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OMERACT- determining a core domain set for Sjögren's disease: International focus group series

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ABSTRACT

Background: Sjögren's Disease (SjD) is a systemic autoimmune disease that is associated with a significant reduction in health-related quality of life (HRQoL). The goal of this study was to better understand HRQoL using a multi-national and rigorously defined SjD population according to 2016 ACR/EULAR classification criteria.
Methods: The Outcome Measures in Rheumatology Clinical Trials (OMERACT) Sjögren's Disease Working Group conducted three regionally based focus groups (United States, Australia/China, the Netherlands) for adult patients with SjD who met classification criteria. The focus groups were semi-structured and designed to elicit feedback regarding important life impact domains, or aspects of disease, that should be included in future research. Additionally, a brief demographic survey was administered. Focus group transcripts were coded and analyzed for theme saturation and interpretation.
Results: There were 29 participants with SjD who completed the focus groups (25 females, 4 males); 28 participants completed the surveys. Five codes and 19 subcodes were identified corresponding to the following relevant domains: pain interference, physical activity, dryness, fatigue, oral health, autonomic function, and sequelae of inflammation, brain fog, pregnancy/fertility, emotional health, social participation and engagement with others including medical providers, and worker productivity.
Conclusion: These findings from a multi-national sample reaffirm the relevance of established symptoms such as pain, fatigue, and dryness while elucidating a broader spectrum of disease impact reported by individuals with SjD. Domains related to cognitive impairment, autonomic dysfunction, oral health, emotional well-being, and social and occupational functioning emerged as salient features of the patient experience. These data support the

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need to expand current outcome frameworks to better capture the multidimensional burden of SjD and inform the development of more comprehensive, patient-centered assessment tools.

Introduction

Sjögren's Disease (SjD) is a systemic autoimmune disease that is characterized by exocrine gland dysfunction that significantly impairs health-related quality of life (HRQoL) with a female to male predominance of 9:1 [1]. Common symptoms such as pain and fatigue can lead to disability, reduced work productivity, and increased healthcare utilization [2]. Additional SjD disease domains that drive reduced HRQoL include ocular and oral dryness, sexual dysfunction, sleep impairment, psychological dysfunction, and impaired physical function, all of which interfere with daily functioning [3]. However, these impacts are underexplored in diverse populations, especially using rigorous qualitative methods as we have noted in our qualitative systematic review [4].

Outcome Measures in Rheumatology (OMERACT) is an international organization comprising clinicians, investigators, patient research partners, industry representatives, and methodologists whose goal is to develop data-driven Core Outcome Sets for rheumatic diseases [5]. In May 2023, the first Sjögren's Disease Special Interest Group was held in Colorado Springs, Colorado to evaluate current outcome domains and measures used in SjD clinical trials [6]. To follow the OMERACT framework, we needed to identify all existing SjD domains that are important to target in clinical trials. To address this gap, we performed a systematic review of clinical trials [7] and qualitative studies (submitted) to identify the range of SjD domains that were previously recognized or studied in the literature. Drawing from these efforts, the OMERACT Sjögren's Disease working group held collaborative meetings engaging clinicians, researchers, patient research partners, and pharmaceutical representatives to construct a comprehensive list of candidate life impact domains (Supplemental Table 1). At our inaugural meeting, we identified a critical need for understanding the lived experience of people with SjD using rigorous methods, strict classification criteria, and diverse geographic representation. To date, only one qualitative study has included patients from multiple countries [8].

Building on our preliminary work, our objective was to conduct a series of focus groups to better our understanding of HRQoL in individuals with SjD and to revise the prioritized list of life impact domains, if necessary. We hypothesized that cultural and geographic factors may influence the perceived severity of SjD impact on HRQoL.

