

ITCHING FOR RELIEF

A NATIONAL REPORT ON THE
PATIENT JOURNEY FOR CHRONIC
SPONTANEOUS URTICARIA



April 2026

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EXECUTIVE SUMMARY

In 2025, the Canadian Skin Patient Alliance (CSPA), a not-for-profit patient organization formed to improve the health and well-being of Canadians with skin, hair and nail disorders through collaboration, advocacy and education, conducted a national survey to understand the patient journey for individuals living in Canada with chronic spontaneous urticaria (CSU). The survey was conducted in collaboration with a study team of dermatologists, a medical student, researchers and a patient representative, with the objective of understanding the diagnostic journey to CSU, the impact of CSU on various facets of patients' lives, including sleep, mental health, career and education, and patient experiences with current treatments.

"When my condition is severe, the urge to rid myself of further suffering is strong, and on days when it's not as itchy, the anxiety of not knowing when the next flare-up will occur... living this way is unacceptable for me."

Between October 2025 and February 2026, the survey was completed by **83** individuals living in Canada who had CSU or were caring for someone with CSU.

Survey highlights:

Demographics

- **79%** female
- Respondents from 8 provinces, with the highest representation from Quebec (**44.6%**), Ontario (**25.7%**), and British Columbia (**10.8%**)
- Average age: **51** years
- **96.4%** were patients and **3.6%** were caregivers

I. HEALTHCARE EXPERIENCES FROM DIAGNOSIS ONWARDS

- Average age of CSU symptom onset: **36.2** years
- 1st healthcare provider visited for symptoms: family physician (**62%**), allergist (**12.7%**)
- Average duration from symptom onset to diagnosis: **6-11** months
- Diagnosis most commonly made by allergist/immunologist (**49.4%**), dermatologist (**25.3%**) and family physician or primary care provider (**17.7%**)

II. IMPACT OF CSU ON FACETS OF PATIENTS' LIVES

Sleep

- **31.3%** of respondents slept an average of 5 hours or less per night
- **83.6%** reported that CSU had a moderate to very severe impact on their sleep
- Major themes from respondents' comments:
 - Significant pain interferes with sleep*
 - Need to wake up during the night to make adjustments*
 - Night-time fears of flare-ups*

Mental health

- **81.8%** reported that CSU had a moderate to very severe impact on mental health
- Major themes from respondents' comments:
 - Loss of control of one's life*
 - Self-esteem is impacted by the reactions of others*
 - Itching has a detrimental effect on quality of life*

Suicidal ideation

- Of significant concern, **30.6%** of respondents reported that they previously had thoughts of wishing they were not alive anymore; major themes:
 - End the suffering and unpredictability of CSU*
 - Desperate feelings emerge at times when relief seems impossible*
 - CSU worsens existing mental health challenges*

Career

- **60%** indicated that CSU's impact on their career has been moderate to very severe
- Major themes from respondents' comments:
 - Disruptions to sleep impacts ability to be productive*
 - Symptoms cause embarrassment in workplace interactions*
 - Difficult symptoms lead to workplace absence*

Education

- Respondents described various ways in which their ability to attend school and successfully perform their educational tasks were impacted by their condition:
 - Interferes with the ability to concentrate*
 - Impact on continuing education*
 - Judgement from others*

Some respondents expressed that effective treatment to reduce symptoms has been life-changing, decreasing the significant impact of their condition on their mental health, career, and education. However, related concerns regarding some treatments' continued coverage, effectiveness, and inability to provide complete control are pervasive.

III. TREATMENT EFFECTIVENESS AND SYMPTOM CONTROL

- Non-prescription skincare products have been used by **87.5%** of respondents to manage CSU, but only **5.7%** reported a significant improvement
- **92.7%** have used high-doses of second-generation H1 antihistamines and **31.2%** had a significant improvement
- Omalizumab (*Xolair™*) has been used (in the past or currently) by **68.3%** of respondents, with **78.6%** experiencing a significant improvement in symptoms, making it the most effective option reported
- Most respondents are currently taking antihistamines (**70.1%**) and biologics (**61.2%**)
- **56.1%** of respondents experience side effects on their current treatment

Control of symptoms

- **68.8%** consider their CSU to be well-controlled or very well-controlled

- However, **38.2%** of respondents report that they would still consider their CSU to be well-controlled even if they were symptomatic. Those that reported their CSU to be uncontrolled or very well-controlled were more likely to equate “well-controlled” as symptom-free, compared to those who considered their condition to be somewhat well-controlled or well-controlled. This indicates that many patients that indicate satisfaction and control with their CSU treatment have experienced some improvement but are still symptomatic; however, they likely express satisfaction because they have normalized their symptomatic state as bearable compared to what they have previously experienced.

Use of biologics

- **54.3%** of respondents are currently taking a biologic
 - Of those that are not, **67.5%** are somewhat or very interested in doing so

Costs of CSU treatments

- **55%** of respondents are paying out-of-pocket for ≥ 2 CSU products each month
 - *High-dose second-generation H1 antihistamines*: **77.6%** use them, and **27.6%** reported that they pay more \$50 or more monthly
 - *Omalizumab*: **71.4%** use it, with **18.2%** of respondents spending more than \$50 monthly, and **7.8%** reporting costs of \$500 or more
 - *Non-prescription skincare products*: **32.1%** spend \$50 or more every month on this category of products for their CSU, while **12.8%** pay at least \$100 monthly

Awareness of and interest in new CSU treatments

- **22.8%** of respondents were unaware of new treatments for CSU;
- Only **12.7%** had been informed of new pipeline products by their HCP
- Respondents are most interested in treatments that: are affordable, lack side effects, provide long-term control of symptoms, improve emotional well-being, increase sleep quality, reduce flare-ups and are fast-acting

IV. CSU STRUGGLES AND TRIGGERS

- **86.5%** of respondents find certain aspects of their condition challenging, most commonly managing the itch, identifying triggers, and dealing with mental health impacts
- Respondents reported multiple factors that exacerbate their hives, primarily friction and stress, indicative of how difficult it is to avoid CSU triggers
- **58.1%** of respondents reported engaging in behaviours to hide their CSU symptoms, including avoiding social interactions and staying indoors

V. TIME SPENT ON ACTIVITIES RELATED TO CSU

- For **43.8%** of respondents, at least some time every month is devoted to shopping for products that may help them care for their condition
- **56%** have a healthcare visit every month due to CSU

FINDINGS REVEAL UNMET NEEDS FOR PATIENTS WITH CSU

The survey findings indicate that the patient journey with CSU is challenging, and although healthcare provider types, including allergists, are knowledgeable on CSU and its treatment paradigms, many patients appear to have challenging experiences with both diagnosis and symptom management.

Though primary care providers were the first provider type seen by 62% of respondents for initial CSU symptoms, only 17.7% of respondents were diagnosed by a primary care provider, indicative of potential misdiagnoses and delays in treatments.

The symptoms of CSU are stressful in both their severity and unpredictability, creating a situation where patients live with an underlying fear of triggering the cycle of wheals and intense itching. The detrimental consequences for sleep translate into fatigue at work and school, further exacerbated by ongoing daytime symptoms that impede productivity. The impact on quality of life and mental health is compounded by restrictions on activities and social avoidance. Of critical concern is the high rate of individuals with CSU that have also experienced suicidal ideation.

