

## **APPENDIX MATERIAL**

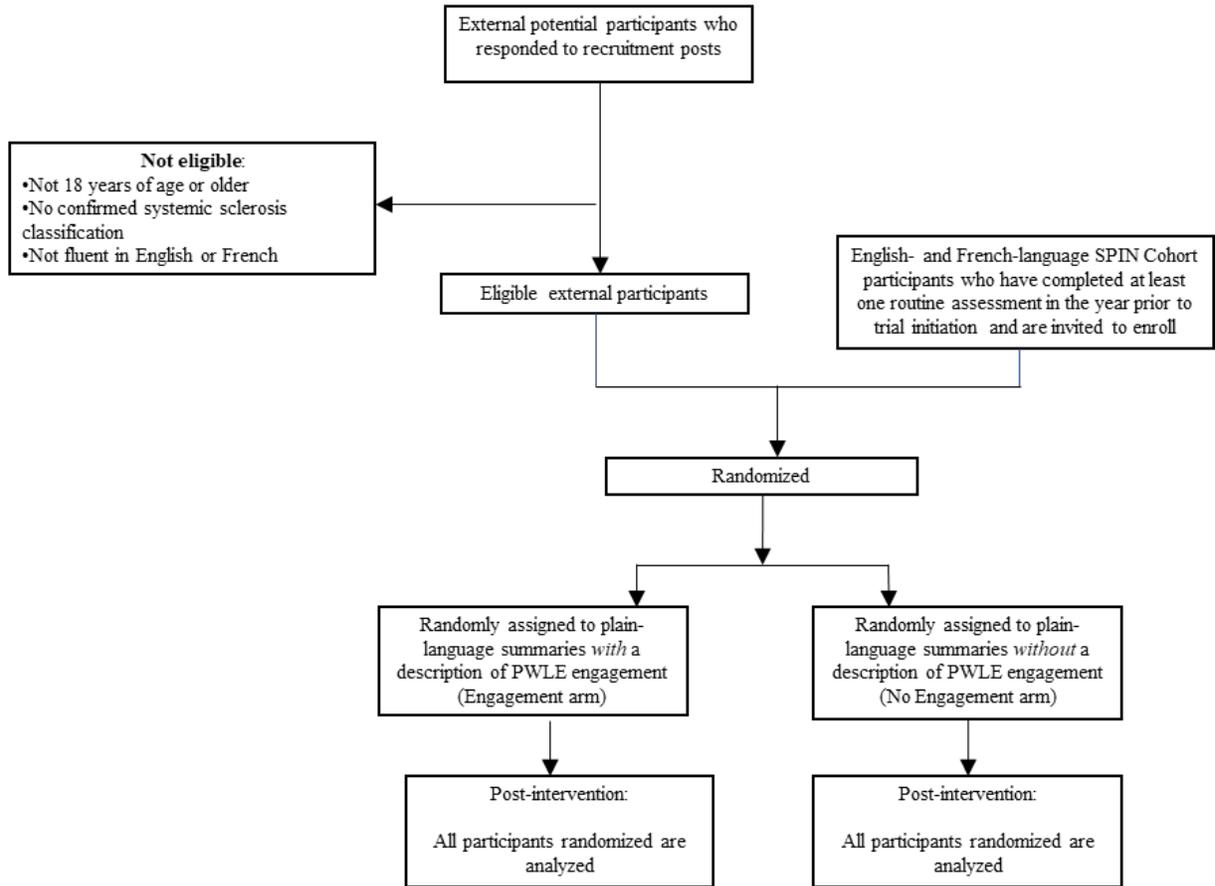
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## Appendix Figure 1. Planned Flow of Participants