Methods

Study design, setting, research team, and reflexivity

Three in-depth and semi-structured focus groups were conducted with ethical approval from the University of Pennsylvania (IRB # 855,507) from September 2024 to March 2025. The COREQ checklist was followed for formatting and reporting standards [9]. The qualitative study was advertised to rheumatologists who were members of the OMERACT Sjögren's Disease Working Group for purposive recruitment of their respective patients based on SjD duration (2 participants per: <5 years, 5–10 years, 10–20 years, >20 years). Patients who met the 2016 American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) SjD Classification Criteria and spoke English were eligible to participate. The focus groups were recruited based on geographical clustering in (1) the United States, 2) Australia, China; and 3) the Netherlands) per recommendations of the OMERACT Filter 2.1, 2.2 handbook (≥3 continents) [5,10]. Local rheumatologists provided eligible participants with a flyer inviting them to participate, which contained an email contact for the principle investigator (DD). Patients then contacted DD for further information, provided informed consent and enrolled onto the study. Focus groups were approximately 60 min in length and were completed by researchers with credentials in qualitative methods at the Mixed Methods Research Laboratory (MMRL) at the University of Pennsylvania (OBC (female), (LA (male)) online, via Zoom, in English. The interviewers did not have any pre-existing relationship with the interviewees prior to the focus groups and were not primary researchers or clinicians for these patients with SjD. However, both participants and interviewers were familiar with the goals/purpose for conducting the research, i.e., to understand important aspects of living with SjD and prioritize domains for future clinical trials. Participants were also asked to complete an optional, deidentified survey regarding demographics, work status, disease duration, comorbidities, and patient global assessment of disease activity (0–10, 10=worst). Deidentified transcripts were produced from Zoom recordings (available only to OBC, LA) and confirmed with Zoom-generated transcripts. After each focus group, debriefing and discussion with study team members and the MMRL were conducted to streamline and focus the questions. Data saturation was ensured by two researchers independently reviewing transcripts iteratively to generate new codes and subcodes. These codes were then discussed amongst researchers to achieve group consensus and subsequently compared to the exhaustive domain list generated by the OMERACT Sjögren's Disease Working Group Sessions (supplemental Tables 1, 2). Participants were paid 100 US dollars for their participation.

Analysis and findings

Themes were either pre-identified for participants (see supplemental Table 1, interview guide) or emerged naturally during discussion. After being recorded and transcribed verbatim, focus groups transcripts were then cleaned, deidentified, and entered into NVivo software for coding and analysis. Research team members (OBC and LA) developed a codebook using a thematic analysis plan, where emerging themes were noted across transcripts. Two research team members (OBC and LA) double-coded all transcripts.

Results

Patient demographics from all three included regions are summarized in Table 1.

United States

Thirteen participants were recruited for the first focus group (United States) of which, 3 had scheduling errors, 2 logged in late, and 1 participant was unable to participate due to unforeseen, weather-related circumstances. Ultimately, 7 participants (6 female, 1 male) with a mean (standard deviation [SD]) age of 57.6 years (± 12.6 years) completed the demographic survey. The mean (SD) SjD duration was 9 years (± 7

Table 1
Demographic and clinical characteristics of included participants with SjD (n=29; 1 missing questionnaire).

Demographic and Clinical Characteristics	United States	Australia/ China	Netherlands
n	7	11	10
Age mean (SD)	57.6 (12.6)	49.3 (12.4)	44.8 (14.0)
Sex, n (%) M	1 (14%)	1 (9%)	2 (20%)
Sjögren's's Disease Duration Mean Years (SD)	9 (7)	15 (10)	14 (7)
Mean Patient Global (SD)	5.1 (2.6)	4.9 (2.7)	5.0 (2.1)

years) and the mean (SD) global assessment was 5.1 (± 2.6). Comorbidities and SjD-related complications included thyroid cancer (n=1), psoriasis (n=1), MALT lymphoma (n=1), hypertension (n=2), neuropathy (n=1), rheumatoid arthritis (n=1), osteopenia (n=1), depression (n=1), and anxiety (n=1).

Australia/China

Of the 12 participants (3 from China, 8 from Australia) recruited for the second focus group, 11 (10 female and 1 male) participated in the focus group; one participant had a scheduling conflict. The mean (SD) age was 49.3 years (± 12.4 years) and mean (SD) SjD duration was 15 years (± 10). The mean (SD) patient global assessment of disease activity was 4.9 (± 2.7). Comorbidities and SjD-related complications included fibromyalgia (n=1), depression (n=2), Hashimoto's thyroid disease (n=3), lupus (n=1), lymphocytic interstitial pneumonia (n=1), hypertension (n=1), and macular degeneration (n=1).

Netherlands

All the 11 participants from Netherlands recruited for the third focus group participated in the focus group (with one missing survey). There were 9 female participants and 2 male participants. The mean (SD) age was 44.8 years (± 14 years) with mean (SD) SjD duration of 14 (± 7) years. The mean (SD) patient global assessment of disease activity was 5.0 (± 2.1). Comorbidities and SjD-related complications included celiac's disease (n=1), erythema multiforme (n=1), lupus (n=1), asthma (n=1), arthritis (n=1), neuropathy (n=1), Raynaud's (n=2), and irritable bowel syndrome (n=1).

Focus group discussions

In general, there was excellent agreement between reviewers when transcribing and coding the following results ($\kappa = 0.89$):

Participant characteristics

All but one focus group member had been on treatment for their SjD for several years at the time of the study. When introducing themselves, several participants mentioned the year they were formally diagnosed but reflected that they had been dealing with their symptoms for years before diagnosis. A few participants even suspected they had been navigating SjD symptoms their whole life.

"I'm 53-years-old, and I have known Sjögren's for about, when I was about 30, 29. So I think it was about 'the year 2000, something like that. And I was already having symptoms for a very long time. I think maybe even from childhood. So maybe, yeah, my whole life. I'm not sure." - Participant 3, Europe

Symptom management and treatment goals

Participants in the USA and Asia/Pacific focus groups hoped for treatments that could cure their SjD, while reversing existing tissue damage. Across all groups, participants emphasized the desire for a better quality of life while living with their disease, such as being able to chew their food, being physically active, and having less pain in their day-to-day life.

