Protocol for A Series of Two-Arm Cohort-Based Parallel Randomized Controlled Trials to Evaluate the Effect of Including a Patient and Public Involvement Statement in Plain-Language Summaries on Perceived Relevance and Trustworthiness of Research: A SPIN-CLEAR Trial Series Sub-study

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INTRODUCTION

Engaging people with lived experience (PWLE) in research is emphasized by the Declaration of Helsinki as an important component of ethical research,[1] and major research funders mandate or encourage engagement of PWLE to improve research quality, relevance, and trust in the findings.[2–5] Greater trust in research is thought to increase the likelihood that people will participate in research and use information from research to make healthcare decisions.[6,7]

Engagement of PWLE in research involves collaborative interaction between PWLE and researchers across the research process, where decisions are guided by the experiences, values, and expertise of PWLE.[8] PWLE may engage in research across a continuum from low to high influence on decision-making,[9–12] 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.

A recent review on the advantages and disadvantages of different ways to engage PWLE in research[13] found that most evidence comes from descriptive case reports, interviews with researchers and PWLE who have engaged in research, and expert opinions. Few studies have tested the effects of engaging PWLE on desired outcomes. The review did not identify any studies that tested whether research that describes having engaged PWLE is perceived as more relevant and trustworthy by study participants and other PWLE compared to research that does not. One cluster randomized controlled trial (RCT), embedded in a larger RCT, examined whether including a leaflet advertising PWLE involvement in the primary trial improved participant recruitment.[14] Participants included 38 community mental health teams in the United

Kingdom and their patients with diagnoses of severe mental illness. The PWLE advertising leaflet was not effective in improving recruitment rates; however, the trial demonstrates that PWLE engagement can be implemented and evaluated in trials, with potentially important impacts not yet investigated, such as the perceived relevance of the trial to PWLE.[14]

Plain-language summaries are commonly used for sharing research in an accessible way with PWLE and other members of the public.[15–17] One way to test whether PWLE involvement increases perceived relevance and trustworthiness of research would be to compare perceptions based on plain-language summaries with a description of meaningful PWLE engagement to perceptions based on summaries without such a description.

The primary objective of each of three planned RCTs will be to compare among PWLE the perceived relevance and trustworthiness of research described in plain-language research summaries with a description of meaningful PWLE engagement versus research described in plain-language summaries 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, and intention to participate in future studies. Once the three RCTs are completed, we will synthesize all primary and secondary results from all three trials.

METHODS

Our planned trials comprise a sub-study of the Scleroderma Patient-centered Intervention Network – Communicating Latest Evidence and Results (SPIN-CLEAR) series of trials,[18] which was launched to compare the effectiveness of different tools to disseminate research results to study participants and other PWLE. We will conduct three two-arm parallel group RCTs. For each RCT, participants with systematic sclerosis (SSc)[19,20] will be recruited from the

multinational SPIN Cohort[21], and via contact lists of people who participated in a previous SPIN-CLEAR Trial and participants from an SPIN online patient-oriented research event.[22] In each trial, participants randomly assigned to Engagement or No Engagement trial arms will review a plain-language summary of results from a SPIN research study and rate primary and secondary outcomes. The summaries will be the same in each arm except that the summaries in the Engagement arm will include a description of meaningful PWLE engagement, whereas the summaries in the No Engagement arm will not mention PWLE engagement.

Each of the three trials has been registered in the ISRCTN registry (ISRCTN17218321; ISRCTN55065343; ISRCTN82301860). The protocol follows Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) 2025 Statement reporting recommendations.[23] Appendix Figure 1 provides the planned flow of participants and Appendix Figure 2 the planned schedule of enrollment, intervention, and assessments. Since these trials share common methods with other SPIN-CLEAR trials, we followed reporting guidance from the Text Recycling Research Project[24] in developing the protocol. Results from all three trials from our sub-study on patient and public involvement statements will be reported in a single manuscript, in which we will also include synthesized results from across the three trials.