Note. PWLE = People with lived experience

**Appendix Figure 2.** Planned Schedule of Enrollment, Intervention, and Assessments

	<b>Enrollment</b>	<b>Allocation</b>	<b>Post-allocation</b>	
<b>TIMEPOINT</b>	<b>Pre-trial</b>		<b>Plain-language Summary Access</b>	<b>Post-Plain- language Summary Access</b>
<b>ENROLMENT:</b>				
<b>Eligibility screen</b>	X			
<b>Informed consent</b>	X			
<b>Randomization and Allocation</b>		X		
<b>SPIN-CLEAR COMMUNICATION TOOL ACCESS:</b>				
<b>Plain-language summary: Engagement arm</b>			X	
<b>Plain-language summary: No Engagement arm</b>			X	
<b>TRIAL ASSESSMENTS:</b>				
<b>Demographics* (age, sex, education, relationship status, living situation, employment)</b>	X			
<b>Primary outcomes (relevance of the research, trust in the results)</b>				X
<b>Secondary outcomes (information completeness, understandability, whether participants were pleased to have received results, intention to participate in future studies)</b>				X

\*Only for non-SPIN Cohort participants. SPIN Cohort participant data will be obtained from the most recent cohort data.

**Appendix Material 1: Statistical Analysis Plan (SAP) for the Scleroderma Patient-Centered Intervention Network – Communicating Latest Evidence and Results (SPIN-CLEAR) Trial #2**

**ADMINISTRATIVE INFORMATION**

**Registered at:** <https://www.isrctn.com/ISRCTN17218321>

**SPIN-CLEAR master protocol available at:** <https://doi.org/10.1186/s13063-025-08846-2>

**SAP Version 2 (2026-02-19):**

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This SAP was drafted by Meira Golberg. All other contributors provided input and reviewed and approved the final version. Dr. Andrea Benedetti is the senior statistician responsible for the integrity of all analyses. Dr. Brett Thombs is the principal investigator and clinical lead.

## **SAP Version 2 (2026-02-19)**

### **Study Design**

These trials will be conducted as part of the Scleroderma Patient-centered Intervention Network – Communicating Latest Evidence and Results (SPIN-CLEAR) series of trials.<sup>1</sup> The SPIN-CLEAR Trials are a series of parallel-arm, randomized controlled trials (RCTs) undertaken to conduct comparative effectiveness trials of tools to disseminate research results to study participants and other people with relevant lived experience (PWLE). Eligible participants will be randomized into trial arms via Qualtrics (1:1 allocation) using simple randomization. In each trial, participants in both the Engagement and No Engagement trial arms will review a plain-language summary of results from a research study and rate primary and secondary outcomes. The summaries in the Engagement arm will include a description of meaningful PWLE engagement, whereas the summaries in the No Engagement arm will not.

### **Study Outcomes**

The primary outcome analyses will compare participants' ratings of 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") with response options 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*). Subgroup differences in all primary and secondary outcomes based on participants’ characteristics (age, country, language, education level, health literacy) will also be considered.

Items were adapted from the Show RESPECT trial<sup>2</sup> with minimal wording modifications based on input of members of the Patient Engagement Advisory Team.

### **Recruitment and Eligibility**

To be eligible for the SPIN Cohort, patients must be classified as having systemic sclerosis (SSc) based on 2013 American College of Rheumatology / European League Against Rheumatism criteria,<sup>3</sup> confirmed by a SPIN physician; be  $\geq 18$  years old; and be fluent in English, French, or Spanish, although only English- and French-language participants will be included in SPIN-CLEAR trials due to the relatively small number of Spanish-language participants and cost and time involved in translating study materials. All SPIN Cohort participants who have completed a SPIN assessment in the year prior to trial initiation are eligible for participation. Non-SPIN Cohort participants who participated in a previous SPIN-CLEAR trial or a SPIN online patient-oriented research event must be aged  $\geq 18$  years, confirm that they have been classified as having SSc by a physician, and be fluent in English or French.

All SPIN Cohort participants provide consent to be contacted about participation in sub-studies when they are enrolled. They also provide permission to use their data for trials even if they do not participate. Eligible SPIN Cohort participants and non-SPIN Cohort participants who participated in a previous SPIN-CLEAR Trial or SPIN online research event 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. In each trial, 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 reminders will be sent to participants who have not yet completed the consent form at 7 days and 11 days after the initial invitation email. Each trial will be closed to enrollment 14 days after sending the initial invitation email.