"The outcomes of a clinical trial in a perfect world or a drug that could be developed would reverse any permanent tissue damage. I know I've got a lot of damage to my glands, my eyes, and my mouth. Yes, reversal of any fibrosis or permanent damage to tissue would be a good outcome." - Participant 6, Asia/Pacific.

When it came to managing their symptoms, participants deployed a variety of tactics depending on their remaining function and the severity of their symptoms. Some discussed carrying water bottles with them to public speaking events and developing a regular exercise routine to maintain their physical functioning. Participants also mentioned using exercise as a pain management strategy. They also discussed managing their fatigue by limiting their social engagements, leaving the paid workforce, and trying multiple different medications.

"But the energy is the most painful, the symptom that weighs the heaviest on my well-being. But before, one and a half years ago, it was also a lot of pain and tension in my muscles and stuff, but I started training. And now I build up some condition with a whole lot of red crosses in my agenda. But now, I'm medicine free because of all of that. And normally, I really have to take paracetamol, naproxen. Did a lot of medication, and most of the time, I don't have to take anything. So that was a good change." - Participant 8, Europe.

"Day-to-day, I have a lot of fatigue. I don't work anymore. I go do yoga and Pilates every day, and that's about all I can manage. And the rheumatologist said that's probably helping me a ton just staying as active when I can." - Participant 6, USA.

Participants also branched out in the discussion and shared their vision and priorities for SjD research. Many wanted studies that could shed light on the role of diet, climate, fertility, lifestyle changes, and hormone cycles on SjD. Others discussed the need for longitudinal studies and qualitative research that could capture the lived experience of those with SjD. Another major concept raised in the discussion was the importance of the lived experience of SjD caregivers. Participants also wanted more research on the cause and potential cure for SjD. Lastly, participants discussed how outcome measurement may be difficult due to the unpredictability of SjD.

*"I think [the domains] cover a lot of the things you run into. And I find that the weirdest thing is also the immeasurability of it all. We talked about flare ups and things that suddenly just pop up, and you can't really explain it. I also find that I sometimes have a flare up, and then my blood work is completely stable. So it doesn't really explain why I feel like s***. Which is a weird thing to sort of come to terms with, and yeah. So I think if you do want to do some sort of study, yes, fine. It's a weird thing where you have to take into consideration that maybe, it's not really measurable, but you can compare it to your better days or your not so good days, rather than to a set baseline or a certain set of expectations." – Participant 4, Europe.*

SjD symptoms

Dryness and fatigue were the most mentioned symptoms of SjD, with participants also frequently mentioning symptoms related dental/oral health, pain, immune function, brain fog, and reproductive health. Other symptoms less commonly mentioned included rashes, panniculitis, fevers, "bone freeze" ,[1] inflammation, tachycardia, malaise, neurological manifestations, and photosensitivity. While the connection between SjD and other diseases was unclear, participants mentioned additional health issues including uterine polyps, lung infection, fibromyalgia, lupus, gland tumors, Raynaud's syndrome, rheumatoid arthritis, herpes in the eyes, parotid gland issues, "minor neuropathy", issues with the trigeminal nerve, and ischemic brainstem stroke.

Dryness

Dryness was the most frequently mentioned SjD symptom and mostly affected participants' eyes, mouths, and skin, having extensive personal, psychosocial, and health impacts. Dry mouth was commonly cited as impacting social participation, as participants could not talk for long periods of time without drinking water. Participants mentioned how dry eyes resulted in redness or irritation, which somewhat impacted their social participation. Participants differed in the severity of their dryness symptoms, with some affected more severely in their mouths, while

[1] Could potentially mean chills. This participant was from the Europe focus group and it was unclear if this was a phrase used where they lived or something that did not translate over to the English language.

others noted more severe involvement of eyes or skin. Others mentioned how the severity of the dryness areas could change over time. Rashes were often mentioned in conjunction with symptoms of dry skin.

"The skin, it is the dryness…. [my] skin's hard, constant moisturizing, constant upkeep. And please don't take offence to the gentleman in the chat. But as women, we like to care for our skin and all that stuff. So, I'm constantly onto it. But I find no matter what you do, it's really hard to keep up with it, keep up with the dryness." – Participant 3, Asia/Pacific.

"Eyes have been a big problem and I've now got to the point where I have to have drops during the day and an ointment at night because my eyes were drying out that much at night that was welding themselves to my eyeballs, which wasn't good in the morning when you wake up your eyes and you felt like you've peeled the layer off." – Participant 10, Asia/Pacific.