Setting and Involvement of People with Lived Experience

SPIN was founded in 2011 as a partnership of researchers, healthcare providers, people with the rare autoimmune disease SSc, and SSc patient organizations to study problems prioritized by people with SSc and develop, test, and disseminate accessible programs to address those problems.[19–21,25] People with SSc are involved in SPIN as leaders, collaborators, and consultants. The SPIN Steering Committee includes 11 members who are people with SSc and have oversight and decision-making roles,[26] > 30 people with SSc contribute to project-specific

Advisory Teams,[27] and others help identify needs and priorities via focus groups and surveys.[28] SPIN's Steering Committee prioritized research to more effectively disseminate research results to study participants and others with SSc. We additionally formed a 13-member Patient Engagement Advisory Team that contributes to all SPIN-CLEAR Trials. In the present trial, members participated in determining the research question, outcomes, and specific design elements. They will contribute to results interpretation, article co-authorship, and conference co-presentation.[29,30] SPIN maintains an ongoing cohort, the SPIN Cohort, with > 1300 active English- and French-language participants from 50 centres in five countries (Australia, Canada, France, United Kingdom, United States).[21] Cohorts are increasingly used as flexible infrastructures to conduct multiple trials to respond to evolving patient needs,[31,32] and the SPIN Cohort was developed to support trials, including the present RCT.

Eligible Participants

Eligible participants will include SPIN Cohort participants and others with systemic sclerosis (SSc; also known as scleroderma) who participated in a SPIN online patient-oriented research event. To be eligible for the SPIN Cohort people with SSc must be classified as having SSc based on 2013 American College of Rheumatology / European League Against Rheumatism criteria,[33] confirmed by a SPIN site physician; be aged ≥ 18 years; and be fluent in English, French, or Spanish, although only English- and French-language participants are included in SPIN-CLEAR Trials due to the relatively small number of Spanish-language participants and cost and time involved in translating study materials. SPIN Cohort participants are recruited at SPIN sites during regular medical visits and provide written informed consent. A medical data form is submitted online by the site to enroll participants. Cohort participants complete outcome measures via the internet upon enrollment and then every 3 months.[19] SPIN Cohort enrollment

started in April 2014 and is ongoing. Non-SPIN Cohort participants who participated in the online research event must be aged ≥ 18 years, 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.

Selection of Research to Disseminate and Tools to Compare

We sought reports on research with a high-level of PWLE engagement (e.g., advising, partnering) across all stages of research to disseminate in each trial. In line with the SPIN-CLEAR master protocol for selecting research to disseminate,[18] we initially searched PubMed ("scleroderma OR systemic sclerosis" in title or abstract) for recent publications on SSc research with dedicated sections on PWLE engagement that reported a high-level of engagement across research stages, but we did not identify any such studies apart from SPIN studies that we have already disseminated to SPIN Cohort participants and via social media. This is consistent with findings from our recent meta-research review that identified very few examples of reported PWLE engagement in rheumatology journals for studies among people with any rheumatic condition.[34] Thus, we selected three recently completed SPIN studies with high levels of PWLE engagement across all research stages that have not yet been published or shared with study participants. Trial 1 will disseminate a study that tested a SSc-specific self-management program[35], Trial 2 a study that evaluated sources and characteristics of pain in SSc[36], and Trial 3 a study that evaluated course and factors associated with itch.[37,38] These studies were initially identified as candidates by SPIN researchers then selected via consultation and consensus with the SPIN-CLEAR Research Selection Committee, which includes four people with SSc and three SSc researchers or healthcare providers.[18]

SPIN-CLEAR Trials compare different dissemination tools or tool variations. The SPIN-CLEAR Dissemination Tool Committee (4 people with SSc, 3 researchers) approved testing the effects of describing PWLE engagement in plain-language summaries.