### **Sample Size**

This study will employ a comparative effectiveness framework. 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), but we are not testing a single universal null hypothesis per trial that there are no differences between any groups or determining, simply, if a description of PWLE engagement achieves an overall effect. Thus, we have designed each comparison between trial arms to have sufficient statistical power on its own, without adjusting for the total number of arms in the trial, and we will analyze each of our primary outcomes independently without adjusting for multiple comparisons.<sup>4-7</sup>

For each comparison between two trial arms, for an assumed effect size between plain-language summaries with a description of PWLE engagement and those without this description of standardized mean difference (SMD) = 0.50, and a 2-tailed test with  $\alpha = 0.05$ ,  $N = 128$  (64 participants per arm) would be needed for  $\geq 80\%$  power.<sup>8</sup> 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.<sup>9,10</sup> Our sample size estimate does not consider increases in power from adjustments for prognostic covariates.<sup>11-13</sup>

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 and no new recruitment, this would result in 918 trial participants. We believe that this is a conservative power and sample size estimate. All previous SPIN questionnaire-based sub-studies have had participation rates higher than 60% (65% to 85%, calculated out of participants who completed recent assessments, as in proposed trials), even though these studies required 45 to 90 minutes to complete, which is substantially longer than the time required to participate in a SPIN-CLEAR trial.<sup>12,14,15</sup>

### **Data Preparation and Analysis**

#### 1. Descriptive Analyses:

- By arm we will compare sociodemographic characteristics for each trial based on the PROGRESS-PLUS framework,<sup>16,17</sup> as well as SSc disease characteristics, and health literacy measured with the Health Literacy Scale<sub>19-12</sub> Item Questionnaire (HLS<sub>19-Q12</sub>).<sup>18</sup>

<b>Variable</b>	<b>Plain-language summary with a description of PWLE engagement (Engagement arm)</b>	<b>Plain-language summary with no mention of PWLE engagement (No Engagement arm)</b>
<b>Demographic</b>		
Female sex, N (%)		
Gender, N (%)		
Woman		
Man		
Other		
Age in years, mean (SD)		
Race or ethnicity, N (%)		
White		
Black		
Other		
Education in years, mean (SD)		
Above high school education (versus below), N (%)		
Married or living as married (versus single), N (%)		
Working full-time or part-time, N (%)		
Country and Language, N (%)		
Canada, English		
Canada, French		
France		
United Kingdom		
United States		
Years since first non-Raynaud's symptoms, mean (SD)		
Disease subtype, N (%)		
Diffuse		
Limited or sine		
Health Literacy Scale <sub>19-12</sub> score, mean (SD)		

PWLE = people with lived experience; N = number of participants; SD = standard deviation.

2. Items to rate outcomes will be presented to trial participants immediately following the dissemination of research results via the plain-language summary on a Qualtrics online survey tool page. Each item represents a primary or secondary outcome and is measured on a 0-10 numerical scale, with a higher score indicating a higher level of agreement with each item. Data collection will be ongoing for each trial from the day participants consent to 14 days later, at which time the Qualtrics online survey will be closed.

All analyses will be conducted in R<sup>19</sup>, and will be 2-sided, using an alpha value of 0.05.

There will be no adjustment for the multiplicity of outcomes.

For the primary outcome analyses, we will use an intent-to-treat analysis that compares all participants as allocated. The primary analysis method for evaluating differences in participant scores across outcome measures will be a linear regression model, treating 0-10 numerical outcome variables as continuous. For all models, we will adjust for pre-specified covariates included in the PROGRESS-Plus framework,<sup>16,17</sup> including age (continuous),<sup>20-22</sup> gender,<sup>20-22</sup> and health literacy measured with the HLS<sub>19</sub>-Q12 (continuous).<sup>18</sup> We will report estimates and 95% confidence intervals for predictors and covariates in all models.

