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PATIENT OPINION

Patient perspectives on clinical trial participation for novel advanced therapies: a focus group study in systemic lupus erythematosus

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Abstract

To identify barriers and facilitators in systemic lupus erythematosus (SLE) regarding participation in clinical trials for novel/advanced agents, such as cellular therapies. Adults from our SLE research registry participated in 1-hour virtual focus groups concerning their perspectives on clinical trials for novel/advanced SLE therapies. Sessions, facilitated by trained moderators, were recorded and transcribed. An inductive thematic analysis approach was used to code the data and generate themes/sub-themes. Nineteen patients participated in four focus groups (two in English, two in French). The mean age (range) was 50.0 (21–77) years and mean disease duration was 21.4 years. Most (90%) participants were female and 79% (15/19) were White, with the remainder being Black, Asian, and Hispanic. Few had previously participated in a clinical trial. Six major themes emerged: two barriers and four facilitators to trial participation. The first barrier was time and logistical constraints, such as employment and travel. The second was risk aversion, including subthemes of concerns of SLE flare, drug side effects and early-phase trials. Facilitators included receiving clear, detailed trial information. Disease instability was another driver, making patients increasingly willing to accept elevated health risks, time commitment and/or logistical challenges. Desire to support the lupus community was also an important factor. Finally, access in clinical trials to mental health counsellors, peer support, and close medical follow-up were strong facilitators of participation. We identified potential barriers and facilitators/driving factors for SLE patients regarding clinical trial participation, which are particularly relevant for novel/advanced agents like cellular therapies.

Keywords Qualitative research · Focus groups · Lupus erythematosus · Systemic · Patient preference · Attitudes · Patient participation · Clinical trials as topic · Cell- and tissue-based therapy

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Introduction

Systemic lupus erythematosus (SLE) is a chronic autoimmune disease affecting approximately 3.4 million people worldwide [1]. The aim of treatment is remission of disease, through immunomodulatory and immunosuppressant medications [1]. In recent years, a variety of novel and experimental treatments have emerged for SLE, including chimeric antigen receptor (CAR) T-cell therapies [2]. As of March 2025, 184 trials for cellular or biologic SLE therapies were registered with clinicaltrials.gov [3]. However, clinical trials in SLE are often impeded by recruitment and retention challenges [4]. Trials concerning novel medications may face additional obstacles related to unknown risks and higher burden of logistical requirements [5], such as inpatient stays. There is a lack of studies specifically examining the unique challenges relevant to innovative lupus treatment trials, leaving important aspects of trial engagement and decision-making underexamined. The objective of our virtual focus group study was to identify barriers and facilitators perceived by people with SLE regarding participation in clinical trials of advanced agents, such as cellular therapies [6].

Methods

We conducted a focus group study involving adults from the McGill University Health Centre (MUHC) SLE observational research patient registry, recruited during annual research visits in July-August 2024. The registry comprises participants from throughout Montreal and surroundings areas in Quebec. In Quebec, physician services, labs, testing and hospitalizations are publicly funded, while drug coverage is obtained through employment or through the provincial drug benefits program [7].

Inclusion criteria consisted of age $\geq$ 18 years, ability to speak and understand French or English, and access to a computer/phone and the videoconferencing application Zoom™. Ethics approval was provided by McGill University Institutional Review Board (IRB #A04-M29-06B) on June 12, 2024, protocol version 3.0. All participants provided written informed consent prior to participation. Participants consented to the recording of focus group discussions and the use of anonymized quotations in publications.

Four 1-hour focus groups were conducted virtually by videocall during September 2024. Our goal was to enroll minimum six participants per session, anticipating last-minute cancelations. Focus groups continued until thematic saturation was achieved after the fourth group, at which point no new concepts emerged. Refer to Appendix 1 for standardized questions posed in each session.

Each participant was given enough time to express their views and opinions, and discussion between participants was encouraged. A trained moderator led the sessions, with a co-moderator taking notes on verbal contributions and non-verbal communication. An iterative approach was used in which insights from earlier groups informed open-ended probing during later sessions. Focus groups began with a review of informed consent and a brief introduction to clinical trials, including advanced SLE therapies (see Supplementary Data S1).

