Trials

STUDY PROTOCOL

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Master protocol for a series of cohort-based randomized controlled trials to test tools to communicate research results to study participants and others with relevant lived experience: the SPIN-CLEAR Trials

Brett D. Thombs[1,2,3,4,5*], Claire Adams[1,2], Elsa-Lynn Nassar[1,5], Marie-Eve Carrier[1], Meira Golberg[1], Kanika Bharthi[1], Amanda Wurz[6], Annabelle South[7], Linda Kwakkenbos[8,9,10], Sabrina Hoa[11], Danielle B. Rice[12,13], Geneviève Guillot[14], Amanda Lawrie-Jones[15], Maureen Sauvé[16], Susan J. Bartlett[4,17], Catherine Fortune[18], Amy Gietzen[19], Karen Gottesman[20], Marie Hudson[1,4], Laura K. Hummers[21], Vanessa L. Malcarne[22,23], Maureen D. Mayes[24], Michelle Richard[25], James Stempel[26], Robyn K. Wojeck[27], Kathleen Blagrave[28], Jill T. Boruff[29], Vanessa Cook[1], Nicole Culos-Reed[30], Ole Fröbert[31,32], Katie Gillies[33], Vera Granikov[34], Lars G. Hemkens[35,36], Elizabeth Yakes Jimenez[37], Agnes Kocher[38], Catarina Leite[39], Mathew A. W. T. Lim[40], Nancy Maltez[41], John Michalski[42], Tracy Mieszczak[43], Mwidimi Ndosi[44,45], Janet Pope[46], François Rannou[47,48], Ken Rozee[25], Sharon E. Straus[49], Matthew R. Sydes[7,50], Lehana Thabane[51], John Varga[52], Tami Yap[40], Merrick Zwarenstein[53], Luc Mouthon[54,55] and Andrea Benedetti[3,4,56] on behalf of SPIN Investigators

Abstract

Background Research results are often not communicated to study participants or others with relevant lived experience. Effective communication of research results would help study participants understand their contribution to research and could improve trust in research and likelihood of research participation. Few randomized controlled trials (RCTs), however, have compared the effectiveness of research communication tools, and it is not known which tools work best for different people. We will conduct the Scleroderma Patient-centered Intervention Network—Communicating Latest Evidence and Results (SPIN-CLEAR) trial series via the multi-national SPIN Cohort to compare tool effectiveness. Primary objectives of each RCT will be to compare tools based on (1) information completeness, (2) understandability, and (3) ease of use. We will additionally evaluate comprehension of key aspects of disseminated research; likelihood that participants would enroll in a similar future study; and, for all primary and secondary outcomes, outcomes by participant characteristics (gender, age, race or ethnicity, country, language, education level, health literacy).

Methods An advisory team of people with systemic sclerosis (SSc, also known as scleroderma) participated in developing research questions, selecting outcomes, and designing the series of parallel-arm RCTs that will each compare

*Correspondence:
Brett D. Thombs
brett.thombs@mcgill.ca
Full list of author information is available at the end of the article

two or more tools or tool variations to a plain-language summary comparator; the common comparator will facilitate across-trial comparisons. In each RCT, people with SSc and researchers will select a recent SSc research study to disseminate. Tools will be developed by experienced tool developers and people with SSc. SPIN Cohort participants (current *N* eligible = 1522 from 50 SPIN sites in Australia, Canada, France, UK, USA) and additional participants recruited via social media and patient organization partners who consent to participate will be randomized to a dissemination tool or plain-language summary comparator and complete outcomes. Analyses will be intent-to-treat and use linear regression models.

Discussion Each trial in the planned series of trials will build upon knowledge from previous trials. Results will contribute to the evidence base on how to best disseminate results to study participants and others with relevant lived experience.

Trial registration ClinicalTrials.gov NCT06373263. Registered on April 17, 2024 (first trial in series).

Keywords Knowledge translation, Patient engagement, Patient and public involvement, Patient-oriented research, Randomized controlled trials, Research dissemination, Scleroderma, Systemic sclerosis

Introduction

Many people participate in research, despite burdens involved [1, 2], because of a desire to help others [3], and most participants want to learn results [4–6]. Despite this, research results from many studies are not communicated to study participants or others with relevant lived experience [7–10]. Sharing research results in an accessible manner would help study participants understand how their participation contributes to science and benefits others and could also help build trust in research, increase likelihood of research participation, and support people with medical conditions to be more knowledgeable partners in their health care [5, 7, 11].

Examples of tools that have been used to share research results with study participants include plain-language summaries, news articles, infographics, comics, podcasts, and videos [4, 12, 13]. Effective communication of results requires evidence on dissemination tools or aspects of tools that most effectively (1) provide information study participants and others with relevant lived experience want to know, (2) in an understandable way, and (3) in an easy-to-use format [4]. Evidence on sharing research results, however, comes predominantly from surveys on how study participants would like to learn about research or ratings of experience with a tool. There are few direct tool comparisons [8]. No systematic review has synthesized evidence from randomized controlled trials (RCTs) of tool comparisons.

A 2021 scoping review on dissemination of results to participants in phase III pragmatic trials [8] included only one RCT, a 2019 trial from the UK [14] that randomly assigned 101 participants in a hypothyroidism intervention trial to a plain-language summary (N= 38 analyzed) or standard press release (N= 31 analyzed) with no differences in understanding results. We identified two additional trials. A 2018 trial from Croatia randomized 212 women from pregnancy and parenting consumer groups to receive a plain-language summary (N= 54 analyzed) or infographic (N= 45 analyzed) on breech delivery methods; there was no difference in knowledge obtained, but participants rated the infographic higher on reading experience and user friendliness [15]. A 2021 trial from the UK [4] evaluated outcomes reported by 180 participants (of 275 randomized) from an ovarian cancer chemotherapy trial randomized factorially to receive (1) an invitation to be sent emailed results or not, (2) a mailed summary or not, and (3) access to a basic or enhanced webpage. Receiving a mailed summary was the only approach associated with greater satisfaction. Other RCTs [16–18] have compared research dissemination tools but have used study samples for which the knowledge was not directly relevant (e.g., evidence on headache treatments in a general practice population without headache concerns [18]).

The Scleroderma Patient-centered Intervention Network (SPIN) [19–22] is a collaboration of researchers, clinicians, and people with systemic sclerosis (SSc; also known as scleroderma). SSc is a rare, chronic, autoimmune connective tissue disease that can affect multiple organ systems and cause immune dysfunction and vascular injury [23]. SPIN maintains an ongoing cohort [19–22] with >1500 active participants from 50 centers in 5 countries (Australia, Canada, France, UK, USA) who complete patient-reported outcomes in English or French every 3 months via the internet and participate in additional sub-studies, including questionnaire-based studies and RCTs. Cohorts are increasingly used as flexible infrastructures to conduct multiple trials to respond to evolving patient needs [24–26]. Conducting a series of trials on research communication tools in the SPIN Cohort will allow us to include a large number of participants, learn from each trial, and incorporate learning into increasingly refined and informative subsequent trials.

The SPIN—Communicating Latest Evidence and Results (SPIN-CLEAR) trial series will contribute to building an evidence base of comparative effectiveness trials of tools to disseminate research results to study participants and others with relevant lived experience. Each trial will compare one or more dissemination tools to a plain-language summary. Primary outcomes, which were prioritized by people with SSc, will include (1) information completeness, (2) understandability, and (3) ease of use of the dissemination tool. In each trial, we will also evaluate comprehension of key aspects of disseminated research; likelihood participants would enroll in a similar future study; 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).

Methods

Study design

We will conduct a series of trials. We have been funded for 8 trials, but additional trials could be conducted depending on scientific and funding considerations. Each trial will be a parallel-arm superiority trial with block randomization by combined language and country of randomization (Canada—English, Canada—French, France, UK, USA, other country) with equal allocation across arms within each block. Each trial will include two or more arms with dissemination tools or tool variations arms and a plain-language summary comparator arm. Having a common comparator will facilitate indirect comparisons across trials.

In each trial, SPIN Cohort participants and additional participants recruited via social media and patient organization partners will receive an email that invites them to participate in the trial, and those who consent will be randomized to receive one of the dissemination tools or the plain-language summary comparator. Trial outcome data for SPIN Cohort participants will be linked deterministically via email addresses to SPIN Cohort demographic data, medical data, and other variables (e.g., health literacy) that are routinely collected in SPIN Cohort assessments; these variables will be collected during each trial from externally enrolled participants through Qualtrics. SPIN has received funding to conduct eight RCTs over a 4-year period.