Dental/oral health

The impact of SjD on participants' oral health was closely linked to symptoms of dry mouth. Dry mouth resulted in trouble speaking for long periods of time, increased cavities and caries, and tooth loss. Some called attention to the high financial burden posed by dental care, with many discussing visiting the dentist frequently for check-ups.

"Another one is for my teeth. That's dropped piece by piece. I'll joke to my friend. The cost on my dental work just, I can buy a car, that cost too much for my teeth. My teeth almost replaced, here and there, piece and piece. Whenever I have a problem with my teeth, I'll go to see a dentist. I'll fix it very quickly. So, I can keep the teeth longer without a problem." – Participant 7, Asia/Pacific.

"And like everybody else, the teeth have been a big problem, and my dentist keeps saying ominously, you're getting down to the lowest number of teeth you can have in your mouth without having to have something done about it. But I'm hanging out for them to start cloning teeth so I can grow my own back." – Participant 10, Asia/Pacific.

Fatigue

While dryness was the most frequently mentioned symptom, fatigue was often mentioned as the SjD symptom with the highest impact. Most of the respondents mentioned fatigue as a significant hindrance to their ability to lead a normal and healthy life. Many discussed fatigue as a sort of "hinge" upon which all aspects of life and managing symptoms fell. For example, participants discussed how they felt improvements to their fatigue would facilitate their ability to better manage other symptoms such as pain and dryness. Fatigue greatly impacted participants' work and social lives.

"I was just going to say that fatigue is the main thing for me and then that just impacts the mental and emotional health. It impacts my ability to function visibly; the social participation then drops. So, it's just things like the fatigue for me is the overriding factor that can then contribute to so many aspects of my life." – Participant 4, Asia/Pacific.

"Especially in my motherhood. I had to take a lot of rest time, and when they were smaller as a baby, then when the baby was sleeping, I was sleeping. That's not specifically Sjögren's's, I think, because a lot of parents are having difficulties with energy, but, I think it's weighing heavier for me because of the Sjögren's's… the energy is the most painful, the symptom that weighs the heaviest on my well-being." – Participant 8, Europe.

Pain

Pain was mentioned by many participants across all three focus groups. When pain was mentioned, participants usually described pain in their joints, which sometimes resulted in them being unable to walk or carry out normal daily activities. Participants also mentioned pain in their muscles and glands.

"I went into body aches and body pains and then I started to get the rashes. So, if I had a bad (episode), like I said, it was difficult to walk for a couple of days." – Participant 9, Asia/Pacific.

Autonomic function

Many participants across all three focus groups discussed issues with their neurologic and autonomic function, often tying in other complicating diseases in relation to their SjD.

"I've got autonomic dysfunction. It does sometimes when I'm really tired or stressed or sick, I get a bit of vasovagals and my blood pressure drops and I've got issues with my heart rate so I'm not really taking any treatment for that. So that's symptomatic and doing things like getting up slowly so letting my blood pressure stabilize. So, it's just lifestyle measures for that." – Participant 5, Asia/Pacific.

SjD extraglandular manifestations

Inflammation and arthritis were mentioned in relation to SjD impact on the immune system although not with focused discussion. Skin problems such as rashes, panniculitis, and papules were also mentioned in relation to immune function and SjD.

"Since 2019, late 2018, early 2020, the systemic inflammation that we all live with from autoimmune activities has started manifesting in my hands and my feet as a form of, I believe it's vasculitis. I'm a very good walker. I can easily walk 10,000 steps if I really want to. I'm still doing it okay, but the skin on my hands and feet get inflamed. And now it's getting very irritated. And I feel like my joint, the perimeter of the feet, the skin is affected and the joint under my pinky toe. Actually, just three weeks ago, I tripped and fell and I broke my left foot bones under my pinky toes. So, this is just my guessing maybe the system inflammation also weakened my bone density that I broke my bones this time. So, it's progressing, but perhaps slowly. And as we all know, the Sjögren's's has so many symptoms, and some of us experience this and some of us don't at all. But there's such a vast array of symptoms and that's my case. The vasculitis is my biggest concern, and now I'm getting my heart and lungs started to get monitored, because it can move on to major organs." – Participant 3, USA.

Brain fog

Some participants mentioned difficulty with concentration, while others explicitly invoked the word "brain fog" to describe the impact of SjD on their mental state. While some participants did not specifically explain the concrete effects of brain fog, two participants described how their brain fog impacted their word recall.

"And [Interviewee 6] was right about the brain fog. I mean, there are so many times I can't think of a word, and it's so frustrating." – Participant 7, USA.

"And I think a lot of problems around brain fog. I knew what I wanted to say but in meetings it'd be coming out back to front. And I think it created a lot of – people don't understand the disease. And I think there was a just a lot of perception in regard to, oh, I was losing it or, and it wasn't. And I really did struggle with the brain fog." – Participant 9, Asia/Pacific.