Respondents are clearly focused on symptom management and more than half are paying out-of-pocket every month for two different products. For those who have found a treatment that has worked for them, the difference in their lives is significant, with positive impacts on their sleep, mental health, and ability to be productive and focused at work and school. However, for others, an effective treatment has not yet been identified, though desperately needed. Nearly 4 out of 10 respondents reported that they would consider their condition to be well-controlled even if they were experiencing symptoms. This suggests that for many patients with CSU, complete elimination of symptoms has not been possible through the treatments that they have tried, which has led to lowered expectations of the level of symptom control that is achievable. This is of importance because it indicates that patients may normalize incomplete control with existing treatments and report satisfaction despite ongoing disease burden.

Given the prevalence of CSU combined with its detrimental consequences on all aspects of patients' lives, it is critical that patients are diagnosed quickly, that safe treatments that provide full symptom management are quickly approved, accessible and affordable, and that clinicians conduct routine evaluation of their patients with CSU for mental health impacts and ensure that they are referred to supportive care.

RECOMMENDATIONS

Based on the survey findings, multiple recommendations have been developed to support individuals living in Canada with CSU. The recommendations are summarized below, along with the stakeholder groups involved in their implementation.

1. Increase awareness of CSU for healthcare providers who are most likely to see a case. At symptom onset, individuals are most likely to visit their family physician or other primary care provider for care. It is therefore critical that these clinicians understand the definition of CSU, how it manifests, as well as effective treatment options. This could reduce the duration between first symptom and diagnosis, with potentially positive impacts on the physical and mental health of patients.



2. Screen every patient with CSU for depression and anxiety. Given the heavy psychological burden imparted by CSU, it is imperative that patients with CSU be routinely evaluated for mental health impacts and provided with resources, programs, or referral to specialists, as needed.

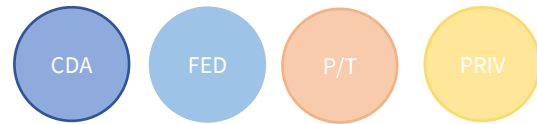


3. Expedite funding decisions for new CSU treatments which are safe and effective. New treatments are needed to provide patients with control over the unpredictable and debilitating symptoms that impact multiple facets of their lives, including career, education, sleep and mental health.



4. Increase insurance coverage and financial assistance for proven CSU treatments and procedures. Patients often incur significant expense for various prescription and non-prescription treatments to obtain relief and be able to function on a daily basis. Affordability/coverage by insurance is a dominant factor in CSU treatment decision-making

for patients; improved insurance coverage as well as availability of financial assistance for treatments is necessary for optimal accessibility.



5. Recognize and facilitate the creation of additional UCARE centres across Canada.

Supporting the establishment of more UCARE (Urticaria Centers of Reference and Excellence) centres would strengthen national capacity to diagnose and manage patients with CSU. Expanding these specialized centres would improve access to expert care, foster multidisciplinary collaboration, and promote the development of innovative clinical research and clinical trials aimed at advancing CSU treatment and patient outcomes. In addition, a broader network of UCARE centres could stimulate greater use of digital patient monitoring tools such as the **CRUSE Control App**, helping patients and physicians better track disease activity and treatment response. This expansion would also facilitate the enrollment of more Canadian patients into the **CURE Registry**, contributing valuable real-world data to international research efforts and improving the global understanding and management of CSU.



*CDA: Canada's Drug Agency (formerly CADTH)
CSPA: Canadian Skin Patient Alliance
FED: Federal government
HCP: Healthcare providers
P/T: Provincial and Territorial governments
PRIV: Private payers
SG: Support groups

BACKGROUND

Chronic spontaneous urticaria (CSU) is a skin condition characterized by the recurrence of hives (wheals), swelling of deep tissues (angioedema), or both that lasts 6 weeks or longer without any obvious external triggers.^{1,2} In contrast to acute urticaria, where a specific cause such as a drug, food, or infection is usually determined, CSU has no identifiable external cause, and most patients do not have an underlying systemic disorder.¹ CSU is also sometimes referred to as “chronic idiopathic urticaria,” although advances in research demonstrate that over 50% of cases are driven by the dysregulation of the patients’ immune system.³⁻⁴

CSU affects approximately 0.5% to 1% of the general population, with higher prevalence in women than men.^{1,4} Onset can occur at any age but is most often observed in adults between 20 and 40 years.⁴ Diagnosis can be challenging due to the clinical presentation of CSU resembling other conditions such as contact dermatitis and urticarial vasculitis.⁵ It has been estimated that 20-30% of cases of acute urticaria in infants and young children will eventually transition to chronic urticaria.⁶ The disease course is highly variable, whereby some patients experience remission within a few years and remain asymptomatic, while others may live with a range of symptoms for decades.⁴

In CSU, certain immune cells in the skin called mast cells become overactive.⁷ These cells release chemicals such as histamine that lead to itching, redness, swelling, and pain.³ For many patients, their immune system is a critical component of the condition, as their body produces antibodies that mistakenly trigger these mast cells.^{2,7} CSU is more common in patients who have other autoimmune conditions, such as thyroid problems, rheumatoid arthritis, and lupus,^{8,9} as has been corroborated by a 2013 Canadian survey of 174 individuals with CSU.¹⁰

The hives that are characteristic of CSU can appear anywhere on one’s body and range from mildly itchy to extremely itchy, may vary in size, and often present as red, white, or flesh-colored bumps with defined borders.⁶ In light skin, people with CSU develop raised red hives that typically itch and often worsen at night.¹ The lesions may appear differently in darker skin, and be less visibly obvious due to their colour being closer to that of the surrounding skin.¹ Though each hive tends to disappear within a day, new ones appear resulting in a difficult cycle for patients.¹ About 40% of patients with CSU also develop angioedema, leading to painful swelling on various parts of the body including the lips, eyelids, or hands and feet.^{3,6,11} This swelling can be painful and have a detrimental impact on patients’ abilities to conduct their routine daily activities.

Given the visible manifestations of CSU and the accompanying pain, burning and discomfort, it is only a natural consequence that patients experience impacts on their quality of life, reporting disrupted sleep, reduced sexual function, fatigue, and difficulty with work or

school performance.^{1,6} The mental health impact associated with CSU is significant, with 17% of patients experiencing depression and 30% presenting with anxiety.¹² Studies show that quality-of-life impairment in CSU can be comparable or greater than individual with moderate-to-severe psoriasis and severe coronary artery disease.¹³

CSU is commonly diagnosed through a thorough medical history and physical examination, and guidelines exist to support the management of patients.^{14,15} Antihistamines are usually considered the first-line of medications prescribed, but they result in full control of the condition for only a small percentage of patients.¹⁶ Higher doses (up to four times the regular dose) are typically prescribed for patients whose CSU symptoms persist. Cyclosporine, topical and oral corticosteroids, and montelukast are other treatment options often attempted with varied results.¹⁷ A 2015 survey of Canadian dermatologists who treat patients CSU found that 37.1% were not satisfied with current treatment methods of CSU, while 43.6% were only somewhat satisfied; 16.1% of the sample reported that over 50% of their patients were refractory to treatment.¹⁸ Since the survey, the injectable biologic omalizumab (Xolair™), approved for use in Canada for individuals over 12 years of age with CSU,¹⁹ has become publicly funded across all Canadian provinces, though some are transitioning to coverage of its biosimilar instead.^{20,21} In 2025, dupilumab (Dupixent™) was approved by Health Canada for CSU indication;²² coverage varies by province and territory and is often dependent on fulfilment of specific criteria or is available through special authorization access.²³⁻³⁵ Since many patients remain uncontrolled with current therapies, there are new treatment options in the pipeline being developed such as Bruton's tyrosine kinase (BTK) inhibitors and anti-KIT antibodies⁸ to block and reduce skin mast cells, and by extension, CSU disease activity.

