PROTOCOL TITLE:

The Scleroderma Patient-centered Intervention Network (SPIN) - Scleroderma Support group Leader EDucation (SSLED) Program Feasibility Trial

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1. Overview

Many people living with a rare disease turn to peer-led support groups to cope with their condition and access educational resources.[1-5] Systemic sclerosis (SSc), or scleroderma, is a rare autoimmune connective tissue disease where peer-led support groups play an important role.[2-4,6,7] There are currently approximately 200 SSc support groups in Canada and the US, most of which are led by people with SSc.[8,9] Many SSc patients, however, cannot access support groups. In other cases, support groups are not sustained due to factors that include the burden on group leaders living with a serious, unpredictable disease and limited group leadership skills of some untrained leaders.[3,4,10] Our partners from Scleroderma Canada and the Scleroderma Foundation in the US are committed to improving support group accessibility and effectiveness. These organizations maintain a list of active support groups, but currently do not provide training or other resources to groups or their leaders. To address this gap, our team, including investigators and patients from the Scleroderma Patient-centered Intervention Network (SPIN), developed the Scleroderma Support group Leader EDucation (SPIN-SSLED) Program, which is designed to improve support group leader confidence and self-efficacy, reduce burnout, improve emotional well-being, and improve health-related quality of life.

The proposed study is requesting ethical approval to conduct a feasibility trial of the SPIN-SSLED Program. In the planned full-scale randomized controlled trial (RCT) that will follow our feasibility trial, we will evaluate whether the SPIN-SSLED Program is effective in improving SSc support group leaders' self-efficacy for carrying out their leader role (primary) and if it reduces burnout, improves emotional well-being, and improves health-related quality of life (secondary). Thus, the SPIN-SSLED Feasibility Trial answers the following research questions: (1) Is a full-scale SPIN-SSLED RCT feasible? (2) Are adaptations needed to the research design for the planned full-scale RCT? (3) Are there ways to improve the SPIN-SSLED Program for delivery in the planned full-scale RCT based on input of support group leaders who participate in the feasibility trial?

To answer these questions, the aim of the SPIN-SSLED Feasibility Trial is to collect data related to the study's *process*, in order to assess the feasibility of the steps that need to take place as part of the main study; *required resources* (e.g., staffing, time, and budget), *management issues* (e.g., optimizing performance of personnel and data systems); and *scientific aspects* (e.g., recruitment rates of eligible leaders, fidelity of intervention delivery, acceptability of intervention to leaders, performance of outcome measures).

2. Background and Rationale

People with rare diseases experience many of the same challenges as those with more common diseases, but also face unique challenges, including gaps in knowledge about their disease and limited treatment and support options.[11-16] Professionally organized support services are often available for people with more common diseases,[1] but are not typically available for people with rare diseases.[11-16] Instead, many people with rare diseases rely on peer-led support groups for education and to cope with their disease.[1-5]

Support groups may be held face-to-face or online, led by professionals or peers, and have a structured or an unstructured format. Activities typically involve an educational or information-sharing component and the exchange of emotional and practical support.[1-5]

Systemic sclerosis (SSc), or scleroderma, is a rare, chronic, autoimmune connective tissue disease characterized by abnormal fibrotic processes and excessive collagen production.[6] Peer-led support groups play an important role for people with the disease.[2-4,7] There are currently approximately 200 active SSc support groups listed by Scleroderma Canada or the Scleroderma Foundation in the USA, most led by people with the disease.[8,9] Many people with SSc, however, do not have access to SSc support groups, and many support groups that are initiated are not sustained due to obstacles that could be addressed by providing training to support group leaders.[3,4] Challenges for patient support group leaders, particularly in rare diseases, include practical difficulties, such as a lack of resources or poor coordination with medical professionals and leader organizations; difficulties with group leadership tasks, such as managing complex group dynamics; and personal challenges, such as managing one's own health condition while supporting others and preventing burnout.[17,18]

A training and education program could provide the necessary information and skills to improve the ability of SSc peer support group leaders to lead sustainable, effective support groups; reduce their emotional and physical burden; and encourage new leaders to set up support groups where none exist or via the internet. In rare diseases, face-to-face delivery of such a training program is not feasible because current and potential leaders are widely dispersed geographically. Videoconferencing has been used successfully to train educators, health service providers, and parents of children with behavioural difficulties, for example,and is as effective as face-to-face training.[19-22] In SSc, videoconferencing can provide a mechanism for creating sufficient scale across provincial and national boundaries to aid in the dissemination of support tools where none are available. Most SSc leaders and support group leaders use the internet. A 2013 study[23] found that 85% of Dutch SSc patients with SSc search the internet for information about SSc. SPIN,[7] which is led by members of our team, routinely collects data from > 1800 people with SSc in the SPIN Cohort.