Each SPIN-CLEAR trial will be registered, and the first SPIN-CLEAR trial has been registered in ClinicalTrials.gov (NCT06373263). The trial series protocol follows Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) 2013 Statement reporting recommendations [27]. All items from the World Health Organization trial registration data set are available as Additional file 1, and the SPIRIT checklist of recommended items to address in a clinical trial protocol is available as Additional file 2. The participant consent form is provided in Additional file 3.

Figure 1 provides the planned flow of participants and Fig. 2 the planned schedule of enrollment, intervention, and assessments for each SPIN-CLEAR trial.

Trial setting and involvement of people with lived experience

SPIN was founded in 2011 as a partnership of researchers, health care providers, people with SSc, and SSc patient organizations to study problems prioritized by people with SSc and develop, test, and disseminate accessible programs to address those problems. The SPIN Cohort [19–22] supports observational studies and cohort-based RCTs [26, 28, 29]. People with SSc are involved in SPIN as leaders, collaborators, and consultants. Eight Steering Committee members who are people with SSc have oversight and decision-making roles [30], > 30 people with SSc contribute to project-specific Advisory Teams [31], and others help identify needs and priorities via focus groups and surveys [32]. SPIN's Steering Committee prioritized research to more effectively disseminate research results to study participants and others with SSc. We formed a 13-member Patient Engagement Advisory Team, and members participated in determining research questions, selecting an approach to testing dissemination tools, and choosing and refining outcomes. In all planned trials, they will contribute to selecting research to share and tools to test, results interpretation, article co-authorship, and conference co-presentation [33, 34].

Eligible participants

Eligible participants will include all active SPIN Cohort participants or external participants who meet SPIN Cohort eligibility criteria. 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 [35], 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 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. 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. All active SPIN Cohort participants who have

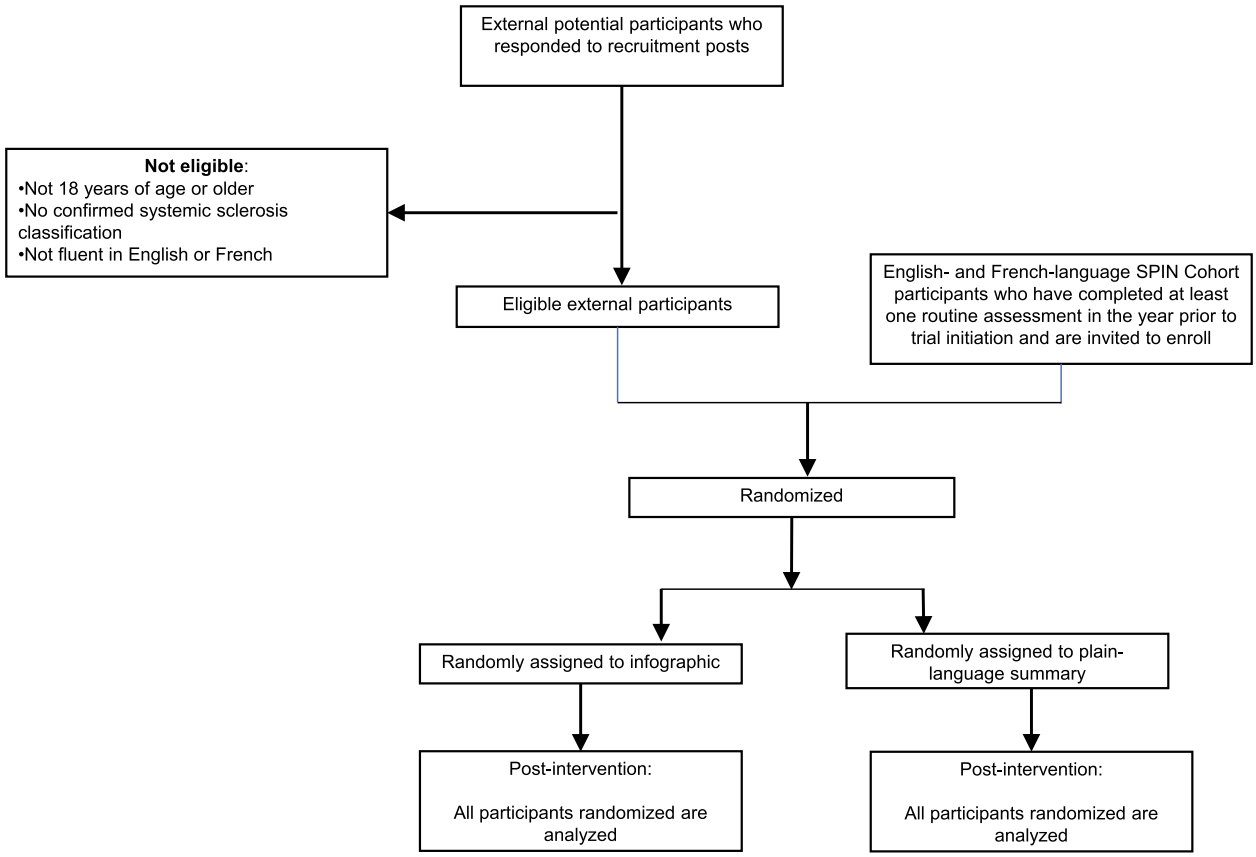

Fig. 1 Trial flow diagram

completed at least one regular quarterly SPIN assessment in the year prior to trial initiation will be eligible. Non-SPIN Cohort participants who are recruited via social media or patient organization partners 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.

Prior to each trial: selecting research to disseminate and tools to test

Selecting research to disseminate

Prior to each trial, we will select a primary human research study or systematic review on SSc disease processes, epidemiology, treatments, or clinical care. To identify a study, we will search PubMed ("scleroderma OR systemic sclerosis" in title or abstract) via DistillerSR [36]. Two team members with lived experience of having SSc will independently review citations and select up to 10 they perceive to be of high interest to people with SSc. Two researchers will review selected citations for methodological quality, and studies of high interest and adequate quality will be reviewed by the SPIN-CLEAR Research Selection Committee. The Research Selection Committee will include 4 people with SSc and 3 researchers or health care providers and will select a study to disseminate for each trial via consensus.

Selecting dissemination tools to test

Prior to each trial, a Dissemination Tool Selection Committee (4 people with SSc, 3 researchers) will review evidence from SPIN-CLEAR trials and other trials to select tools for testing, focusing on evidence on (1) information completeness, (2) understandability, and (3) ease of use. The committee will select tools by discussion and consensus and make a recommendation to the larger research team. For our initial trial, we will test an infographic against a plain-language summary comparator, which was determined via consensus by SPIN-CLEAR investigators, including people with SSc, researchers, and health care professionals.

Development of dissemination tools

Each dissemination tool, including plain-language summaries, will be co-created by an experienced tool developer in consultation with a person with SSc and

	Enrollment	Allocation	Post-allocation	
TIMEPOINT	**Pre-trial**		**Communication Tool Access**	**Post-Communication Tool Access**
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
Randomization and Allocation		X		
SPIN-CLEAR COMMUNICATION TOOL ACCESS:				
One or more non-lay summary tools			X	
Lay summary comparator			X	
TRIAL ASSESSMENTS:				
Demographics* (age, sex, education, relationship status, living situation, employment)	X			
Primary outcomes (information completeness, understandability, ease of use)				X
Secondary outcomes (whether participants were pleased to have received results, intention to participate in future studies)				X

Fig. 2 Schedule of enrollment, interventions, and assessments

a researcher. Each tool in a trial will be created by a separate team. Prior to initiating tool development, two researchers who are knowledgeable about SSc will review the study to be disseminated, identify key elements, including components of interest to people with SSc, and create a key elements page that will be used by tool developers to ensure that the same main elements are communicated across tools. Tool prototypes will be developed following a user-centered design approach [37] and targeted to people with high school education or less. Prototypes will be presented to SPIN's Steering Committee, which includes people with SSc and researchers, 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.