Sessions were video-recorded and transcribed using a subscription-based software. The transcripts were manually verified, identifying information was removed and participants anonymized. Analysis of transcripts were conducted by two reviewers who are fluent in English and French. An inductive thematic analysis approach [8] was used by one co-moderator (OAS) to code the qualitative data and generate themes and sub-themes. For each transcript, statements were coded individually and the participant code of the individual who voiced the idea, along with those who expressed verbal or non-verbal agreement, were recorded. The coding data across all focus groups were reviewed to identify themes and sub-themes and the frequencies were tabulated. Figure 1 provides a visual presentation of the coding data as a histogram, showing the number of participants ($n = 19$) who ever expressed agreement (verbal or non-verbal) with each theme or sub-theme. Only themes and sub-themes with at least four endorsements were included in the figure; the full dataset is available in Table 1 in Supplementary Data S2. The coding and thematic analysis were verified by the other co-moderator (JLFL), and consensus was achieved. Another author (SB) reviewed the analysis for clarity and completeness. For the purposes of this paper, all French-language quotes were translated by OAS and are presented in italics, with the original quotations available in Supplementary Data S2. The main researchers who conducted the study include a research coordinator (OAS) and research assistant (JLFL), supervised by the lead investigator (SB), a rheumatologist and Senior Scientist at the MUHC specializing in lupus. Of the remaining co-authors, five are rheumatologists and one is the CEO of a national lupus organization. While the focus group moderation and data analysis was done by non-physicians, the remaining research team's clinical backgrounds and interest in improving trial access may have informed the interpretation and discussion of findings. Reporting of this research follows the "Standards for Reporting Qualitative Research" checklist by O'Brien et al. [9].