Pregnancy/fertility

One participant in the Asia/Pacific focus group described her troubles conceiving a baby and carrying her pregnancy to term. She described having multiple miscarriages and was eventually able to conceive and birth her children while on steroids. Other participants mentioned worries during their pregnancies related to potential birth defects and described how they were closely monitored by their doctors during their pregnancies. Another participant recounted that her obstetrician did not know anything about SjD during her first pregnancy, requiring the patient to invest her own time and effort into self-advocacy.

"I had a lot of trouble conceiving and the thing that did the trick for me is steroids, while I was going on IVF with my first child. And then the second time around, I took steroids from the get go and I conceived much easily. So, my rheumatologist thinks there might be some link there as well. So, once my

immune system, all that inflammation is controlled with the steroids, I was able to conceive much more easily the second time around." – Participant 5, Asia/Pacific.

Impact of SjD and proposed domains

Social and emotional health

Participants repeatedly discussed struggling with the unpredictability of their condition, and with inadequate information about the extent of their symptoms. Participants also commented that friends and family would sometimes not understand the impact of their SjD, expecting them to consistently be able to take part in a wide range of activities, despite their SjD making their energy levels very unpredictable.

"And I guess another issue would be family and friends. I don't think sometimes they get what you're going through. Like there's days I'll make, "Okay, let's go out. We'll go out." And then that day, I'm having such a bad day that I have to cancel and my friends go, "Oh, you're canceling it again." But they don't understand it. And even when I first started, my husband, I don't think he kind of got it either. He does now. But I think it's an adjustment all around for social and, I don't know, maybe I'm the only one that sees that, but I think it's a social thing also." - Participant 7, USA.

Financial health

There was an even mix of focus group participants who were engaged in paid work, and those who were no longer able to work as a direct result of their SjD. However, among the people who were working, many of them adjusted their schedules or careers to accommodate for their fatigue and other symptoms. For example, one person changed careers to a less physically involved job to prolong their time in the formal work force, while another was taking courses at a slower rate.

"I was a car mechanic, at the beginning, and I didn't know about Sjogren's. But I was feeling in my body, I don't grow old in this way. The nice hobby with computers and other stuff, and I went for a job change, and now I'm a networking engineer. And there's a lot of work behind the desk. And from that time, my life has been a lot better. With some medication, of course, I can live good through the days." Participant 1, Europe.

Of the people who were no longer in the paid workforce, there was discussion of how their work performance and professional reputations had suffered as they struggled to get accurately diagnosed and manage their symptoms.

"I think the greatest changes in my life came as I slowly became too fatigued to do the work that I loved because I did work shift work for many years. But then in the end, it got to the point where I simply couldn't cope with the night shifts and then the early morning starts and then gradually, it just came back to working Monday to Friday." Participant 10, Asia/Pacific.

Patient-provider relationships

Due to the complexity of their conditions, the SjD patients had varied and complicated relationships with their medical providers, especially in the American focus group. Several of those participants discussed their struggles with getting an accurate diagnosis. In general, the participants were very happy with their current doctor but were distrustful or frustrated with providers they had previously seen for rheumatologic workup. Some participants pursued alternative and integrative medical approaches. A few people discussed getting relief from their symptoms through acupuncture, while another recommended the group try Chinese herbal medicine. Participants in the American focus group also mentioned needing to educate their providers about SjD in order to get competent care from them.

"I feel bad that I didn't follow through the Sjögren's's Ambassador program because as much as we want the doctors to do this better more, we also have to give ourselves more to help ourselves. So, educating the doctors is something we can also do more." - Participant 3, USA.

Comparatively, members of the European, and Asia/Pacific focus groups discussed being more satisfied with their current care, although they also emphasized the need to explain their condition to their non-SjD care providers. For example, one member of the European participant focus group struggled to get medical treatment for a lung infection because doctors believed their symptoms were simply part of their SjD. Another participant mentioned their doctor struggled to distinguish between their SjD symptoms and their perimenopause symptoms.

"Sometimes because you already know you have the Sjögren's's syndrome. But when you feel some other problems, you may (think) that's caused by my current disease or any others. So, do I need to see the doctor? Which doctors do I need to see other than my regular Sjögren's's doctor? That's my problem." - Participant 7, Asia/Pacific.

SjD provisional domains

At the end of the focus group session, participants were asked to comment specifically on the six provisional life impact domains (Supplemental Table 2, question #3). Participants generally thought that the six proposed domains encompassed their experience with SjD. Many commented on the interconnectedness of the six domains. Participants said that the domains of pain, fatigue, and dryness impacted their mental/emotional health, physical health, and social participation. Participants felt that addressing the three aforementioned domains would improve their outcomes in the latter three domains.