Usability testing of tools

For each tool, we will recruit people with SSc via social media who are as diverse as possible with respect to country, language (English and French), race or ethnicity, gender, age, education level, and health literacy to participate in usability testing. People who participate in usability testing will, individually, review the tool and complete the System Usability Scale (SUS), a widely used standardized 10-item measure designed to assess perceived usability [38]. The SUS has been validated and applied to assess usability of educational interventions, written products, and in knowledge translation [39–41]. A strength of the SUS is that its items can be adapted via minor word changes to fit different classes of products or aspects of individual products; measure performance is robust with these adaptations [38, 42]. We, thus, modified several items to fit our purpose of assessing the usability of knowledge translation tools (see Additional file 4).

Once participants have completed the SUS, we will hold a follow-up discussion group with all participants involved in usability testing via Zoom that will be facilitated by two research team members. The discussion group will be semi-structured and focused around the SUS items. We will also ask brief open-ended questions to elicit further feedback, including "What would you change about this tool?" and "Do you have any other suggestions for us?." A summary of SUS responses and meeting notes from the discussion group will be provided to tool developers, and any necessary revisions will be made to the tool. People involved in usability testing will not participate in the trials as participants.

Menu of dissemination tools to consider for testing

Our menu of possible dissemination tools to test in each trial will include infographics, news articles, comics, podcasts, short videos, and study-specific websites [4, 12–14]. Any additional dissemination approaches identified during our study will also be considered. Tool variations may include the presenter (e.g., person with SSc, researcher, both together), information highlighted, or complexity level, for instance.

*Infographics*use engaging visuals intended to communicate complex evidence-based information in an attractive and user-friendly format [43–46]. We will develop infographics based on key principles including clearly defining the audience and purpose; sharing a story with brief, clear messaging; highlighting main ideas; using an attractive title and images; and following evidence-based graphic design principles [43–46].

*News style articles*are the most common format for disseminating research results outside of academic dissemination [47], including by SSc patient organizations. We will work with a university media relations team to develop news articles, following key recommendations for development, including length of 300 to 400 words [48, 49].

*Comics*are increasingly used to communicate research findings [12, 50, 51]. We will work with an artist who has developed comics for SPIN patient education material and will incorporate recommendations on using comics to disseminate research [50, 51].

*Podcasts*are audio-only programs on a specific topic. We will develop short (5 to 10 min) podcasts that may be delivered by health professionals, people with SSc, or health professionals and people with SSc together in monolog, interview, or discussion formats, following advice from experienced medical education podcasters [52, 53].

Videos. Short (3 to 5 min) videos will be like podcasts in delivery options and can additionally use documentary style formats. We will work with a professional videographer who has produced SPIN videos previously.

Study-specific webpage. Similar to a previous trial [4], a simple webpage would include multiple components, including infographic-type material, a "Frequently Asked Questions" section, and a short video.

Plain-language summary comparator arm

In all trials, the comparator will be a plain-language summary, since plain-language summaries are considered a "standard" dissemination tool and are commonly used. They are intended to provide a brief, easily understood overview [54–56]. We will utilize a template developed and tested for the United States Patient-centered Outcome Research Institute (PCORI) [56]. Sections 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 [56, 57], our summaries will be < 500 words; use short, positive, active-voice sentence structures and everyday words; and maintain reading level between 8 and 9 th grade based on Flesch–Kincaid Grade Level [58], and readability score between 60 and 70 based on Flesch Reading Ease [59]. Summaries will be reviewed based on a checklist that we developed from best-practice recommendations [54–56, 60].

Trial outcomes and measures

Team members with lived experience of having SSc met to review outcomes used in previous knowledge translation trials and encouraged the use of 3 primary outcomes: (1) mean information completeness score ("The information presented in the [tool – e.g., 'infographic', 'plain-language summary'] told me everything I wanted to know about the study"), (2) mean understandability score ("The information presented in the [tool] was easy to understand"), and (3) mean ease of use score ("The [tool] was designed in a way that made it easy to use"), all of which will be assessed with 0–10 numerical rating scales (0 = *strongly disagree*, 10 = *strongly agree*) [4].

Secondary outcomes will include (1) whether participants were pleased to have received results ("I am glad that I received the study results") and (2) intention to participate in future studies ("In the future, I would agree to participate in a similar study to the one presented in the [tool]"), all rated on 0–10 numerical rating scales (0 = *strongly disagree*, 10 = *strongly agree*) [4]. Open-ended items will include "What did you like about the way the information was communicated?," "What did you dislike about the way the information was communicated?," and "How could we improve the way the information is

communicated?." Resources used and cost of developing each tool will be tracked.

Similar outcome items were used in a previous trial from the UK [4]. We made minimal wording modifications based on input from members of the Patient Engagement Advisory Team, and we will use 0–10 numerical rating scales rather 4-level ordinal items to more precisely differentiate participant experiences [61, 62]. 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 [63–65], as is the case with our outcomes. Pearson correlations between items in the trial from the UK [4] were between 0.40 and 0.61, suggesting reasonable convergence but that they measure different constructs. There was a satisfactory distribution of responses across item response levels for all items.

Items to rate outcomes will be presented to trial participants following the dissemination tool or plain-language summary on a *Qualtrics* online survey platform. We estimate that participants will require between 5 and 15 min to review dissemination tools, and we will record this. There will not be any limits on how many times participants can access the tools prior to responding to the outcome measurements. We will send email and text 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 [26, 28, 66]. Sociodemographic and medical data will be collected directly in each trial survey from non-SPIN participants.

Sample size

We are interested in estimating magnitudes of differences between tools within and across trials and in characterizing and comparing tools on 3 criteria. We will not be testing a single universal null hypothesis per trial that there are no differences between any groups or determining which tool is, simply, better for all people. Thus, we have powered trials per comparison between arms without adjusting for multiple trial arms and will not adjust for multiple primary outcomes [67–70]. For each comparison between two trial arms, for an assumed effect size of standardized mean difference (SMD) = 0.5, a two-tailed test with $\alpha = 0.05$, $N = 128$ (64 per arm) provides ≥ 80% power. To accommodate three trial arms under the same assumptions, we would need an estimated total sample size of $N = 192$ [71]. We assumed an effect size of SMD = 0.50 because there is no established meaningful important difference (MID) for our outcome variables, and an SMD = 0.50 has been found to estimate MIDs reasonably well in many studies [72, 73]. Sample size estimates do not consider expected increases in power from adjustments for prognostic covariates [74–76].

In all scenarios, the number of eligible participants we anticipate enrolling is enough to support 3 parallel trial arms. As of August 12, 2024, the SPIN Cohort included 1522 participants eligible for the proposed trials. If we assume a participation rate of at least 60% among active SPIN Cohort participants without any new participants or sites, this would result in 913 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) [77–79], even though those studies required 45 to 90 min to complete, which is substantially longer than the time required to participate in a SPIN-CLEAR trial. Recruitment of trial participants among people with SSc external to the SPIN Cohort, via social media and patient organization partners, will further increase the number of participants.

Recruitment

An advantage of trials conducted in cohorts is that the trial sample has been recruited prior to initiating trials [24–26, 80, 81]. 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.

One month prior to the start of the first trial, eligible SPIN Cohort participants will be informed of the launch of the *SPIN Scleroderma Research News*, an e-newsletter for people with SSc about scleroderma research. A notice will also be placed on SPIN's social media and disseminated by SPIN patient organization partners promoting the newsletter to people who are not in the SPIN Cohort and encouraging people to request to receive it by clicking on a Qualtrics survey link, where they will be asked to provide their name and email address.

At each trial start date, eligible SPIN Cohort and external participants will be invited by email to access the most recent edition of *SPIN Scleroderma Research News* and participate in the study. Information in the invitation email will include brief text describing the topic of the scleroderma 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.

Recruitment emails and text 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.

Randomization

In each trial, participants who login to Qualtrics and consent will be immediately and automatically randomized via Qualtrics using block randomization by country and language (Canada—English, Canada—French, France, UK, USA, other country) to research dissemination tool or plain-language summary comparator trial arms [82]. We will use block sizes of 2 with the "Evenly Present Elements" in Qualtrics. Small block sizes or the awareness of block sizes can lead to bias due to their affect on allocation concealment, making it easier to predict upcoming allocations [83]. This is no risk of this in the SPIN-CLEAR trials. Recruitment emails will be sent to all SPIN Cohort participants at once, 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. Qualtrics will be programmed to immediately direct each participant to the dissemination tool or plain-language summary to which they have been randomly assigned.

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 research dissemination tools 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 brief trials, 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.