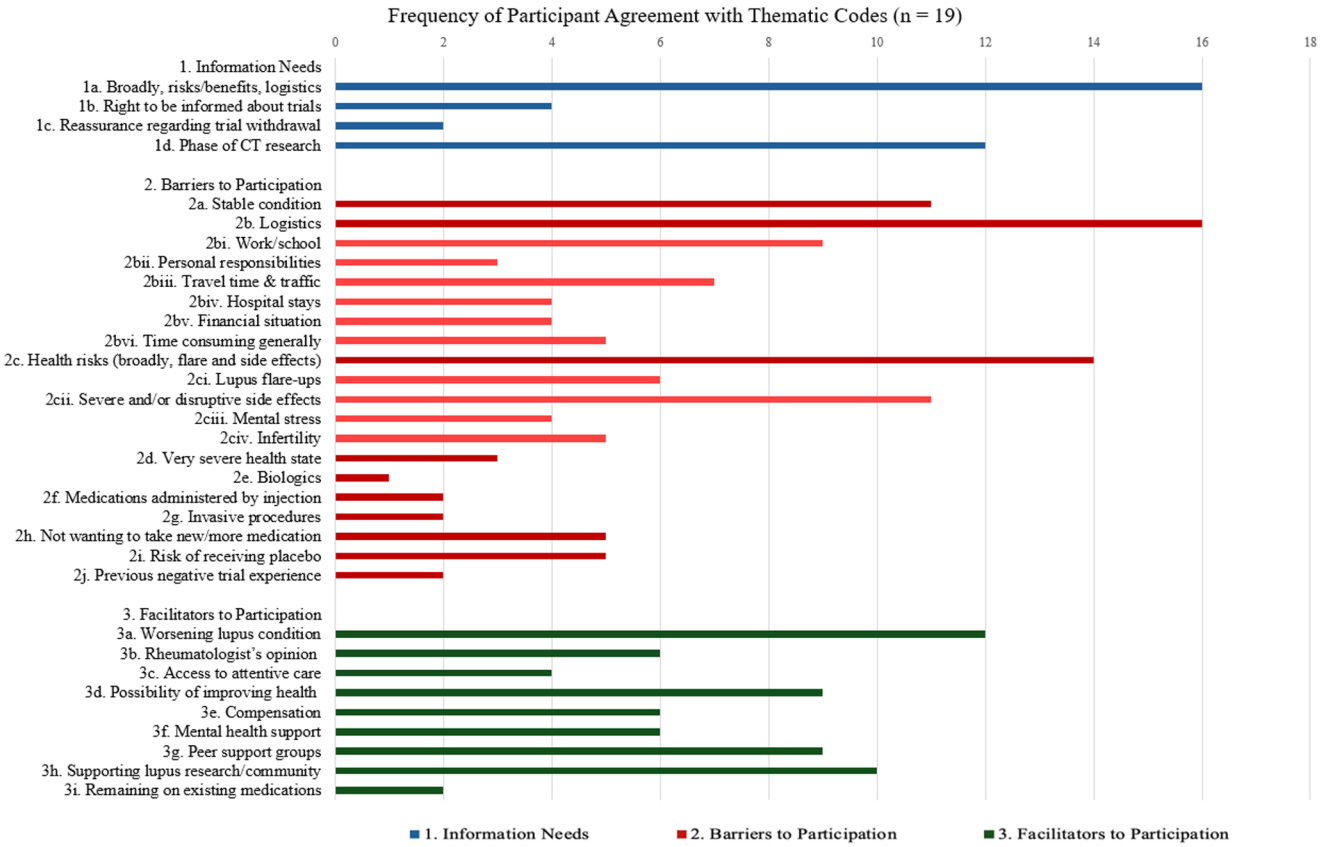

Fig. 1 Frequency of Participant Agreement with Themes (n = 19, if n ≥ 4)

Results

Of the thirty-two individuals who consented, twenty-nine were scheduled to participate in one of four focus groups (two in English and two in French), as three could not be scheduled. Ultimately, nineteen people participated, while ten did not attend their scheduled session. Focus group sizes were 7 (English), 4 (French), 3 (French) and 5 (English). Mean age (range) of participants was 50 (21–77) years and the majority (90%) were female, with the remainder male. Most participants 79% (15/19) were White, with the rest being Black, Asian and Hispanic. Mean time since SLE diagnosis was 21.4 (standard deviation 13.7) years. In terms of geographic location, 53% live within and 47% live outside of the greater Montreal area. Those living outside of Montreal came from Monteregie, the Laurentides, Mauricie, Centre du Quebec, Saguenay-Lac-Saint-Jean, and southeastern Ontario.

Six main themes emerged regarding participation in trials of advanced SLE therapies: themes I-II concerned barriers (logistics, risk aversion), and themes III-VI related to facilitators (comprehensive information, unstable SLE activity, altruism, and support received during participation).

Theme I: logistical constraints

Logistical constraints, including time commitments or travel, were major barriers to clinical trial involvement for the majority (16/19) of participants. Of the three who did not see logistical barriers, two had previously participated in a clinical trial. Increasing frequency and length of visits (including overnight stays in the hospital) and overall duration of the study were seen as clear obstacles to participation.

Half of participants (9/18) mentioned being unable to devote significant amount of time to a trial due to employment circumstances, namely working full-time, being self-employed or being a full-time student. Participants prioritized their careers, and understandably did not want to use their vacation time to be in a clinical trial. Ability to take time off from work was limited by individual employment and financial situations. For example, one individual commented on their lack of paid time off and employer inflexibility, and that any research trial involvement would require financial compensation to make up for income loss.

> Q1: "I couldn't because I work and in the past when I had a little bit of complications, sometimes going to medical appointments and all that, I had problems

> even if I had my documents saying I was at the hospital […] The days that I miss [work], I don't think that I would be paid so it would necessitate [compensation]" (Hispanic woman in her 40s) (original quote in Supplementary Data S2).

Several individuals who were retired or had flexible work schedules expressed that they would potentially participate in a clinical trial. Other group members cited commitments outside of employment such as caretaking for family members or pets as barriers.

