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The Scleroderma Patient-centered Intervention Network – Scleroderma Support group Leader Education (SPIN-SSLED) Program: Non-randomised Feasibility Trial

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ABSTRACT

Objectives: The Scleroderma Patient-centered Intervention Network – Scleroderma Support group Leader EDucation (SPIN-SSLED) Program was designed to improve confidence and self-efficacy and to reduce burden for support group leaders. Objectives of the feasibility trial were to (1) evaluate feasibility of program delivery, including required resources, management issues, and scientific aspects; and (2) assess user satisfaction and identify any modifications needed to improve program content or delivery based on participant feedback.

Design: Non-randomised feasibility trial.

Setting: North American scleroderma patient organisations.

Participants: Current support group leaders or potential new leaders referred by patient organisations.

Intervention: The program included 13 modules delivered live via videoconference over 3 months (April to July 2018) in 60- to 90-minute sessions.

Outcome Measures: (1) Elements of feasibility, including enrolment and consent procedures, percentage of referred group leaders who consented to participate, session attendance, and technical support requirements; (2) program usability, understandability, organisation, and clarity; (3) leader satisfaction with the program; and (4) planned trial outcome measures, including support group leader self-efficacy, burnout, emotional distress, and physical function.

Results: All 12 referred potential participants consented to enrol, and 10 were included in 2 training groups of 5 participants each. Participants attended 95% of sessions. Required technical support was minimal, and videoconferencing technology functioned well. Overall

program satisfaction rating was 9.4/10. Mean item rating on the 8 items of the Client Satisfaction Questionnaire-8 was 3.83 (1 = low satisfaction; 4 = high satisfaction). Pre-post scores on the Scleroderma Support Group Leader Self-efficacy Scale increased by 1.7 standard deviations (large effect); scores on burnout, emotional distress, and physical function improved by 0.44, 0.38, and 0.45 standard deviations (moderate effects).

Conclusion: The SPIN-SSLED Program was feasibly delivered, including management, resource, and scientific aspects. Participant satisfaction was high. The program is ready to be tested in a full-scale randomised controlled trial.

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Trial Registration: NCT03508661

Key Words: patient education; peer support; feasibility trial; scleroderma; support groups; systemic sclerosis

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is the first trial to test the feasibility of delivering an education and training program via videoconference to peer support group leaders.
- The education and training program was developed in a partnership that included scleroderma peer support group leaders, patient organisation leaders, and researchers and health care professionals.
- Trial outcomes included elements of feasibility (e.g., management, resources, scientific aspects); program usability, understandability, organisation, and clarity; leader satisfaction with the program; and planned trial outcome measures.
- This was a non-randomised feasibility trial that only included 10 participants in 2 training groups and did not include a control group; generalisability of results outside of scleroderma is not known.

INTRODUCTION

People with rare diseases face the same challenges as those with more common diseases plus unique challenges, including limited disease education and lack of specialised support options.[1-12] Professionally organised support services for common diseases are often available through the healthcare system,[13, 14] but are not typically available in rare diseases.[10, 15] As a result, some people with rare diseases rely on peer-led support groups for disease-specific education and support.[16-20] Support group activities typically involve an educational or information-sharing component and the exchange of emotional and practical support.[14, 18-22].

Systemic sclerosis (SSc), or scleroderma, is a rare chronic, autoimmune connective tissue disease characterised by abnormal fibrotic processes and excessive collagen production.[23-25] Support groups, most led by people with SSc, play an important role for many people with the disease.[17, 26-30] Many people with SSc, however, cannot access support groups because they are not available close to where they live, and many initiated support groups are not sustained due to challenges that could be addressed via leader training.[18, 19]

A systematic review of randomised controlled trials (RCTs) that evaluated the effects of training programs for patient leaders of illness-based support groups on the competency, self-efficacy, burden, and emotional well-being of group leaders identified only one RCT that met inclusion criteria.[31] That trial [32] evaluated confidence and self-efficacy of cancer

support group leaders randomised to either 4-month long high-resource (N = 29; website, discussion forum, 2-day face-to-face training) or low-resource (N = 23; website, discussion forum) interventions. The RCT did not find evidence that the high-resource program was more effective. However, the trial was substantially underpowered, not enough information was provided to determine intervention content or how it was delivered, and the risk of bias was high due to methodological limitations.

The Scleroderma Patient-centered Intervention Network (SPIN) partnered with SSc patients and patient organisations to develop the Scleroderma Support group Leader EDucation (SPIN-SSLED) Program. The program is a 13-session group videoconference training program, designed to improve skills and self-efficacy, reduce burnout, and improve emotional and physical function among support group leaders. The objectives of the SPIN-SSLED feasibility trial were to (1) evaluate the feasibility of steps needed to take place in a planned full-scale trial, including the *required resources* (e.g., staffing, time, and budget), *management issues* (e.g., related to optimising performance of personnel and data systems), and *scientific aspects* (e.g., recruitment rates of eligible leaders, acceptability of intervention to leaders, assessing performance of outcome measures) and (2) identify any modifications needed to improve the content or delivery of the SPIN-SSLED Program based on participant feedback.

METHODS

The SPIN-SSLED feasibility trial was a non-randomised study. It was registered prior to enrolling participants (NCT03508661) and, although not a randomised study, is reported based on items from the CONSORT extension for randomised pilot and feasibility trials.[33] There

were no changes to the feasibility trial protocol and no changes to planned outcomes after commencement of the trial.

Participants

Eligible participants for the SPIN-SSLED feasibility trial were current SSc support group leaders or were identified by Scleroderma Canada or the Scleroderma Foundation (United States) as a new leader who will initiate a new support group, were able to use the internet to access and participate in training sessions and to complete study questionnaires online, were available to participate at times when sessions were scheduled, and were English-speaking, since both groups in the feasibility trial were conducted in English. The full-scale trial will include groups conducted in French, but individuals who participated in the feasibility study will be excluded from the full-scale RCT. Thus, to ensure that there will be an adequate number of French-speaking participants in the full-scale RCT, only English-speaking leaders were included in the feasibility study.

Procedures

For the purpose of testing the feasibility of administering the SPIN-SSLED Program, we sought 10 group leaders to participate in two separate training groups of 5 participants each. We asked Scleroderma Canada and the Scleroderma Foundation to generate an initial list of 12 interested potential participants and obtained permission for the SPIN team to send them an email with an invitation to participate in the feasibility trial and a copy of the consent form. Following the initial email, SPIN personnel contacted potential participants by phone within 48 hours to describe the study, assess their eligibility, review the consent form, and answer questions they may have had about the study. Eligible leaders who verbally agreed to enrol in the study received a second email with the consent form again attached, and they were able to consent via email 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." The first 10 people to respond and consent were enrolled, and the other 2 were put on a waiting list. All leaders who consented to participate and enrolled received an email invitation including a clickable link to the online data management platform where they were asked to complete baseline study measures. The email also included the date of their first training session, the topic of the first session and information on how to login to the videoconferencing system, as well as a link to the SPIN-SSLED online forum platform, where the program manual and associated PowerPoint slides were available. Ongoing email and phone technical support was available to help leaders with the consent process, access to the data management platform to complete study measures, and training sessions.

The trial was approved by the ethics committee of the Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal.

Intervention

The SPIN-SSLED Program was developed by a team of researchers and health care professionals with expertise in SSc, patient organisation representatives and a Support Group Advisory Team comprised of people with SSc who are current SSc support group leaders. The program content and design were based on results of our preliminary research on support groups in SSc, including individual interviews and surveys with leaders, members, and non-attenders,[17-20] and informed by instructional material for support group leaders in other diseases that 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-centred 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.[34-37] To implement this, each module introduces a topic

and provides an overview of key information. Then, there is a guided discussion among training group participants about possible approaches and solutions to problems.

The SPIN-SSLED Program included 13 modules that are delivered live via videoconference over the course of 3 months. Each module is 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, and (13) support group leader resources. The program includes 11 filmed vignettes that demonstrate effective group facilitation techniques and ways to respond to problems that arise with the behaviours of specific group members or group interactions. In addition to the live modules, SPIN-SSLED participants receive a program manual that summarises didactic material that is provided in the sessions.

Based on our previous experience with videoconferencing and consistent with previous trials of videoconference training, 5 group leaders were assigned to each training group to maximise effective interaction and participation.[38-41] Training sessions were delivered using the GoToMeeting® videoconferencing platform, a high-performance platform that has been used successfully for similar applications.[42-44] In addition to the videoconference sessions, participants had access to a secure, monitored SPIN-SSLED online forum via the Slack® communication tool to interact with other participants about program content. The two training groups were held in the evening.

Feasibility Outcomes

Outcomes related to process and resources were assessed throughout the duration of the feasibility trial, and leader feedback was obtained upon completion of the program. The collected

measures of feasibility included assessments of the (1) enrolment and consent procedure, (2) percentage of referred and eligible group leaders who consented to participate, (3) personnel requirements to assist participants with accessing the GoToMeeting® videoconferencing platform for sessions and the online survey program Qualtrics® for online data collection pre-training and post-training, (4) technological performance of the videoconferencing system, and (5) any challenges for study personnel.

Individual semi-structured interviews were conducted with all participants via telephone upon completion of the 13 modules. The semi-structured interviews were guided by items of the Patient Education Materials Assessment Tool for Audiovisual Materials (PEMAT) [45] and addressed topics related to usability, understandability, organisation, and clarity of the SPIN-SSLED program, including its videoconference-based delivery. The PEMAT included a single rating of satisfaction from 0 (worst possible) to 10 (best possible).

SPIN-SSLED Planned Trial Outcome Measures

In the planned full-scale RCT, 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 the program reduces burnout, improves emotional well-being, and improves physical function among support group leaders (secondary). The SPIN-SSLED feasibility trial was not intended to test hypotheses and did not have adequate power for this, but we collected trial outcome measures at the time of consent to participate in the trial and following completion of the program to evaluate the percentage of measures that were completed and to evaluate performance of the measures. Participants were emailed invitations to complete baseline and post-intervention measures using the online survey program Qualtrics®.

Leader Self-Efficacy: The Scleroderma Support Group Leader Self-efficacy Scale (SSGLSS) [46] was developed by our research team, including the members of the SPIN Support Group Advisory Team, to measure support group leader self-efficacy for performing leader tasks. Initial items were obtained from the Group Leader Self-Efficacy Instrument, a 37-item self-report questionnaire that assesses self-efficacy for performing group leader skills.[47] The Group Leader Self-Efficacy Instrument is intended for use with group psychotherapy leaders, so many of its items are not relevant or appropriate for support group leaders. Items from this instrument were reviewed for relevancy, and relevant items were considered for inclusion, along with items from a questionnaire intended for leaders of cancer and multiple sclerosis support groups [48] and items that we generated from the results of a published study on the experiences of leaders of cancer support groups.[49] All items were then reviewed by members of our research team to remove items that were repetitive or not relevant for SSc and to generate new items to reflect important SSc-specific content based on their own experiences or on qualitative interviews that we conducted with SSc support group leaders (N = 10). Items were then reviewed iteratively by all members of the research team until a consensus was reached on included items. The resulting 32-item scale is scored on a 6-point Likert scale from 1 (strongly disagree*)* to 6 (strongly agree) with possible total scores from 32 to 192 and higher scores indicating greater self-efficacy. The SSGLSS was validated in two samples of SSc support group leaders (N = 102, N = 55) and found to have good internal consistency (Cronbach's alpha 0.96 and 0.95) and hypothesis-consistent convergent validity with the Oldenburg Burnout Inventory (OLBI).

Burnout: Leader burnout was assessed with the OLBI,[50-52] which is a 16-item measure that assesses exhaustion and disengagement due to burnout. The OLBI was initially

designed for work-related burnout, but has been adapted for numerous settings and in multiple countries and languages.[52] Our research team revised the wording of each OLBI item to reflect the support group environment rather than a work environment (e.g., "I find my work to be a positive challenge" was revised to "I find my role as a support group leader to be a positive challenge"). The OLBI has a two-factor structure (exhaustion and disengagement) with good measurement properties.[50-52] Items are scored on a 4-point scale; higher scores indicate higher levels of exhaustion and disengagement. Internal consistency reliability (Cronbach's alpha) in patients with SSc was 0.84 for exhaustion and 0.80 for disengagement.[46]

Emotional Distress: The Patient Health Questionnaire-8 (PHQ-8) was used to assess emotional distress.[53] 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,[53] which has been shown to be a valid measure of depressive symptoms in patients with SSc.[54]

Physical Function: Physical function was measured using the Physical Function subscale of the 29-item Patient Reported Outcomes Measurement Information System (PROMIS-29) 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. Total raw scores are obtained by summing item scores for each domain. The PROMIS-29 version 2.0 has been validated in SSc.[55]

Participant Satisfaction: Satisfaction with the SPIN-SSLED Program was evaluated with the Client Satisfaction Questionnaire-8 (CSQ-8),[56] a standardised survey that is used to assess satisfaction with health services. Items are scored on a Likert scale from 1 (low satisfaction) to 4 (high satisfaction) with total scores ranging from 8 to 32. The CSQ-8 has been widely validated across a range of populations and health services programs.[57]

***Adverse Events*:** Following each session, we emailed participants and requested that they report any concerns that they had about the sessions or their experience in the sessions.

Sample size

Guidance on appropriate sample size for feasibility trials varies substantially in the published literature. For the purposes of establishing feasibility of delivery of the SPIN-SSLED Program, we determined that conducting two different training groups would allow us to evaluate intervention content and delivery aspects, and, thus, we sought to recruit a total of 10 participants to conduct two training groups.

Data Analysis

Feasibility outcomes included leader eligibility and recruitment, leader enrolment, and technological performance of the videoconferencing system. Qualitative information via interviews and weekly reports by participants was collected to inform any necessary changes to the program or trial methods that could be implemented prior to beginning a full-scale trial. Descriptive statistics were used to provide means and standard deviations for SPIN-SSLED Program outcome measures.

