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Evaluating tools to communicate scleroderma research results to patients - SPIN-CLEAR Trial Series PPI Sub-study #1

Submission date
21/10/2025

Recruitment status
No longer recruiting

Registration date
27/10/2025

Overall study status
Completed

Last Edited
24/03/2026

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Engaging people with lived experience (PWLE) in research is an important component of ethical research, and major research funders mandate or encourage engagement of PWLE to improve research relevance and trust in the findings. PWLE can be engaged in research across all stages and have different levels of influence on decision-making, including (1) consulting by providing opinions or perspectives on a topic or problem related to planned or ongoing research; (2) being involved or advising via two-way conversations with researchers on one or more aspects of a research study; and (3) partnering, which involves working as equals with researchers to collaborate and make decisions related to multiple aspects of one or more studies.
The Scleroderma Patient-centered Intervention Network – Communicating Latest Evidence and Results (SPIN-CLEAR) trial series will test different ways of communicating research results to study participants and others with relevant lived experience. This trial is one of three trials that comprise a sub-study of the SPIN-CLEAR series of trials. The primary objective of this trial will be to compare among PWLE the perceived relevance and trustworthiness of research described in a plain-language research summary with a description of meaningful PWLE engagement versus research described in a plain-language summary with no mention of PWLE engagement. We will also evaluate ratings of information completeness, understandability of the plain-language summaries, whether participants were pleased to have received results, intention to participate in future studies, and for all primary and secondary outcomes, subgroup analyses of effects by participant characteristics (age, gender, race or ethnicity, country, language, education level, health literacy). The research that will be disseminated in the plain-language summaries is a study that tested a systemic sclerosis (SSc; scleroderma)-specific self-management program.

Who can participate?
SPIN is a collaboration of researchers, clinicians, and people with SSc. People with SSc in the SPIN Cohort and other people with SSc who participated in a previous SPIN-CLEAR trial or SPIN patient-oriented research event can participate. Participants must be aged 18 years and over, confirm that they have been classified as having SSc by a physician, and be fluent in English or French. People not able to access or respond to questionnaires via the internet are excluded.

What does the study involve?
Those who consent will be randomized to receive a plain-language summary with a description of PWLE engagement or a plain-language summary with no mention of PWLE engagement. Items to rate outcomes will be presented to participants following the plain-language summary on a Qualtrics online survey platform. We estimate that participants will require between 5 and 15 minutes to review the plain-language summary, and we will record this. There will not be any limits on how many times participants can access the summary prior to responding to the outcome measurements. We will send email reminders to participants who have consented but not completed all outcome measures at 7-days and 11-days post-consent, and data collection will end on day 14 by closing the Qualtrics survey. Outcomes will be linked to sociodemographic, medical, and health literacy data collected via the SPIN Cohort, which has been done with 100% linking success in previous trials.

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

Where is the study run from?
The study is run by the SPIN research team at the Jewish General Hospital (Montréal, Québec, Canada).

When is the study starting and how long is it expected to run for?
March 2026 to April 2026

Who is funding the study?
Canadian Institutes of Health Research (CIHR) (Canada)

Who is the main contact?
Dr Brett D. Thombs, brett. thombs@mcgill.ca

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
2024-4165-2

Study information

Scientific Title
A randomized controlled trial to compare the effectiveness of dissemination tools to share research results with patients - A SPIN-CLEAR Trial Series Patient and Public Involvement Statement Sub-study #1

Study objectives
Current study objectives as of 24/03/2026:
This trial is one of three trials that comprise a sub-study of the Scleroderma Patient-centered Intervention Network – Communicating Latest Evidence and Results (SPIN-CLEAR) series of trials, which was launched to compare the effectiveness of different tools to disseminate research results to study participants and other people with lived experience (PWLE).

This trial will compare a plain-language research summary with a description of PWLE engagement versus a plain-language summary.

Results from this trial will be published in one SPIN-CLEAR Sub-study report comprising all three trials in the sub-study series. Results can be used by researchers and patient organizations who disseminate research results so that they can tailor the way they disseminate results to patient needs.

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Previous study objectives as of 23/02/2026:
This trial is one of three trials that comprise a sub-study of the Scleroderma Patient-centered Intervention Network – Communicating Latest Evidence and Results (SPIN-CLEAR) series of trials, which was launched to compare the effectiveness of different tools to disseminate research results to study participants and other people with lived experience (PWLE).

This trial will compare a plain-language research summary with a description of PWLE engagement versus a plain-language summary with no mention of PWLE engagement on the perceived relevance and trustworthiness of the research.

Results from this trial will be published in one SPIN-CLEAR Sub-study report comprising all three trials in the sub-study series. Results can be used by researchers and patient organizations who disseminate research results so that they can tailor the way they disseminate results to patient needs.

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Previous study objectives:
Sharing research results with patients is required by ethical regulations. Yet, most researchers do not share results from their studies with patients. The investigators plan to conduct a series of randomized controlled trials among people with scleroderma, a rare autoimmune disease, in a large international cohort, to identify the most effective methods for communicating study results with patients.

The second trial in the series will compare plain-language research summaries with a description of people with lived experience (PWLE) engagement versus plain-language summaries with no mention of PWLE engagement on the perceived relevance and trustworthiness of the research.