Potential clinical trial involvement was limited by travel, as nearly half of our focus group members lived outside of the greater Montreal area. Individuals additionally noted traffic as an obstacle. Certain people voiced that they may be open to participation if travel and hotel costs were covered by the trial. Some individuals indicated needing compensation for their time, while others only described compensation to recuperate travel and other trial-related expenses.

Theme II: risk aversion

The vast majority of participants (14/19) stated their apprehension regarding uncertain health risks and fear that participation may worsen their health. Of the five who did not indicate risk aversion, three were the same people who didn't express concern about logistics (two of whom had previous trial experience). The other two individuals were in unstable health states and said they would tolerate elevated risks.

Recurrently, worry was expressed by those in a stable state that being in a trial might cause their lupus to flare (i.e. if they were required to stop their current medications). Individuals brought up concerns surrounding severe side effects of clinical trial treatments, including risks related to cancer or infections. Individuals of reproductive years (four women and one man) voiced that risk of infertility would be a major deterrent. Some feared disruptive albeit non-life-threatening side effects (e.g. nausea, pain), particularly individuals who have experienced many adverse drug effects. Tolerance of risk was related to the specific set of potential adverse outcomes and the patient's circumstances, including lupus stability, additional health concerns or disability, and personal characteristics. One individual noted that a deterioration in her condition would affect not only herself, but also her ability to support the needs of family members. Another person expressed that she only has one working eye and that she would not consider any trial with potential visual adverse events.

> Q2: "if there's a chance of other side effects, you know, and they're not sure what it's going to be, you know, why would I?" (White man in his 70s).

> Q3: "[regarding] side effects, like, if they tell me that it's a risk that I can't have kids, yeah no, because I would put my future first, obviously" (Black woman in her 20s, without children).

Some were concerned that potential adverse effects from clinical trial medications might threaten one's autonomy. It was additionally discussed that weighing risks and benefits is a reality of living with SLE. Nevertheless, the uncertainty regarding the consequences of a new treatment posed high stress for many participants, with one person noting that this stress may itself trigger a flare in their condition.

> Q4: "What would discourage me is that I don't have a lot of autonomy, so to lose any more [due to side effects]" (White woman in her 50s) (original quote in Supplementary Data S2).

> Q5: "You might take part in the clinical trial, knowing that one part of you will be better and maybe another part will be worse again. So you have to weigh, what do you want? And everybody's circumstances are different, right?" (White woman in her 60s).

Participants discussed that they would be much more comfortable with involvement in later-stage clinical trials in which there was knowledge of potential risks and benefits. This was mentioned in terms of informed decision-making and exposing oneself to a lower risk of severe adverse effects. Notably, one individual specifically brought up being uncomfortable with biologics. Furthermore, several participants mentioned reluctance regarding the potential to receive a placebo in a clinical trial.

Theme III: comprehensive information

The third theme emphasized the requirement for comprehensive information about clinical trial involvement to facilitate informed participation. One focus group delved deeper into this, and four individuals concurred that they felt their doctor had a professional responsibility to keep them informed about clinical trial opportunities to allow for ongoing informed patient decision-making. This was substantiated by testimony that one patient perceived that a previous medical professional had denied them access to a new treatment to their detriment. Interest in new treatments was framed as tied to the chronic nature of SLE,

necessitating ongoing medication, and dissatisfaction with current options.

> Q6: "What I expect is that the doctor comes back with potential options for me that I will then [evaluate]. It's my responsibility to be in charge of my own body and my own health and to make my own decisions. Then I will be in a position to have that conversation with them and then decide for myself whether I want to continue on the existing treatment or try something new. I think the challenge as well is that with autoimmune disorders, it's not typically something that gets cured [… so] if there's something better out there, or that has less side effects, absolutely, you'd want to know" (White woman in her 50s).