Biases can occur due to "allegiances" when researchers are invested in the interventions they are testing (e.g., a specific psychotherapy approach). To protect against this, we will use separate developers for each tool being tested, will employ best-practice methods in tool development, and will centrally review all tools. None of the tool developers with our team is associated with or have an allegiance with any tool that we envision testing.

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. External trial participants will provide sociodemographic and medical data following consent to each trial, as we have done previously [26]. Data security measures in place at Qualtrics are described in the Qualtrics security statement [84].

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, Montreal. All information obtained from participants during the trial 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 SPIN-CLEAR identification numbers for external participants).

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

Data analysis

For each trial, we will compare participants by trial arm on sociodemographic and clinical characteristics using descriptive statistics. The primary analysis method for evaluating trial outcomes will be a linear regression model, using trial arms as allocated (intent-to-treat). In all models, we will adjust for pre-specified covariates that are included in the PROGRESS-Plus framework [85, 86], including gender, age, and health literacy, as measured by the Health Literacy $Scale_{19}$–12 Item Questionnaire (HLS_{19}-Q12) [87]. All covariates, including health literacy scores, are routinely collected in the SPIN Cohort and will be collected at trial enrollment for non-SPIN Cohort participants. Multiple imputation by chained equations (mice package in R, 20 imputed datasets, 15 cycles per imputed dataset) will be used to account for missing data [88], which we expect to be minimal. Pooled standard errors and 95% confidence intervals will be estimated using Rubin's rules [89]. Analyses will be conducted once per trial, after the close of the 14-day trial period.

Based on PROGRESS-Plus [85, 86], we will perform subgroup analyses stratified by age (current $N=$ 651 for 18–44 years, $N=$ 1673 for 45–64 years, $N=$ 695 for ≥65 years), gender (current $N=$ 2592 woman, $N=$ 384 man, $N=$ 26 other), country (current $N\geq$ 335 for Canada, France, USA), language ($N=$ 837 for English, $N=$ 685 for French), education level ($N=$ 360 ≤12 years, 1043 >12 years), and health literacy (HLS_{19}-Q12, recommended cut-off at 66.67 out of 100 for "Sufficient" or "Excellent" health literacy versus "Problematic" or "Inadequate"; *N*to be determined as data are being collected) [87]. Models in each subgroup stratum will be specified consistent with the primary analysis method. We will additionally test for subgroup effects by adding the subgroup variable, if not already included as a covariate, to the primary analysis model plus a subgroup variable ×dissemination tool interaction term. We will use the Instrument to assess the Credibility of Effect Modification Analyses (ICEMAN) criteria to evaluate the credibility of subgroup effects [90].

The Statistical Analysis Plan for the first planned trial is shown in Additional file 5.

Trial coordination and data monitoring

The trials will be coordinated by the SPIN Team in Montreal, Canada. The SPIN Steering Committee and trial investigators will oversee each trial. The SPIN Director and trial investigators will be responsible for routine monitoring of data quality and RCT protocol execution. The SPIN Steering Committee will be updated on the progress of each trial. These groups are independent from trial sponsors.

Risks and potential benefits

We do not anticipate any serious risks or safety concerns associated with participating in SPIN-CLEAR trials. The only possible harm we identified is that being informed of research results may lead to disappointment if the results are not as hoped [8]. We will not query participants about any specific harms. Nonetheless, any reported adverse event that is reported by participants to researchers will be recorded, and when necessary, the event will be discussed with clinical members of the team and a referral to SPIN's health care professionals from the relevant recruiting site will be made. Any serious adverse events that occur will also 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 with lived SSc experience 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, Montreal (#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 trial. 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.

All trials will be registered prior to initiation and reported per the Consolidated Standards for Reporting Trials (CONSORT) statement [91], relevant CONSORT extensions [25, 67, 92, 93], and Template for Intervention Description and Replication guidance for reporting interventions [94]. There are no reporting guidelines for trials of tools to disseminate research to study participants and others with relevant lived experience, but we will refer to Standards for UNiversal reporting of patient Decision Aid Evaluation studies guidelines [95] 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. Our Knowledge Mobilization Plan (see Additional file 6) 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 and how we will monitor success.

All research team members, including people with lived experience, who meet International Committee of Medical Journal Editors authorship criteria will be included as authors of manuscripts that result from our planned trials. Authorship order will be determined based on contributions to each trial. Manuscripts will be drafted by team members involved in the trials. No external professional writers will be involved.

Discussion

Research ethics guidance mandates that study results be shared with participants [96–100], and knowledge translation strategies from major funding agencies emphasize dissemination to others with relevant lived

experiences [11, 101, 102]. Yet, most researchers do not share results with patients, and we do not know which dissemination tools or tool features best facilitate effective communication. We were able to identify only 3 RCTs [4, 14, 15] that have compared tool effectiveness among study participants or other invested knowledge users, and none assessed which tools work best for which patients. Comparative effectiveness trials are needed to build an evidence base to help us understand what tools are most effective for communicating different types of research to different patients. We will use the multinational SPIN Cohort to conduct a series of RCTs to compare tools among people with SSc.

There are limitations to consider related to our proposed trials. No single trial or series of trials will generate results that are generalizable to all types of studies or populations. Our results will easily generalize to other SSc research settings and to other autoimmune rheumatic disease populations. They will also inform, indirectly, other research settings and populations. Conducting repeated trials in the same population, as we will do, is both a strength and a limitation. It is a strength because, in the context of a limited evidence base, it will allow us to hold the population relatively constant for our tool comparisons. It is a potential limitation because specific characteristics of the population will be present across evaluations, and this will need to be considered and described carefully as we accumulate and disseminate results.

Our planned series of trials represents a novel approach to studying how best to communicate research results. It will substantially augment the overall evidence base on communicating research results to study participants and others with relevant lived experience.

Trial status

This is protocol version #1, finalized on January 31, 2025. Recruitment and enrollment for the first trial has not begun. We anticipate initiating recruitment for the first trial in our planned series in February 2025. Recruitment for each trial will last approximately 2 weeks.

Abbreviations

CONSORT	Consolidated Standards for Reporting Trials
MID	Meaningful important difference
PCORI	United States Patient-centered Outcome Research Institute
RCT	Randomized controlled trials
SMD	Standardized mean difference
SPIN	Scleroderma Patient-centered Intervention Network
SPIN-CLEAR	Scleroderma Patient-centered Intervention Network—Communicating Latest Evidence and Results
SPIRIT	Standard Protocol Items Recommendations for Interventional Trials
SSc	Systemic sclerosis

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-025-08846-2.

Additional file 1.

Additional file 2. SPIRIT checklist for Trials.

Additional file 3. Consent form.

Additional file 4.

Additional file 5. Statistical Analysis Plan.

Additional file 6. Knowledge Mobilization Plan.

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CHU Rangueil, Toulouse, France; Christelle Nguyen, Université Paris Descartes, Université de Paris, Paris, France, and Assistance Publique—Hôpitaux de Paris, Paris, France; Karen Nielsen, Scleroderma Society of Ontario, Hamilton, Ontario, Canada; Mandana Nikpour, St Vincent's Hospital and University of Melbourne, Melbourne, Victoria, Australia; Louis Olagne, Centre Hospitalier Universitaire Gabriel-Montpied, Clermont-Ferrand, France; Vincent Poindron, Les Hôpitaux Universitaires de Strasbourg, Nouvel Hôpital Civil, Strasbourg, France; Susanna Proudman, Royal Adelaide Hospital and University of Adelaide, Adelaide, South Australia, Australia; Grégory Pugnet, CHU Rangueil, Toulouse, France; Loïc Raffray, CHU La Réunion, Saint-Denis, La Réunion, France; Alexis Régent, Assistance Publique—Hôpitaux de Paris, Hôpital Cochin, Paris, France; Frederic Renou, CHU La Réunion, Saint-Denis, La Réunion, France; Sébastien Rivière, Assistance Publique—Hôpitaux de Paris, Hôpital St-Antoine, Paris, France; David Robinson, University of Manitoba, Winnipeg, Manitoba, Canada; Esther Rodríguez Almazar, Servicio de Reumatologia del Hospital 12 de Octubre, Madrid, Spain; Tatiana Sofia Rodríguez-Reyna, Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Mexico City, Mexico; Sophie Roux, Université de Sherbrooke, Sherbrooke, Quebec, Canada; Perrine Smets, Centre Hospitalier Universitaire Gabriel-Montpied, Clermont-Ferrand, France; Vincent Sobanski, Centre Hospitalier Régional Universitaire de Lille, Hôpital Claude Huriez, Lille, France; Robert F. Spiera, Hospital for Special Surgery, New York City, NY, USA; Virginia Steen, Georgetown University, Washington, DC, USA; Evelyn Sutton, Dalhousie University, Halifax, Nova Scotia, Canada; Carter Thorne, Southlake Regional Health Centre, Newmarket, Ontario, Canada; Damien Wagner, CHU La Réunion, Saint-Denis, La Réunion, France; Pearce Wilcox, St. Paul's Hospital and University of British Columbia, Vancouver, British Columbia, Canada; Mara Cañedo Ayala, Jewish General Hospital, Montreal, Quebec, Canada; Cassidy Dal Santo, Jewish General Hospital, Montreal, Quebec; Tiffany Dal Santo, Jewish General Hospital, Montreal, Quebec; Monica D'Onofrio, Jewish General Hospital, Montreal, Quebec; Sophie Hu, Jewish General Hospital, Montreal, Quebec, Canada; Marieke Alexandra Neyer, Jewish General Hospital, Montreal, Quebec, Canada.