Scleroderma Canada and the Scleroderma Foundation are committed to developing a shared infrastructure to improve support groups effectiveness and accessibility, including the quality of existing support groups and increasing the availability of support group services by training new leaders to initiate support groups in underserved areas and via the internet. These organizations have partnered with our team to develop and test the SPIN-SSLED Program, a 3-month-long group training program designed to be delivered via videoconferencing to provide information and skills to improve leader support group leaders' confidence and self-efficacy to carry out their leadership roles and reduce the burden on them of leading a support group. If effective, the organizations will adopt the SPIN-SSLED Program to provide ongoing training for support group leaders.

To better understand reasons for attending and not attending support groups and support group leader training needs, we conducted one-on-one interviews with 30 support group members, non-attenders, and leaders. We then developed a survey, which was completed by 600 North American and 700 European and Australian SSc patients (approximately 45% non-attenders, 40% group members, and 15% leaders; manuscripts in press[4], submitted for review, or in preparation). The proposed SPIN-SSLED Program Feasibility Trial builds on this background research and will evaluate the feasibility of delivering the SPIN-SSLED Program and of our planned full-scale trial design. We will enroll 10 SSc support group leaders and randomly allocate 10 into 2 SPIN-SSLED Program training groups (5 leaders per group). At

the end of the feasility trial intervention, we will interview the 10 group leaders who took part in the training in order to identify aspects of the program that might be improved. We will use this information to make any necessary revisions to the program or our trial methods before conducting a full-scale trial.

3. Objectives

(1) To evaluate the feasibility of steps needed to take place in the full-scale trial, including the *required resources* (e.g., staffing, time, and budget), *management issues* (e.g., related to optimizing performance of personnel and data systems), and *scientific aspects* (e.g., recruitment rates of eligible leaders, fidelity of intervention delivery, acceptability of intervention to leaders, assessing performance of outcome measures); (2) To make any necessary modifications to the SPIN-SSLED Program based on participant feedback.

4. Setting, Sample, and Randomization

Trial Design: There are no existing training programs for SSc support group leaders. Thus, the planned full-scale SPIN-SSLED trial will be a pragmatic RCT that tests whether providing the SSLED Program to leaders of SSc support groups will improve outcomes compared to leaders assigned to a wait-list control. Pragmatic RCTs differ from explanatory or mechanistic trials in that they are intended to test the effectiveness of adding an intervention to routine practice in order to inform practice and policy decisions rather than explain intervention mechanisms.[24,25,26] SSc support group leaders who are enrolled will be randomly allocated to the training program or a wait-list control, and those allocated to training will be clustered in training groups where they will interact with each other. We will need to account for clustering in the training arm, but not the control arm. Thus, we will use a partially nested RCT trial design (PN-RCT).[27] The PN-RCT design is a hybrid between a conventional RCT, in which individual participants are randomized, and a cluster RCT, in which pre-existing clusters (e.g., primary care practices, classrooms) are randomized to intervention or control arms. In the PN-RCT design, analyses account for dependence within intervention arm clusters, but treat leaders assigned to the control arm individually, as in a conventional RCT. The SPIN-SSLED Feasibility Trial will adhere to this design.

Participants: To be eligible for the SPIN-SSLED Feasibility Trial leaders must be a current SSc support group leader or have been identified by Scleroderma Canada or the Scleroderma Foundation as a new leader who will initiate a new support group, must be able to use the internet to access and participate in training sessions and to complete study questionnaires online, must be available to participate at times when sessions are scheduled and be English-speaking. Individuals who are offered participation in the feasibility study will be excluded from the subsequent full-scale RCT. As the majority of leaders who are members of the organizations from which we are recruiting are English-speaking, in order to ensure that there will be an adequate number of French-speaking participants in the RCT, only English-speaking leaders will be included in the feasibility study. Therefore, for the proposed feasibility study, only English-speaking leaders will be recruited, and the resulting program will be subsequently translated into French. The full-scale trial will be conducted in English and French.

Recruitment, Consent and Randomization: Our partners from the Scleroderma Canada and the Scleroderma Foundation will contact group leaders to describe the SPIN-SSLED Feasibility Trial and ascertain interest in participating. SPIN-SSLED personnel will send email invitations with the consent form to interested support group leaders. Following this, support group leaders will be contacted by phone within 48 hours to describe the study, review the consent form, and answer questions assessing

eligibility. Eligible patients who verbally accept the offer to enrol in the study will receive an email with the consent form for the study, which they can sign by replying, "**I have read the consent form and understand the terms of the feasibility study. I agree to participate in the study testing the feasibility of the SPIN-SSLED Program."** We will enrol 10 English-speaking SSc support group leaders who we will randomly assign to 2 SPIN-SSLED Program training groups (5 leaders per group). All participants will receive an email invitation including a clickable link to the online survey platform Qualtrics where they will be asked to complete study measures. The email will also include the date of leaders' first training session, the topic of the first session and information on how to login to the videoconferencing system. Email and phone technical support will be available to help leaders with the consent process, when they access Qualtrics to complete study measures, and for training sessions.