Engagement and No Engagement Plain-Language Summaries

To develop the core content of the three plain-language summaries, which will be the same in the Engagement and No Engagement trial arms, we will utilize a template developed and tested by the Patient-Centered Outcomes Research Institute (PCORI).[15] Sections of each summary will include (1) What was the research about? (2) What were the results? (3) Who was in the study? (4) What did the research team do? (5) What were the limits of the study? and (6) How can people use the results? Consistent with PCORI guidance,[15,39] the core content of the summaries will be (1) < 500 words; use short, positive, active-voice sentence structures and everyday words; (2) maintain reading level between 8th and 9th grade based on Flesch–Kincaid Grade Level, and (3) have a readability score between 60 and 70 based on Flesch Reading Ease.[40,41] For the Engagement arm plain-language summaries, we will add an additional section, (7) How were people with scleroderma involved in the research team?

Each of the three 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. Each PWLE-researcher dyad will meet via Zoom to review the study and identify key elements to disseminate, including components of interest to people with SSc, and create a key elements page. After the meeting, the researcher will use the key elements page to draft two versions of the three plain-language summaries; version one of each plain-language summary will include descriptions of meaningful PWLE engagement (Engagement arm), whereas version two will not mention PWLE engagement (No Engagement arm). We will

follow a user-centered design approach[42] and target content to people with high school education or less. Plain-language summary prototypes will be reviewed by the PWLE partner and researcher and agreed-upon versions will be presented to SPIN's Steering Committee for review. The committee will either (1) approve without changes, (2) approve conditionally with requests for certain changes, or (3) state any major concerns and request changes. Modifications will be made where necessary and prototypes sent back to the Steering Committee for review until approval is reached. The plain-language summaries will be developed in English and translated to French by two research team members who are native French speakers.

In each trial, participants will login to a *Qualtrics* online survey and be randomized to the Engagement or No Engagement trial arms, where they will be asked to review a plain-language summary and rate outcomes. We estimate that participants will require between 5 and 10 minutes to read and review a plain-language summary and we will record this.

Trial Outcomes and Measures

Team members, including researchers and PWLE, reviewed outcomes used in previous knowledge translation trials and selected outcomes for the SPIN-CLEAR Trial series. The two primary outcomes in each planned RCT will include relevance of the research ("The information in this plain-language summary is relevant to me") and trust in the results ("I trust that the information in this plain-language summary is accurate and unbiased"). Each item will be measured on a 0-10 numerical rating scale (0 = *strongly disagree*, 10 = *strongly agree*). Secondary outcomes will include other outcomes used in all SPIN-CLEAR Trials, including (1) information completeness ("The information presented in the plain-language summary told me everything I wanted to know about the study"), (2) understandability ("The information presented in the plain-language summary was easy to understand"), (3) whether participants

were pleased to have received results ("I am glad that I received the study results"), and (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"), all rated on 0-10 numerical rating scales (0 = *strongly disagree*, 10 = *strongly agree*).

Similar outcome items were used in a previous trial from the United Kingdom,[43] and only minimal wording modifications were made based on input from members of the Patient Engagement Advisory Team. However, we will use 0-10 numerical rating scales rather 5-level ordinal items to more precisely differentiate participant experiences.[44,45] Single-item outcomes have been shown to perform equivalently to multi-item outcome measures with reduced burden to participants when constructs being assessed are unidimensional, clearly defined, and narrow in scope, as is the case with our outcomes.[46–48]

Items to rate outcomes will be presented to trial participants following the plain-language summary on a *Qualtrics* online survey platform. There will not be any limits on how many times participants can access the plain-language summary prior to responding to the outcome measurements. We will send email reminders to participants who have consented but have 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.