Authors' contributions
All authors were responsible for study conception and design and will be responsible for implementation of the trial or acquisition, analysis, and interpretation of trial data. BDT drafted the initial version of the protocol manuscript along with CA, MEC, MG, KBharthi, and AB. All authors provided a critical review and approved the final manuscript for submission. BDT is the guarantor.

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Data availability
All data and materials will be provided upon reasonable requests to the corresponding author.

Declarations

Ethics approval and consent to participate
The SPIN Cohort was approved by the Research Ethics Committee of the Jewish General Hospital, Montreal (JGH REC Protocol #12–123), and by ethics committees of each recruiting site. The SPIN-CLEAR trial was approved by the Research Ethics Committee 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 study.

Consent for publication
Not applicable.

Competing interests
All authors declare that they have no competing interests.

Author details
[1]Lady Davis Institute of the Jewish General Hospital, 3755 Côte-Sainte-Catherine Road, Montreal, QC H4.83H3 T 1E2, Canada. [2]Department of Psychiatry, McGill University, Montreal, QC, Canada. [3]Department of Epidemiology, Biostatistics, and Occupational Health, McGill University, Montreal, QC, Canada. [4]Department of Medicine, McGill University, Montreal, QC, Canada. [5]Department of Psychology, McGill University, Montreal, QC, Canada. [6]School of Kinesiology, University of the Fraser Valley, Chilliwack, BC, Canada. [7]MRC Clinical Trials Unit at UCL, Institute of Clinical Trials and Methodology, University College London, London, UK. [8]Department of Clinical Psychology, Behavioural Science Institute, Radboud University, Nijmegen, the Netherlands. [9]Department of IQ Healthcare, Radboud University Medical Center, Nijmegen, the Netherlands. [10]Centre for Mindfulness, Department of Psychiatry, Radboud University Medical Center, Nijmegen, the Netherlands. [11]Division of Rheumatology, Université de Montréal, Centre Hospitalier de L, Montreal, QC, Canada. [12]Department of Psychology, St Joseph's Healthcare Hamilton, Hamilton, ON, Canada. [13]Department of Psychiatry & Behavioural Neurosciences, McMaster University, Hamilton, ON, Canada. [14]Sclérodermie Québec, Longueuil, QC, Canada. [15]Scleroderma Australia and Scleroderma Victoria, Melbourne, VIC, Australia. [16]Scleroderma Society of Ontario and Scleroderma Canada, Hamilton, ON, Canada. [17]Research Instituteof the, McGill University Health Centre, Montreal, QC, Canada. [18]Ottawa Scleroderma Support Group, Ottawa, ON, Canada. [19]National Scleroderma Foundation, Tri-State Chapter, Buffalo, NY, USA. [20]National Scleroderma Foundation, Los Angeles, CA, USA. [21]Johns Hopkins University School of Medicine, Baltimore, MD, USA. [22]San Diego State University, San Diego, CA, USA. [23]San Diego Joint Doctoral Program in Clinical Psychology, San Diego State Universityand, University of California, San Diego, CA, USA. [24]University of Texas McGovern School of Medicine, Houston, TX, USA. [25]Scleroderma Atlantic, Halifax, NS, Canada. [26]Scleroderma Chicago, Chicago, IL, USA. [27]Amgen Inc, Thousand Oaks, CA, USA. [28]Research Ethics Board, Centre Intégré Universitaire de Santé Et de Services Sociaux du Centre-Ouest-de-L'Île-de-Montréal, Montreal, QC, Canada. [29]Schulich Library of Physical Sciences, Life Sciences, and Engineering, McGill University, Montreal, QC, Canada. [30]Faculty of Kinesiology, University of Calgary, Calgary, AB, Canada. [31]Department of Cardiology, Orebro University Hospital, Orebro, Sweden. [32]Department of Clinical Medicine, Faculty of Health, Aarhus University, Aarhus, Denmark. [33]Aberdeen Centre for Evaluation, University of Aberdeen, Aberdeen, UK. [34]Centre de Recherche du Centre Hospitalier de L, Université de Montréal, Montreal, QC, Canada. [35]Pragmatic Evidence Lab, Research Center for Clinical Neuroimmunology and Neuroscience Basel, University of Basel and University Hospital Basel, Basel, Switzerland. [36]Department of Clinical Research, University of Basel and University Hospital Basel, Basel, Switzerland. [37]College of Population Health, University of New Mexico Health Sciences Center, Albuquerque, NM, USA. [38]Institute of Nursing Science, University of Basel, Basel, Switzerland. [39]University of Minho, Braga, Portugal. [40]Melbourne Dental School, University of Melbourne, Carlton, Melbourne, VIC, Australia. [41]Department of Rheumatology, Ottawa Hospital, Ottawa, ON, Canada. [42]National Scleroderma Foundation, Michigan Chapter, Detroit, MI, USA. [43]Scleroderma Support Group, Rochester, NY, USA. [44]School of Health and Social Wellbeing, University of the West of England, Bristol, UK. [45]Academic Rheumatology Unit, University Hospitals Bristol and Weston, National Health Service Foundation Trust, Bristol, UK. [46]Division of Rheumatology, St Joseph's Hospital, Western University, London, ON, Canada. [47]Université Paris Descartes, Université de Paris, Paris, France. [48]Paris, France. [49]Knowledge Translation Program, Li Ka Shing Knowledge Institute of St. Michael's Hospital, University of Toronto, Toronto, ON, Canada. [50]British Heart Foundation Data Science Centre, Health Data Research UK, London, UK. [51]Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, ON, Canada. [52]Division of Rheumatology, Department of Internal Medicine, University of Michigan, Ann Arbor, MI, USA. [53]Centre for Studies in Family Medicine, Department of Family Medicine, Schulich School of Medicine & Dentistry, University of Western Ontario, London,

ON, Canada. [54]Service de Médecine Interne, Centre de Référence Maladies Autoimmunes Et Autoinflammatoires Systémiques Rares d'Ile de France, de l', Est Et de L'Ouest, Hôpital Cochin, Paris, France. [55]Assistance Publique Hôpitaux de Paris-Centre, Hôpital Cochin, Université Paris Cité, Paris, France. [56]Respiratory Epidemiology and Clinical Research Unit, McGill University Health Centre, Montreal, QC, Canada.