The Canadian Skin Patient Alliance (CSPA) is a not-for-profit organization founded to support those living in Canada with skin, hair and nail disorders through education, advocacy and collaboration with affiliate member organizations that support specific skin patient communities. In 2025, CSPA conducted an online survey of patients with CSU (either formally diagnosed by a healthcare provider [HCP] or self-diagnosed) and caregivers to individuals with CSU to more comprehensively understand the patient journey with this condition in Canada, including diagnosis routes, experiences with treatments, unmet needs, and impact on daily living and quality of life. The survey results will be used to inform the development of CSPA educational programs and patient advocacy activities to address the gaps identified by this research. Additionally, the findings have generated the development of a number of recommendations for government, clinicians, and patient advocacy groups on processes and policies to support patients with CSU and reduce the detrimental impact of this condition. Finally, this report will serve as a baseline measure, and be used to track progress in the care and support of patients in Canada with CSU.

METHODS

CSPA formed a study team comprising of dermatologists, a survey methodologist, a medical student and a patient representative to collaborate on the development of the patient survey. The survey comprised both multiple choice and open-ended questions regarding patient demographics, the journey from symptom onset to diagnosis, experience with treatments, and impact of CSU on daily life.

The survey was programmed into Microsoft Forms in English and French, and designed to be completed within 20 minutes.

Survey eligibility criteria

- Diagnosed with CSU by a HCP or self-diagnosed, or acts as a caregiver to an individual with CSU
- Resides in Canada

Survey dissemination

The following methods were utilized to disseminate the online survey:

- CSPA's website, newsletter, and social media channels
- Paid advertisements across media channels
- Patient advocacy and/or support groups for CSU
- Network of dermatologists
- Skin Canada Bulletins

“Living with CSU has been life-limiting; I am always on edge wondering when the next flare will strike, or whether my Xolair™ treatment will stop working... it's constantly there in my mind whether I have symptoms or not.”

RESULTS

Surveys were completed by 83 respondents from across Canada between October 1, 2025 and February 1, 2026. Of these, 96.4% were responding as individuals with CSU, while 3.6% were responding on behalf of the individuals with CSU for whom they provide care.

i. DEMOGRAPHICS

The majority of survey respondents self-reported as biologically female (79.2%) (**Figure 1**). Of the 75 individuals that indicated their gender identity, 78.7% identified as female, 18.7% as male, 1.3% as transgender, and 1.3% preferred not to answer.

The average age of respondents was 51 years (range = 8 to 74 years) and half were under the age of 50 years (**Figure 2**).

Figure 1. Biological Sex of Respondents (n = 77)

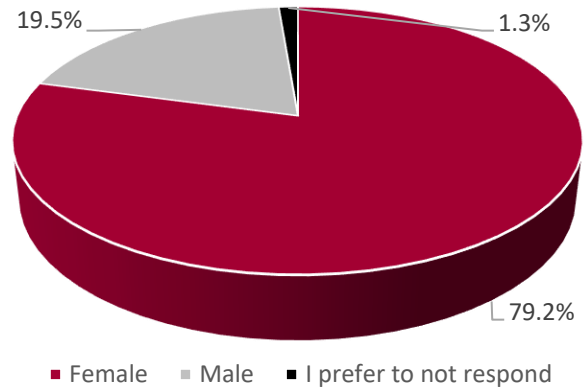
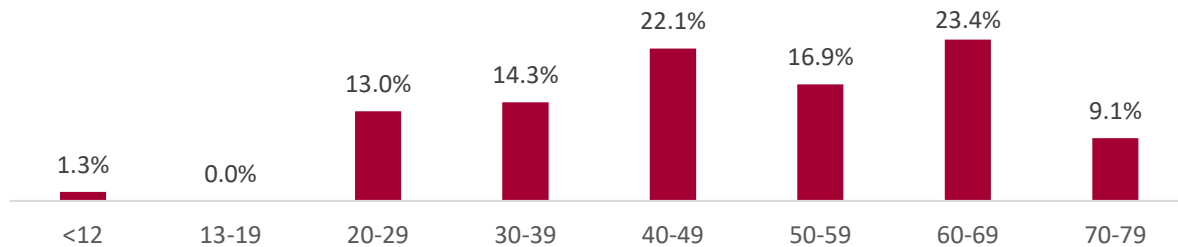
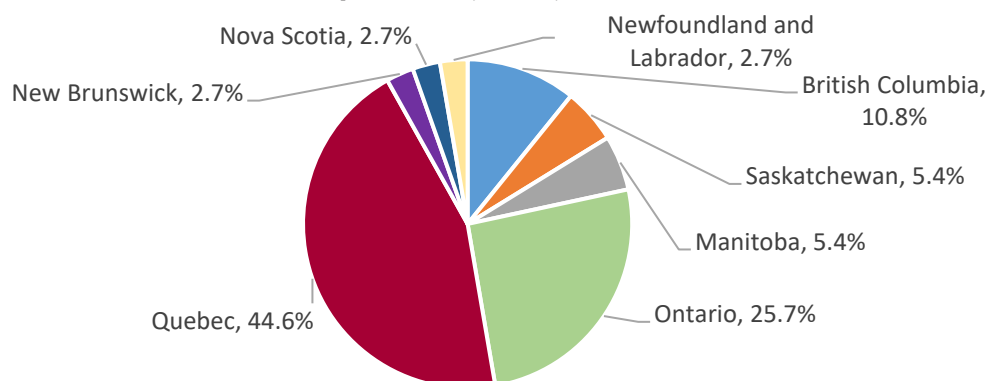


Figure 2. Age in Years of Respondents (n = 77)



Eight of the ten Canadian provinces were represented in the survey responses; provincial distribution was disproportionate to population size with respondents most commonly from Quebec (44.6%), followed by Ontario (25.7%), and British Columbia (10.8%) (**Figure 3**).

Figure 3. Provincial Distribution of Respondents (n = 74)



Based on postal codes provided by 71 of the respondents, 80.3% resided in urban cities, while the remaining lived in rural regions.

Seventy-seven respondents indicated their cultural, ethnic or racial background, with the most common response being White (88.3%), followed by Black (5.2%), Indigenous (3.9%), and Portuguese, Southeast Asian and South Asian (1.3% each).