Hypothesis tests were not conducted, but effect sizes for pre-post differences are shown. Data were analysed using the statistics software program, IBM SPSS.

Patient and Public Involvement

The SPIN Support Group Advisory Team has been involved in all stages of SPIN's research on support groups in SSc, including preliminary research on support groups in SSc, the development of the SPIN-SSLED program, and the design and implementation of the feasibility trial. Members of the Team initially participated in the design of the Scleroderma Support Group Survey, which informed developing of the program by collecting information on the experiences and training needs of SSc support group leaders, priorities of SSc support group members, and reasons why people do not attend SSc support groups.[17-20] Team members participated in the development of the SSGLSS,[46] which was administered in the feasibility trial and will be the primary outcome for the planned full-scale trial. Team members provided input into the development of the SPIN-SSLED Program and its modules, filmed the vignettes used in the program, and were involved in decisions related to the conduct of the feasibility trial.

RESULTS

Participant Characteristics

The trial was conducted between April and July 2018. Scleroderma Canada and the Scleroderma Foundation each provided our team with names of 6 potential participants. All agreed to participate in the program. We initially enrolled 10 participants, but one was hospitalised prior to initiating the program. Thus, prior to starting the trial, we added one participant who had been wait-listed.

All 10 participants were female. The mean age was 58 years (standard deviation [SD] = 11 years). There were 6 participants from Canada and 4 from the United States. All 10 described themselves as White, and one also described herself as Aboriginal. Of the 10 participants, 9 were people with SSc. Mean years since diagnosis among those with SSc was 11 years. Participant characteristics are shown in Table 1.

Table 1. Participant Characteristics

Characteristics	**N Participants = 10**
Female sex, *n (%)*	10 (100%)
Age in years, *mean (SD)*	57.7 (11.1)
Country, *n (%)*	
Canada[a]	6 (60%)
United States[b]	4 (40%)
Race/ethnicity,[c] *n (%)*	
White	10 (100%)
Aboriginal	1 (10%)
Relationship status, *n (%)*	
Married or living as married	8 (80%)
Separated or divorced	2 (20%)
Education in years, *mean (SD)*	17.5 (2.7)
Occupational status, *n (%)*	
Homemaker	1 (10%)
Part- or full-time employment[b]	2 (20%)
Disability	3 (30%)

Retired	4 (40%)
SSc diagnosis, *n (%)*	
Limited SSc	4 (40%)
Diffuse SSc	5 (50%)
Not diagnosed with SSc	1 (10%)
Years since SSc diagnosis, *mean (SD)*	10.9 (7.4)
Current leader of SSc support group	10 (100%)
Years as a SSc support group leader, *mean (SD)*	3.6 (3.7)

[a] Participants from British Columbia, Manitoba, Ontario, Quebec (2), and Saskatchewan.
[b] Participants from California (3) and Florida.
[c] Participants could select more than one race/ethnicity.

Feasibility Outcomes

All 10 participants completed all baseline and post-trial measures, including the PEMAT interview. Participant attendance at the weekly sessions was high (95%; 123 of 130 sessions). No sessions were missed or delayed due to technological difficulties, and time for technological support from our team was between 1-2 hours for the entire program. Per the PEMAT interviews and per our observations, the GoToMeeting system worked fluidly and supported the training groups well.

A summary of responses to the PEMAT interviews is shown in Table 2. As can be seen in the table, there were relatively minor suggestions for improving the program. Overall, feedback was extremely positive. The overall mean grade given by participants for the SPIN-SSLED Program was 9.4/10. No concerns related to adverse events were reported.

Table 2. Summary of Responses to the Patient Education Materials Assessment Tool for Audiovisual Materials (PEMAT) Interviews

PEMAT Item	Summary of Responses
Are you currently a leader of a support group, a co-leader or planning on becoming a support group leader?	4 co-leaders, 5 leaders, 1 plans to become leader.
PROCESS	
Did you find that the weekly frequency of the training sessions was adequate?	10 yes.
Did you find the length of each training session appropriate?	10 yes; 3 added that grief module was not long enough, 1 said grief module was too long.
Was it difficult to find the motivation to attend the training session every week?	9 no; 1 sometimes due to scheduling.
PURPOSE	
Did you understand the objectives of the SPIN-SSLED training program modules?	10 yes.
Did you find the information provided in the SPIN-SSLED training program relevant?	10 yes.
WORDS AND LANGUAGE	
Did you find that the content of the program manual was clear, concise and easy to follow?	10 yes.
Did you find that the content delivered in the training sessions and the discussion about the content was easy to understand and useful?	10 yes.
CONTENT AND ORGANISATION	
Did you find that the content of the SPIN-SSLED modules was presented logically and well-organised?	10 yes.
Did you find that the order of the modules was logical and that linkages were clear?	9 yes; 1 said that order was “staggered”.
Did you find the discussion among other participants helpful?	10 yes; 1 mentioned that sometimes she had questions and challenges specific to herself that she didn’t have time to get addressed.
VIDEO VIGNETTES	
Did the fact that the video vignettes scenarios were performed by scleroderma patients make the program more relatable?	9 yes; 1 had difficulty hearing the videos (participant with hearing impairment).
Were you able to clearly understand the people speaking in the videos?	9 yes; 2 no; 1 indicated there were small things they didn't quite hear (participant with hearing impairment).

Did you develop an understanding of the challenges that could arise in a support group from watching the videos and obtain useful information or strategies to address them?	8 yes, 2 no (not hearing properly; 1participant with hearing impairment).
TECHNOLOGY	
Did you use a computer, phone, tablet or all these devices to access the SPIN-SSLED Training Program?	7 used computer, 4 used phone, 1 used tablet (> 10 due to >1 method for some participants).
Did the initial invitation email provide you with the information you needed to understand how to log in for the training session?	10 yes.
Did you experience any technical difficulties while using GoToMeeting?	8 no; 2 minor.
Did you experience any technical difficulties while using Slack chatroom?	7 no; 3 did not use it. Use overall was minimal.
Did you use the guide we provided to use GoToMeeting and the Slack chatroom?	5 yes; 5 no.
OVERALL APPRECIATION	
Can you please tell us about your experience with the SPIN-SSLED Training Program, including things that you liked about the program and things that could be improved?	Positive aspects of program: informative, organised, videos, "Supporting Yourself as a Leader" and "Grief and Crisis" modules were identified as very important. Positive aspects of SPIN-SLLED program leader: clear, conscientious, answered questions thoroughly, gave opportunities for feedback, was available between sessions. To improve: discuss financial support for support group expenses, expand grief module over 2 sessions, do sessions in winter instead of summer so that individuals with scleroderma can only enjoy the outdoors in summer, adding more videos.
What grade (on a 0-10 scale, 0 being the worst and 10 being the best possible score) would you give the program? 0 (worst) to 10 (best).	5 rated 10, 1 rated 9, 1 rated 9.5, 2 rated 8, 1 rated "9 or 10". Mean score: 9.4/10
Would you recommend this program to someone with scleroderma?	10 yes.
Is there anything you want to give us feedback about that was not included in this interview?	The remote support group meetings module was less important to 1 participant. Suggestion to make recordings of support group discussions available online.

SPIN-SSLED Planned Trial Outcome Measures

Table 3 shows the responses to each of the 32 items of the SSGLSS, which will be the primary outcome measure in the full-scale trial. Pre-training, the mean (SD) was 124.4 (22.0), which was similar to the scores of our two international samples from the SSGLSS validation study (N = 102, mean SSGLSS = 122.9 (21.7); N = 55, mean SSGLSS = 123.9 (19.4)). Post-training, the mean total score increased to 159.2 (17.1). The standardised mean difference effect size was 1.70, which is considered a large effect size. SSGLSS items are scored on a 1-6 scale, and the average item score increase pre-post training was 1.1 points.

Table 3. Pre- and Post- Intervention Item and Total Scores for the Scleroderma Support Group Leader Self-efficacy Scale: Possible item scores range from 1 to 6 with higher scores reflecting greater self-efficacy

Items	Pre-Trial N	Pre-Trial Mean (SD)	Post-Trial N	Post-Trial Mean (SD)	Standardised Mean Difference Effect Size (95% confidence interval – total only)
1. Obtain financial or other resources needed to run the group	10	3.5 (1.7)	10	4.8 (1.2)	0.61
2. Promote the group to health professionals as an important resource for patients	10	4.5 (0.7)	10	5.4 (0.7)	1.80
3. Share responsibilities, including administrative and practical tasks, with a co-facilitator or other group members	10	4.8 (1.6)	10	5.5 (0.5)	0.52
4. Manage group members who are overly talkative or monopolize the discussion	10	3.9 (1.1)	10	4.8 (0.6)	1.13
5. Manage group members who assume the role of the "know-it-all"	10	3.9 (1.1)	10	4.6 (0.8)	0.73
6. Support members of the group who are grieving	10	3.3 (1.5)	10	4.7 (0.8)	0.97
7. Help overly shy group members feel comfortable interacting with the group	10	3.9 (1.1)	10	4.9 (0.7)	1.14
8. Help group members cope with difficult events, such as the death of a member	10	3.0 (1.8)	10	4.7 (0.8)	0.90
9. Effectively recruit new members	10	3.5 (1.4)	10	4.9 (0.7)	1.18
10. Address the different needs of groups members at varying stages of the disease	10	3.7 (1.6)	10	4.8 (0.6)	0.77
11. Manage conflicts and disagreements between group members	10	3.3 (1.4)	10	4.5 (0.7)	0.95
12. Help the group establish appropriate group rules, such as maintaining confidentiality	10	4.3 (1.1)	10	5.8 (0.4)	2.31
13. Effectively publicize the group	10	3.5 (1.1)	10	5.1 (0.7)	1.86
14. Intervene effectively when group rules are not being followed	10	4.0 (1.1)	10	5.0 (0.7)	1.30
15. Obtain the support I need to cope with the emotional demands of leading the group	10	2.9 (1.2)	10	4.9 (1.0)	1.65
16. Respond constructively to feedback from group members	10	4.6 (0.8)	10	5.3 (0.8)	1.01
17. Help group members relate to other members of a different age	10	4.1 (1.0)	10	5.1 (0.7)	1.30
18. Provide the structure needed for successful meetings	10	5 (0.9)	10	5.6 (0.5)	1.03
19. Keep the group meetings interesting and relevant to both new and returning members	10	4.2 (0.9)	10	5.2 (0.8)	1.35

20. Manage group members who oversimplify or minimize the concerns of other members	10	3.5 (1.4)	10	4.9 (0.9)	0.99
21. Facilitate the group meetings so that all members have an opportunity to speak	10	4.6 (0.8)	10	5.1 (0.9)	0.68
22. Help the group stay focused on topics that are relevant to members	10	4.4 (0.7)	10	5.3 (0.7)	1.88
23. Obtain feedback from members about the group	10	4.3 (0.8)	10	5.0 (0.8)	1.04
24. Organise and plan activities for group members, such as having guest speakers	10	4.5 (1.4)	10	5.5 (0.7)	0.86
25. Help members feel comfortable in the group and relate to one another	10	4.4 (0.8)	10	5.2 (0.6)	1.43
26. Obtain feedback from members about my leadership	10	3.6 (0.7)	10	4.8 (0.9)	1.79
27. Help group members relate to other members of a different cultural background	10	3.9 (1.2)	10	4.5 (1.0)	0.50
28. Communicate reasonable boundaries about my availability outside of the group	10	3.7 (1.3)	10	4.5 (1.0)	0.64
29. Talk to a group member about her or his behaviour if it is disruptive to the group	10	2.7 (1.3)	10	4.5 (0.9)	1.58
30. Ask a member to leave the group due to her of his disruptive behaviour	10	1.6 (1.0)	10	4.2 (1.1)	2.32
31. Help group members relate to other members of a different gender	10	4.4 (1.1)	10	5.0 (0.8)	0.65
32. Recruit a co-facilitator or other group members to help me with leadership responsibilities	10	4.9 (1.3)	10	5.1 (0.9)	0.16
Total Score (Possible Range 32 to 192)	10	124.4 (22.0)	10	159.2 (17.0)	1.70 (0.67, 2.72)

Table 4 shows results for health outcomes, including burnout (OLBI), emotional distress (PHQ-8), and physical function (PROMIS-29). For all of these outcomes, the standardised mean difference effect size of post-trial score improvement was between 0.38 and 0.45, which are typically considered moderate effect sizes.

Table 4. Pre- and Post- Intervention Total Scores for Secondary Outcome Measures

Measure	Pre-Trial N	Pre-Trial Mean (SD)	Post-Trial N	Post-Trial Mean (SD)	Standardised Mean Difference Effect Size (95% confidence interval)
Oldenburg Burnout Inventory (higher scores = greater burnout)	10	33.2 (4.6)	10	31.0 (4.9)	0.44 (-0.44, 1.33)
Patient Health Questionnaire-8 (higher scores = greater symptoms of depression)	10	10.8 (2.7)	10	9.8 (2.4)	0.38 (-0.50, 1.27)
PROMIS-29 Physical Function (higher raw scores = greater function)	10	17.1 (2.2)	10	18.2 (2.4)	0.45 (-0.42, 1.36)

As shown in Table 5, the mean post-training score on the CSQ-8 was 30.6 (2.2). On a per item basis, the mean item score (possible range 1-4) was 3.8, reflecting a very high level of satisfaction with the experience of trainees with the SPIN-SSLED Program.