Patients discussed that they would require thorough, relevant, and easy-to-understand information regarding the detailed logistics of clinical trial involvement, including length of medical visits and any procedures or testing required. Information about potential risks or benefits was essential, as was how adverse effects would be treated. Many participants were unfamiliar with the specific commitments a trial entails and a few expressed worries regarding abandonment by trial organizers in the event of adverse effects and/or if the patient chose to withdraw from the trial. Individuals repeatedly brought up their trust in their rheumatologists and that they would greatly rely on their opinions when deciding whether to participate.

Theme IV: unstable SLE course

The fourth theme we identified was SLE activity as a driver of clinical trial participation. Several individuals shared that they had not yet found a treatment that stabilized their SLE, and that their need for new SLE treatments motivated them to consider a clinical trial. Moreover, when asked under what circumstances participants may be open to trial involvement, many (12/19) said a deterioration in their SLE control would be a motivator. Amid active SLE, patients saw clinical trial participation as a potential avenue to improve their wellbeing and quality of life. Conversely, the majority of individuals who identified as stable repeatedly expressed not wanting to jeopardize their good health by participating in a drug trial.

The patients who expressed the need for a new treatment were significantly less risk-averse than stable patients, describing themselves often as in a state of desperation. Some mentioned being increasingly willing to accept elevated or uncertain health risks, even so far as a significant risk of cancer. These individuals were open to a more substantial time commitment, including overnight stays and travel, despite logistical challenges.

> Q7: "I am ready to try pretty much anything to improve my quality of life. I've had some severe side effects, and I am able to live with them […]. I am really happy that there are clinical trials, I have been waiting for them for so long" (White woman in her 50s) (original quote in Supplementary Data S2).

> Q8: "I hate to say it, but sometimes it depends on how desperate you are. You know how you've tried lots of options that aren't working, you do have to decide on taking a drug that you don't know much about. […] I've been on many, many medications. So that's why I say desperation sometimes sets in where you're like, I just need remission." (White woman in her 50s).

One participant provided testimony relating to previous withdrawal from a clinical trial due to experiencing a severe flare. She described that when very ill, the rigour and stress of a drug trial became unmanageable and that she perhaps would have continued had there been more flexibility.

> Q9: "The one drug trial that I withdrew from, I was very sick and I was interested, but I was so overwhelmed and exhausted […] I just had to back out because the stress of knowing I had made such a commitment to going, it was rigorous. […] when you're too sick, you're maybe too sick" (White woman in her 60s).

Theme V: supporting the lupus community

The fifth theme was clinical trial involvement being seen as a benevolent act advancing science and helping the lupus community. Nearly half of individuals (10/19) showed agreement with this notion, and there was a strong interest in the idea of the lupus community and supporting one another. One focus group discussion even included an interaction between an individual on a medication thanking another who had shared that they were involved in a trial of that drug. Advancing lupus treatment research was widely viewed as an altruistic side benefit of participation, rather than a principal motivating factor, due to the potential health risks and time commitment involved.

> Q10: "I'd love to be in a study to help other people with lupus, you know, but to risk my health for that. I don't know if I'd be willing to do that." (White man in his 70s).

Q11: "I really want to tell [participant name] thank you for doing the [medication] trial, because I'm on [medication] right now. I go once a month to get infused. So thank you." (Black woman in her 20s).

Theme VI: support received during trial participation

The final theme explores various forms of support that could be provided to those enrolled in a clinical trial, that may facilitate involvement. Nearly half (9/19) of individuals expressed desire for peer support groups in which patients could connect with others who intimately understand the experience of having lupus. One testimony below describes how this experience in a previous trial provided them great benefit. The idea of peer support was widely popular as a potential benefit of research involvement. Numerous focus group participants were interested in mental health support, both to manage the uncertainty in a clinical trial and to manage stress related to lupus. One patient additionally suggested implementing a support phone line to remotely address any concerns while participating in a trial.

Q12: "I've had lupus since I'm 14 [… and participating in a clinical trial] was the first time I was able to converse with other lupus patients […] and it was the greatest feeling just to know that I wasn't alone and that somebody else is answering me on a personal level" (White woman in her 60s).