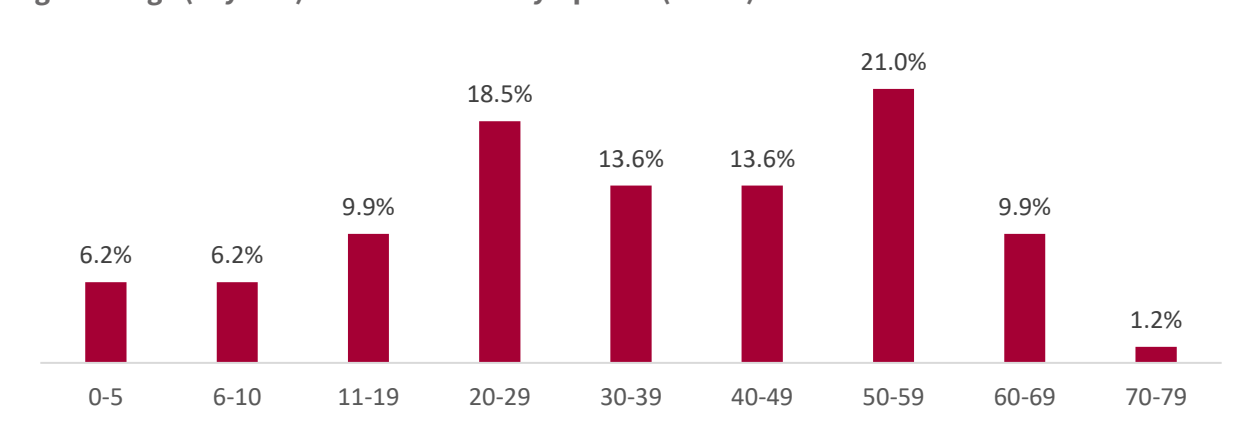
The survey findings are presented in the following five sections.

Section I: Healthcare Experiences from Diagnosis Onwards

i. SYMPTOM ONSET

Of 81 respondents, the average age of CSU symptom onset was 36.2 years (range = 2 months to 72 years), and 22.2% reported that they first experienced symptoms before the age of 20 years (**Figure 4**). Nearly one-third of respondents indicated that their symptom onset happened when they were 50 years or older.

Figure 4. Age (in years) of Onset of CSU Symptoms (n = 81)

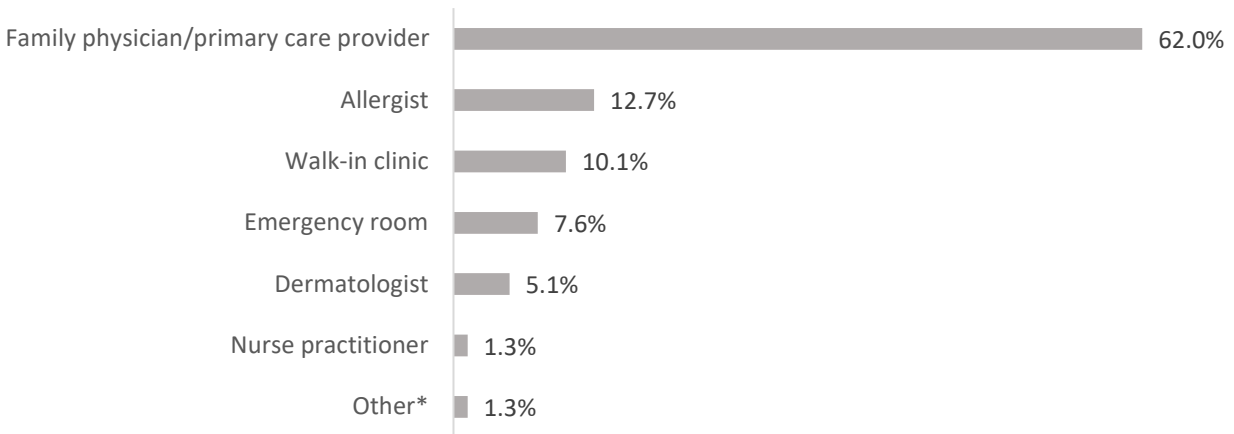


Of 83 respondents, 38.6% initially felt that their symptoms were due to a specific cause, most commonly foods (such as chocolate, fruits, meat, fish, or wheat), the COVID or influenza vaccine, stress or weather/environmental allergens.

“Never knowing when I’m having an attack is stressful, especially after eating certain foods that trigger a stronger reaction. Sometimes I also get stomach pains in addition to hives on my skin.”

Commonly, the first HCP/service that respondents visited regarding their CSU symptoms was their family physician or primary care provider (PCP; 62%), followed by allergist (12.7%) and walk-in clinic (10.1%) (**Figure 5**).

Figure 5. First HCP Visited for CSU Symptoms (n = 79)

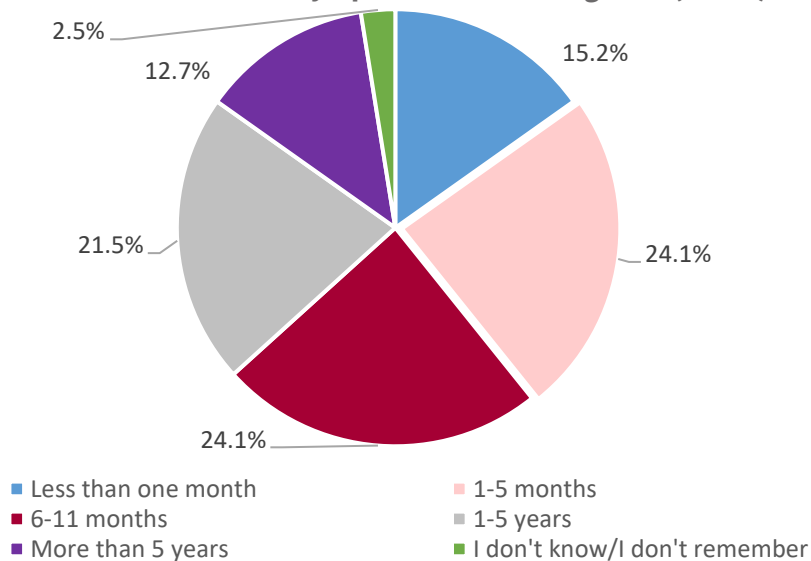


*University clinic (undisclosed healthcare provider type)