Trial outcome data will be linked to sociodemographic, medical, and health literacy data that has been collected via the SPIN Cohort, as part of a previous SPIN-CLEAR Trial, or as part of SPIN's recent online patient-oriented research event. We have linked in this way with 100% linking success in previous trials.[48–50]

Sample Size

We are interested in estimating magnitudes of differences between plain-language summaries with descriptions of PWLE engagement to plain-language summaries without this description on two primary criteria (relevance of research and trust in results). We will not be testing a single universal null hypothesis in each trial that there are no differences between groups or determining whether descriptions of PWLE are generally "effective". Rather, we intend to describe possible effects on each primary outcome. Thus, we have powered the trial per comparison between arms without adjusting for multiple primary outcomes.[51–54] For each comparison between two trial arms, for an assumed effect size of standardized mean difference (SMD) = 0.50, and a 2-tailed test with a = 0.05, N = 128 (64 participants per arm) would be needed for ≥ 80% power.[55] We assumed an effect size of SMD = 0.50 because there are no established minimal important differences for our outcome variables, and an SMD = 0.50 has been found to estimate minimal important differences reasonably well in many studies.[56,57] If we assume a SMD of 0.25 under the same conditions, N = 506 (253 participants per arm) would be needed for ≥ 80% power.

The number of eligible participants we anticipate enrolling exceeds our estimate. As of August 12, 2025, the SPIN Cohort included 1,531 participants eligible for the trials. If we assume a participation rate of at least 60% among active SPIN Cohort participants, this would result in 918 trial participants. The 60% is less than what we have obtained in other SPIN questionnaire-based sub-studies (65% to 85%, calculated out of participants who completed recent assessments, as in the proposed trials),[58–60] even though those studies required 45 to 90 minutes to complete, which is substantially longer than the time required to participate these trials.

Recruitment

An advantage of trials conducted in cohorts is that the trial sample has been recruited prior to initiating trials.[31,32,49,61,62] SPIN Cohort participants, upon cohort enrollment, provide consent to be contacted about participation in sub-studies and provide permission to use their data for trials, even if they do not participate, which will allow us to compare participants and non-participants.

In each trial, SPIN Cohort participants and non-SPIN Cohort participants who participated in a previous SPIN-CLEAR Trial or an online patient-oriented research event[22] will be emailed an invitation to participate. Information in the invitation email will include brief text describing the topic of the study being shared and a Qualtrics survey link. By clicking on the Qualtrics survey link, potential trial participants will be taken to a page where they can view the study consent form and consent or decline to participate. People who consent will be randomized to receive a plain-language summary that includes a description of PWLE engagement in the research (Engagement arm) or a plain-language summary without this description (No Engagement arm).

Recruitment emails and reminders will be sent to potential participants who have not yet completed the consent form at 7 days and 11 days after the initial invitation email. The trial will be closed to enrollment 14 days after sending the initial invitation email.

Randomization

In each trial, participants who login to Qualtrics and consent will be immediately and automatically randomized via Qualtrics to the Engagement arm or No Engagement arm.[63] The Qualtrics system does not allow SPIN researchers to see who joins the trial and when, and participants are allocated immediately upon consent, which will ensure complete allocation concealment. For each trial, Qualtrics will be programmed to direct each participant to

Engagement or No Engagement arm pages depending on their random assignment. Eligible participants may participate in multiple trials. The randomization process will be done independently in each trial. Participants who participate in multiple trials could, as a result be in the Engagement arm in one or more trials and the No Engagement arm in other trials.

Blinding and Protecting Against Sources of Bias

Since randomization and allocation will occur immediately and automatically upon consent in Qualtrics, we will have complete allocation concealment. Trial participants will consent to evaluate plain-language summaries without being informed that this is being done via a randomized trial, so they will be blind to study comparisons and hypotheses. They will not interact with any study personnel during the trial, except in rare instance where technical assistance may be needed. We will lock access to tool links once outcomes are completed to discourage sharing tools and crossover between trial arms. We will use intent-to-treat analyses with multiple imputation to reduce risk of bias from missing data and will control for key baseline demographic and other variables (e.g., health literacy) to account for possible imbalances between trial arms. It is possible that participants who are randomized to different trial arms in different trials could notice that the plain-language summary in one or more trials includes a statement on PWLE engagement whereas another does not. Since they are not, though, aware that they are evaluating the plain-language summaries as part of a comparative trial, we believe that there is minimal risk that this would influence results.