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References

1. Naidoo N, Nguyen VT, Ravaud P, Young B, Amiel P, Schanté D, et al. The research burden of randomized controlled trial participation: a systematic thematic synthesis of qualitative evidence. BMC Med. 2020;18(1):6. https://doi.org/10.1186/s12916-019-1476-5.
2. Lingler JH, Schmidt KL, Gentry AL, Hu L, Terhorst LA. A new measure of research participant burden: brief report. J Empir Res Hum Res Ethics. 2014;9(4):46–9. https://doi.org/10.1177/1556264614545037.
3. Sheridan R, Martin-Kerry J, Hudson J, Parker A, Bower P, Knapp P. Why do patients take part in research? An overview of systematic reviews of psychosocial barriers and facilitators. Trials. 2020;21(1):259. https://doi.org/10.1186/s13063-020-4197-3.
4. South A, Joharatnam-Hogan N, Purvis C, James EC, Diaz-Montana C, Cragg WJ, et al. Testing approaches to sharing trial results with participants: the Show RESPECT cluster randomised, factorial, mixed methods trial. PLOS Med. 2021;18(10): e1003798. https://doi.org/10.1371/journal.pmed.1003798.
5. Bruhn H, Campbell M, Entwistle V, Humphreys R, Jayacodi S, Knapp P, et al. What, how, when and who of trial results summaries for trial participants: stakeholder-informed guidance from the RECAP project. BMJ Open. 2022;12(3): e057019. https://doi.org/10.1136/bmjopen-2021-057019.
6. Long CR, Stewart MK, Cunningham TV, Warmack TS, McElfish PA. Health research participants' preferences for receiving research results. Clin Trials. 2016;13(6):582–91. https://doi.org/10.1177/1740774516665598.
7. Raza MZ, Bruhn H, Gillies K. Dissemination of trial results to participants in phase III pragmatic clinical trials: an audit of trial investigators intentions. BMJ Open. 2020;10(1): e035730. https://doi.org/10.1136/bmjopen-2019-035730.
8. Bruhn H, Cowan EJ, Campbell MK, Constable L, Cotton S, Entwistle V, et al. Providing trial results to participants in phase III pragmatic effectiveness RCTs: a scoping review. Trials. 2021;22(1):361. https://doi.org/10.1186/s13063-021-05300-x.
9. Schroter S, Price A, Malički M, Richards T, Clarke M. Frequency and format of clinical trial results dissemination to patients: a survey of authors of trials indexed in PubMed. BMJ Open. 2019;9(10): e032701. https://doi.org/10.1136/bmjopen-2019-032701.
10. Long CR, Purvis RS, Flood-Grady E, Kimminau KS, Rhyne RL, Burge MR, et al. Health researchers' experiences, perceptions and barriers related to sharing study results with participants. Health Res Policy Syst. 2019;17(1):25. https://doi.org/10.1186/s12961-019-0422-5.
11. Canadian Institutes of Health Research. Knowledge translation strategy 2004–2009. Available from: https://cihr-irsc.gc.ca/e/26574.html. Cited 2024 Dec 2.
12. Kearns C, Eathorne A, Kearns N, Anderson A, Hatter L, Semprini A, et al. How best to share research with study participants? A randomised crossover trial comparing a comic, lay summary, and scientific abstract. J Vis Commun Med. 2022;45(3):172–81. https://doi.org/10.1080/17453054.2022.2056321.
13. National Institutes of Health Pragmatic Trials Collaboratory. Rethinking clinical trials: dissemination to patients. Available from https://rethinkingclinicaltrials.org/chapters/dissemination/dissemination-different-stakeholders/dissemination-to-patientsv2/. Cited 2024 Dec 2.
14. Racine E, Hurley C, Cheung A, Sinnott C, Matvienko-Sikar K, Smithson WH, et al. Participants' perspectives and preferences on clinical trial result dissemination: the TRUST Thyroid Trial experience. HRB Open Res. 2019;1:14. https://doi.org/10.12688/hrbopenres.12817.2.
15. Buljan I, Malički M, Wager E, Puljak L, Hren D, Kellie F, et al. No difference in knowledge obtained from infographic or plain language summary of a Cochrane systematic review: three randomized controlled trials. J Clin Epidemiol. 2018;97:86–94. https://doi.org/10.1016/j.jclinepi.2017.12.003.
16. Kerwer M, Stoll M, Jonas M, Benz G, Chasiotis A. How to put it plainly? Findings from two randomized controlled studies on writing plain language summaries for psychological meta-analyses. 2021;12: 771399. https://doi.org/10.3389/fpsyg.2021.771399.
17. Buljan I, Tokalić R, Roguljić M, Zakarija-Grković I, Vrdoljak D, Milić P, et al. Framing the numerical findings of Cochrane plain language summaries: two randomized controlled trials. BMC Med Res Methodol. 2020;20(1):101. https://doi.org/10.1186/s12874-020-00990-4.
18. Buljan I, Tokalić R, Roguljić M, Zakarija-Grković I, Vrdoljak D, Milić P, et al. Comparison of blogshots with plain language summaries of Cochrane systematic reviews: a qualitative study and randomized trial. Trials. 2020;21(1):1–10. https://doi.org/10.1186/s13063-020-04360-9.
19. Kwakkenbos L, Jewett LR, Baron M, Bartlett SJ, Furst D, Gottesman K, et al. The Scleroderma Patient-centered Intervention Network (SPIN) Cohort: protocol for a cohort multiple randomised controlled trial (cmRCT) design to support trials of psychosocial and rehabilitation interventions in a rare disease context. BMJ Open. 2013;3(8): e003563. https://doi.org/10.1136/bmjopen-2013-003563.
20. Thombs BD, Jewett LR, Assassi S, Baron M, Bartlett SJ, Costa Maia A, et al. New directions for patient-centred care in scleroderma: the Scleroderma Patient-centred Intervention Network (SPIN). Clin Exp Rheumatol. 2012;30(2 Suppl 71):S23–9.
21. Dougherty DH, Kwakkenbos L, Carrier ME, Salazar G, Assassi S, Baron M, et al. The Scleroderma Patient-Centered Intervention Network Cohort: baseline clinical features and comparison with other large scleroderma cohorts. Rheumatology. 2018;57(9):1623–31. https://doi.org/10.1093/rheumatology/key139.
22. https://www.spinsclero.com/. The Scleroderma Patient-centered Intervention Network. Available from: https://www.spinsclero.com/. Cited 2024 Dec 2.
23. Denton CP, Khanna D. Systemic sclerosis. Lancet. 2017;390(10103):1685–99. https://doi.org/10.1016/S0140-6736(17)30933-9.
24. Relton C, Torgerson D, O'Cathain A, Nicholl J. Rethinking pragmatic randomised controlled trials: introducing the "cohort multiple randomised controlled trial" design. BMJ. 2010;340: c1066. https://doi.org/10.1136/bmj.c1066.
25. Kwakkenbos L, Imran M, McCall SJ, McCord KA, Fröbert O, Hemkens LG, et al. CONSORT extension for the reporting of randomised controlled trials conducted using cohorts and routinely collected data (CONSORT-ROUTINE): checklist with explanation and elaboration. BMJ. 2021;373: n857. https://doi.org/10.1136/bmj.n857.
26. Thombs BD, Kwakkenbos L, Levis B, Bourgeault A, Henry RS, Levis AW, et al. Effects of a multi-faceted education and support programme on anxiety symptoms among people with systemic sclerosis and anxiety during COVID-19 (SPIN-CHAT): a two-arm parallel, partially nested, randomised, controlled trial. Lancet Rheumatol. 2021;3(6):e427–37. https://doi.org/10.1016/S2665-9913(21)00060-6.
27. Chan AW, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200–7. https://doi.org/10.7326/0003-4819-158-3-201302050-00583.
28. Kwakkenbos L, Carrier ME, Welling J, Levis B, Levis AW, Sauve M, et al. Randomized controlled trial of an internet-based self-guided hand exercise program to improve hand function in people with systemic sclerosis: the Scleroderma Patient-centered Intervention Network Hand Exercise Program (SPIN-HAND) Trial. Trials. 2022;23(1):994. https://doi.org/10.1186/s13063-022-06923-4.
29. Nordlund J, Henry RS, Kwakkenbos L, Carrier ME, Levis B, Nielson WR, et al. The Scleroderma Patient-centered Intervention Network Self-Management (SPIN-SELF) Program: protocol for a two-arm parallel partially nested randomized controlled feasibility trial with progression to full-scale trial. Trials. 2021;22(1):856. https://doi.org/10.1186/s13063-021-05827-z.
30. Scleroderma Patient-centered Intervention Network. Steering Committee. Available from: https://www.spinsclero.com/teamsandcommittees/steeringcommittee. Cited 2024 Dec 2.
31. Scleroderma Patient-centered Intervention Network. Teams & committees. Available from: https://www.spinsclero.com/teamsandcommittees. Cited 2024 Dec 2.