Table 5. Post-Intervention Items, Frequencies, and Total Scores for the Client Satisfaction Questionnaire-8: Item response options very across items, but all scored 1-4

Items	1 Point (Dissatisfied) n (%)	2 Points (Mildly Satisfied) n (%)	3 Points (Mostly Satisfied) n (%)	4 Points (Quite Satisfied) n (%)	Item Mean (SD)
1. How would you rate the quality of the SPIN-SSLED training?	0 (0%)	0 (0%)	1 (10%)	9 (90%)	3.9 (0.3)

2. Did the SPIN-SSLED program provide you the kind of training you wanted?	0 (0%)	0 (0%)	2 (20%)	8 (80%)	3.8 (0.4)
3. To what extent has the SPIN-SSLED training met your needs?	0 (0%)	0 (0%)	4 (40%)	6 (60%)	3.6 (0.5)
4. If a friend were in need of similar training, would you recommend the SPIN-SSLED program to him/her?	0 (0%)	0 (0%)	2 (20%)	8 (80%)	3.8 (0.4)
5. How satisfied are you with the amount of training you received from the SPIN-SSLED program?	0 (0%)	0 (0%)	2 (20%)	8 (80%)	3.8 (0.4)
6. Has the SPIN-SSLED training helped you to deal more effectively with your support group leader role?	0 (0%)	0 (0%)	0 (10%)	10 (100%)	4.0 (0.0)
7. In an overall, general sense, how satisfied are you with the SPIN-SSLED training?	0 (0%)	0 (0%)	1 (20%)	9 (90%)	3.9 (0.3)
8. If you were to seek help again, would you come back to the SPIN-SSLED training?	0 (0%)	0 (0%)	2 (20%)	8 (80%)	3.8 (0.4)
Total Score (Possible Range 8 to 32)					30.6 (2.2)

DISCUSSION

Feasibility of delivering the SPIN-SSLED Program in the context of a trial, participant satisfaction, and program content were evaluated in the SPIN-SSLED feasibility trial. Results

informed revisions to the content of the program and provided confidence that the program can be effectively and efficiently delivered in a full-scale trial.

With respect to overall experience with the program and program content, participants reported that the content was clear and well-organised. Overall satisfaction with their experience in the SPIN-SSLED Program was rated as 9.4 out of 10 on average. Participant satisfaction was similarly high when evaluated with the 8 items of the CSQ. Several participants encouraged the research team to expand on the single module related to grief. Based on comments and follow-up discussions with participants, the program was revised to include two modules on grief, including one module on grief and loss that leaders have experienced because they or somebody close to them has been diagnosed with SSc and a second module on providing support to group members who are struggling with grief and loss. In order to add a second module on grief and loss, the two modules on managing group dynamics were reduced to a single module. To facilitate this, rather than viewing all of the short video vignettes included in those modules as part of the training sessions, participants suggested that they could view the vignettes prior to the sessions and then suggest specific modules for review and discussion in the training sessions.

With respect to program delivery, participants indicated that they were able to access the sessions via the GoToMeeting platform and did not experience any technical difficulties that interrupted their training sessions. One difficulty that was reported involved a participant with a hearing impairment who was unable to hear all of the vignette videos well. This information will help us to assess for reasons why participants may need additional support in the full-scale trial and will allow us to make accommodations. From a management standpoint, total time for technical support due to access difficulties across the trial period for the two groups was between 1-2 hours. Participants

attended 95% of sessions, and all 10 participants completed all baseline and post-trial outcome assessments.

There were limitations that should be considered in evaluating the results of the SPIN-SSLED feasibility trial. First, we were provided with a small list of potential participants from our patient organisation partners, and it is possible that these support group leaders were more motivated or otherwise more likely to participate and engage than the leaders who will participate in the full-scale trial. Second, we did not randomise participants to the intervention and to a wait-list control group as we will do in the planned full-scale trial. Third, we only conducted 2 training groups and only included a total of 10 participants. The reason for not using a control group and limiting the feasibility trial to 2 groups is that there is a finite number of English- and French-speaking SSc support group leaders, and we wanted to be able to assess feasibility aspects but maximize the number of participants eligible for the full-scale trial. It is possible that the pre-selection of potential participants and the lack of the possibility of randomised assignment to a non-intervention group may have resulted in over-estimation of the percentage of participants who will enrol in the full-scale trial and the degree to which they will actively participate. Given the small number of French-speaking leaders available for the full-scale trial, we did not include a French group in the feasibility trial. However, all measures have been used successfully previously with French-speaking research participants. Finally, the trial only included leaders of SSc support groups, and this may limit generalisability to other patient populations, but it will be useful to inform our planned full-scale trial of the SPIN-SSLED Program.

There are no existing training programs for SSc support group leaders, and a systematic review did not identify any training or education programs that have been demonstrated to be effective for support group leaders in any medical condition.[31] The planned full-scale SPIN-SSLED trial, which was recently funded by the Canadian Institutes of Health Research, is scheduled to begin in 2019

(http://webapps.cihr-irsc.gc.ca/decisions/p/project_details.html?applId=388187&lang=en). It will be a pragmatic RCT that will test whether providing the SPIN-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.[58, 59] 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. To account for clustering in the training arm, but not the control arm, we will use a partially nested RCT trial design (PN-RCT).[60-62] The PN-RCT design is a hybrid between a conventional RCT, in which individual participants are randomised, and a cluster RCT, in which pre-existing clusters (e.g., primary care practices, classrooms) are randomised 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. Participants will be existing support group leaders or new leaders referred by Scleroderma Canada (English) or Sclérodermie Québec (French), the Scleroderma Foundation (USA), Scleroderma & Raynaud's UK, the Scleroderma Association of New South Wales (Australia), and Scleroderma New Zealand.

In sum, the SPIN-SSLED feasibility trial ensured that trial methodology was feasibly implemented and that the online intervention was user-friendly and acceptable to participants. Participants provided suggestions for adjustments to content that will be implemented before undertaking a full-scale RCT of the SPIN-SSLED program to assess effectiveness.

AUTHORS CONTRIBUTIONS

BDT, VLM, GE-B, SP, MS, MH, and RWP were responsible for the study conception and design. BDT, LD, MP, KA, MEC, LT, and SH were responsible for implementation of the trial or acquisition, analysis, and interpretation of trial data. BDT drafted the manuscript. All authors provided a critical review and approved the final manuscript. BDT is the guarantor.

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COMPETING INTERESTS STATEMENT

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare that they have no competing interests.

DATA SHARING STATEMENT

All data extracted and analysed for the present study are available from the corresponding author.

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CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	6
	2b	Specific objectives or research questions for pilot trial	7
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	7
Participants	4a	Eligibility criteria for participants	7-8
	4b	Settings and locations where the data were collected	8
	4c	How participants were identified and consented	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-10
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	11-13
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	7
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size	7a	Rationale for numbers in the pilot trial	13
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	13-14
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	14-15
	13b	For each group, losses and exclusions after randomisation, together with reasons	14-15
Recruitment	14a	Dates defining the periods of recruitment and follow-up	14
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	15
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	All tables
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	21-22
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	16
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	25
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	25
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	26
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	26
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	4
Protocol	24	Where the pilot trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	27
	26	Ethical approval or approval by research review committee, confirmed with reference number	9

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

The Scleroderma Patient-centered Intervention Network – Scleroderma Support group Leader Education (SPIN-SSLED) Program: Non-randomised Feasibility Trial

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The Scleroderma Patient-centered Intervention Network – Scleroderma Support group Leader Education (SPIN-SSLED) Program: Non-randomised Feasibility Trial

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ABSTRACT

Objectives: The Scleroderma Patient-centered Intervention Network – Scleroderma Support group Leader EDucation (SPIN-SSLED) Program was designed to improve confidence and self-efficacy and to reduce burden for support group leaders. Objectives of the feasibility trial were to (1) evaluate feasibility of program delivery, including required resources, management issues, and scientific aspects; and (2) assess user satisfaction and identify any modifications needed to improve program content or delivery based on participant feedback.

Design: Non-randomised feasibility trial.

Setting: North American scleroderma patient organisations.

Participants: Current support group leaders or potential new leaders referred by patient organisations.

Intervention: The program included 13 modules delivered live via videoconference over 3 months (April to July 2018) in 60- to 90-minute sessions.

Outcome Measures: (1) Elements of feasibility, including enrolment and consent procedures, percentage of referred group leaders who consented to participate, session attendance, and technical support requirements; (2) program usability, understandability, organisation, and clarity; (3) leader satisfaction with the program; and (4) planned trial outcome measures, including support group leader self-efficacy, burnout, emotional distress, and physical function.

Results: All 12 referred potential participants consented to enrol, and 10 were included in 2 training groups of 5 participants each. Participants attended 95% of sessions. Required technical support was minimal, and videoconferencing technology functioned well. Overall

program satisfaction rating was 9.4/10. Mean item rating on the 8 items of the Client Satisfaction Questionnaire-8 was 3.83 (1 = low satisfaction; 4 = high satisfaction). Pre-post scores on the Scleroderma Support Group Leader Self-efficacy Scale increased by 1.7 standard deviations (large effect); scores on burnout, emotional distress, and physical function improved by 0.44, 0.38, and 0.45 standard deviations (moderate effects).

Conclusion: The SPIN-SSLED Program was feasibly delivered, including management, resource, and scientific aspects. Participant satisfaction was high. The program is ready to be tested in a full-scale randomised controlled trial.

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Trial Registration: NCT03508661

Key Words: patient education; peer support; feasibility trial; scleroderma; support groups; systemic sclerosis

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is the first trial to test the feasibility of delivering an education and training program via videoconference to peer support group leaders.
- The education and training program was developed in a partnership that included scleroderma peer support group leaders, patient organisation leaders, and researchers and health care professionals.
- Trial outcomes included elements of feasibility (e.g., management, resources, scientific aspects); program usability, understandability, organisation, and clarity; leader satisfaction with the program; and planned trial outcome measures.
- This was a non-randomised feasibility trial that only included 10 participants in 2 training groups and did not include a control group; generalisability of results outside of scleroderma is not known.

INTRODUCTION

People with rare diseases face the same challenges as those with more common diseases plus unique challenges, including limited disease education and lack of specialised support options.[1-12] Professionally organised support services for common diseases are often available through the healthcare system,[13, 14] but are not typically available in rare diseases.[10, 15] As a result, some people with rare diseases rely on peer-led support groups for disease-specific education and support.[16-20] Support group activities typically involve an educational or information-sharing component and the exchange of emotional and practical support.[14, 18-22].

Systemic sclerosis (SSc), or scleroderma, is a rare chronic, autoimmune connective tissue disease characterised by abnormal fibrotic processes and excessive collagen production.[23-25] Support groups, most led by people with SSc, play an important role for many people with the disease.[17, 26-30] Many people with SSc, however, cannot access support groups because they are not available close to where they live, and many initiated support groups are not sustained due to challenges that could be addressed via leader training.[18, 19]

A systematic review of randomised controlled trials (RCTs) that evaluated the effects of training programs for patient leaders of illness-based support groups on the competency, self-efficacy, burden, and emotional well-being of group leaders identified only one RCT that met inclusion criteria.[31] That trial [32] evaluated confidence and self-efficacy of cancer

support group leaders randomised to either 4-month long high-resource (N = 29; website, discussion forum, 2-day face-to-face training) or low-resource (N = 23; website, discussion forum) interventions. The RCT did not find evidence that the high-resource program was more effective. However, the trial was substantially underpowered, not enough information was provided to determine intervention content or how it was delivered, and the risk of bias was high due to methodological limitations.

The Scleroderma Patient-centered Intervention Network (SPIN) partnered with SSc patients and patient organisations to develop the Scleroderma Support group Leader EDucation (SPIN-SSLED) Program. The program is a 13-session group videoconference training program, designed to improve skills and self-efficacy, reduce burnout, and improve emotional and physical function among support group leaders. The objectives of the SPIN-SSLED feasibility trial were to (1) evaluate the feasibility of steps needed to take place in a planned full-scale trial, including the *required resources* (e.g., staffing, time, and budget), *management issues* (e.g., related to optimising performance of personnel and data systems), and *scientific aspects* (e.g., recruitment rates of eligible leaders, acceptability of intervention to leaders, assessing performance of outcome measures) and (2) identify any modifications needed to improve the content or delivery of the SPIN-SSLED Program based on participant feedback.

METHODS

The SPIN-SSLED feasibility trial was a non-randomised study. It was registered prior to enrolling participants (NCT03508661) and, although not a randomised study, is reported based on items from the CONSORT extension for randomised pilot and feasibility trials.[33] There

were no changes to the feasibility trial protocol and no changes to planned outcomes after commencement of the trial.

Participants

Eligible participants for the SPIN-SSLED feasibility trial were current SSc support group leaders or were identified by Scleroderma Canada or the Scleroderma Foundation (United States) as a new leader who will initiate a new support group, were able to use the internet to access and participate in training sessions and to complete study questionnaires online, were available to participate at times when sessions were scheduled, and were English-speaking, since both groups in the feasibility trial were conducted in English. The full-scale trial will include groups conducted in French, but individuals who participated in the feasibility study will be excluded from the full-scale RCT. Thus, to ensure that there will be an adequate number of French-speaking participants in the full-scale RCT, only English-speaking leaders were included in the feasibility study.

Procedures

For the purpose of testing the feasibility of administering the SPIN-SSLED Program, we sought 10 group leaders to participate in two separate training groups of 5 participants each. We asked Scleroderma Canada and the Scleroderma Foundation to generate an initial list of 12 interested potential participants and obtained permission for the SPIN team to send them an email with an invitation to participate in the feasibility trial and a copy of the consent form. Following the initial email, SPIN personnel contacted potential participants by phone within 48 hours to describe the study, assess their eligibility, review the consent form, and answer questions they may have had about the study. Eligible leaders who verbally agreed to enrol in the study received a second email with the consent form again attached, and they were able to consent via email 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." The first 10 people to respond and consent were enrolled, and the other 2 were put on a waiting list. All leaders who consented to participate and enrolled received an email invitation including a clickable link to the online data management platform where they were asked to complete baseline study measures. The email also included the date of their first training session, the topic of the first session and information on how to login to the videoconferencing system, as well as a link to the SPIN-SSLED online forum platform, where the program manual and associated PowerPoint slides were available. Ongoing email and phone technical support was available to help leaders with the consent process, access to the data management platform to complete study measures, and training sessions.