Data loss will occur if participants consent to participate in the trial and do not complete outcomes. However, in recent SPIN trials, follow-up over periods up to 6 months was > 90%.<sup>23,24</sup> Thus, we believe that loss will be minimal in this 15-minute trial, but we will account for any missing data by using multiple imputation. Multiple imputation will be done with chained equations, using the mice package.<sup>25</sup> We will generate 20 imputed datasets,

using 15 cycles per dataset. Variables in the mice procedure will include: trial arm, all primary and secondary outcomes, age, gender (woman vs. man, other), years of education, country and language (Canada – English, Canada – French, France, United Kingdom, United States, other), housing location (city, suburb, or town/village), married or living as married vs. single, work status (employed vs. not employed), race or ethnicity (White, Black, other), all SSc disease characteristics, and health literacy score. Pooled standard errors and associated confidence intervals will be estimated using Rubin’s rules.<sup>26</sup>

3. In secondary analysis, we will perform subgroup analyses stratified by age (18-44 years, 45-64 years,  $\geq 65$  years), gender (woman, man, other if sufficient number of participants), country and language (Canada – English, Canada – French, France, United Kingdom, United States, other), education level ( $\leq 12$  years,  $> 12$  years), and health literacy (HLS19-Q12, recommended cut-off at 66.67 out of 100 for “Sufficient” or “Excellent” health literacy versus “Problematic” or “Inadequate”).<sup>18</sup> We will apply the primary analysis method within each subgroup category. We will additionally test for subgroup effects by adding the subgroup variable, if not already included as a covariate, and subgroup variable x trial arm interaction term in the model specified as in the primary analysis method. We will use the Instrument to assess the Credibility of Effect Modification Analyses criteria to evaluate the credibility of subgroup effects.<sup>27</sup>
4. Analyses of secondary outcomes will apply the same methods as used for primary outcomes.

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## **Appendix Material 2. Knowledge Mobilization Plan**

Our knowledge mobilization plan describes (1) how we incorporated integrated knowledge translation into our research plan; (2) our target audiences and how tools for end-of-grant dissemination will be tailored; and (3) what we hope to achieve from our knowledge mobilization and how we will monitor success.

### **INTEGRATED KNOWLEDGE MOBILIZATION**

Integrated knowledge mobilization requires that knowledge users are part of the research team and participate in the planning, conduct, interpretation, and dissemination of research.

People who will use and benefit from our proposed research include (1) people with lived experience (PWLE), including those who contribute to research as participants or partners, and others in the broader community with relevant lived experience; (2) individuals and organizations who disseminate research results to PWLE, including trialists, knowledge mobilization researchers, other researchers and patient organizations; and (3) members of institutions that require or support researchers to disseminate research results to PWLE, including research ethics committee leadership and staff and funding agency personnel.

Our Scleroderma Patient-centered Intervention Network (SPIN) is a true PWLE-researcher partnership. People with systemic sclerosis (SSc; scleroderma) are involved in organizational oversight, goal setting, project prioritization, allocation of funding, and individual project oversight. Steering Committee members, including 11 people with SSc, prioritized research to more effectively disseminate research results to study participants and others with SSc, and we received a Canadian Institutes of Health Research Project Grant to support this.

The 13 members of our Patient Engagement Advisory Team are embedded in the research team and worked with researchers to define research questions; develop our approach;

and select outcomes. They will have key decision-making roles and contribute to selecting research to share, dissemination tool development, interpretation of research findings, and dissemination of results, including article co-authorship and co-presentation at patient conferences. Other key knowledge users who have been involved in proposal development and will be involved throughout the planned research include clinical trialists who disseminate their results to participants, patient organization leaders (including several members of our Patient Engagement Advisory Team plus other organizational partners) whose organizations disseminate research results to people with SSc, and a research ethics specialist who is involved in requiring and supporting researchers to disseminate results. We will continue to meet with all knowledge users in committees and in regular full research team quarterly meetings.

## **TARGET AUDIENCES AND END-OF-GRANT DISSEMINATION**

Table 1 shows our targeted audiences (people with SSc, patient organizations, trialists and other researchers who disseminate results, knowledge mobilization researchers, research ethics committees, funding agencies) for end-of-grant dissemination and tools that we will use to mobilize knowledge. Multiple approaches for dissemination will be used for each target audience.

**Study website (all users):** We will create a website that will have information about our series of trials, including results and implementation resources. Separate tabs will be designed for different users. Each page will incorporate multiple media (e.g., videos, infographics, plain-language summary) targeted to the specific users.