32. Tao L, Fedoruk C, Turner KA, Cumin J, Carrier ME, Carboni-Jiménez A, et al. The Scleroderma Research Topics Survey for patients and health care professionals: a Scleroderma Patient-centered Intervention Network project. J Scleroderma Relat Disord. 2019;4(3):165–72. https://doi.org/10.1177/2397198319842969.
33. Cook V, Gietzen A, Nassar EL, Wurz A, Thombs BD. Patient–researcher co-presentation of research results to people living with systemic sclerosis. Lancet Rheumatol. 2023;5(4):e180–1. https://doi.org/10.1016/S2665-9913(23)00063-2.
34. Wurz A, Ellis K, Nordlund J, Carrier ME, Cook V, Gietzen A, et al. Researcher and patient experiences of co-presenting research to people living with systemic sclerosis at a patient conference: a qualitative interview study. Res Involv Engagem. 2024;10(1):13. https://doi.org/10.1186/s40900-024-00546-6.
35. van den Hoogen F, Khanna D, Fransen J, Johnson SR, Baron M, Tyndall A, et al. 2013 classification criteria for systemic sclerosis: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. Arthritis Rheumatol. 2013;65(11):2737–47. https://doi.org/10.1002/art.38098.
36. Evidence Partners. DistillerSR: literature review software. Available from: https://www.distillersr.com/products/distillersr-systematic-review-software. Cited 2024 Dec 2.
37. Dopp AR, Parisi KE, Munson SA, Lyon AR. A glossary of user-centered design strategies for implementation experts. Transl Behav Med. 2019;9(6):1057–64. https://doi.org/10.1093/tbm/iby119.
38. Lewis JR. The System Usability Scale: past, present, and future. Int J Hum-Comput Interact. 2018;34(7):577–90. https://doi.org/10.1080/10447318.2018.1455307.
39. Saposnik G, Tobler PN, Caceres F, Terzaghi MA, Ruff C, Maurino J, et al. Usability of an educational intervention to overcome therapeutic inertia in multiple sclerosis care. Front Neurol. 2018;9:522. https://doi.org/10.3389/fneur.2018.00522.
40. Kastner M, Makarski J, Hayden L, Lai Y, Chan J, Treister V, et al. Improving KT tools and products: development and evaluation of a framework for creating optimized, Knowledge-activated Tools (KaT). Implement Sci Commun. 2020;1(1):47. https://doi.org/10.1186/s43058-020-00031-7.
41. Ng AWY, Lo HWC, Chan AHS. Measuring the usability of safety signs: a use of System Usability Scale (SUS). Lecture Notes in Engineering and Computer Science. 2011;2:1296–301.
42. Bangor A, Kortum PT, Miller JT. An empirical evaluation of the System Usability Scale. Int J Hum-Comput Interact. 2008;24(6):574–94. https://doi.org/10.1080/10447310802205776.
43. Dunlap JC, Lowenthal PR. Getting graphic about infographics: design lessons learned from popular infographics. J Vis Lit. 2016;35(1):42–59. https://doi.org/10.1080/1051144X.2016.1205832.
44. Murray IR, Murray AD, Wordie SJ, Oliver CW, Murray AW, Simpson AHRW. Maximising the impact of your work using infographics. Bone Jt Res. 2017;6(11):619–20. https://doi.org/10.1302/2046-3758.611.BJR-2017-0313.
45. Martin LJ, Turnquist A, Groot B, Huang SYM, Kok E, Thoma B, et al. Exploring the role of infographics for summarizing medical literature. Health Prof Educ. 2019;5(1):48–57. https://doi.org/10.1016/j.hpe.2018.03.005.
46. Hernandez-Sanchez S, Moreno-Perez V, Garcia-Campos J, Marco-Lledó J, Navarrete-Muñoz EM, Lozano-Quijada C. Twelve tips to make successful medical infographics. Med Teach. 2021;43(12):1353–9. https://doi.org/10.1080/0142159X.2020.1855323.
47. Brownson RC, Eyler AA, Harris JK, Moore JB, Tabak RG. Getting the word out: new approaches for disseminating public health science. J Public Health Manag Pract. 2018;24(2):102–11. https://doi.org/10.1097/PHH.0000000000000673.
48. Marchewka M. What is the ideal press release length? Newswire; 2024. Available from: https://www.newswire.com/blog/what-is-the-ideal-press-release-length. Cited 2024 Dec 2.
49. Model Systems Knowledge Translation Center. Press release template and instructions. Available from: https://msktc.org/knowledge-translation/disseminate-your-audiences/press-release-template-and-instructions. Cited 2024 Dec 2.
50. Coon JT, Orr N, Shaw L, Hunt H, Garside R, Nunns M, et al. Bursting out of our bubble: using creative techniques to communicate within the systematic review process and beyond. Syst Rev. 2022;11(1):56. https://doi.org/10.1186/s13643-022-01935-2.
51. Rainford J. Stripping back the novelty: a critical reflection on the dual use of a comic-based approach to engage participants and publics. Methodol Innov. 2021;14(3):20597991211060680. https://doi.org/10.1177/20597991211060681.
52. Sandars J. Twelve tips for using podcasts in medical education. Med Teach. 2009;31(5):387–9. https://doi.org/10.1080/01421590802227958.
53. Mobasheri A, Costello KE. Podcasting: an innovative tool for enhanced osteoarthritis education and research dissemination. Osteoarth Cartil Open. 2021;3(1): 100130. https://doi.org/10.1016/j.ocarto.2020.100130.
54. Quaiser F. E4D-Plain-Language-Summaries-Toolkit - General.pdf. Evidence for Democracy. Available from: https://drive.google.com/file/d/1d-NSSG-kd-vysFBB5vJUmCreAILGGrbX/view?usp=sharing&usp=embed_facebook&usp=embed_facebook. Cited 2024 Dec 2.
55. Pitcher N, Mitchell D, Hughes C. Guidance for writing a Cochrane plain language summary. Cochrane 2021. Available from: https://community.cochrane.org/sites/default/files/uploads/inline-files/PLS%20guidance%20final%20draft%20%28v%2020%29.pdf. Cited 2024 Dec 2.
56. Maurer M, Siegel JE, Firminger KB, Lowers J, Dutta T, Chang JS. Lessons learned from developing plain language summaries of research studies. Health Lit Res Pract. 5(2):e155-e161. https://doi.org/10.3928/24748307-20210524-01
57. Patient-Centered Outcomes Research Institute. Returning study results to participants: an important responsibility. Available from: https://www.pcori.org/research-related-projects/about-our-research/returning-study-results-participants-important-responsibility. Cited 2024 Dec 2.
58. Flesch R. A new readability yardstick. J Appl Psychol. 1948;32(3):221–33. https://doi.org/10.1037/h0057532.
59. Kincaid JP, Fishburne J, Rogers RL, Chissom BS. Derivation of new readability formulas (Automated Readability Index, Fog Count and Flesch Reading Ease Formula) for navy enlisted personnel. Naval Technical Training Command, Millington TN Research Branch; 1975.
60. National Institutes of Health Research. Plain English summaries. Available from: https://www.nihr.ac.uk/documents/plain-english-summaries/27363. Cited 2024 Dec 2.
61. Downie WW, Leatham PA, Rhind VM, Wright V, Branco JA, Anderson JA. Studies with pain rating scales. Ann Rheum Dis. 1978;37(4):378–81. https://doi.org/10.1136/ard.37.4.378.
62. Hjermstad MJ, Fayers PM, Haugen DF, et al. Studies comparing numerical rating scales, verbal rating scales, and visual analogue scales for assessment of pain intensity in adults: a systematic literature review. J Pain Symptom Manage. 2011;41(6):1073–93. https://doi.org/10.1016/j.jpainsymman.2010.08.016.
63. Allen MS, Iliescu D, Greiff S. Single item measures in psychological science. Eur J Psychol Assess. 2022;38(1):1–5. https://doi.org/10.1027/1015-5759/a000699.
64. Fisher GG, Matthews RA, Gibbons AM. Developing and investigating the use of single-item measures in organizational research. J Occup Health Psychol. 2016;21(1):3–23. https://doi.org/10.1037/a0039139.
65. Cheung F, Lucas RE. Assessing the validity of single-item life satisfaction measures: results from three large samples. Qual Life Res. 2014;23(10):2809–18. https://doi.org/10.1007/s11136-014-0726-4.
66. Kwakkenbos L, Østbø N, Carrier ME, Nielson WR, Fedoruk C, Levis B, et al. Randomized feasibility trial of the Scleroderma Patient-centered Intervention Network Self-Management (SPIN-SELF) Program. Pilot Feasibility Stud. 2022;8(1):45. https://doi.org/10.1186/s40814-022-00994-5.
67. Juszczak E, Altman DG, Hopewell S, Schulz K. Reporting of multi-arm parallel-group randomized trials: extension of the CONSORT 2010 statement. JAMA. 2019;321(16):1610–20. https://doi.org/10.1001/jama.2019.3087.
68. Rothman KJ. No adjustments are needed for multiple comparisons. Epidemiology. 1990;1(1):43–6.
69. Schulz KF, Grimes DA. Multiplicity in randomised trials I: endpoints and treatments. Lancet. 2005;365(9470):1591–5. https://doi.org/10.1016/S0140-6736(05)66461-6.
70. Parker RA, Weir CJ. Non-adjustment for multiple testing in multi-arm trials of distinct treatments: rationale and justification. Clin Trials. 2020;17(5):562–6. https://doi.org/10.1177/1740774520941419.