The trial was approved by the ethics committee of the Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal.

Intervention

The SPIN-SSLED Program was developed by a team of researchers and health care professionals with expertise in SSc, patient organisation representatives and a Support Group Advisory Team comprised of people with SSc who are current SSc support group leaders. The program content and design were based on results of our preliminary research on support groups in SSc, including individual interviews and surveys with leaders, members, and non-attenders,[17-20] and informed by instructional material for support group leaders in other diseases that 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-centred 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.[34-37] To implement this, each module introduces a topic

and provides an overview of key information. Then, there is a guided discussion among training group participants about possible approaches and solutions to problems.

The SPIN-SSLED Program included 13 modules that are delivered live via videoconference over the course of 3 months. Each module is 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, and (13) support group leader resources. See Table 1 for module content. The program includes 11 filmed vignettes that demonstrate effective group facilitation techniques and ways to respond to problems that arise with the behaviours of specific group members or group interactions. In addition to the live modules, SPIN-SSLED participants receive a program manual that summarises didactic material that is provided in the sessions.

Table 1. Content of Program Modules

Module Title	Module Description
1. The Support Group Leader's Role	This module discusses the benefits of being a support group leader, the expectations of what the role of leader involves (e.g. facilitation of meetings and interactions but not giving medical advice), and tips for being an effective and supportive leader.
2. Starting a Support Group	This module discusses the purpose of a support group, what people with scleroderma hope to gain from support group, why some don't attend, establishing leadership (e.g. one leader, co-leader), membership (e.g. patients only, open to family, and friends), logistics of starting a group (e.g. time, place and meeting duration).

3. Structuring Support Group Meetings	This module discusses formatting group meeting and how to successfully integrate both educational activities with emotional and practical support for members, setting up a meeting agenda.
4. Scleroderma 101	This module shows a filmed conference by a physician specialized in scleroderma who explain the different types of scleroderma, symptoms, causes, treatments, and alternative approaches. The module also includes tips to evaluate credibility of information sources on the Internet.
5. Successful Support Group Culture	This module discusses the importance of establishing expectations and guidelines for the support group with members, the importance of confidentiality, how to create and maintain positive and productive support group culture using (1) encouraging statements, (2) open-ended questions, (3) body language, (4) linking similar experiences between members, and (5) summarizing discussions. This module uses video vignettes to illustrate these techniques.
6. Managing Group Dynamics Part I	This module discusses managing difficult support group dynamics such as members who are "quick fixers", overly talkative, how to maintain a positive group environment, conflict management and resolution for minor and larger issues. This module uses video vignettes to illustrate these techniques.
7. Managing Group Dynamics Part II	This module discussed how to identify and respond to members who are overly shy or who are chronically negative, and what to do when members bring unsubstantiated, inaccurate or potentially misleading medical information to the group. This module uses video vignettes to illustrate these techniques.
8. Grief and Crisis in Scleroderma	The module discusses different situations that may bring grief to members, stages of grief, supporting group members in grief, dealing with medical crises or death of group members.
9. Advertising and Recruiting for the Support Group	This module discusses how to advertise and promote a support group, how to recruit new members for support groups on ongoing basis, advertising through patient organizations and strategies to retain members.

10. The Continuity of the Group	This module discusses the importance of understanding and overcoming reluctance in seeking feedback, the importance of feedback in the support group experience, how to obtain and respond to feedback, how to identify reasons why members may stop attending meetings and strategies to help maintain membership, how to keep members engaged and move your support group forward by making changes.
11. Supporting Yourself as a Leader	This module discuses understanding what leader burnout is, understanding why it can happen and what the warning signs are, understanding the best way to address burnout including identifying methods of coping, understanding at what point it may be best for a leader to step down from his or her role, strategies to prevent experiencing leader burnout.
12. Remote support groups	This module discusses the benefits of an online support group, finding the right technology, scheduling and programming, advertising and reaching your target audience, tips for successful online meetings.
13. Resources	This module discusses strategies on how to obtain information and resources, how to communicate information effectively to members, the responsibilities of the national organization, meeting the resource needs of the group, access to the SPIN-SSLED Online Resource Center to download scleroderma talks, educational videos, and research articles for leaders and members of support groups.

Based on our previous experience with videoconferencing and consistent with previous trials of videoconference training, 5 group leaders were assigned to each training group to maximise effective interaction and participation.[38-41] Training sessions were delivered using the GoToMeeting® videoconferencing platform, a high-performance platform that has been used successfully for similar applications.[42-44] In addition to the videoconference sessions, participants had access to a secure, monitored SPIN-SSLED online forum via the Slack® communication tool to interact with other participants about program content. The two training groups were held in the evening.

Feasibility Outcomes

Outcomes related to process and resources were assessed throughout the duration of the feasibility trial, and leader feedback was obtained upon completion of the program. The collected

measures of feasibility included assessments of the (1) enrolment and consent procedure, (2) percentage of referred and eligible group leaders who consented to participate, (3) personnel requirements to assist participants with accessing the GoToMeeting® videoconferencing platform for sessions and the online survey program Qualtrics® for online data collection pre-training and post-training, (4) technological performance of the videoconferencing system, and (5) any challenges for study personnel.

Individual semi-structured interviews were conducted with all participants via telephone upon completion of the 13 modules using items based on the Patient Education Materials Assessment Tool for Audiovisual Materials (PEMAT) [45] and addressed topics related to usability, understandability, organisation, and clarity of the SPIN-SSLED program, including its videoconference-based delivery. The PEMAT included a single rating of satisfaction from 0 (worst possible) to 10 (best possible).

SPIN-SSLED Planned Trial Outcome Measures

In the planned full-scale RCT, 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 the program reduces burnout, improves emotional well-being, and improves physical function among support group leaders (secondary). The SPIN-SSLED feasibility trial was not intended to test hypotheses and did not have adequate power for this, but we collected trial outcome measures at the time of consent to participate in the trial and following completion of the program to evaluate the percentage of measures that were completed and to evaluate performance of the measures. Participants were emailed invitations to complete baseline and post-intervention measures using the online survey program Qualtrics®.

Leader Self-Efficacy: The Scleroderma Support Group Leader Self-efficacy Scale (SSGLSS) [46] was developed by our research team, including the members of the SPIN Support Group Advisory

Team, to measure support group leader self-efficacy for performing leader tasks. Initial items were obtained from the Group Leader Self-Efficacy Instrument, a 37-item self-report questionnaire that assesses self-efficacy for performing group leader skills.[47] The Group Leader Self-Efficacy Instrument is intended for use with group psychotherapy leaders, so many of its items are not relevant or appropriate for support group leaders. Items from this instrument were reviewed for relevancy, and relevant items were considered for inclusion, along with items from a questionnaire intended for leaders of cancer and multiple sclerosis support groups [48] and items that we generated from the results of a published study on the experiences of leaders of cancer support groups.[49] All items were then reviewed by members of our research team to remove items that were repetitive or not relevant for SSc and to generate new items to reflect important SSc-specific content based on their own experiences or on qualitative interviews that we conducted with SSc support group leaders (N = 10). Items were then reviewed iteratively by all members of the research team until a consensus was reached on included items. The resulting 32-item scale is scored on a 6-point Likert scale from 1 (strongly disagree) to 6 (strongly agree) with possible total scores from 32 to 192 and higher scores indicating greater self-efficacy. The SSGLSS was validated in two samples of SSc support group leaders (N = 102, N = 55) and found to have good internal consistency (Cronbach's alpha 0.96 and 0.95) and hypothesis-consistent convergent validity with the Oldenburg Burnout Inventory (OLBI). A strength of using the SSGLSS as the primary outcome measure is that both the intervention and the SSGLSS were designed to reflect training needs of SSc support group leaders.

Burnout: Leader burnout was assessed with the OLBI,[50-52] which is a 16-item measure that assesses exhaustion and disengagement due to burnout. The OLBI was initially designed for work-related burnout, but has been adapted for numerous settings and in multiple countries and languages.[52] Our research team revised the wording of each OLBI item to reflect the support group environment rather than a work environment (e.g., "I find my work to be a positive challenge" was revised to "I find my role as a support group leader to be a positive challenge"). The OLBI has a two-factor structure (exhaustion and disengagement) with good measurement properties.[50-52] Items are scored on a 4-point scale; higher scores indicate higher levels of exhaustion and disengagement. Internal consistency reliability (Cronbach's alpha) in patients with SSc was 0.84 for exhaustion and 0.80 for disengagement.[46]

Emotional Distress: The Patient Health Questionnaire-8 (PHQ-8) was used to assess emotional distress.[53] 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,[53] which has been shown to be a valid measure of depressive symptoms in patients with SSc.[54]

Physical Function: Physical function was measured using the Physical Function subscale of the 29-item Patient Reported Outcomes Measurement Information System (PROMIS-29) 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. Total raw scores are obtained by summing item scores for each domain. The PROMIS-29 version 2.0 has been validated in SSc.[55]

Participant Satisfaction: Satisfaction with the SPIN-SSLED Program was evaluated with the Client Satisfaction Questionnaire-8 (CSQ-8),[56] a standardised survey that is used to assess satisfaction with health services. Items are scored on a Likert scale from 1 (low satisfaction) to 4 (high satisfaction) with total scores ranging from 8 to 32. The CSQ-8 has been widely validated across a range of populations and health services programs.[57]

***Adverse Events*:** Following each session, we emailed participants and requested that they report any concerns that they had about the sessions or their experience in the sessions.

Sample size

Guidance on appropriate sample size for feasibility trials varies substantially in the published literature. For the purposes of establishing feasibility of delivery of the SPIN-SSLED Program, we determined that conducting two different training groups would allow us to evaluate intervention content and delivery aspects, and, thus, we sought to recruit a total of 10 participants to conduct two training groups.

Data Analysis

Feasibility outcomes included leader eligibility and recruitment, leader enrolment, and technological performance of the videoconferencing system. Qualitative information via interviews and weekly reports by participants was collected, and all suggestions for changes to the program or trial methods that could be implemented prior to beginning a full-scale trial were recorded. Descriptive

statistics were used to provide means and standard deviations for SPIN-SSLED Program outcome measures. Since the purpose of this feasibility trial was to evaluate feasibility and identify any modifications to the intervention or trial plan, the trial was not designed or powered to test hypotheses about outcomes. Thus, consistent with best practices,[33] hypothesis tests were not conducted, but effect sizes for pre-post differences are shown. Data were analysed using the statistics software program, IBM SPSS.

Patient and Public Involvement

The SPIN Support Group Advisory Team has been involved in all stages of SPIN's research on support groups in SSc, including preliminary research on support groups in SSc, the development of the SPIN-SSLED program, and the design and implementation of the feasibility trial. Members of the Team initially participated in the design of the Scleroderma Support Group Survey, which informed developing of the program by collecting information on the experiences and training needs of SSc support group leaders, priorities of SSc support group members, and reasons why people do not attend SSc support groups.[17-20] Team members participated in the development of the SSGLSS,[46] which was administered in the feasibility trial and will be the primary outcome for the planned full-scale trial. Team members provided input into the development of the SPIN-SSLED Program and its modules, filmed the vignettes used in the program, and were involved in decisions related to the conduct of the feasibility trial.

RESULTS

Participant Characteristics

The trial was conducted between April and July 2018. Scleroderma Canada and the Scleroderma Foundation each provided our team with names of 6 potential participants. All agreed to participate in the program. We initially enrolled 10 participants, but one was hospitalised prior to initiating the program. Thus, prior to starting the trial, we added one participant who had been wait-listed.

All 10 participants were female. The mean age was 58 years (standard deviation [SD] = 11 years). There were 6 participants from Canada and 4 from the United States. All 10 described themselves as White, and one also described herself as Aboriginal. Of the 10 participants, 9 were people with SSc. Mean years since diagnosis among those with SSc was 11 years. Participant characteristics are shown in Table 2.

Table 2. Participant Characteristics

Characteristics	**N Participants = 10**
Female sex, *n (%)*	10 (100%)
Age in years, *mean (SD)*	57.7 (11.1)
Country, *n (%)*	
Canada[a]	6 (60%)
United States[b]	4 (40%)
Race/ethnicity,[c] *n (%)*	
White	10 (100%)
Aboriginal	1 (10%)
Relationship status, *n (%)*	
Married or living as married	8 (80%)
Separated or divorced	2 (20%)

Education in years, *mean (SD)*	17.5 (2.7)
Occupational status, *n (%)*	
Homemaker	1 (10%)
Part- or full-time employment[b]	2 (20%)
Disability	3 (30%)
Retired	4 (40%)
SSc diagnosis, *n (%)*	
Limited SSc	4 (40%)
Diffuse SSc	5 (50%)
Not diagnosed with SSc	1 (10%)
Years since SSc diagnosis, *mean (SD)*	10.9 (7.4)
Current leader of SSc support group	10 (100%)
Years as a SSc support group leader, *mean (SD)*	3.6 (3.7)

[a] Participants from British Columbia, Manitoba, Ontario, Quebec (2), and Saskatchewan.
[b] Participants from California (3) and Florida.
[c] Participants could select more than one race/ethnicity.

Feasibility Outcomes

All 10 participants completed all baseline and post-trial measures, including the PEMAT interview. Participant attendance at the weekly sessions was high (95%; 123 of 130 sessions). No sessions were missed or delayed due to technological difficulties, and time for technological support from our team was between 1-2 hours for the entire program. Per the PEMAT interviews and per our observations, the GoToMeeting system worked fluidly and supported the training groups well.

A summary of responses to the PEMAT interviews is shown in Table 3. As can be seen in the table, there were relatively minor suggestions for improving the program. Overall, feedback was

extremely positive. The overall mean grade given by participants for the SPIN-SSLED Program was 9.4/10. No concerns related to adverse events were reported.