Our results can be used by researchers and patient organizations who disseminate research results so that they can tailor the way they disseminate results to patient needs.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/08/2025, CIUSSS West-Central Montreal Research Ethics Board (3755, Chemin de la Côte Ste-Catherine, bureau A-925, Montréal, H3T 1E2, Canada; +1 (0)514 340 8222 ext 22445; cer@jgh.mcgill.ca), ref: 2024-4165

Primary study design
Interventional

Study design
Two-arm parallel-group randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Comparison of research dissemination tools to people living with systemic sclerosis (SSc; scleroderma)

Interventions
Current interventions as of 23/02/2026:

The investigators will use the multinational SPIN Cohort to conduct a series of RCTs to compare tools among people with systemic sclerosis, or scleroderma. This trial in the sub-study series of trials will compare a plain-language research summary with a description of PWLE engagement (Engagement arm) against a plain-language summary with no mention of PWLE engagement (No Engagement arm).

The plain-language summary will be co-created by a research team member experienced in knowledge translation in collaboration and a person with SSc who was engaged in the study being disseminated. The summary will disseminate a study that tested a SSc-specific self-management program.

A template developed and tested by the Patient-Centered Outcomes Research Institute (PCORI) will be utilized to develop the plain-language summary. In the Engagement arm, the plain-

language summary will include a description of PWLE engagement. In the No Engagement arm, the plain-language summary will not mention PWLE engagement. SPIN Cohort participants (n = 1,250 and growing), participants of previous SPIN-CLEAR trials, and participants of a SPIN patient-oriented research event will be invited to enrol, and those enrolled will be randomized to a dissemination tool and complete outcomes.

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Previous interventions:

The investigators will use the multinational Scleroderma Patient-centered Intervention Network (SPIN) Cohort to conduct a series of RCTs to compare tools among people with systemic sclerosis, or scleroderma. The second trial in the series will compare plain-language research summaries with a description of people with lived experience (PWLE) engagement (Engagement arm) against plain-language summaries with no mention of PWLE engagement (No Engagement arm).

Plain-language summaries will be co-created by a research team member experienced in knowledge translation in collaboration and a person with SSc who was engaged in the study being disseminated. We will utilize a template developed and tested by the Patient-Centered Outcomes Research Institute (PCORI) to develop the plain-language summaries. In the Engagement arm, plain-language summaries will include a description of PWLE engagement. In the No Engagement arm, plain-language summaries will not mention PWLE engagement. The three plain-language summaries will describe three recently completed but not yet published SPIN studies with high levels of PWLE engagement across all research stages. PIN Cohort participants (n = 1,250 and growing) will be invited to enrol, and those enrolled will be randomized to a dissemination tool and complete outcomes.

Intervention Type
Behavioural

Primary outcome(s)
1. Relevance of the research: "The information in this plain-language summary is relevant to me". Response options = 0-10 numerical rating scales (0 = strongly disagree, 10 = strongly agree). Time frame: immediately post-intervention (intervention and outcomes in one login - outcomes approx.. 30 min after randomization).
2. Trustworthiness of the research: "I trust that the information in this plain-language summary is accurate and unbiased". Response options = 0-10 numerical rating scales (0 = strongly disagree, 10 = strongly agree). Time frame: immediately post-intervention (intervention and outcomes in one login - outcomes approx.. 30 min after randomization)

Key secondary outcome(s)
1. Information completeness: "The information presented in the plain-language summary told me everything I wanted to know about the study". Response options = 0-10 numerical rating scales (0 = strongly disagree, 10 = strongly agree). Time frame: immediately post-intervention (intervention and outcomes in one login - outcomes approx. 30 min after randomization).
2. Understandability: "The information presented in the plain-language summary was easy to understand". Response options = 0-10 numerical rating scales (0 = strongly disagree, 10 = strongly agree). Time frame: immediately post-intervention (intervention and outcomes in one login - outcomes approx. 30 min after randomization).
3. Pleased to have received results: "I am glad that I received the study results". Response

options = 0-10 numerical rating scales (0 = strongly disagree, 10 = strongly agree). Time frame: immediately post-intervention (intervention and outcomes in one login - outcomes approx. 30 min after randomization).
4. Intention to participate in future studies: “In the future, I would agree to participate in a similar study to the one presented in the plain-language summary”. Response options = 0-10 numerical rating scales (0 = strongly disagree, 10 = strongly agree). Time frame: immediately post-intervention (intervention and outcomes in one login - outcomes approx. 30 min after randomization).

Completion date
27/04/2026

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 23/02/2026:

Eligible participants will include SPIN Cohort participants and others with systemic sclerosis (SSc; also known as scleroderma) who participated in previous SPIN-CLEAR trials or a SPIN online patient-oriented research event.
1. Enrollment in SPIN Cohort, which requires a systemic sclerosis (SSc) classification by a site physician based on 2013 American College of Rheumatology/European League Against Rheumatism criteria, ≥18 years old, being fluent in English or French, and have completed one SPIN Cohort assessment in the last year.
2. External enrollment with patient-reported physician classification of SSc and aged 18 years or older.

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Previous key inclusion criteria:

1. Enrollment in SPIN Cohort, which requires a systemic sclerosis (SSc) classification by a site physician based on 2013 American College of Rheumatology/European League Against Rheumatism criteria, ≥18 years old, being fluent in English or French, and have completed one SPIN Cohort assessment in the last year.
2. External enrollment with patient-reported physician classification of SSc and aged 18 years or older.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit

100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Patients not able to access or respond to questionnaires via the internet

Date of first enrolment
30/03/2026

Date of final enrolment
13/04/2026

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
Montréal
Canada
H3T 1E2

Sponsor information

Organisation
Jewish General Hospital

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, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
All data and materials will be provided upon reasonable requests to the corresponding author, Dr Brett Thombs (brett.thombs@mcgill.ca).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		08/05/2025	27/10/2025	Yes	No
Other files	version 3	16/03/2026	24/03/2026	No	No
Protocol file	version 2.0	16/03/2026	24/03/2026	No	No