ii. DIAGNOSIS OF CSU

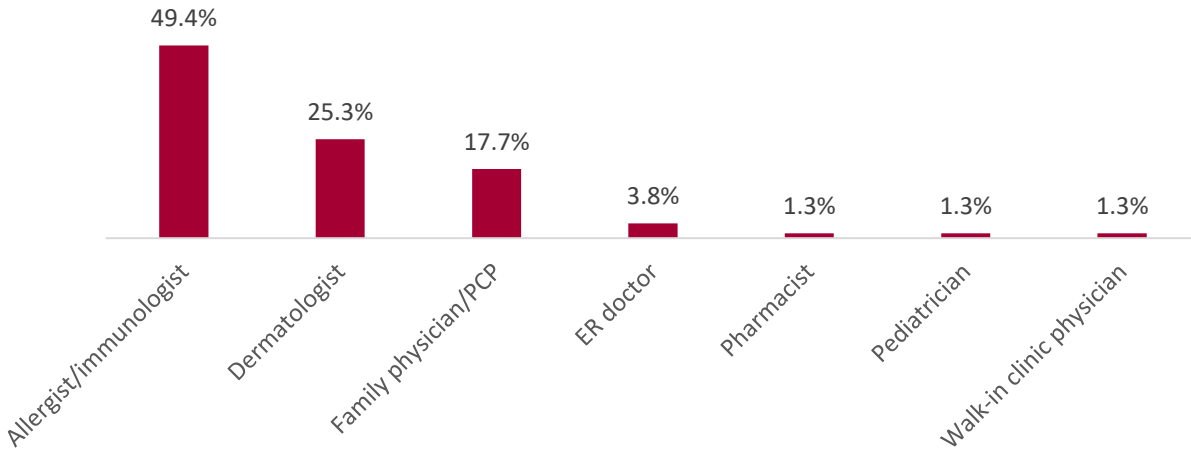
Respondents were asked about the duration from symptom onset to diagnosis, and the most common response was 6-11 months (**Figure 6**). For more than one-third of respondents, it took longer than one year to receive a diagnosis of CSU, evident of either neglecting to seek care until symptoms were present for some time, or perhaps challenges with finding an HCP who could recognize and diagnose CSU.

Figure 6. Duration From CSU Symptom Onset to Diagnosis (n = 79)



Nearly half of respondents were first diagnosed by an allergist/immunologist, followed by a dermatologist (25.3%) and family physician or primary care provider (PCP) (17.7%) **(Figure 7)**.

Figure 7. HCP that First Diagnosed the Respondents' CSU (n = 79)

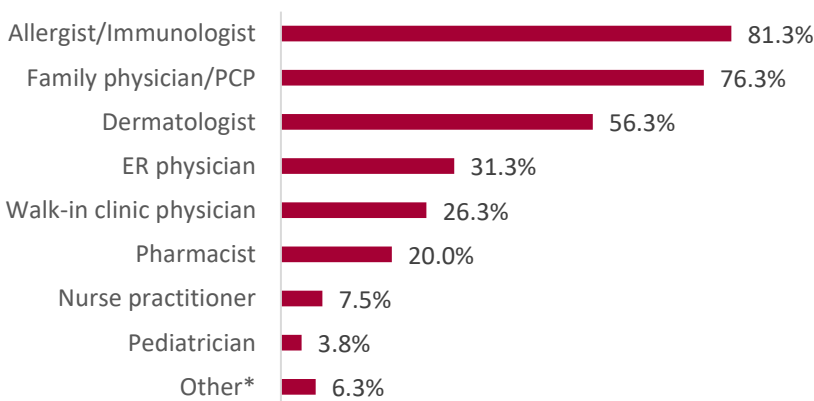


iii. HEALTHCARE SYSTEM EXPERIENCES FOR CSU

When asked about the various HCPs they have visited for CSU care, most respondents reported that they had sought care from allergists/immunologists (81.3%), family physicians/PCPs (76.3%) and dermatologists (56.3%), indicating that patients have multiple HCPs in their care team **(Figure 8)**. Nearly one-third of respondents also reported that they had visited an ER for their symptoms, demonstrating the severity of their symptoms.

"CSU has definitely changed my life. It is even more frustrating that the so-called experts don't understand it. My daughter has been affected too, seeing her mom sick."

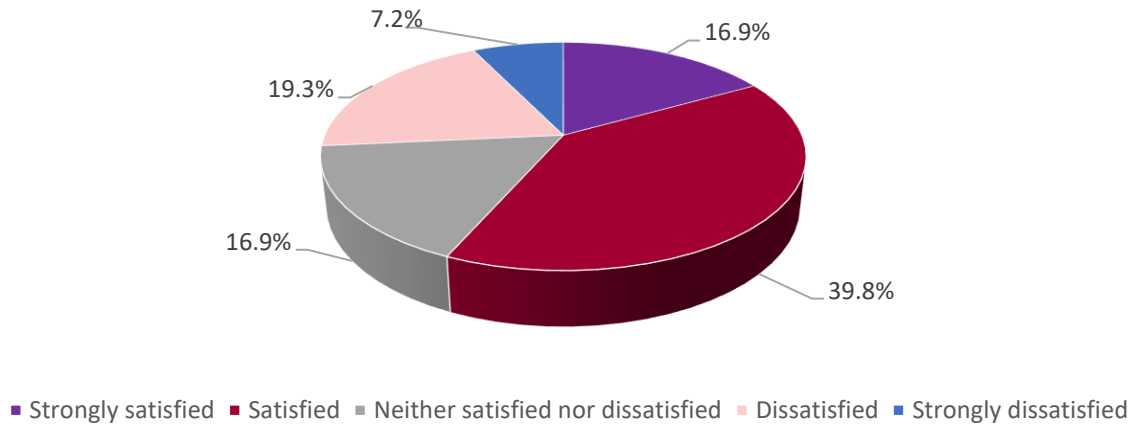
Figure 8. HCPs From Which Respondents Have Sought Care for CSU (n = 80)



*acupuncturist, naturopath, internist, hematologist

When asked about their satisfaction with the healthcare system for management of their CSU, 56.5% of respondents reported that they were satisfied or very satisfied (**Figure 9**). Of note, more than one-quarter of patients expressed dissatisfaction with their experiences.

Figure 9. Respondents' Satisfaction with the Care They Have Received for CSU (n = 83)



Only three of the 80 respondents had never visited an HCP for their CSU symptoms (and were self-diagnosed). When asked why they did not, all three reported that they preferred to obtain health advice online (for example, from social media influencers and skincare websites), while two of the three also indicated that they could not be bothered or did not have time to seek care.

Section II: Impact of CSU on Facets of Patients' Lives

i. SLEEP

Respondents were asked about their average number of hours of sleep per night and 31.3% reported 5 hours or less (**Figure 10**), indicating inadequate rest.

Figure 10. Average Number of Hours of Sleep per Night (n = 67)