Table 3. Summary of Responses to the Patient Education Materials Assessment Tool for Audiovisual Materials (PEMAT) Interviews

PEMAT Item	Summary of Responses
Are you currently a leader of a support group, a co-leader or planning on becoming a support group leader?	4 co-leaders, 5 leaders, 1 plans to become leader.
PROCESS	
Did you find that the weekly frequency of the training sessions was adequate?	10 yes.
Did you find the length of each training session appropriate?	10 yes; 3 added that grief module was not long enough, 1 said grief module was too long.
Was it difficult to find the motivation to attend the training session every week?	9 no; 1 sometimes due to scheduling.
PURPOSE	
Did you understand the objectives of the SPIN-SSLED training program modules?	10 yes.
Did you find the information provided in the SPIN-SSLED training program relevant?	10 yes.
WORDS AND LANGUAGE	
Did you find that the content of the program manual was clear, concise and easy to follow?	10 yes.
Did you find that the content delivered in the training sessions and the discussion about the content was easy to understand and useful?	10 yes.
CONTENT AND ORGANISATION	
Did you find that the content of the SPIN-SSLED modules was presented logically and well-organised?	10 yes.
Did you find that the order of the modules was logical and that linkages were clear?	9 yes; 1 said that order was “staggered”.

Did you find the discussion among other participants helpful?	10 yes; 1 mentioned that sometimes she had questions and challenges specific to herself that she didn't have time to get addressed.
VIDEO VIGNETTES	
Did the fact that the video vignettes scenarios were performed by scleroderma patients make the program more relatable?	9 yes; 1 had difficulty hearing the videos (participant with hearing impairment).
Were you able to clearly understand the people speaking in the videos?	9 yes; 2 no; 1 indicated there were small things they didn't quite hear (participant with hearing impairment).
Did you develop an understanding of the challenges that could arise in a support group from watching the videos and obtain useful information or strategies to address them?	8 yes, 2 no (not hearing properly; 1 participant with hearing impairment).
TECHNOLOGY	
Did you use a computer, phone, tablet or all these devices to access the SPIN-SSLED Training Program?	7 used computer, 4 used phone, 1 used tablet (> 10 due to >1 method for some participants).
Did the initial invitation email provide you with the information you needed to understand how to log in for the training session?	10 yes.
Did you experience any technical difficulties while using GoToMeeting?	8 no; 2 minor.
Did you experience any technical difficulties while using Slack chatroom?	7 no; 3 did not use it. Use overall was minimal.
Did you use the guide we provided to use GoToMeeting and the Slack chatroom?	5 yes; 5 no.
OVERALL APPRECIATION	
Can you please tell us about your experience with the SPIN-SSLED Training Program, including things that you liked about the program and things that could be improved?	Positive aspects of program: informative, organised, videos, "Supporting Yourself as a Leader" and "Grief and Crisis" modules were identified as very important. Positive aspects of SPIN-SLLED program leader: clear, conscientious, answered questions thoroughly, gave opportunities for feedback, was available between sessions. To improve: discuss financial support for support group expenses, expand grief module over 2 sessions, do sessions in winter instead of summer so that individuals with scleroderma can only enjoy the outdoors in summer, adding more videos.

What grade (on a 0-10 scale, 0 being the worst and 10 being the best possible score) would you give the program? 0 (worst) to 10 (best).	5 rated 10, 1 rated 9, 1 rated 9.5, 2 rated 8, 1 rated "9 or 10". Mean score: 9.4/10
Would you recommend this program to someone with scleroderma?	10 yes.
Is there anything you want to give us feedback about that was not included in this interview?	The remote support group meetings module was less important to 1 participant. Suggestion to make recordings of support group discussions available online.

SPIN-SSLED Planned Trial Outcome Measures

Table 4 shows the responses to each of the 32 items of the SSGLSS, which will be the primary outcome measure in the full-scale trial. Pre-training, the mean (SD) was 124.4 (22.0), which was similar to the scores of our two international samples from the SSGLSS validation study (N = 102, mean SSGLSS = 122.9 (21.7); N = 55, mean SSGLSS = 123.9 (19.4)). Post-training, the mean total score increased to 159.2 (17.1). The standardised mean difference effect size was 1.70, which is considered a large effect size.[58] SSGLSS items are scored on a 1-6 scale, and the average item score increase pre-post training was 1.1 points.

Table 4. Pre- and Post- Intervention Item and Total Scores for the Scleroderma Support Group Leader Self-efficacy Scale: Possible item scores range from 1 to 6 with higher scores reflecting greater self-efficacy

Items	Pre-Trial N	Pre-Trial Mean (SD)	Post-Trial N	Post-Trial Mean (SD)	Standardised Mean Difference Effect Size (95% confidence interval – total only)
1. Obtain financial or other resources needed to run the group	10	3.5 (1.7)	10	4.8 (1.2)	0.61
2. Promote the group to health professionals as an important resource for patients	10	4.5 (0.7)	10	5.4 (0.7)	1.80
3. Share responsibilities, including administrative and practical tasks, with a co-facilitator or other group members	10	4.8 (1.6)	10	5.5 (0.5)	0.52
4. Manage group members who are overly talkative or monopolize the discussion	10	3.9 (1.1)	10	4.8 (0.6)	1.13
5. Manage group members who assume the role of the "know-it-all"	10	3.9 (1.1)	10	4.6 (0.8)	0.73
6. Support members of the group who are grieving	10	3.3 (1.5)	10	4.7 (0.8)	0.97
7. Help overly shy group members feel comfortable interacting with the group	10	3.9 (1.1)	10	4.9 (0.7)	1.14
8. Help group members cope with difficult events, such as the death of a member	10	3.0 (1.8)	10	4.7 (0.8)	0.90
9. Effectively recruit new members	10	3.5 (1.4)	10	4.9 (0.7)	1.18
10. Address the different needs of groups members at varying stages of the disease	10	3.7 (1.6)	10	4.8 (0.6)	0.77
11. Manage conflicts and disagreements between group members	10	3.3 (1.4)	10	4.5 (0.7)	0.95
12. Help the group establish appropriate group rules, such as maintaining confidentiality	10	4.3 (1.1)	10	5.8 (0.4)	2.31
13. Effectively publicize the group	10	3.5 (1.1)	10	5.1 (0.7)	1.86
14. Intervene effectively when group rules are not being followed	10	4.0 (1.1)	10	5.0 (0.7)	1.30
15. Obtain the support I need to cope with the emotional demands of leading the group	10	2.9 (1.2)	10	4.9 (1.0)	1.65
16. Respond constructively to feedback from group members	10	4.6 (0.8)	10	5.3 (0.8)	1.01
17. Help group members relate to other members of a different age	10	4.1 (1.0)	10	5.1 (0.7)	1.30
18. Provide the structure needed for successful meetings	10	5 (0.9)	10	5.6 (0.5)	1.03
19. Keep the group meetings interesting and relevant to both new and returning members	10	4.2 (0.9)	10	5.2 (0.8)	1.35

20. Manage group members who oversimplify or minimize the concerns of other members	10	3.5 (1.4)	10	4.9 (0.9)	0.99
21. Facilitate the group meetings so that all members have an opportunity to speak	10	4.6 (0.8)	10	5.1 (0.9)	0.68
22. Help the group stay focused on topics that are relevant to members	10	4.4 (0.7)	10	5.3 (0.7)	1.88
23. Obtain feedback from members about the group	10	4.3 (0.8)	10	5.0 (0.8)	1.04
24. Organise and plan activities for group members, such as having guest speakers	10	4.5 (1.4)	10	5.5 (0.7)	0.86
25. Help members feel comfortable in the group and relate to one another	10	4.4 (0.8)	10	5.2 (0.6)	1.43
26. Obtain feedback from members about my leadership	10	3.6 (0.7)	10	4.8 (0.9)	1.79
27. Help group members relate to other members of a different cultural background	10	3.9 (1.2)	10	4.5 (1.0)	0.50
28. Communicate reasonable boundaries about my availability outside of the group	10	3.7 (1.3)	10	4.5 (1.0)	0.64
29. Talk to a group member about her or his behaviour if it is disruptive to the group	10	2.7 (1.3)	10	4.5 (0.9)	1.58
30. Ask a member to leave the group due to her of his disruptive behaviour	10	1.6 (1.0)	10	4.2 (1.1)	2.32
31. Help group members relate to other members of a different gender	10	4.4 (1.1)	10	5.0 (0.8)	0.65
32. Recruit a co-facilitator or other group members to help me with leadership responsibilities	10	4.9 (1.3)	10	5.1 (0.9)	0.16
Total Score (Possible Range 32 to 192)	10	124.4 (22.0)	10	159.2 (17.0)	1.70 (0.67, 2.72)

Table 5 shows results for health outcomes, including burnout (OLBI), emotional distress (PHQ-8), and physical function (PROMIS-29). For all of these outcomes, the standardised mean difference effect size of post-trial score improvement was between 0.38 and 0.45, which are typically considered small to moderate effect sizes.[58]

Table 5. Pre- and Post- Intervention Total Scores for Secondary Outcome Measures

Measure	Pre-Trial N	Pre-Trial Mean (SD)	Post-Trial N	Post-Trial Mean (SD)	Standardised Mean Difference Effect Size (95% confidence interval)
Oldenburg Burnout Inventory (higher scores = greater burnout)	10	33.2 (4.6)	10	31.0 (4.9)	0.44 (-0.44, 1.33)
Patient Health Questionnaire-8 (higher scores = greater symptoms of depression)	10	10.8 (2.7)	10	9.8 (2.4)	0.38 (-0.50, 1.27)
PROMIS-29 Physical Function (higher raw scores = greater function)	10	17.1 (2.2)	10	18.2 (2.4)	0.45 (-0.42, 1.36)

As shown in Table 6, the mean post-training score on the CSQ-8 was 30.6 (2.2). On a per item basis, the mean item score (possible range 1-4) was 3.8, reflecting a very high level of satisfaction with the experience of trainees with the SPIN-SSLED Program.

Table 6. Post-Intervention Items, Frequencies, and Total Scores for the Client Satisfaction Questionnaire-8: Item response options very across items, but all scored 1-4

Items	1 Point (Dissatisfied) n (%)	2 Points (Mildly Satisfied) n (%)	3 Points (Mostly Satisfied) n (%)	4 Points (Quite Satisfied) n (%)	Item Mean (SD)
1. How would you rate the quality of the SPIN-SSLED training?	0 (0%)	0 (0%)	1 (10%)	9 (90%)	3.9 (0.3)

2. Did the SPIN-SSLED program provide you the kind of training you wanted?	0 (0%)	0 (0%)	2 (20%)	8 (80%)	3.8 (0.4)
3. To what extent has the SPIN-SSLED training met your needs?	0 (0%)	0 (0%)	4 (40%)	6 (60%)	3.6 (0.5)
4. If a friend were in need of similar training, would you recommend the SPIN-SSLED program to him/her?	0 (0%)	0 (0%)	2 (20%)	8 (80%)	3.8 (0.4)
5. How satisfied are you with the amount of training you received from the SPIN-SSLED program?	0 (0%)	0 (0%)	2 (20%)	8 (80%)	3.8 (0.4)
6. Has the SPIN-SSLED training helped you to deal more effectively with your support group leader role?	0 (0%)	0 (0%)	0 (10%)	10 (100%)	4.0 (0.0)
7. In an overall, general sense, how satisfied are you with the SPIN-SSLED training?	0 (0%)	0 (0%)	1 (20%)	9 (90%)	3.9 (0.3)
8. If you were to seek help again, would you come back to the SPIN-SSLED training?	0 (0%)	0 (0%)	2 (20%)	8 (80%)	3.8 (0.4)
Total Score (Possible Range 8 to 32)					30.6 (2.2)

DISCUSSION

Feasibility of delivering the SPIN-SSLED Program in the context of a trial, participant satisfaction, and program content were evaluated in the SPIN-SSLED feasibility trial. Results

informed revisions to the content of the program and provided confidence that the program can be effectively and efficiently delivered in a full-scale trial.

With respect to overall experience with the program and program content, participants reported that the content was clear and well-organised. Overall satisfaction with their experience in the SPIN-SSLED Program was rated as 9.4 out of 10 on average. Participant satisfaction was similarly high when evaluated with the 8 items of the CSQ. Several participants encouraged the research team to expand on the single module related to grief. Based on comments and follow-up discussions with participants, the program was revised to include two modules on grief, including one module on grief and loss that leaders have experienced because they or somebody close to them has been diagnosed with SSc and a second module on providing support to group members who are struggling with grief and loss. In order to add a second module on grief and loss, the two modules on managing group dynamics were reduced to a single module. To facilitate this, rather than viewing all of the short video vignettes included in those modules as part of the training sessions, participants suggested that they could view the vignettes prior to the sessions and then suggest specific modules for review and discussion in the training sessions.

With respect to program delivery, participants indicated that they were able to access the sessions via the GoToMeeting platform and did not experience any technical difficulties that interrupted their training sessions. One difficulty that was reported involved a participant with a hearing impairment who was unable to hear all of the vignette videos well. This information will help us to assess for reasons why participants may need additional support in the full-scale trial and will allow us to make accommodations. In the full-scale trial, we will assess for hearing and any other impairments that might limit participation, and we will seek appropriate assistance to be able to provide adaptations to meet participant needs. From a management standpoint, total time for technical

support due to access difficulties across the trial period for the two groups was between 1-2 hours. Participants attended 95% of sessions, and all 10 participants completed all baseline and post-trial outcome assessments.