Data Collection and Management

Informed consent and data collection will be done via the Qualtrics survey platform. To ensure accuracy and linkage to SPIN Cohort data for SPIN Cohort enrollees, an email authentication check will ensure that emails entered match eligible SPIN Cohort participant

emails. Data security measures in place at Qualtrics are described in the Qualtrics security statement.[64]

The SPIN Cohort uses a secure electronic data management platform designed and managed by the Information Management Services of the Centre for Clinical Epidemiology, Jewish General Hospital, Montréal. All information obtained from participants during the trials will be treated confidentially within the limits of the law. To protect the privacy of participants, a unique participant identification number has been automatically assigned to each participant (SPIN Cohort identification numbers for Cohort participants and trial identification numbers for external participants).

During the trials, access to the trial database will be limited to study investigators. Once the trials end and results are reported, anonymized data will be made available upon reasonable request. No biological specimens will be collected.

Data Analysis

For each of the three trials and across the three trials, we will compare participants by trial arm on sociodemographic and clinical characteristics via descriptive statistics. For each primary (relevance of the research, trustworthiness of the results) and secondary outcome measure (information completeness, understandability, satisfaction with receiving results, likelihood of enrolling in a similar future study), we will (1) conduct analyses separately in each trial and then (2) synthesize analyses across trials.

For analyses conducted in each individual trial, the primary analysis will use a linear regression model, using trial arms as allocated (intent-to-treat) (lm function in R[65]). In these analyses, we will adjust for pre-specified covariates based on the PROGRESS-Plus

framework,[66,67] including gender, age (continuous), and health literacy as measured with the HLS19-Q12 (continuous).

To synthesize results comparing Engagement versus No Engagement conditions across trials, the primary analysis will use a linear mixed effects model, which will account for multiple observations for participants who participate in multiple trials (lmer function from the lme4 package[68] in R[65]). To account for variability in outcomes between participants, we will fit a random intercept by participant. Participants in multiple trials may be assigned to different arms in each trial. To account for differences in outcomes between trial arms within participants in multiple trials, we will evaluate whether we should also include a random slope by comparing fit and residual errors between random intercept and random slope models. As in the analyses done separately for each trial, we will adjust for pre-specified covariates based on the PROGRESS-Plus framework,[66,67] including gender, age (continuous), and health literacy as measured with the HLS19-Q12 (continuous). To account for potential clustering of outcomes within each trial, we will also include a fixed effect for trial.

For analyses of each trial and synthesized across trials, we will use multiple imputation by chained equations (mice package in R[69], 20 imputed datasets, 15 cycles per dataset) to account for missing data, which we expect to be minimal. Pooled standard errors and 95% confidence intervals will be estimated using Rubin's rules.[70] Based on PROGRESS-Plus, [66,67] we will perform subgroup analyses in each trial and synthesized across trials by gender (women, men, other if sufficient number of participants), age (18-44 years, 45-64 years, ≥ 65 years), country and language (Canada – English, Canada – French, 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).[71] We will use the Instrument to assess the Credibility of Effect Modification Analyses criteria to evaluate subgroup effect credibility.[72]

The Statistical Analysis Plan is shown in Appendix Material 1.

TRIAL COORDINATION AND DATA MONITORING

The trials will be coordinated by the SPIN Team in Montréal, Canada. The SPIN Steering Committee and trial investigators will oversee the trials. The SPIN Director (Dr. Thombs) and trial investigators will be responsible for monitoring data quality and protocol execution. The SPIN Steering Committee will be updated on progress and outcomes. These groups are independent from trial funders.