"My thoughts are that they're interdependent so I'm wondering what the relationship between fatigue and physical function is. Often, whether there's an intersection between some of the challenges and those secondary manifestations. So, I know, particularly for me, the fatigue really impacts on my mental and emotional health, similarly with pain, so I think it's probably getting to the root cause of what might be the biggest issue that probably is one of those things that highlight what the priority is. I suppose for me, if I can get the fatigue right, I can address some of those mental and emotional things and that's social participation." – Participant 2, Asia/Pacific.

Social participation

Participants across all groups mentioned difficulties in social participation, particularly due to their fatigue. Many felt that their SjD negatively impacted their ability to fulfill their social roles in relation to their family. Participants also discussed difficulty participating in social activities such as parties. Due to the somewhat "invisible" nature of SjD, participants described their frustrations with their loved one and friends who sometimes did not understand the severity of their SjD symptoms.

"I joke to my friends because I travel a lot. And when they see me traveling around the world really, and it's a, "Are you really sick? Do you really have that Sjogren?" Yeah. That's right. I'm faking it, and I'm lying about it, and I'm exaggerating." – Participant 3, USA.

"The aspect that it's invisible. Like, nobody can see it… normally, you cannot see it, and people think a lot about it. And also, when [I was] younger, I think I was not taken seriously before I had my diagnosis. So at first, it was, yeah, it's between your head. You have a lot to do with, but it was obviously not only just something in my head. But now, it helped me. The diagnosis helped me, because I could label it, but also it was a struggle, because a lot of people don't get it." – Participant 8, Europe.

Importantly, while the impact of SjD on work was commonly discussed across all focus groups, the Asia/Pacific and American focus groups placed work and employment under the "social participation" domain, while the participants in the Europe focus group were adamant and in agreement that social participation and work/employment should be considered separately.

"They (the interviewer) mentioned though that work is part of social participation, I get a bit worried, because these for me are really separate things. Social participation, going to friends and stuff and going to work, because work for me is the thing that I really have to be at. Whereas friends

are for me less, like I can more easily say no to that. So for me those would be different." – Participant 7, Europe.

Mental/emotional health

Some participants highlighted mental and emotional health as central to their overall health, while others did not react as strongly to the mental/emotional health domain. In relation to the mental/emotional domain, participants discussed their experiences with grief, feelings around difficulty conceiving, uncertainty regarding which doctor to see, and struggles fulfilling their social roles. One European participant discussed the grief she felt in not being able to fulfill her dreams and wishes due to SjD; while she was unsure if this experience would fall under mental/emotional health, others in the focus group asserted these feelings belonged under the domain. Others discussed how improving their mental and emotional health would lead to better symptom management.

"I really think the mental and emotional health for me personally is first and foremost. Because if you're happy and you're dealing with things, you tend to find the symptoms – they don't impact your life as much. But sorry, I don't mean to sound ignorant or to sound like I'm downplaying anything but I just find that if I'm feeling or I'm in a better mood, I could handle those symptoms a bit better." – Participant 3, Asia/Pacific.

" [I experience a lot of] anxiety and fear. Fear for how it's going to progress to affect my life quality. I live alone, and I'm well connected. I'm not isolated, but I live alone. And this recent bone fracture was obviously very frightening experience all of a sudden. And I have my bedroom upstairs with a full bed also upstairs. So, those are the moments that – I mean, it happens to anybody who falls, but just when you have all these other symptoms. And then when my eyes got so bad couple nights, it just, it's so overwhelming and the fear sets in and that leads to depression. And that's when I try to stop myself, okay, if it hasn't happened yet, I need to not worry about how it's going to go and how my life is going to unfold. But that can happen when you live with a systemic illness." – Participant 3, USA.

Physical function, dryness, fatigue, and pain

Participants tended to interchangeably label the domains of dryness, fatigue, and pain under the "physical function" domain. Many participants did not extensively comment on the dryness, fatigue, or pain domains, simply reiterating that they did indeed experience these symptoms. Some participants from the Europe group used the word "stamina" (ie. lack thereof) to describe the condition of tiredness they experience as a result from SjD instead of "fatigue". One participant from the Europe focus group suggested their physical condition be evaluated based on a person's functional abilities in daily life and their ability to exercise.

"The fatigue is there and also other symptoms are still there. But, if you only zoom in on the symptom, I think it's a bigger thing to watch. Like, is it possible for you to do the exercises? Is it possible for you to do with all the rules you have and all the things you do in daily life? Is it possible to do more of that somewhere? I think if I had that earlier, then maybe I was not so struggling with my condition and the rebuild of it." – Participant 8, Europe.

Discussion

This large, international, focus group series was conducted with participants meeting strict SjD classification criteria from 4 continents (North America, Asia, Australia, and Europe). We confirmed key domains, or areas of interest, of people living with SjD in a multi-national qualitative work in a population that was rigorously screened to meet classification criteria. In addition to pain, fatigue, and dryness, key themes that arose from discussions included: physical activity/function, oral health, autonomic function, disease activity, sequelae of inflammation (chronicity), brain fog, pregnancy/fertility, emotional health, social participation and engagement with others including medical providers, and work productivity (Fig. 1).