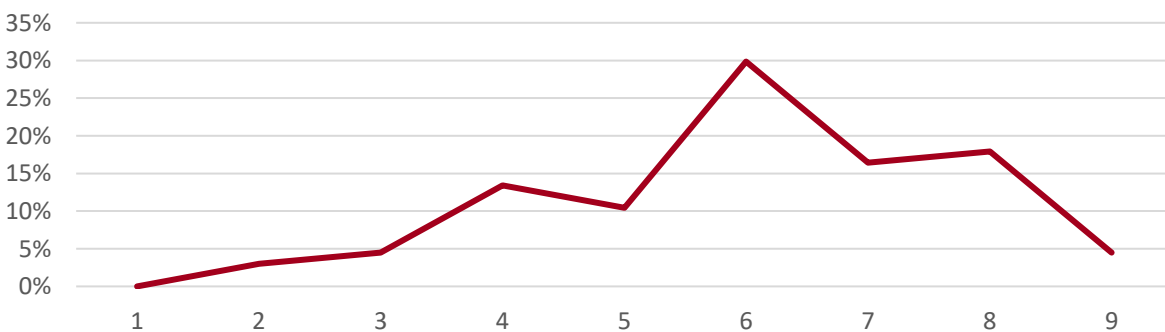
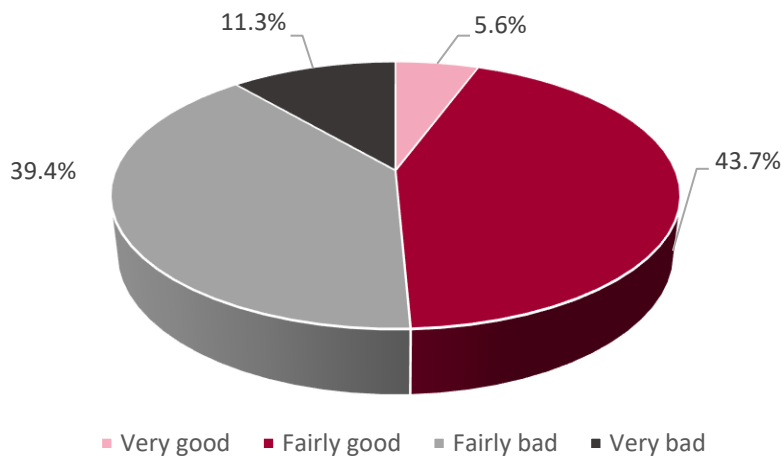


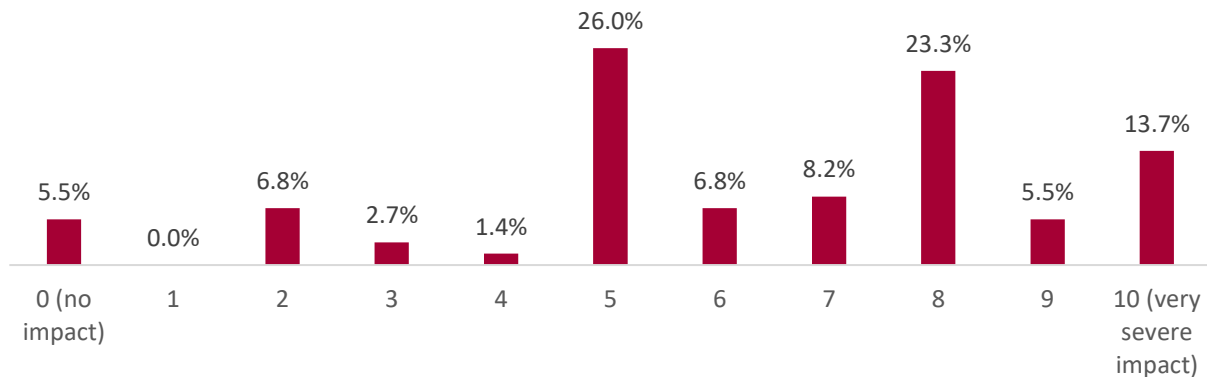
Figure 11. Quality of Sleep (n = 71)



Only 5.6% of 71 respondents reported having very good sleep, while 50.7% deemed the quality of their sleep to be fairly bad or very bad (**Figure 11**), further suggesting the detrimental impact of CSU on their ability to sleep at night, and function during the day.

Respondents confirmed that their condition had been the cause of their difficult nights, with 83.6% reporting that CSU has had a moderate to very severe impact on their sleep (**Figure 12**).

Figure 12. Impact of CSU on Sleep (n = 73)



Respondents were given the opportunity to explain the effect of their condition on their sleep and provide more context to their impact rating. Major themes that surfaced from their elaborative comments are summarized below.

“Due to the fatigue and swelling, I cannot sleep regular hours. I tend to get too drowsy after a meal, so have to sleep right after, and my night sleep is difficult because I wake up often due to feeling too hot, or swelling in my throat, fingers, arms or stomach.”

Significant pain interferes with sleep

- Joint and muscle pain prevents and disrupts sleep
- Burning sensation causes discomfort throughout the night and fatigue during the day

Skin is sensitive to heat and texture

- Itchiness is aggravated by warmth caused by blankets or pyjamas
- Air-conditioning or other cooling source is often needed for relief

Need to wake up during the night to make adjustments

- Modifications must be made overnight such as removal of blanket, or taking medication, in order to achieve some sleep
- Clothing is a source of stress, causing friction against skin and leading to itch and swelling, often necessitating undressing

Night-time fears

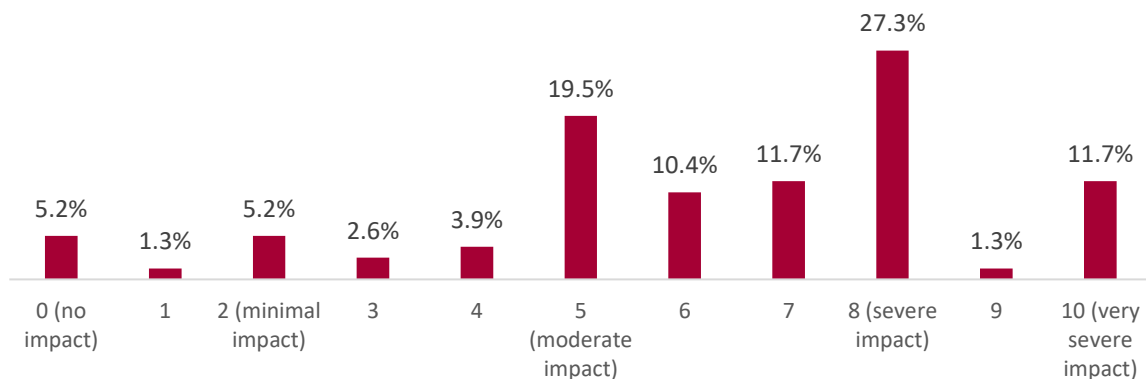
- Because symptoms are often exacerbated at night, there is fear of going to sleep and being woken up with new manifestations such as swelling of tongue or wheals
- Itchiness at night can be severe, and the notion of lack of sleep and ramifications on the following day cause worry and stress

Respondents also spoke of how treatment has made dramatic differences in their ability to sleep, eliminating or reducing itchiness and discomfort, and allowing more hours of rest.

ii. MENTAL HEALTH

Of 77 respondents, 81.8% reported that CSU has resulted in a moderate to very severe impact on their mental health (**Figure 13**).