71. Cohen J. Statistical power analysis for the behavioral sciences. 2nd ed. Routledge; 2013. https://doi.org/10.4324/9780203771587.
72. Norman GR, Sloan JA, Wyrwich KW. Interpretation of changes in health-related quality of life: the remarkable universality of half a standard deviation. Med Care. 2003;41(5):582–92. https://doi.org/10.1097/01.MLR.0000062554.74615.4C.
73. Turner D, Schünemann HJ, Griffith LE, et al. The minimal detectable change cannot reliably replace the minimal important difference. J Clin Epidemiol. 2010;63(1):28–36. https://doi.org/10.1016/j.jclinepi.2009.01.024.
74. Kahan BC, Jairath V, Doré CJ, Morris TP. The risks and rewards of covariate adjustment in randomized trials: an assessment of 12 outcomes from 8 studies. Trials. 2014;15(1):139. https://doi.org/10.1186/1745-6215-15-139.
75. Benkeser D, Díaz I, Luedtke A, Segal J, Scharfstein D, Rosenblum M. Improving precision and power in randomized trials for COVID-19 treatments using covariate adjustment, for binary, ordinal, and time-to-event outcomes. Biometrics. 2021;77(4):1467–81. https://doi.org/10.1111/biom.13377.
76. Lee PH. Covariate adjustments in randomized controlled trials increased study power and reduced biasedness of effect size estimation. J Clin Epidemiol. 2016;76:137–46. https://doi.org/10.1016/j.jclinepi.2016.02.004.
77. Gordon JK, Showalter K, Wu Y, et al. Systemic sclerosis and COVID-19 vaccines: a SPIN Cohort study. Lancet Rheumatol. 2022;4(4):e243–6. https://doi.org/10.1016/S2665-9913(21)00416-1.
78. Harb S, Peláez S, Carrier ME, et al. Barriers and facilitators to physical activity for people with scleroderma: a Scleroderma Patient-centered Intervention Network (SPIN) Cohort study. Arthritis Care Res. 2022;74(8):1300–10. https://doi.org/10.1002/acr.24567.
79. Østbø N, Yakes Jimenez E, Carrier M, Kwakkenbos L, Thombs B. Use and perceptions of nutrition information resources among people with systemic sclerosis: a Scleroderma Patient-centered Intervention Network (SPIN) Cohort study. Clin Exp Rheumatol. 2024;42(8):1606–14.
80. Gal R, Monninkhof EM, van Gils CH, Groenwold RHH, van den Bongard DHJG, Peeters PHM, et al. The Trials within Cohorts design faced methodological advantages and disadvantages in the exercise oncology setting. J Clin Epidemiol. 2019;113:137–46. https://doi.org/10.1016/j.jclinepi.2019.05.017.
81. Bibby AC, Torgerson DJ, Leach S, Lewis-White H, Maskell NA. Commentary: considerations for using the 'Trials within Cohorts' design in a clinical trial of an investigational medicinal product. Trials. 2018;19(1):18. https://doi.org/10.1186/s13063-017-2432-3.
82. Sverdlov O, Ryeznik Y, Anisimov V, Kuznetsova OM, Knight R, Carter K, et al. Selecting a randomization method for a multi-center clinical trial with stochastic recruitment considerations. BMC Med Res Methodol. 2024;24(1):52. https://doi.org/10.1186/s12874-023-02131-z.
83. Clark L, Burke L, Margaret Carr R, Coleman E, Roberts G, Torgerson DJ. A review found small variable blocking schemes may not protect against selection bias in randomized controlled trials. J Clin Epidemiol. 2022;141:90–8. https://doi.org/10.1016/j.jclinepi.2021.09.009.
84. Qualtrics. Security statement. Available from: https://www.qualtrics.com/security-statement/. Cited 2024 Dec 2.
85. Cochrane. Cochrane methods: equity. PROGRESS-Plus. Available from: https://methods.cochrane.org/equity/projects/evidence-equity/progress-plus. Cited 2024 Dec 2.
86. O'Neill J, Tabish H, Welch V, Petticrew M, Pottie K, Clarke M, et al. Applying an equity lens to interventions: using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. J Clin Epidemiol. 2014;67(1):56–64. https://doi.org/10.1016/j.jclinepi.2013.08.005.
87. Pelikan JM, Link T, Straßmayr C, Waldherr K, Alfers T, Bøggild H, et al. Measuring comprehensive, general health literacy in the general adult population: the development and validation of the HLS_{19}-Q12 instrument in seventeen countries. Int J Environ Res Public Health. 2022;19(21):14129. https://doi.org/10.3390/ijerph192114129.
88. van Buuren S, Groothuis-Oudshoorn K. mice: multivariate imputation by chained equations in R. J Stat Softw. 2011;45:1–67. https://doi.org/10.18637/jss.v045.i03.
89. Rubin DB. Multiple imputation for nonresponse in surveys. New York: John Wiley & Sons; 1987.
90. Schandelmaier S, Briel M, Varadhan R, Schmid CH, Devasenapathy N, Hayward RA, et al. Development of the Instrument to assess the Credibility of Effect Modification Analyses (ICEMAN) in randomized controlled trials and meta-analyses. CMAJ. 2020;192(32):E901–6. https://doi.org/10.1503/cmaj.200077.
91. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340: c869. https://doi.org/10.1136/bmj.c869.
92. Boutron I, Altman DG, Moher D, Schulz KF, Ravaud P, CONSORT NPT Group. CONSORT statement for randomized trials of nonpharmacologic treatments: a 2017 update and a CONSORT extension for nonpharmacologic trial abstracts. Ann Intern Med. 2017;167(1):40–7. https://doi.org/10.7326/M17-0046.
93. Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, et al. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ. 2008;337: a2390. https://doi.org/10.1136/bmj.a2390.
94. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348: g1687. https://doi.org/10.1136/bmj.g1687.
95. Hoffman AS, Sepucha KR, Abhyankar P, Sheridan S, Bekker H, LeBlanc A, et al. Explanation and elaboration of the Standards for UNiversal reporting of patient Decision Aid Evaluations (SUNDAE) guidelines: examples of reporting SUNDAE items from patient decision aid evaluation literature. BMJ Qual Saf. 2018;27(5):389–412. https://doi.org/10.1136/bmjqs-2017-006985.
96. Fernandez CV, Kodish E, Weijer C. Informing study participants of research results: an ethical imperative. IRB. 2003;25(3):12–9.
97. Shalowitz DI, Miller FG. The search for clarity in communicating research results to study participants. J Med Ethics. 2008;34(9): e17. https://doi.org/10.1136/jme.2008.025122.
98. Lévesque E, Joly Y, Simard J. Return of research results: general principles and international perspectives. J Law Med Ethics. 2011;39(4):583–92. https://doi.org/10.1111/j.1748-720X.2011.00625.x.
99. World Medical Association. World Medical Association Declaration of Helsinki ethical principles for medical research involving human participants. JAMA. 2024. Online ahead of print. https://doi.org/10.1001/jama.2024.21972.
100. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council. Tri-council policy statement: ethical conduct for research involving humans; c2018. Available from: https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html. Cited 2024 Dec 2.
101. National Institutes of Health. A checklist for communicating science and health research to the public. Available from: https://www.nih.gov/about-nih/what-we-do/science-health-public-trust/checklist-communicating-science-health-research-public. Cited 2024 Dec 2.
102. National Institutes of Health Research. How to disseminate your research. Available from: https://www.nihr.ac.uk/how-disseminate-your-research. Cited 2024 Dec 2.

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