Importantly, we achieved thematic saturation of our OMERACT Sjögren's Disease Working Group domains by combining previously compiled domains generated through group discussion amongst our members (comprising patients, clinicians, researchers, and industry representatives) and extensive literature review coupled with our qualitative work (Supplemental Table 1). While dryness and pain were domains that all participants felt to be central and relevant to SjD, fatigue as well as the ability to participate in social roles and activities, either vocationally or avocationally, impacted participants most. Small, nuanced differences were noted between continent and culture regarding what constituted social participation; some participants included work participation in this definition while others did not. In general, participants from Europe felt that the impact of SjD on social and work participation were separate concepts; however, participants from the US, Australia, and China felt they represented the same concept. Another key aspect that emerged was the ability to engage with the medical community and a layer of apprehension, for some, regarding medical advice received from medical professionals not familiar with SjD. Another important aspect identified by participants was the difficulty of serving in a parenting or caregiver role.

Symptoms attributed to extraglandular manifestations of SjD, including dysautonomia and brain fog, also emerged as interfering aspects of SjD that can affect daily life. Participants reported word-recall difficulty and issues with memory that made daily life frustrating. On another note, several participants also commented on the unpredictability of disease flare-ups and their ability to plan their schedules and activities reliably because of this. The unpredictability of symptoms also segued into discussion that choosing the most important life impact candidate domains for research was difficult because features of SjD varied day-to-day. Ultimately, after open elicitation, when participants were given the provisional candidate domain list compared to the exhaustive domain list from our prior systematic review, the key domains of interest related to the lived experience were similar [6,7]. Goals of future research varied per individual and ranged from the desire to have better symptomatic management and adjunctive therapy related to HRQoL to curative treatment.

Prior qualitative literature regarding SjD-only participants has been limited. The collective qualitative body of knowledge regarding SjD is often described in the context of dry eye disease, dry mouth, overlap autoimmune conditions, or presumed SjD diagnoses. This study found similar findings to Unger et al. [8] which described a broad arrange of impacts regarding physical symptoms, physical activity and function, social participation and work force engagement, interaction with healthcare, and financial health. A large emphasis on the ability to engage in social roles and activities should be noted across these focus groups and may be helpful to further define and track change in future study. We also found consistency in reported deficits to social, family, and workplace participation in our qualitative systematic review [4]. In light of these findings, clinical trials may consider social participation, workplace engagement and productivity and the symptomatology that leads to these impairments as part of primary and secondary outcomes in future study.

This study has several key strengths including international input from various geographic perspectives. It also includes participants meeting strict SjD classification criteria and who are in various stages of disease (early through late stage) with known comorbidities. Other strengths to this study include careful consideration of the research team and reflexivity (interviewers were trained in qualitative methods with a focus on medical illness but not close familiarity with SjD to bias focus group discussion or analysis). A limitation of our work is that the focus groups were conducted in English, which hinders the ability to gather perspectives from those who do not speak English and may bias towards higher educational levels when recruiting from non-English speaking countries. Future working group studies plan to address these language barriers.

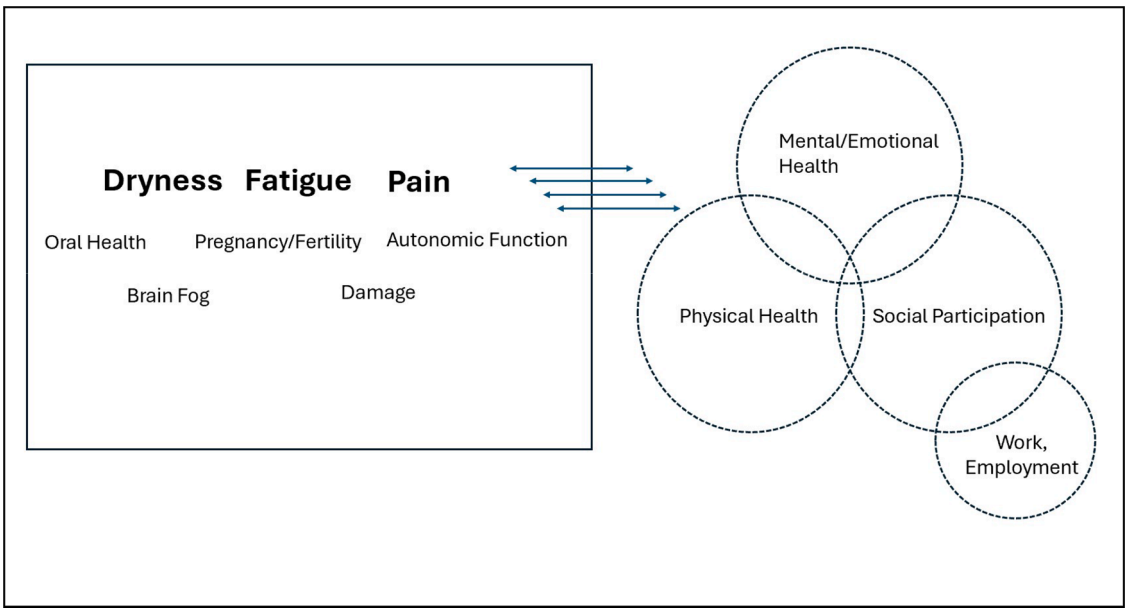

Fig. 1. Important impact domains derived from international focus group discussions.