RISKS AND POTENTIAL BENEFITS

We do not anticipate any serious risks or safety concerns associated with participating in the trials. The only possible harm we identified is that being informed of study results may lead to disappointment if the results are not as hoped.[7] Nonetheless, any reported adverse events will be recorded, and where necessary, the event will be discussed with clinical team members and a referral to one of SPIN's healthcare professionals will be made. Any serious adverse events will be reported to the Research Ethics Board of the Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal.

Possible benefits from participation in the trials include learning about new SSc research in a format designed for people living with SSc and being able to contribute to research. There will be no financial compensation for participants in the trials.

ETHICS AND DISSEMINATION

The SPIN Cohort was approved by the Research Ethics Board of the Jewish General Hospital, Montréal (#12-123), and by ethics committees of each recruiting site. The SPIN-

CLEAR series of trials has been approved by the Research Ethics Board of the Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal (#2024-4165). All participants will provide electronic consent via Qualtrics prior to participating in the trials. Any modifications to the protocol, which may impact the conduct of the study, including changes of study objectives, study design, eligible participants, sample sizes, study procedures, or significant administrative aspects, will undergo a formal amendment to the protocol. Any such amendment will be submitted to the research ethics committee for approval and documented in the trial's registration.

Each of the three trials were registered on the ISRCTN registry (ISRCTN17218321; ISRCTN55065343; ISRCTN82301860) and will be reported as per the Consolidated Standards for Reporting Trials (CONSORT) statement,[73] relevant CONSORT extensions,[31,51,74,75] and Template for Intervention Description and Replication guidance for reporting interventions.[76] There are no reporting guidelines for trials of patient and public dissemination tools to share research results, but we will refer to Standards for UNiversal reporting of patient Decision Aid Evaluation studies guidelines[77] for evaluations of patient decision aids and incorporate relevant items.

Our findings will inform others who disseminate research to study participants and others with relevant lived experience, including researchers and patient organizations, research ethics committees who monitor ethical obligations for sharing research results, and funding agencies.

KNOWLEDGE MOBILIZATION

The SPIN-CLEAR Knowledge Mobilization Plan is shown in Appendix Material 2. The Plan describes (1) how we incorporated integrated knowledge translation into our planned series of trials; (2) our target audiences and how tools to use our findings will be developed; and (3)

what we hope to achieve and how we will monitor success. We actively engaged patients and stakeholder partners in our project planning and plan to engage them in conduct and dissemination of these trials and the SPIN-CLEAR trial series. Our strategy includes multiple dissemination tools tailored to different target audiences: scientific publications, patient organizations news articles, patient-oriented tools (e.g., infographics, website), and conferences including patient-researcher co-presentation.[30] To monitor the effectiveness of our knowledge mobilization, we will track publication citations, hits on the SPIN-CLEAR website that will have information about our series of trials including results and implementation resources, and document the number of conference presentations and invited presentations and how many people attended each.

DISCUSSION

Engagement of PWLE is emphasized as an important component of ethical research[1] and is encouraged or mandated by major funding agencies.[2–5] Engaging PWLE in research is widely considered to improve research quality, relevance, and trust that the findings should be used for healthcare decision-making.[7,78–80] These determinations, however, are largely based on anecdotal evidence from patients and researchers who have experience working together and experts in patient-engaged research,[13] but they have not been empirically tested. This series of trials will investigate whether including a description of PWLE engagement in plain-language summaries contributes to greater perceived relevance and trustworthiness of research among PWLE.

There are limitations to consider related to our proposed trials. This will be the first trial series to test outcomes of including descriptions of PWLE engagement in plain-language summaries. Our findings will be directly applicable to people with SSc and their carers, as well as SSc clinicians, researchers, and patient organizations. Results will be indirectly applicable to

other patient populations and in other areas of health-related research to inform PWLE engagement and research dissemination practices. We will carefully outline limitations and any constraints on the generalizability of our findings in publications.

Trial Status

This is protocol version #3, finalized on March 16, 2026. Participant recruitment and enrollment in the trials have not begun. We anticipate initiating recruitment for the first trial in March 2026.

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