderma who are interested in attending an online research event about recent studies on scleroderma.

What does the study involve?
Registered attendees will attend a 90-minute online research event. They will be randomly placed in one of two virtual rooms, where they will either watch: (A) four recordings where a researcher and a patient present together, or (B) four recordings where only a researcher presents.

Each recording will be followed by a live question-and-answer period. After each presentation, participants will answer short questions on Zoom about how complete, understandable, relevant, and trustworthy they found the information. Some participants may also be invited to take part in a short interview after the event to share their experience in more detail.

What are the possible benefits and risks of participating?
There are no direct health benefits from participating, but participants may find the research presentations informative. The findings will help improve how research is shared with patients in the future. The only possible harm we identified is that being informed of research results may lead to disappointment if the results are not as hoped.

Where is the study run from?
The study is run by the SPIN research team at the Jewish General Hospital (Montreal, Canada) in collaboration with 15 scleroderma patient organizations.

When is the study starting and how long is it expected to run for?
The online event will occur in November 2025. The follow-up interviews will be completed within a few weeks.

Who is funding the study?
This study is funded by the Canadian Institutes of Health Research (CIHR).

Who is the main contact?
Brett D. Thombs, PhD, Jewish General Hospital, brett.thombs@mcgill.ca

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Randomized controlled trial to evaluate patient and researcher co-presentation of research results: the scleroderma patient-centered intervention network – patients alongside investigators in research-sharing (SPIN-PAIRS) trial

Acronym
SPIN-PAIRS

Study objectives
The SPIN Patients Alongside Investigators in Research-Sharing (SPIN-PAIRS) Trial will be conducted as part of a 90-minute virtual research event for people living with systemic sclerosis and family members or others close to them, and will compare researcher and patient partner co-presentation versus researcher-alone presentation. Post-trial, interviews will be conducted with patient and researcher presenters, separately, and with patient trial participants to better understand and explain trial results and obtain information to improve and optimize co-presentation implementation.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/07/2025, Research Ethics Board of the Integrated University Health and Social Services Center of West-Central Montreal (Centre Intégré Universitaire de Santé et de Services Sociaux du Centre-Ouest-de-L'île-de-Montréal) (3755 Chemin de la Côte Sainte-Catherine, Montreal, H3T 1E2, Canada; +1 (514) 630-2123; recherche.comtl@ssss.gouv.qc.ca), ref: 2025-4165

Study design
Mixed-method involving a two-arm parallel-group randomized controlled trial (RCT) embedded in a 90-minute virtual research event and interview study

Primary study design
Interventional

Secondary study design
Mixed quantitative and qualitative components

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Patient and researcher co-presentation of research results compared to researcher-alone presentation among people with systemic sclerosis.

Interventions
This will be a mixed-method study with (1) a two-arm parallel-group randomized controlled trial (RCT) embedded in a 90-minute virtual research event and (2) interviews with patient and researcher co-presenters, separately, and with trial participants.

Researchers and patient partners will be recruited to present research, and participants will be recruited to attend and rate the presentations. To avoid presentation-related biases, pre-event, researchers will record researcher-alone presentations. They will then receive co-presentation training and develop co-presentations with patient partners, which will also be recorded.

On the day of the event, consented and registered participants will be sent a Qualtrics link to join the online event. Those who click on the link will be randomly assigned to the co-presentation or researcher-alone presentation rooms via randomization in Qualtrics. Based on randomization, participants will be emailed a Zoom link for their assigned room. The co-presentation and researcher-alone presentation events will occur simultaneously and last 90 minutes (4 presentations, which will each include 10 minutes for the presentation, 8 minutes for live questions and answers, and 2 minutes to complete outcome measures; 5 minutes each for welcoming and closing). Participants will not be aware that they are being randomized or that there are separate events with different presentation formats occurring simultaneously. The same studies will be presented in each arm.

Intervention Type
Behavioural

Primary outcome measure
Participant ratings of presentation (1) information completeness, (2) perceived understandability, (3) relevance to patients, and (4) trust in the research findings, collected immediately from participants after each presentation using Zoom's poll feature at one timepoint. Response options for all items will be on a 0 to 10 scale (0 = strongly disagree to 10 = strongly agree).

Secondary outcome measures
1. Subgroup analyses of all primary outcomes by age (18 to 44 years, 45 to 64 years, 65 years or older), gender (women, men, other if sufficient number of participants), race or ethnicity (White, other), country (Canada, France, United States, other), education level (≤12 years, >12 years), and health literacy (HLS19-Q12 ≥66.67 = sufficient or excellent, HLS19-Q12 <66.67 = inadequate or problematic).
2. Qualitative interviews with patient and researcher presenters, separately, and with event attendees to obtain perspectives to help us better understand and explain trial results and obtain information to improve and optimize co-presentation implementation.

Overall study start date
01/08/2024

Completion date
15/12/2025

Eligibility

Key inclusion criteria
1. Adults aged 18 years or older
2. Diagnosed with systemic sclerosis by a physician

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
116

Key exclusion criteria
Not meeting the key inclusion criteria

Date of first enrolment
22/11/2025

Date of final enrolment
22/11/2025

Locations

Countries of recruitment
Canada

Study participating centre
Centre Intégré Universitaire de Santé et de Services Sociaux du Centre-Ouest-de-l'Île-de-Montréal
3755 Chemin de la Côte Sainte-Catherine
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
https://www.jgh.ca/

ROR
https://ror.org/056jjra10

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Our strategy includes multiple dissemination tools: scientific publications, patient organization news articles, patient-oriented tools, toolkits, conferences, and co-presentation workshops. Our patient organization partners intend to work with our Scleroderma Patient-centered Intervention Network (SPIN) to make our patient-oriented research event an annual event. If co-presentation is found to be effective, co-presentation will be the required format in future years. A key aspect of our plan is the development and dissemination of virtual and in-person training to support others in implementing co-presentation.

Intention to publish date
01/08/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the corresponding author, Dr Brett Thombs (brett.thombs@mcgill.ca). Anonymised IPD can be requested by contacting the Principal Investigator and submitting a proposal for analysis. IPD will be available 1 year after trial completion.

IPD sharing plan summary
Available on request