5. Intervention

The SPIN-SSLED Program was developed by a team of researchers with expertise in SSc, patient organization representatives, and a Patient Advisory Board comprised of current SSc support group leaders. The program content and design is based on results of our preliminary research on support groups in SSc and informed by instructional material for support group leaders we identified via the internet and by consultations with support group leaders. The program uses a problem-based learning approach. Problem-based learning is a learner-centered approach that integrates theory and practice by providing the necessary knowledge and skills, presenting a complex, real-world problem, then working to identify an approach to solving the problem.[29,30] To implement this, each module, or learning session, will introduce a topic and provide an overview of key information. Then, there will be a guided discussion among training group participants about possible approaches and solutions.

The program includes 13 modules that will be delivered live via webinar over the course of the 3-month program. Each module will be delivered in a 60- to 90-minute session. Module topics include (1) the leader's role; (2) starting a support group; (3) structuring a support group meeting; (4) scleroderma 101; (5) successful support group culture; (6) managing support group dynamics I; (7) managing support group dynamics II; (8) grief and crisis in scleroderma; (9) marketing and recruitment; (10) the continuity of the group; (11) supporting yourself as a leader; (12) virtual support group meetings, (13) support group leader resources. In addition to the live modules, SPIN-SSLED participants will receive a workbook that summarizes didactic material that is provided and will be shown filmed vignettes demonstrating effective group facilitation techniques and ways to respond to support group issues. SPIN-SSLED participants will also have access to an online resource center that includes a range of helpful tools for leaders including files of SSc related videos to show at meetings and an online forum for leaders to post questions, open only to leaders enrolled in the training program. Based on our previous experience with videoconferencing and consistent with previous trials of videoconference training, to maximize effective interaction and participation, 5 group leaders will be assigned to each training group.[31,32] Training sessions will be delivered using the GoToMeeting® videoconferencing platform, a high-performance platform that has been used successfully for similar applications.[33,34]

6. Measures

Participant Demographic and Disease-related Variables: A demographics questionnaire will be administered to all participants before the trial. The demographics questionnaire designed for this study

includes basic demographic information, such as gender, age and employment status. The questionnaire also includes disease-related variables, such as years since scleroderma diagnosis.

SPIN-SSLED Feasibility Measures: The aim of the SPIN-SSLED Feasibility Trial is to collect data related to the study's *process*, in order to assess the feasibility of the steps that need to take place as part of the full-scale RCT, including *required resources and management* (e.g., personnel and data management issues) and *scientific aspects* (e.g., acceptability, outcome assessments), as well as to obtain feedback on possible ways to improve the training program. Data will be used to determine whether it is feasible to carry out a full-scale trial, or whether changes need to be made to the trial design or training program. The feasibility trial outcomes related to process and resources will be assessed throughout the duration of the feasibility trial, and leader feedback will be obtained upon completion of the program.

The collected measures of feasibility include:

- How well the enrolment and randomization procedure work;
- The percentage of eligible group leaders who consent to participation;
- Personnel requirements to call enrolled leaders and help them with accessing the SPIN-SSLED Program online data collection platform;
- Challenges for study personnel;
- Technological performance of the videoconferencing system

We will also evaluate the degree to which the SPIN-SSLED Program is delivered with a high level of fidelity to the program manual. To do this, all SPIN-SSLED sessions will be audited for fidelity by two members of the research team. We will use standard methods for evaluating intervention fidelity,[35] including observation of entire sessions for a randomly selected sample of 25% of video-recorded sessions. Raters will evaluate adherence to each session's goals and content. Consistent with best-practice recommendations for assessing treatment fidelity,[35] this will be done using a checklist coding system based on a standardized format and adapted for the specific components of the SPIN-SSLED Program manual.

Finally, individual interviews will be conducted upon completion of the 13-modules to assess the accessibility of the intervention, barriers to participating, and user feedback, as well as to explore leaders' experience of taking part in the intervention. Participants who have completed any of the 13 modules will be asked to participate in the interviews.

SPIN-SSLED Program Outcome Measures: In the planned full-scale randomized controlled trial (RCT) that will follow our feasibility trial, we will evaluate whether the SPIN-SSLED Program is effective in improving SSc support group leaders' self-efficacy for carrying out their leader role (primary) and if it reduces burnout, improves emotional well-being, and improves health-related quality of life (secondary). In the SPIN SSLED Feasibility Trial, outcome measures will be evaluated at the time of random allocation to a SPIN-SSLED Program training group and after completion of the Program (3 months post).