Another form of support discussed as a benefit of trial involvement was the availability of attentive medical care. Individuals, based on personal experiences or existing knowledge, noted that clinical trials, through close following of participants, invertedly offered comprehensive and timely medical care for any ailment. This was especially valued given to the chronic nature of lupus and the complexity of their health needs. This support additionally relieved stress related to the possibility of adverse effects.

Q13: "[A benefit is] the care that you're going to receive during the trial […] pretty much anything that happens, they're going to look out for you. I think that makes a big difference too, knowing that they're there to help you every step of the way and any questions you have or issues, they're pretty much going to tend to them […] right away" (Black woman in her 40s).

Discussion

This focus group study provides valuable insights into the factors influencing SLE patients' willingness to engage in clinical trials for both novel and traditional treatments. Our findings align with and build upon existing research. Logistical barriers to clinical trial participation are well-documented [10, 11], as is patients' interest in receiving trial information [12]. Factors associated with SLE clinical trials involvement are female sex, older age and higher disease severity [13–15]. Subjects in SLE trials are disproportionately White, despite higher disease incidence and mortality rates in non-White populations [14, 16, 17]. Other studies corroborate our observation that supporting the lupus community (by participating in trials) is important to many patients with SLE, and that patients rely on healthcare provider opinions regarding suitability of a trial [10, 13, 18]. Furthermore, other research supports our finding that patients who consider their condition stable are less interested in clinical trial participation [13, 17], while those with severe illnesses tend to be more willing to participate, even despite trial risks and logistics [13, 18]. Concern about adverse effects has commonly been observed, although the influence on decision-making varies [10, 11, 12, 17]. Our study findings of trial participant deterrence related to logistic barriers and risk aversion are of greater importance than expressed in previous work, which may reflect the increased burden and uncertain risks associated with novel/advanced therapy trials.

Our research highlights the unique experience of living with SLE. Patients were understandably protective of their health, and many expressed visceral fear when discussing the possibility of flaring. Individuals elaborated that a decline in their health may affect their autonomy and ability to care for others. Discussions revealed the complexity of living with lupus, where patients must weigh health benefits against risks, such as taking immunosuppressants despite potential toxicity [19]. The nature of chronic conditions and imperfect current treatments drive certain patients to seek new therapies, which may explain the widespread interest among participants in receiving information regarding clinical trials [20]. Participants with unstable disease in particular emphasized a need for novel SLE treatments. Such individuals appear significantly less risk averse and more tolerant of logistical demands. Declining health was described by several participants as causing "desperation" that would prompt trial consideration. These testimonies highlight the vulnerability of being in an acute health condition when consenting to a clinical trial [21].

The insights produced from this research may help inform more patient-centered clinical trial design and recruitment strategies that better align with the needs and concerns of

people with SLE, and support participant engagement and retention. Our study revealed a strong interest amongst lupus patients in increased access to medical care (despite theoretical universal access in Canada), mental healthcare (often not publicly funded in Canada) and peer support. Our findings support the importance of a Lupus Therapeutics initiative presently underway, Patient Advocates for Lupus Studies (PALS). PALS is a peer-to-peer education program, designed to increase awareness of the potential risks and benefits of lupus clinical trials, and address the lack of diversity among trial participants [22, 23]. This program could connect previous clinical trial participants to prospective patients to support informed decision-making [22].

This report is one of the first studies to explore SLE patient perspectives on participating in clinical trials specifically for novel or advanced therapies (such as CART), which is increasingly important. Trials of such novel therapies often face added recruitment and retention challenges due to treatment complexity, potential risks, and higher trial demands. A recent paper on this topic emphasizes these issues [24]. Our study deepens understanding of how risk aversion on one hand and disease instability on another influences SLE patients' decision-making as they contemplate enrolling in a trial. The reality that people with severe disease may accept greater risks, raises important ethical considerations, on one hand about vulnerability but on the other hand the need to offer trials to people with severe disease. As well, our study identifies key facilitators of participation, including clear trial information, peer and mental health support (an issue previously under-emphasized) and attentive medical care. This study thus offers actionable insights for more patient-centered trial design.