Conclusion

In this large, international series of focus groups using a rigorously defined SjD population, we confirmed key aspects of living with the disease including but not limited to dryness, fatigue, mental/emotional health, pain, physical function, and social participation. These findings provide a robust foundation for establishing a comprehensive and saturated set of patient-prioritized domains to guide the refinement of patient-centered instruments that better capture the lived experience of individuals with SjD in future clinical trials.

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CRediT authorship contribution statement

Dana D. DiRenzo: Conceptualization, Methodology, Investigation, Project administration, Supervision, Writing – original draft, Writing – review & editing. **Lee Ang:** Investigation, Data curation, Project administration, Writing – review & editing. **Caroline O'Brien:** Investigation, Data curation, Project administration, Writing – review & editing. **Adrian Lee:** Methodology, Formal analysis, review & editing. **Rachael A. Gordon:** Conceptualization, Methodology, Investigation, review & editing. **Kyle Franke:** review & editing. **Howard Yang:** Data Curation, review & editing. **Alan Baer:** Data Curation, review & editing. **Thomas Grader-Beck:** Data Curation, review & editing. **Sandhya Pulukool:** Data Curation, review & editing. **Lane Destro:** Data Curation, review & editing. **Kathy Hammitt:** Data Curation, review & editing. **Coralie Bouillot:** Conceptualization, Methodology, Investigation, Data Curation, review & editing. **Jing He:** Conceptualization, Methodology, Investigation, Writing – review & editing. **Yuebo Jin:** Data Curation, review & editing. **Alberta Hoi:** Data Curation, review & editing. **Simon J. Bowman:** Data Curation, review & editing. **Raphaele Seror:** Data Curation, review & editing. **Maureen Rischmueller:** Data Curation, review & editing. **Suzanne Arends:** Data Curation, review & editing. **Sara S. McCoy**: Conceptualization, Methodology, Investigation, Supervision, Writing – original draft, Writing – review & editing. All authors reviewed and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Dana DiRenzo reports administrative support and statistical analysis were provided by Novartis. Dana DiRenzo reports administrative support and statistical analysis were provided by Bristol-Myers Squibb Company. Dana DiRenzo reports administrative support and statistical analysis were provided by Johnson & Johnson. Dana DiRenzo reports financial support was provided by Sjogrens Syndrome Foundation. Dana DiRenzo reports a relationship with Novartis that includes: consulting or advisory. Dana DiRenzo reports a relationship with Amgen Inc that includes: consulting or advisory. Dana DiRenzo reports a relationship with Argenx Us, Inc. that includes: consulting or advisory. Adrian Lee reports a relationship with Novartis that includes: consulting or advisory. Rachael Gordon reports a relationship with Novartis that includes: consulting or advisory. Alan Baer reports a relationship with Bristol Myers Squibb Co that includes: consulting or advisory. Thomas Grader-Beck reports a relationship with Novartis that includes: consulting or advisory. Simon Bowman reports a relationship with AbbVie Inc that includes: consulting or advisory. Simon Bowman reports a relationship with Aera that includes: consulting or advisory. Simon Bowman reports a relationship with Amgen Inc that includes: consulting or advisory. Simon Bowman reports a relationship with argenx BV that includes: consulting or advisory. Simon Bowman reports a relationship with Aurinia Pharmaceuticals Inc that includes: consulting or advisory. Simon Bowman reports a relationship with Bain & Company Inc United Kingdom that includes: consulting or advisory. Simon Bowman reports a relationship with Bristol-Myers Squibb Company that includes: consulting or advisory. Simon Bowman reports a relationship with EcoR1 that includes: consulting or advisory. Simon Bowman reports a relationship with Galapagos that includes: consulting or advisory. Simon Bowman reports a relationship with IQVIA that includes: consulting or advisory. Simon Bowman reports a relationship with Johnson & Johnson MedTech that includes: consulting or advisory. Simon Bowman reports a relationship with Kiniksa Pharmaceuticals Corp that includes: consulting or advisory. Simon Bowman reports a relationship with Novartis that includes: consulting or advisory. Simon Bowman reports a relationship with Scitaris that includes: consulting or advisory. Simon

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Supplementary materials

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