There were limitations that should be considered in evaluating the results of the SPIN-SSLED feasibility trial. First, we were provided with a small list of potential participants from our patient organisation partners, and it is possible that these support group leaders were more motivated or otherwise more likely to participate and engage than the leaders who will participate in the full-scale trial. Second, we did not randomise participants to the intervention and to a wait-list control group as we will do in the planned full-scale trial. Third, we only conducted 2 training groups and only included a total of 10 participants. The reason for not using a control group and limiting the feasibility trial to 2 groups is that there is a finite number of English- and French-speaking SSc support group leaders, and we wanted to be able to assess feasibility aspects but maximize the number of participants eligible for the full-scale trial. It is possible that the pre-selection of potential participants and the lack of the possibility of randomised assignment to a non-intervention group may have resulted in over-estimation of the percentage of participants who will enrol in the full-scale trial and the degree to which they will actively participate. Given the small number of French-speaking leaders available for the full-scale trial, we did not include a French group in the feasibility trial. However, all measures have been used successfully previously with French-speaking research participants. Finally, the trial only included leaders of SSc support groups, and this may limit generalisability to other patient populations, but it will be useful to inform our planned full-scale trial of the SPIN-SSLED Program.

There are no existing training programs for SSc support group leaders, and a systematic review did not identify any training or education programs that have been demonstrated to be effective for support group leaders in any medical condition.[31] The planned full-scale SPIN-SSLED trial, which

was recently funded by the Canadian Institutes of Health Research, is scheduled to begin in 2019 (http://webapps.cihr-irsc.gc.ca/decisions/p/project_details.html?applId=388187&lang=en). It will be a pragmatic RCT that will test whether providing the SPIN-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.[59, 60] 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. To account for clustering in the training arm, but not the control arm, we will use a partially nested RCT trial design (PN-RCT).[61-63] The PN-RCT design is a hybrid between a conventional RCT, in which individual participants are randomised, and a cluster RCT, in which pre-existing clusters (e.g., primary care practices, classrooms) are randomised 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. Participants will be existing support group leaders or new leaders referred by Scleroderma Canada (English) or Sclérodermie Québec (French), the Scleroderma Foundation (USA), Scleroderma & Raynaud's UK, the Scleroderma Association of New South Wales (Australia), and Scleroderma New Zealand.

In sum, the SPIN-SSLED feasibility trial ensured that trial methodology was feasibly implemented and that the online intervention was user-friendly and acceptable to participants. Participants provided suggestions for adjustments to content that will be implemented before undertaking a full-scale RCT of the SPIN-SSLED program to assess effectiveness.

AUTHORS CONTRIBUTIONS

BDT, VLM, GE-B, SP, MS, MH, and RWP were responsible for the study conception and design. BDT, LD, MP, KA, MEC, LT, and SH were responsible for implementation of the trial or acquisition, analysis, and interpretation of trial data. BDT drafted the manuscript. All authors provided a critical review and approved the final manuscript. BDT is the guarantor.

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COMPETING INTERESTS STATEMENT

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare that they have no competing interests.

DATA SHARING STATEMENT

All data extracted and analysed for the present study are available from the corresponding author.

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CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	6
	2b	Specific objectives or research questions for pilot trial	7
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	7
Participants	4a	Eligibility criteria for participants	7-8
	4b	Settings and locations where the data were collected	8
	4c	How participants were identified and consented	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-10
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	11-13
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	7
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size	7a	Rationale for numbers in the pilot trial	13
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	13-14
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	14-15
	13b	For each group, losses and exclusions after randomisation, together with reasons	14-15
Recruitment	14a	Dates defining the periods of recruitment and follow-up	14
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	15
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	All tables
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	21-22
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	16
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	25
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Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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The Scleroderma Patient-centered Intervention Network – Scleroderma Support group Leader Education (SPIN-SSLED) Program: Non-randomised Feasibility Trial

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The Scleroderma Patient-centered Intervention Network – Scleroderma Support group Leader Education (SPIN-SSLED) Program: Non-randomised Feasibility Trial

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ABSTRACT

Objectives: The Scleroderma Patient-centered Intervention Network – Scleroderma Support group Leader EDucation (SPIN-SSLED) Program was designed to improve confidence and self-efficacy and to reduce burden for support group leaders. Objectives were to (1) evaluate feasibility of program delivery, including required resources, management issues, and scientific aspects (e.g., performance of outcome measures); and (2) assess user satisfaction and identify any modifications needed to improve program content or delivery based on participant feedback.

Design: Non-randomised feasibility trial.

Setting: North American patient organisations.

Participants: Current support group leaders or potential new leaders referred by patient organisations.

Intervention: The program included 13 modules delivered live via videoconference over 3 months (April to July 2018) in 60- to 90-minute sessions.

Outcome Measures: (1) Elements of feasibility, including enrolment and consent procedures, percentage of referred group leaders who consented to participate, session attendance, and technical support requirements; (2) program usability, understandability, organisation, and clarity; (3) leader satisfaction with the program; and (4) planned trial outcome measures, including support group leader self-efficacy, burnout, emotional distress, and physical function.

Results: All 12 referred potential participants consented to enrol, and 10 were included in 2 training groups of 5 participants each. Participants attended 95% of sessions. Required

technical support was minimal, and videoconferencing technology functioned well. Overall program satisfaction rating was 9.4/10. Mean item rating on the 8 items of the Client Satisfaction Questionnaire-8 was 3.83 (1 = low satisfaction; 4 = high satisfaction). Pre-post scores on the Scleroderma Support Group Leader Self-efficacy Scale increased by 1.7 standard deviations (large effect); scores on burnout, emotional distress, and physical function improved by 0.44, 0.38, and 0.45 standard deviations (moderate effects).

Conclusion: The SPIN-SSLED Program was feasibly delivered, including management, resource, and scientific aspects. Participant satisfaction was high. The program is ready to be tested in a full-scale randomised controlled trial.

Funding Source: Canadian Initiative for Outcomes in Rheumatology cAre

Trial Registration: NCT03508661

Key Words: patient education; peer support; feasibility trial; scleroderma; support groups; systemic sclerosis

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is the first trial to test the feasibility of delivering an education and training program via videoconference to peer support group leaders.
- The education and training program was developed in a partnership that included scleroderma peer support group leaders, patient organisation leaders, and researchers and health care professionals.
- Trial outcomes included elements of feasibility (e.g., management, resources, scientific aspects); program usability, understandability, organisation, and clarity; leader satisfaction with the program; and planned trial outcome measures.
- This was a non-randomised feasibility trial that only included 10 participants in 2 training groups and did not include a control group; generalisability of results outside of scleroderma is not known.

INTRODUCTION

People with rare diseases face the same challenges as those with more common diseases plus unique challenges, including limited disease education and lack of specialised support options.[1-12] Professionally organised support services for common diseases are often available through the healthcare system,[13, 14] but are not typically available in rare diseases.[10, 15] As a result, some people with rare diseases rely on peer-led support groups for disease-specific education and support.[16-20] Support group activities typically involve an educational or information-sharing component and the exchange of emotional and practical support.[14, 18-22].

Systemic sclerosis (SSc), or scleroderma, is a rare chronic, autoimmune connective tissue disease characterised by abnormal fibrotic processes and excessive collagen production.[23-25] Support groups, most led by people with SSc, play an important role for many people with the disease.[17, 26-30] Many people with SSc, however, cannot access support groups because they are not available close to where they live, and many initiated support groups are not sustained due to challenges that could be addressed via leader training.[18, 19]

A systematic review of randomised controlled trials (RCTs) that evaluated the effects of training programs for patient leaders of illness-based support groups on the competency, self-efficacy, burden, and emotional well-being of group leaders identified only one RCT that met inclusion criteria.[31] That trial [32] evaluated confidence and self-efficacy of cancer

support group leaders randomised to either 4-month long high-resource (N = 29; website, discussion forum, 2-day face-to-face training) or low-resource (N = 23; website, discussion forum) interventions. The RCT did not find evidence that the high-resource program was more effective. However, the trial was substantially underpowered, not enough information was provided to determine intervention content or how it was delivered, and the risk of bias was high due to methodological limitations.

The Scleroderma Patient-centered Intervention Network (SPIN) partnered with SSc patients and patient organisations to develop the Scleroderma Support group Leader EDucation (SPIN-SSLED) Program. The program is a 13-session group videoconference training program, designed to improve skills and self-efficacy, reduce burnout, and improve emotional and physical function among support group leaders. The objectives of the SPIN-SSLED feasibility trial were to (1) evaluate the feasibility of steps needed to take place in a planned full-scale trial, including the *required resources* (e.g., staffing, time, and budget), *management issues* (e.g., related to optimising performance of personnel and data systems), and *scientific aspects* (e.g., recruitment rates of eligible leaders, acceptability of intervention to leaders, assessing performance of outcome measures) and (2) identify any modifications needed to improve the content or delivery of the SPIN-SSLED Program based on participant feedback.

METHODS

The SPIN-SSLED feasibility trial was a non-randomised study. It was registered prior to enrolling participants (NCT03508661) and, although not a randomised study, is reported based on items from the CONSORT extension for randomised pilot and feasibility trials.[33] There

were no changes to the feasibility trial protocol and no changes to planned outcomes after commencement of the trial.

Participants

Eligible participants for the SPIN-SSLED feasibility trial were current SSc support group leaders or were identified by Scleroderma Canada or the Scleroderma Foundation (United States) as a new leader who will initiate a new support group, were able to use the internet to access and participate in training sessions and to complete study questionnaires online, were available to participate at times when sessions were scheduled, and were English-speaking, since both groups in the feasibility trial were conducted in English. The full-scale trial will include groups conducted in French, but individuals who participated in the feasibility study will be excluded from the full-scale RCT. Thus, to ensure that there will be an adequate number of French-speaking participants in the full-scale RCT, only English-speaking leaders were included in the feasibility study.

Procedures

For the purpose of testing the feasibility of administering the SPIN-SSLED Program, we sought 10 group leaders to participate in two separate training groups of 5 participants each. We asked Scleroderma Canada and the Scleroderma Foundation to generate an initial list of 12 interested potential participants and obtained permission for the SPIN team to send them an email with an invitation to participate in the feasibility trial and a copy of the consent form. Following the initial email, SPIN personnel contacted potential participants by phone within 48 hours to describe the study, assess their eligibility, review the consent form, and answer questions they may have had about the study. Eligible leaders who verbally agreed to enrol in the study received a second email with the consent form again attached, and they were able to consent via email 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." The first 10 people to respond and consent were enrolled, and the other 2 were put on a waiting list. All leaders who consented to participate and enrolled received an email invitation including a clickable link to the online data management platform where they were asked to complete baseline study measures. The email also included the date of their first training session, the topic of the first session and information on how to login to the videoconferencing system, as well as a link to the SPIN-SSLED online forum platform, where the program manual and associated PowerPoint slides were available. Ongoing email and phone technical support was available to help leaders with the consent process, access to the data management platform to complete study measures, and training sessions.

The trial was approved by the ethics committee of the Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal.

Intervention

The SPIN-SSLED Program was developed by a team of researchers and health care professionals with expertise in SSc, patient organisation representatives and a Support Group Advisory Team comprised of people with SSc who are current SSc support group leaders. The program content and design were based on results of our preliminary research on support groups in SSc, including individual interviews and surveys with leaders, members, and non-attenders,[17-20] and informed by instructional material for support group leaders in other diseases that 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-centred 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.[34-37] To implement this, each module introduces a topic

and provides an overview of key information. Then, there is a guided discussion among training group participants about possible approaches and solutions to problems.

The SPIN-SSLED Program included 13 modules that are delivered live via videoconference over the course of 3 months. Each module is 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, and (13) support group leader resources. See Table 1 for module content. The program includes 11 filmed vignettes that demonstrate effective group facilitation techniques and ways to respond to problems that arise with the behaviours of specific group members or group interactions. In addition to the live modules, SPIN-SSLED participants receive a program manual that summarises didactic material that is provided in the sessions.

Table 1. Content of Program Modules

Module Title	Module Description
1. The Support Group Leader's Role	This module discusses the benefits of being a support group leader, the expectations of what the role of leader involves (e.g. facilitation of meetings and interactions but not giving medical advice), and tips for being an effective and supportive leader.
2. Starting a Support Group	This module discusses the purpose of a support group, what people with scleroderma hope to gain from support group, why some don't attend, establishing leadership (e.g. one leader, co-leader), membership (e.g. patients only, open to family, and friends), logistics of starting a group (e.g. time, place and meeting duration).

3. Structuring Support Group Meetings	This module discusses formatting group meeting and how to successfully integrate both educational activities with emotional and practical support for members, setting up a meeting agenda.
4. Scleroderma 101	This module shows a filmed conference by a physician specialized in scleroderma who explain the different types of scleroderma, symptoms, causes, treatments, and alternative approaches. The module also includes tips to evaluate credibility of information sources on the Internet.
5. Successful Support Group Culture	This module discusses the importance of establishing expectations and guidelines for the support group with members, the importance of confidentiality, how to create and maintain positive and productive support group culture using (1) encouraging statements, (2) open-ended questions, (3) body language, (4) linking similar experiences between members, and (5) summarizing discussions. This module uses video vignettes to illustrate these techniques.
6. Managing Group Dynamics Part I	This module discusses managing difficult support group dynamics such as members who are "quick fixers", overly talkative, how to maintain a positive group environment, conflict management and resolution for minor and larger issues. This module uses video vignettes to illustrate these techniques.
7. Managing Group Dynamics Part II	This module discussed how to identify and respond to members who are overly shy or who are chronically negative, and what to do when members bring unsubstantiated, inaccurate or potentially misleading medical information to the group. This module uses video vignettes to illustrate these techniques.
8. Grief and Crisis in Scleroderma	The module discusses different situations that may bring grief to members, stages of grief, supporting group members in grief, dealing with medical crises or death of group members.
9. Advertising and Recruiting for the Support Group	This module discusses how to advertise and promote a support group, how to recruit new members for support groups on ongoing basis, advertising through patient organizations and strategies to retain members.