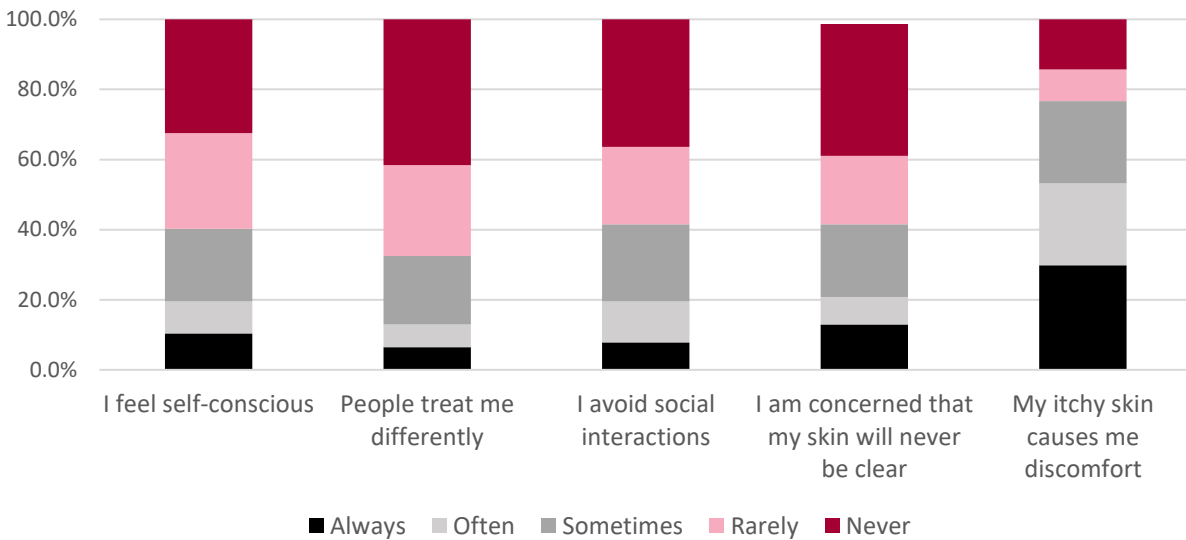
Figure 13. Impact of CSU on Mental Health (n = 77)



Respondents were asked additional questions to better explore the impact of CSU on their behaviours and self-perceptions, and 53.2% reported that their itchy skin often or always caused them discomfort, indicating the pervasiveness of this condition (**Figure 14**). It is

unsurprising that more than 40% of respondents feel self-conscious at least some of the time due to CSU, and that for 63.6%, their condition has caused them to avoid social interactions. These impacts further emphasize how CSU interferes with an individual’s well-being and feeling of being in control of their life.

Figure 14. Impact of CSU on Behaviours and Self-Perceptions (n = 77)



The following themes emerged from the respondents’ explanations of their responses.

Loss of control of one’s life

- When unsure of the CSU triggers, there is an underlying fear that infiltrates every day
- Even when triggers are known, life feels restricted due to need for vigilance
- Unable to enjoy the activities that used to provide joy and relaxation
- Uncertain if and when circumstances will improve in the future
- Unpredictable nature of the condition means every morning is filled with worry

Unsettled feelings and low mood

- Constant feelings of fear and hopelessness
- Worry about triggering CSU symptoms causes anxiety
- Lack of effective treatments results in fear of the future
- Worry is compounded when HCP also seems uncertain about how to support patient

Self-esteem is impacted by reactions of others

- Visible nature of symptoms leads to self-consciousness and embarrassment
- Judgment from others who assume that the condition is contagious

Isolation

- Feeling that no one else can understand the suffering
- Want to hide and be alone during a flare

Itching impacts quality of life

- Cannot function due to intense itching with little relief
- Constantly feel irritable because of the discomfort
- Frustration with itchiness affects mood, impacting relationships

"I can't just go to a friend's home to eat, or go to a party. I have to be very careful with what I eat now. No one can accommodate the sensitivities so it's difficult to invite me, and friends are inviting me less and less. I'm becoming anxious, depressed. My long-term partner has left the relationship because of this."

iii. SUICIDAL IDEATION

Respondents were asked about prior suicidal ideation, and were provided with suicide hotline numbers and resources, in recognition of the notion that the question might surface difficult emotions. Of 72 respondents with CSU, **30.6%** reported that they had previously had thoughts of wishing they were not alive anymore. This subgroup was given the opportunity to elaborate on their response, and their explanations are categorized below.

"It wasn't conceivable for me to continue living like that, with hives covering my entire body. This disease is a living hell. Someone who hasn't experienced it can't understand."

End the suffering and unpredictability of CSU

- During flares and exacerbation, feelings of hopelessness are common
- Mentally challenging to not know what may trigger symptoms
- Does not feel like it is possible to ever be free from this condition
- Physical and mental pain seem unbearable during severe attacks

Feelings emerge at times when relief seems impossible

- Difficult to attempt treatment after treatment with little improvement
- Clinicians are not always knowledgeable on CSU, contributing to feelings of hopelessness both pre-and post-diagnosis
- Feeling like others do not want to be near them

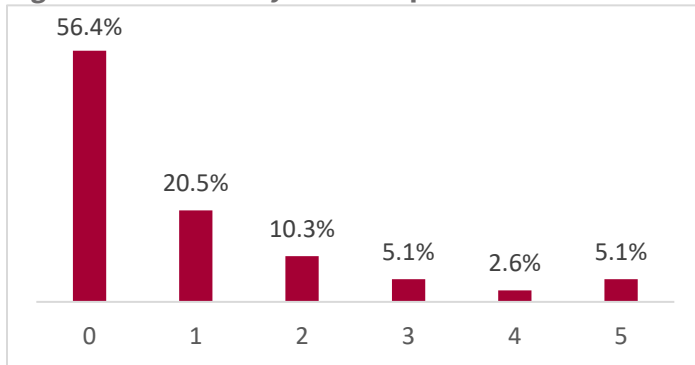
- Constantly bracing self for rejection from others has led to complete lack of self-worth

Worsens existing mental health challenges

- CSU aggravates mental health conditions such as anxiety and depression
- Stress triggers CSU symptoms, leading to lack of sleep and resulting fatigue which impacts overall mood and ability to cope

iv. CAREER

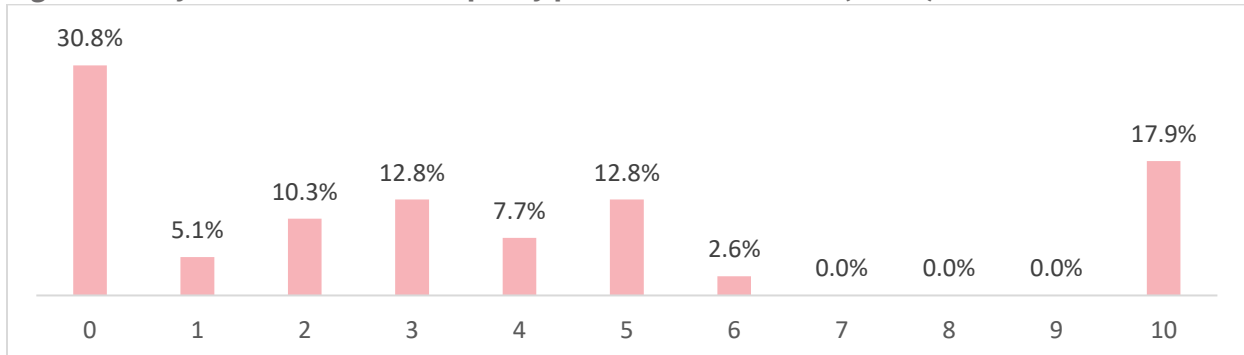
Figure 15. Missed Days of Work per Month Due to CSU (n = 39)



Of 39 respondents in the workforce, 43.6% indicate that they miss at least one day of work every month due to CSU symptoms, and 5.1% are absent for an entire week (**Figure 15**). Two additional respondents reported that they have intentionally chosen jobs with non-regular work hours or the ability to work remotely due to their condition.