Our research has various strengths and limitations. The sample lacked racial diversity, with most participants being White and no representation of Indigenous individuals, a key marginalized population in North America, who are disproportionately affected by lupus including more severe disease [25, 26]. Although, the ethnic distribution in our sample (21% identifying as non-White, 47% residing outside the greater Montreal area) broadly aligns with the regional context, as visible minorities represent 33% of the population in Montreal and 13% in Quebec [27, 28]. Many of our subjects were middle-aged, which was likely related to the long-standing MUHC research cohort. However, the reality is that SLE is a chronic disease, spanning many decades. Most participants were trial-naïve, reflecting that the majority of SLE patients are never offered to participate (although many decline when approached). Volunteer bias is inherently an issue of focus groups, which may limit the generalizability of our sample, particularly considering our sample stems from an existing research registry. Further studies could attempt to address the research question with different methods to mitigate this bias, such as a broad survey of SLE patients. As well, bias may have been introduced due to the fact that the qualitative data was coded by a single researcher and validated by another.

There are pros and cons inherent to focus groups. Participant engagement might have been affected by discomfort, shyness or social-desirability bias. The iterative approach of moderation, where probing questions were informed by previous groups, may have skewed the discussion, though it helped stimulate conversation and flesh out themes. Discussions were limited by absenteeism in some sessions, with two groups ultimately containing 3 and 4 individuals, despite efforts to facilitate participation (e.g. virtual format, flexible scheduling, reminders). A strength of focus group methodology is that group interactions elicit reflection and elucidation, building to a whole greater than the sum of its parts. With respect to the virtual format specifically, group engagement may have been affected by the lack of in-person interaction, participant distraction or silent participation and occasional technical difficulties. At the same time, the virtual setting was advantageous in facilitating study participation among chronically ill patients, particularly those in rural regions.

Conclusions

This focus group study provides insights into SLE patients' perceptions of barriers and facilitators to participation in clinical trials for cellular or biologic therapies. Key barriers include logistical constraints such as time commitment, employment and travel, and risk aversion. Important facilitating factors include providing clear and comprehensive information, the need for new treatments among patients with lupus instability, perceived benefit to the lupus community, and the availability of peer groups, mental support and attentive healthcare in a trial. These insights may help inform more patient-centered trial design and recruitment strategies that better align with the needs and concerns of people with SLE and encourage participant retention.

Appendix 1

Interview Questions.

Question 1: Would you like your doctor to provide you with information about new/advanced therapies that are under trial?

Question 2: Would you consider participating in a clinical drug trial?

Question 3: What factors make it more or less likely for you to participate in a clinical drug trial? What would encourage you? What would discourage you?

Examples of potential barriers:

- If the study required frequent study visits (e.g. every week, every month…).
- If a study required you to stay in hospital one night (or several nights, or 2 weeks) to be monitored, as part of the study. (If these are barriers to your participation, why? …distance to hospital, family responsibilities, work? What efforts could the people running the study offer to overcome these barriers?)
- Fear of side effects (short-term, long-term, related to fertility or reproduction i.e. later pregnancy) (If fear of side effects is a barrier to your participation, which side effects would you be most concerned about… e.g. infection, death, cancer, infertility, effects on future pregnancy/offspring? What would help reassure you?).

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Data availability The data underlying this article will be shared on reasonable request to the corresponding author.

Declarations

Conflict of interest The authors have no relevant financial or non-financial interests to disclose.

Financial support or other benefits from commercial sources The authors have none to declare.

Ethics and consent This study received ethics approval from the McGill University Institutional Review Board (IRB #A04-M29-06B); All participants provided written informed consent prior to participation. Participants consented to the recording of focus group discussions and the use of anonymized quotations in publications.

Previous publication An abstract related to the study appeared as a poster at the American College of Rheumatology Annual Scientific Meeting, held from October 24 to 29, 2025 in Chicago, Illinois, USA. See reference 6 for bibliographic information.

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