10. The Continuity of the Group	This module discusses the importance of understanding and overcoming reluctance in seeking feedback, the importance of feedback in the support group experience, how to obtain and respond to feedback, how to identify reasons why members may stop attending meetings and strategies to help maintain membership, how to keep members engaged and move your support group forward by making changes.
11. Supporting Yourself as a Leader	This module discuses understanding what leader burnout is, understanding why it can happen and what the warning signs are, understanding the best way to address burnout including identifying methods of coping, understanding at what point it may be best for a leader to step down from his or her role, strategies to prevent experiencing leader burnout.
12. Remote support groups	This module discusses the benefits of an online support group, finding the right technology, scheduling and programming, advertising and reaching your target audience, tips for successful online meetings.
13. Resources	This module discusses strategies on how to obtain information and resources, how to communicate information effectively to members, the responsibilities of the national organization, meeting the resource needs of the group, access to the SPIN-SSLED Online Resource Center to download scleroderma talks, educational videos, and research articles for leaders and members of support groups.

Based on our previous experience with videoconferencing and consistent with previous trials of videoconference training, 5 group leaders were assigned to each training group to maximise effective interaction and participation.[38-41] Training sessions were delivered using the GoToMeeting® videoconferencing platform, a high-performance platform that has been used successfully for similar applications.[42-44] In addition to the videoconference sessions, participants had access to a secure, monitored SPIN-SSLED online forum via the Slack® communication tool to interact with other participants about program content. The two training groups were held in the evening.

Feasibility Outcomes

Outcomes related to process and resources were assessed throughout the duration of the feasibility trial, and leader feedback was obtained upon completion of the program. The collected

measures of feasibility included assessments of the (1) enrolment and consent procedure, (2) percentage of referred and eligible group leaders who consented to participate, (3) personnel requirements to assist participants with accessing the GoToMeeting® videoconferencing platform for sessions and the online survey program Qualtrics® for online data collection pre-training and post-training, (4) technological performance of the videoconferencing system, and (5) any challenges for study personnel.

Individual semi-structured interviews were conducted with all participants via telephone upon completion of the 13 modules using items based on the Patient Education Materials Assessment Tool for Audiovisual Materials (PEMAT) [45] and addressed topics related to usability, understandability, organisation, and clarity of the SPIN-SSLED program, including its videoconference-based delivery. The PEMAT included a single rating of satisfaction from 0 (worst possible) to 10 (best possible).

SPIN-SSLED Planned Trial Outcome Measures

In the planned full-scale RCT, 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 the program reduces burnout, improves emotional well-being, and improves physical function among support group leaders (secondary). The SPIN-SSLED feasibility trial was not intended to test hypotheses and did not have adequate power for this, but we collected trial outcome measures at the time of consent to participate in the trial and following completion of the program to evaluate the percentage of measures that were completed and to evaluate performance of the measures. Participants were emailed invitations to complete baseline and post-intervention measures using the online survey program Qualtrics®.

Leader Self-Efficacy: The Scleroderma Support Group Leader Self-efficacy Scale (SSGLSS) [46] was developed by our research team, including the members of the SPIN Support Group Advisory

Team, to measure support group leader self-efficacy for performing leader tasks. Initial items were obtained from the Group Leader Self-Efficacy Instrument, a 37-item self-report questionnaire that assesses self-efficacy for performing group leader skills.[47] The Group Leader Self-Efficacy Instrument is intended for use with group psychotherapy leaders, so many of its items are not relevant or appropriate for support group leaders. Items from this instrument were reviewed for relevancy, and relevant items were considered for inclusion, along with items from a questionnaire intended for leaders of cancer and multiple sclerosis support groups [48] and items that we generated from the results of a published study on the experiences of leaders of cancer support groups.[49] All items were then reviewed by members of our research team to remove items that were repetitive or not relevant for SSc and to generate new items to reflect important SSc-specific content based on their own experiences or on qualitative interviews that we conducted with SSc support group leaders (N = 10). Items were then reviewed iteratively by all members of the research team until a consensus was reached on included items. The resulting 32-item scale is scored on a 6-point Likert scale from 1 (strongly disagree) to 6 (strongly agree) with possible total scores from 32 to 192 and higher scores indicating greater self-efficacy. The SSGLSS was validated in two samples of SSc support group leaders (N = 102, N = 55) and found to have good internal consistency (Cronbach's alpha 0.96 and 0.95) and hypothesis-consistent convergent validity with the Oldenburg Burnout Inventory (OLBI). A strength of using the SSGLSS as the primary outcome measure is that both the intervention and the SSGLSS were designed to reflect training needs of SSc support group leaders, and the items of the SSGLSS all reflect material covered in the program.

Burnout: Leader burnout was assessed with the OLBI,[50-52] which is a 16-item measure that assesses exhaustion and disengagement due to burnout. The OLBI was initially designed for work-related burnout, but has been adapted for numerous settings and in multiple countries and languages.[52] Our research team revised the wording of each OLBI item to reflect the support group environment rather than a work environment (e.g., "I find my work to be a positive challenge" was revised to "I find my role as a support group leader to be a positive challenge"). The OLBI has a two-factor structure (exhaustion and disengagement) with good measurement properties.[50-52] Items are scored on a 4-point scale; higher scores indicate higher levels of exhaustion and disengagement. Internal consistency reliability (Cronbach's alpha) in patients with SSc was 0.84 for exhaustion and 0.80 for disengagement.[46]

Emotional Distress: The Patient Health Questionnaire-8 (PHQ-8) was used to assess emotional distress.[53] 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,[53] which has been shown to be a valid measure of depressive symptoms in patients with SSc.[54]

Physical Function: Physical function was measured using the Physical Function subscale of the 29-item Patient Reported Outcomes Measurement Information System (PROMIS-29) 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. Total raw scores are obtained by summing item scores for each domain. The PROMIS-29 version 2.0 has been validated in SSc.[55]

Participant Satisfaction: Satisfaction with the SPIN-SSLED Program was evaluated with the Client Satisfaction Questionnaire-8 (CSQ-8),[56] a standardised survey that is used to assess satisfaction with health services. Items are scored on a Likert scale from 1 (low satisfaction) to 4 (high satisfaction) with total scores ranging from 8 to 32. The CSQ-8 has been widely validated across a range of populations and health services programs.[57]

***Adverse Events*:** Following each session, we emailed participants and requested that they report any concerns that they had about the sessions or their experience in the sessions.

Sample size

Guidance on appropriate sample size for feasibility trials varies substantially in the published literature. For the purposes of establishing feasibility of delivery of the SPIN-SSLED Program, we determined that conducting two different training groups would allow us to evaluate intervention content and delivery aspects, and, thus, we sought to recruit a total of 10 participants to conduct two training groups.

Data Analysis

Feasibility outcomes included leader eligibility and recruitment, leader enrolment, and technological performance of the videoconferencing system. Qualitative information via interviews and weekly reports by participants was collected, and all suggestions for changes to the program or trial methods that could be implemented prior to beginning a full-scale trial were recorded. Descriptive

statistics were used to provide means and standard deviations for SPIN-SSLED Program outcome measures. Since the purpose of this feasibility trial was to evaluate feasibility and identify any modifications to the intervention or trial plan, the trial was not designed or powered to test hypotheses about outcomes. Thus, consistent with best practices,[33] hypothesis tests were not conducted, but effect sizes for pre-post differences are shown. Data were analysed using the statistics software program, IBM SPSS.

Patient and Public Involvement

The SPIN Support Group Advisory Team has been involved in all stages of SPIN's research on support groups in SSc, including preliminary research on support groups in SSc, the development of the SPIN-SSLED program, and the design and implementation of the feasibility trial. Members of the Team initially participated in the design of the Scleroderma Support Group Survey, which informed developing of the program by collecting information on the experiences and training needs of SSc support group leaders, priorities of SSc support group members, and reasons why people do not attend SSc support groups.[17-20] Team members participated in the development of the SSGLSS,[46] which was administered in the feasibility trial and will be the primary outcome for the planned full-scale trial. Team members provided input into the development of the SPIN-SSLED Program and its modules, filmed the vignettes used in the program, and were involved in decisions related to the conduct of the feasibility trial.

RESULTS

Participant Characteristics

The trial was conducted between April and July 2018. Scleroderma Canada and the Scleroderma Foundation each provided our team with names of 6 potential participants. All agreed to participate in the program. We initially enrolled 10 participants, but one was hospitalised prior to initiating the program. Thus, prior to starting the trial, we added one participant who had been wait-listed.

All 10 participants were female. The mean age was 58 years (standard deviation [SD] = 11 years). There were 6 participants from Canada and 4 from the United States. All 10 described themselves as White, and one also described herself as Aboriginal. Of the 10 participants, 9 were people with SSc. Mean years since diagnosis among those with SSc was 11 years. Participant characteristics are shown in Table 2.

Table 2. Participant Characteristics

Characteristics	**N Participants = 10**
Female sex, *n (%)*	10 (100%)
Age in years, *mean (SD)*	57.7 (11.1)
Country, *n (%)*	
Canada[a]	6 (60%)
United States[b]	4 (40%)
Race/ethnicity,[c] *n (%)*	
White	10 (100%)
Aboriginal	1 (10%)
Relationship status, *n (%)*	
Married or living as married	8 (80%)
Separated or divorced	2 (20%)

Education in years, *mean (SD)*	17.5 (2.7)
Occupational status, *n (%)*	
Homemaker	1 (10%)
Part- or full-time employment[b]	2 (20%)
Disability	3 (30%)
Retired	4 (40%)
SSc diagnosis, *n (%)*	
Limited SSc	4 (40%)
Diffuse SSc	5 (50%)
Not diagnosed with SSc	1 (10%)
Years since SSc diagnosis, *mean (SD)*	10.9 (7.4)
Current leader of SSc support group	10 (100%)
Years as a SSc support group leader, *mean (SD)*	3.6 (3.7)

[a] Participants from British Columbia, Manitoba, Ontario, Quebec (2), and Saskatchewan.
[b] Participants from California (3) and Florida.
[c] Participants could select more than one race/ethnicity.

Feasibility Outcomes

All 10 participants completed all baseline and post-trial measures, including the PEMAT interview. Participant attendance at the weekly sessions was high (95%; 123 of 130 sessions). No sessions were missed or delayed due to technological difficulties, and time for technological support from our team was between 1-2 hours for the entire program. Per the PEMAT interviews and per our observations, the GoToMeeting system worked fluidly and supported the training groups well.

A summary of responses to the PEMAT interviews is shown in Table 3. As can be seen in the table, there were relatively minor suggestions for improving the program. Overall, feedback was

extremely positive. The overall mean grade given by participants for the SPIN-SSLED Program was 9.4/10. No concerns related to adverse events were reported.

Table 3. Summary of Responses to the Patient Education Materials Assessment Tool for Audiovisual Materials (PEMAT) Interviews

PEMAT Item	Summary of Responses
Are you currently a leader of a support group, a co-leader or planning on becoming a support group leader?	4 co-leaders, 5 leaders, 1 plans to become leader.
PROCESS	
Did you find that the weekly frequency of the training sessions was adequate?	10 yes.
Did you find the length of each training session appropriate?	10 yes; 3 added that grief module was not long enough, 1 said grief module was too long.
Was it difficult to find the motivation to attend the training session every week?	9 no; 1 sometimes due to scheduling.
PURPOSE	
Did you understand the objectives of the SPIN-SSLED training program modules?	10 yes.
Did you find the information provided in the SPIN-SSLED training program relevant?	10 yes.
WORDS AND LANGUAGE	
Did you find that the content of the program manual was clear, concise and easy to follow?	10 yes.
Did you find that the content delivered in the training sessions and the discussion about the content was easy to understand and useful?	10 yes.
CONTENT AND ORGANISATION	
Did you find that the content of the SPIN-SSLED modules was presented logically and well-organised?	10 yes.
Did you find that the order of the modules was logical and that linkages were clear?	9 yes; 1 said that order was “staggered”.

Did you find the discussion among other participants helpful?	10 yes; 1 mentioned that sometimes she had questions and challenges specific to herself that she didn't have time to get addressed.
VIDEO VIGNETTES	
Did the fact that the video vignettes scenarios were performed by scleroderma patients make the program more relatable?	9 yes; 1 had difficulty hearing the videos (participant with hearing impairment).
Were you able to clearly understand the people speaking in the videos?	9 yes; 2 no; 1 indicated there were small things they didn't quite hear (participant with hearing impairment).
Did you develop an understanding of the challenges that could arise in a support group from watching the videos and obtain useful information or strategies to address them?	8 yes, 2 no (not hearing properly; 1 participant with hearing impairment).
TECHNOLOGY	
Did you use a computer, phone, tablet or all these devices to access the SPIN-SSLED Training Program?	7 used computer, 4 used phone, 1 used tablet (> 10 due to >1 method for some participants).
Did the initial invitation email provide you with the information you needed to understand how to log in for the training session?	10 yes.
Did you experience any technical difficulties while using GoToMeeting?	8 no; 2 minor.
Did you experience any technical difficulties while using Slack chatroom?	7 no; 3 did not use it. Use overall was minimal.
Did you use the guide we provided to use GoToMeeting and the Slack chatroom?	5 yes; 5 no.
OVERALL APPRECIATION	
Can you please tell us about your experience with the SPIN-SSLED Training Program, including things that you liked about the program and things that could be improved?	Positive aspects of program: informative, organised, videos, "Supporting Yourself as a Leader" and "Grief and Crisis" modules were identified as very important. Positive aspects of SPIN-SLLED program leader: clear, conscientious, answered questions thoroughly, gave opportunities for feedback, was available between sessions. To improve: discuss financial support for support group expenses, expand grief module over 2 sessions, do sessions in winter instead of summer so that individuals with scleroderma can only enjoy the outdoors in summer, adding more videos.

What grade (on a 0-10 scale, 0 being the worst and 10 being the best possible score) would you give the program? 0 (worst) to 10 (best).	5 rated 10, 1 rated 9, 1 rated 9.5, 2 rated 8, 1 rated "9 or 10". Mean score: 9.4/10
Would you recommend this program to someone with scleroderma?	10 yes.
Is there anything you want to give us feedback about that was not included in this interview?	The remote support group meetings module was less important to 1 participant. Suggestion to make recordings of support group discussions available online.