**Scientific journal articles and conference presentations (researchers, ethics committees, funding agencies):** In addition to publishing a protocol for the trial series, we will publish a trial report for each trial and an article that provides guidance on selection and development of

patient-oriented dissemination tools. We also plan to publish a living systematic review on the effectiveness of tools for disseminating research results to people with lived experience and the broader community. We will target journals that focus on clinical trials, ethics, rare diseases and rheumatology. We will also present our results at conferences focused on clinical trials, ethics, rheumatology, rare diseases, and scleroderma.

**News articles (people with SSc, patient organizations):** SPIN regularly provides bulletin material for our patient organization partners, where we will share the results of each trial.

**Patient dissemination tools (people with SSc, patient organizations):** We will use tools tested in our trials to disseminate results to study participants and other PWLE via email and social media. SPIN has over 2,000 Facebook and 700 Twitter followers, and several of our recent posts have been viewed over 5,800 times each, a very large number in a rare-disease context.

**Toolkits (patient organizations, researchers, ethics committees, funding agencies):** We will develop short, downloadable toolkits that incorporate evidence from our trials to help knowledge users select and develop tools for their dissemination plans. We will post these on our website, share with patient organization partners, provide as part of our workshops, and publish in our planned scientific article on selecting and developing patient dissemination tools.

**Patient conferences (people with SSc, patient organizations):** We will present the results from the trials at North American (e.g., Scleroderma Canada; National Scleroderma Foundation) and global scleroderma (e.g., World Scleroderma Foundation) and rare disease conferences (e.g., Canadian Organization for Rare Disorders), as well as at provincial meetings, and we will develop patient-tailored presentations for these venues.

**Educational workshops (patient organizations, researchers, ethics committees, funding agencies):** We will provide training workshops at professional conferences and online, which we have done successfully previously.

**Patient-oriented workshops (people with SSc):** At patient-oriented conferences and online in collaboration with our patient organization partners, we will provide training for patients who wish to gain expertise in working with researchers to translate findings into accessible and understandable patient tools.

## **KNOWLEDGE MOBILIZATION GOALS AND MONITORING**

Our research and knowledge mobilization plan may lead to increased dissemination of research results to PWLE, and we will update audits that team members have conducted to evaluate this (e.g., Raza et al., *BMJ Open*, 2020). We believe our research will provide knowledge that will allow us to support other researchers to embed similar trials of patient dissemination tools within their trials to expand knowledge to different settings and populations.

We will evaluate if there is an increase in trials on patient dissemination tools by tracking trials registered and published. To monitor influence on science, we will track citations to our publications. To monitor how many people are using our material, we will track hits on our study website and on links to news articles and patient dissemination tools that we create. Educating people who disseminate to patients and institutions that support this (e.g., ethics committees, funding agencies) is an important goal, and we will document how many people attend our workshops and how many relevant funding organizations (e.g., CIHR, Arthritis Society) refer to our material in their guidance. There are no evidence-based criteria for determining whether knowledge mobilization has reached a threshold for success. Rather, we will integrate different components into an overall program evaluation.

**Table 1. Target Audience and Dissemination Tools**

DISSEMINATION TOOLS	AUDIENCE					
	PWLE	Patient Organizations	Trialists and Other Researchers	Knowledge Mobilization Researchers	Research Ethics Committees	Funding Agencies
<b>Written and Visual</b>						
Study website with pages targeted to different audiences	✓	✓	✓	✓	✓	✓
Scientific journal articles: individual trial results			✓	✓	✓	✓
Scientific journal articles: synthesis of trial results and other trial evidence			✓	✓	✓	✓
Scientific journal articles: guidance on dissemination tool selection and development			✓	✓	✓	✓
News articles – social media, email, patient organization partners	✓	✓				
Infographics – social media, email, patient organization partners	✓	✓				
Plain-language summaries – social media, email, patient organization partners	✓	✓				
Toolkit for selecting and developing research dissemination tools for people with SSc		✓	✓	✓	✓	✓
<b>Primarily Oral with Graphical Tools</b>						
Scientific conference presentations			✓	✓	✓	✓
Patient-oriented conference presentations	✓	✓				
<b>Interactive</b>						
Educational workshops		✓	✓	✓	✓	✓
Patient-oriented workshops	✓					

PWLE = people with lived experience.