- The Scleroderma Support Group Leader Self-efficacy Scale (SSGLSS) was developed by our research team to measure support group leader self-efficacy for performing leader tasks. Initial items were extracted from previous measures developed for leaders of cancer support groups.[36-38] All items were reviewed by our research team for relevancy and repetitiveness, and edited for clarity. Additional items were generated to reflect content important to SSc not included in the

initial item set. Items were reviewed iteratively by all members of the research team until a consensus was reached. The final 32-item scale is scored on a 1-6 Likert scale (1=*strongly disagree*; 6=*strongly agree*).

- Burnout will be assessed with the Oldenburg Burnout Inventory (OLBI).[39,40] The OLBI is a 16-item measure of burnout that assesses levels of exhaustion and disengagement in work populations. Items were adapted and reviewed by project investigators for use within the support group leader population. Items are scored on a 4-point scale from 1 (strongly disagree) to 4 (strongly agree)

- Emotional distress will be assessed with the PHQ-8.[41,42] The PHQ-8 items measure depressive symptoms over the last 2 weeks on a 4-point scale, ranging from 0 (not at all) to 3 (nearly every day) with higher scores indicating more depressive symptoms. The PHQ-8 performs equivalently to the PHQ-9,[41] which is a valid measure of depressive symptoms in leaders with SSc.[42]

- Leader-reported health status will be measured using the 29-item Patient Reported Outcomes Measurement Information System (PROMIS-29) profile version 2.0. The PROMIS-29 measures 8 domains of health status with 4 items for each of 7 domains (physical function, anxiety, depression, fatigue, sleep disturbance, social roles and activities, pain interference) plus a single item for pain intensity. Items are scored on a 5-point scale (range 1-5), with different response options for different domains, and the single pain intensity item is measured on an 11-point rating scale. Higher scores represent more of the domain being measured; that is, better physical function and ability to participate in social roles and activities, but higher levels of anxiety, depression, fatigue, sleep disturbance, pain interference, and pain intensity. Total raw scores are obtained by summing item scores for each domain, which are converted into T-scores standardized from the general US population (mean=50, SD=10). The PROMIS-29 version 2.0 has been validated in SSc.[43,44]

Harms/Adverse events: The present study is of minimal risk. We do not anticipate that there will be any adverse events from participating in the leader training sessions.

Sample size: Guidance on appropriate sample size for feasibility trials varies substantially in the published literature. Published guidelines[45] suggest that approximately 10% of the estimated sample size for the full-scale RCT should be included in the feasibility study. We anticipate that we will randomize approximately 100 leaders in the full-scale trial. Thus, we will include 10 patients in the feasibility trial.

Data Analysis and Storage: A description of feasibility outcomes will be presented, including leader eligibility and recruitment, leader enrolment and randomization, technological performance of the videoconferencing system, and treatment fidelity. Qualitative information will inform any necessary changes to the program or trial methods before conducting a full-scale trial. Descriptive statistics will be used to provide means and standard deviations for SPIN-SSLED Program outcome measures.

Outcome measures will be completed using the online surveying tool Qualtrics. Once the online survey data is collected, data will be exported to the statistics software program, IBM SPSS. Cleaning of the data will occur within SPSS, by the researchers, Dr. Thombs and Mr. Razykov, until a final database, containing all survey responses, is created. All information obtained about the participants during this study will be treated confidentially within the limits of the law. Only the researchers involved in this

project will have access to the survey data. To protect the participants' privacy, upon inclusion in the SPIN-SSLED study, a unique participant identification number will automatically be assigned to each participant. An encrypted database will be created for the SPIN-SSLED program, which includes the patient identification number. Only requests authorized by the principal investigator (Dr. Brett Thombs) will be granted access to this encrypted information. The survey is run through Qualtrics, a company whose computer servers are located in the USA. Data security measures in place at Qualtrics are described in the Qualtrics security statement (http://www.qualtrics.com/security-statement/). Information obtained from the survey will be kept for 10 years on encrypted hard drives by the researchers responsible for this study. Access to the data will be limited to the investigators of the study: Mr. Razykov, and Drs. Brett Thombs, Marie Hudson, Robert Platt, Ghassan El-Baalbaki, Vanessa Malcarne, and Sandra Peláez.

9. Risks and Potential Benefits:

We do not anticipate any safety concerns with the use of the SPIN-SSLED program. Participation in the SPIN-SSLED Feasibility Trial will involve weekly online training sessions, completion of online measures and participation in a post-program interview. Although it is hypothesized that the SPIN-SSLED Program will improve leaders' self-efficacy for performing leader tasks, reduce burnout, improve emotional well-being, and health-related quality of life, it cannot be guaranteed that leaders will receive any benefits from this study. However, information learned from this research may lead to more effective SSc support group leader training programs, which may benefit those living with SSc in the future. There will be no financial compensation for leaders who are participating in the SPIN-SSLED Feasibility Trial.

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