SPIN-SSLED Planned Trial Outcome Measures

Table 4 shows the responses to each of the 32 items of the SSGLSS, which will be the primary outcome measure in the full-scale trial. Pre-training, the mean (SD) was 124.4 (22.0), which was similar to the scores of our two international samples from the SSGLSS validation study (N = 102, mean SSGLSS = 122.9 (21.7); N = 55, mean SSGLSS = 123.9 (19.4)). Post-training, the mean total score increased to 159.2 (17.1). The standardised mean difference effect size was 1.70, which is considered a large effect size.[58] SSGLSS items are scored on a 1-6 scale, and the average item score increase pre-post training was 1.1 points.

Table 4. Pre- and Post- Intervention Item and Total Scores for the Scleroderma Support Group Leader Self-efficacy Scale: Possible item scores range from 1 to 6 with higher scores reflecting greater self-efficacy

Items	Pre-Trial N	Pre-Trial Mean (SD)	Post-Trial N	Post-Trial Mean (SD)	Standardised Mean Difference Effect Size (95% confidence interval – total only)
1. Obtain financial or other resources needed to run the group	10	3.5 (1.7)	10	4.8 (1.2)	0.61
2. Promote the group to health professionals as an important resource for patients	10	4.5 (0.7)	10	5.4 (0.7)	1.80
3. Share responsibilities, including administrative and practical tasks, with a co-facilitator or other group members	10	4.8 (1.6)	10	5.5 (0.5)	0.52
4. Manage group members who are overly talkative or monopolize the discussion	10	3.9 (1.1)	10	4.8 (0.6)	1.13
5. Manage group members who assume the role of the "know-it-all"	10	3.9 (1.1)	10	4.6 (0.8)	0.73
6. Support members of the group who are grieving	10	3.3 (1.5)	10	4.7 (0.8)	0.97
7. Help overly shy group members feel comfortable interacting with the group	10	3.9 (1.1)	10	4.9 (0.7)	1.14
8. Help group members cope with difficult events, such as the death of a member	10	3.0 (1.8)	10	4.7 (0.8)	0.90
9. Effectively recruit new members	10	3.5 (1.4)	10	4.9 (0.7)	1.18
10. Address the different needs of groups members at varying stages of the disease	10	3.7 (1.6)	10	4.8 (0.6)	0.77
11. Manage conflicts and disagreements between group members	10	3.3 (1.4)	10	4.5 (0.7)	0.95
12. Help the group establish appropriate group rules, such as maintaining confidentiality	10	4.3 (1.1)	10	5.8 (0.4)	2.31
13. Effectively publicize the group	10	3.5 (1.1)	10	5.1 (0.7)	1.86
14. Intervene effectively when group rules are not being followed	10	4.0 (1.1)	10	5.0 (0.7)	1.30
15. Obtain the support I need to cope with the emotional demands of leading the group	10	2.9 (1.2)	10	4.9 (1.0)	1.65
16. Respond constructively to feedback from group members	10	4.6 (0.8)	10	5.3 (0.8)	1.01
17. Help group members relate to other members of a different age	10	4.1 (1.0)	10	5.1 (0.7)	1.30
18. Provide the structure needed for successful meetings	10	5 (0.9)	10	5.6 (0.5)	1.03
19. Keep the group meetings interesting and relevant to both new and returning members	10	4.2 (0.9)	10	5.2 (0.8)	1.35

20. Manage group members who oversimplify or minimize the concerns of other members	10	3.5 (1.4)	10	4.9 (0.9)	0.99
21. Facilitate the group meetings so that all members have an opportunity to speak	10	4.6 (0.8)	10	5.1 (0.9)	0.68
22. Help the group stay focused on topics that are relevant to members	10	4.4 (0.7)	10	5.3 (0.7)	1.88
23. Obtain feedback from members about the group	10	4.3 (0.8)	10	5.0 (0.8)	1.04
24. Organise and plan activities for group members, such as having guest speakers	10	4.5 (1.4)	10	5.5 (0.7)	0.86
25. Help members feel comfortable in the group and relate to one another	10	4.4 (0.8)	10	5.2 (0.6)	1.43
26. Obtain feedback from members about my leadership	10	3.6 (0.7)	10	4.8 (0.9)	1.79
27. Help group members relate to other members of a different cultural background	10	3.9 (1.2)	10	4.5 (1.0)	0.50
28. Communicate reasonable boundaries about my availability outside of the group	10	3.7 (1.3)	10	4.5 (1.0)	0.64
29. Talk to a group member about her or his behaviour if it is disruptive to the group	10	2.7 (1.3)	10	4.5 (0.9)	1.58
30. Ask a member to leave the group due to her of his disruptive behaviour	10	1.6 (1.0)	10	4.2 (1.1)	2.32
31. Help group members relate to other members of a different gender	10	4.4 (1.1)	10	5.0 (0.8)	0.65
32. Recruit a co-facilitator or other group members to help me with leadership responsibilities	10	4.9 (1.3)	10	5.1 (0.9)	0.16
Total Score (Possible Range 32 to 192)	10	124.4 (22.0)	10	159.2 (17.0)	1.70 (0.67, 2.72)

Table 5 shows results for health outcomes, including burnout (OLBI), emotional distress (PHQ-8), and physical function (PROMIS-29). For all of these outcomes, the standardised mean difference effect size of post-trial score improvement was between 0.38 and 0.45, which are typically considered small to moderate effect sizes.[58]

Table 5. Pre- and Post- Intervention Total Scores for Secondary Outcome Measures

Measure	Pre-Trial N	Pre-Trial Mean (SD)	Post-Trial N	Post-Trial Mean (SD)	Standardised Mean Difference Effect Size (95% confidence interval)
Oldenburg Burnout Inventory (higher scores = greater burnout)	10	33.2 (4.6)	10	31.0 (4.9)	0.44 (-0.44, 1.33)
Patient Health Questionnaire-8 (higher scores = greater symptoms of depression)	10	10.8 (2.7)	10	9.8 (2.4)	0.38 (-0.50, 1.27)
PROMIS-29 Physical Function (higher raw scores = greater function)	10	17.1 (2.2)	10	18.2 (2.4)	0.45 (-0.42, 1.36)

As shown in Table 6, the mean post-training score on the CSQ-8 was 30.6 (2.2). On a per item basis, the mean item score (possible range 1-4) was 3.8, reflecting a very high level of satisfaction with the experience of trainees with the SPIN-SSLED Program.

Table 6. Post-Intervention Items, Frequencies, and Total Scores for the Client Satisfaction Questionnaire-8: Item response options very across items, but all scored 1-4

Items	1 Point (Dissatisfied) n (%)	2 Points (Mildly Satisfied) n (%)	3 Points (Mostly Satisfied) n (%)	4 Points (Quite Satisfied) n (%)	Item Mean (SD)
1. How would you rate the quality of the SPIN-SSLED training?	0 (0%)	0 (0%)	1 (10%)	9 (90%)	3.9 (0.3)

2. Did the SPIN-SSLED program provide you the kind of training you wanted?	0 (0%)	0 (0%)	2 (20%)	8 (80%)	3.8 (0.4)
3. To what extent has the SPIN-SSLED training met your needs?	0 (0%)	0 (0%)	4 (40%)	6 (60%)	3.6 (0.5)
4. If a friend were in need of similar training, would you recommend the SPIN-SSLED program to him/her?	0 (0%)	0 (0%)	2 (20%)	8 (80%)	3.8 (0.4)
5. How satisfied are you with the amount of training you received from the SPIN-SSLED program?	0 (0%)	0 (0%)	2 (20%)	8 (80%)	3.8 (0.4)
6. Has the SPIN-SSLED training helped you to deal more effectively with your support group leader role?	0 (0%)	0 (0%)	0 (10%)	10 (100%)	4.0 (0.0)
7. In an overall, general sense, how satisfied are you with the SPIN-SSLED training?	0 (0%)	0 (0%)	1 (20%)	9 (90%)	3.9 (0.3)
8. If you were to seek help again, would you come back to the SPIN-SSLED training?	0 (0%)	0 (0%)	2 (20%)	8 (80%)	3.8 (0.4)
Total Score (Possible Range 8 to 32)					30.6 (2.2)

DISCUSSION

Feasibility of delivering the SPIN-SSLED Program in the context of a trial, participant satisfaction, and program content were evaluated in the SPIN-SSLED feasibility trial. Results

informed revisions to the content of the program and provided confidence that the program can be effectively and efficiently delivered in a full-scale trial.

With respect to overall experience with the program and program content, participants reported that the content was clear and well-organised. Overall satisfaction with their experience in the SPIN-SSLED Program was rated as 9.4 out of 10 on average. Participant satisfaction was similarly high when evaluated with the 8 items of the CSQ. Several participants encouraged the research team to expand on the single module related to grief. Based on comments and follow-up discussions with participants, the program was revised to include two modules on grief, including one module on grief and loss that leaders have experienced because they or somebody close to them has been diagnosed with SSc and a second module on providing support to group members who are struggling with grief and loss. In order to add a second module on grief and loss, the two modules on managing group dynamics were reduced to a single module. To facilitate this, rather than viewing all of the short video vignettes included in those modules as part of the training sessions, participants suggested that they could view the vignettes prior to the sessions and then suggest specific modules for review and discussion in the training sessions.

With respect to program delivery, participants indicated that they were able to access the sessions via the GoToMeeting platform and did not experience any technical difficulties that interrupted their training sessions. One difficulty that was reported involved a participant with a hearing impairment who was unable to hear all of the vignette videos well. This information will help us to assess for reasons why participants may need additional support in the full-scale trial and will allow us to make accommodations. In the full-scale trial, we will assess for hearing and any other impairments that might limit participation, and we will seek appropriate assistance to be able to provide adaptations to meet participant needs. From a management standpoint, total time for technical

support due to access difficulties across the trial period for the two groups was between 1-2 hours. Participants attended 95% of sessions, and all 10 participants completed all baseline and post-trial outcome assessments.

There were limitations that should be considered in evaluating the results of the SPIN-SSLED feasibility trial. First, we were provided with a small list of potential participants from our patient organisation partners, and it is possible that these support group leaders were more motivated or otherwise more likely to participate and engage than the leaders who will participate in the full-scale trial. Second, we did not randomise participants to the intervention and to a wait-list control group as we will do in the planned full-scale trial. Third, we only conducted 2 training groups and only included a total of 10 participants. The reason for not using a control group and limiting the feasibility trial to 2 groups is that there is a finite number of English- and French-speaking SSc support group leaders, and we wanted to be able to assess feasibility aspects but maximize the number of participants eligible for the full-scale trial. It is possible that the pre-selection of potential participants and the lack of the possibility of randomised assignment to a non-intervention group may have resulted in over-estimation of the percentage of participants who will enrol in the full-scale trial and the degree to which they will actively participate. Given the small number of French-speaking leaders available for the full-scale trial, we did not include a French group in the feasibility trial. However, all measures have been used successfully previously with French-speaking research participants. Finally, the trial only included leaders of SSc support groups, and this may limit generalisability to other patient populations, but it will be useful to inform our planned full-scale trial of the SPIN-SSLED Program.

There are no existing training programs for SSc support group leaders, and a systematic review did not identify any training or education programs that have been demonstrated to be effective for support group leaders in any medical condition.[31] The planned full-scale SPIN-SSLED trial, which

was recently funded by the Canadian Institutes of Health Research, is scheduled to begin in 2019 (http://webapps.cihr-irsc.gc.ca/decisions/p/project_details.html?applId=388187&lang=en). It will be a pragmatic RCT that will test whether providing the SPIN-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.[59, 60] 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. To account for clustering in the training arm, but not the control arm, we will use a partially nested RCT trial design (PN-RCT).[61-63] The PN-RCT design is a hybrid between a conventional RCT, in which individual participants are randomised, and a cluster RCT, in which pre-existing clusters (e.g., primary care practices, classrooms) are randomised 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. Participants will be existing support group leaders or new leaders referred by Scleroderma Canada (English) or Sclérodermie Québec (French), the Scleroderma Foundation (USA), Scleroderma & Raynaud's UK, the Scleroderma Association of New South Wales (Australia), and Scleroderma New Zealand.

In sum, the SPIN-SSLED feasibility trial ensured that trial methodology was feasibly implemented and that the online intervention was user-friendly and acceptable to participants. Participants provided suggestions for adjustments to content that will be implemented before undertaking a full-scale RCT of the SPIN-SSLED program to assess effectiveness.

AUTHORS CONTRIBUTIONS

BDT, VLM, GE-B, SP, MS, MH, RWP and members of the SPIN-SSLED Patient Advisory Team were responsible for the study conception and design. BDT, LD, MP, KA, MEC, LT, and SH were responsible for implementation of the trial or acquisition, analysis, and interpretation of trial data. BDT drafted the manuscript. All authors provided a critical review and approved the final manuscript. BDT is the guarantor.

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COMPETING INTERESTS STATEMENT

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare that they have no competing interests.

DATA SHARING STATEMENT

De-identified data extracted and analysed for the present study are available from the corresponding author upon request.

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CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	3-4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	6
	2b	Specific objectives or research questions for pilot trial	7
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	7
Participants	4a	Eligibility criteria for participants	7-8
	4b	Settings and locations where the data were collected	8
	4c	How participants were identified and consented	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-10
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	11-13
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	7
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size	7a	Rationale for numbers in the pilot trial	13
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	13-14
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	14-15
	13b	For each group, losses and exclusions after randomisation, together with reasons	14-15
Recruitment	14a	Dates defining the periods of recruitment and follow-up	14
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	15
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	All tables
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	21-22
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	16
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	25
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	25
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	26
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	26
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	4
Protocol	24	Where the pilot trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	27
	26	Ethical approval or approval by research review committee, confirmed with reference number	9

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.