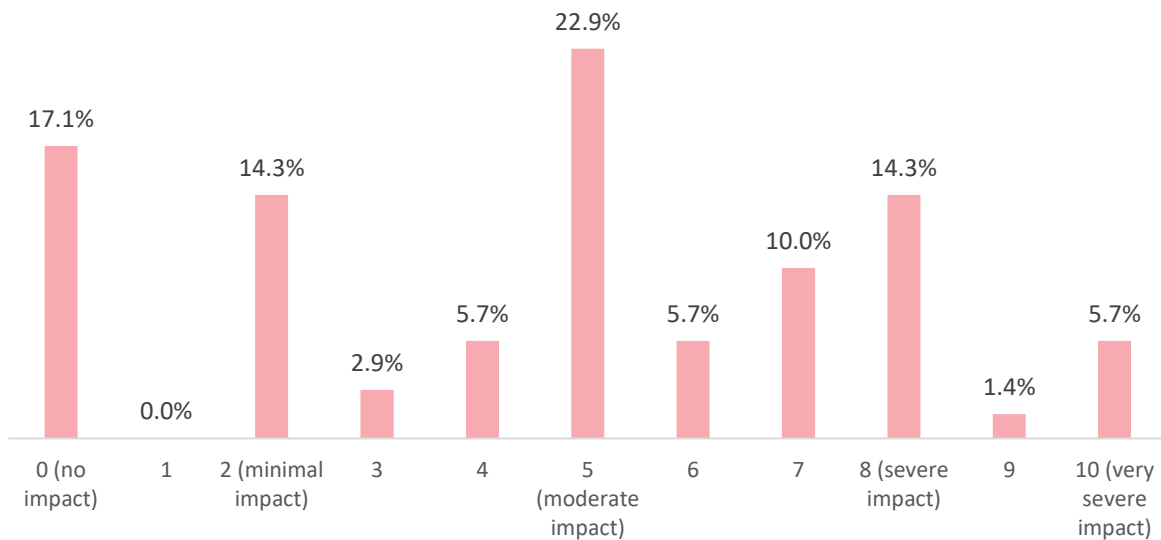
When asked about how many days per month they work at lower productivity than usual due to symptoms, 69.2% reported sub-optimal abilities for at least one day per month, and 33.3% indicated that this occurs for at least five days (**Figure 16**).

Figure 16. Days Worked at Lower Capacity per Month Due to CSU (n = 39)



Of 70 respondents currently or previously in the workforce, 60% indicated that the impact of CSU on their career has been moderate to very severe, demonstrating that this condition has difficult consequences that can affect their identity as well as their finances (**Figure 17**).

Figure 17. Impact of CSU on Career (n = 77)



Respondents described multiple ways that CSU has impacted their ability to gain employment and function in their workplace, as summarized below.

Impacts ability to focus and be seen as productive

- Treatments can lead to drowsiness which negatively affects work performance
- Decreased productivity is noticed by employer

Disruptions to sleep which impacts ability to work

- Productivity and ability to keep up with work responsibilities is lessened due to fatigue
- Severe insomnia results in missed workdays

Causes embarrassment in workplace interactions

- Restrictions in ability to participate in work events
- Employer and co-workers have observed flare-ups, which has led to rumours and gossip
- Because others see the visible manifestations of CSU, they ask questions, leading to disclosure of personal medical history

"I had an attack overseas on a work trip and it was humiliating. I couldn't attend the events with my boss, and even had to remove restrictive clothing in public with coworkers present."

Difficult symptoms led to workplace absence

- Could not attend work due to swelling, hives, or in ability to wear clothing due to symptoms
- Sick days and vacation days were used due to symptoms, leaving no time for relaxation

A subset of respondents discussed the positive impact of treatment on lessening the impact of CSU on their career, mentioning how difficult symptoms used to be, and how treatment has allowed them to perform responsibilities, wear their work uniform and focus on work tasks.

v. EDUCATION

Respondents described various ways in which their abilities to attend school and successfully perform their educational tasks were impacted by their condition.

Interferes with ability to concentrate

- Itching attacks and other symptoms hinder focus
- Symptoms result in missed classes and reduced productivity
- Stress of the combination of CSU and school further triggered symptoms
- Treatment side effects often include fatigue which further impaired memory
- Being unable to sleep due to symptoms resulted in fatigue during class

Impact on continuing education

- CSU symptom-related absences led to challenges with meeting educational milestones
- Must consider treatment side effects when choosing educational programs since ability to attend class and meet deadlines can be impacted

"My condition causes me to miss days in the lab. I almost failed my thesis defense."

Judgement from others

- Teachers and peers assume symptoms are contagious
- Easier to miss class than handle other's reactions

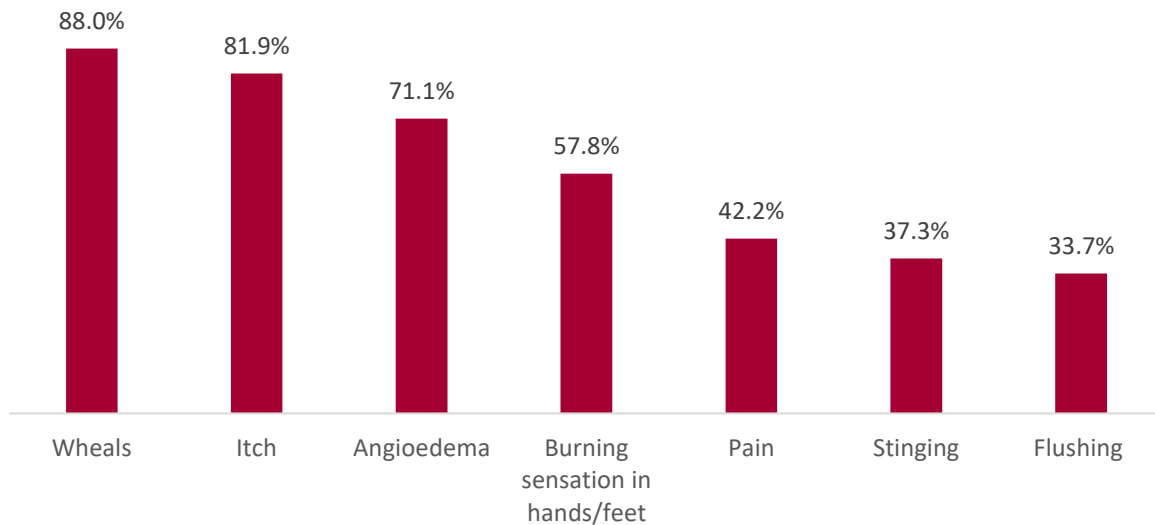
"With all the side effects of Xolair™ and Rupall™, I am cognitively impaired and don't want to take on education that requires much focus or submission deadlines, attendance in class, etc."

Section III: CSU Treatment Effectiveness and Symptom Control

i. SYMPTOMS OF CSU

Respondents were asked about the manifestations of CSU that they typically experience when symptomatic, and the majority selected wheals, itch, swelling, as well as burning in their hands and/or feet (**Figure 18**).

Figure 18. Symptoms that the Respondents Typically Experience with CSU (n = 83)



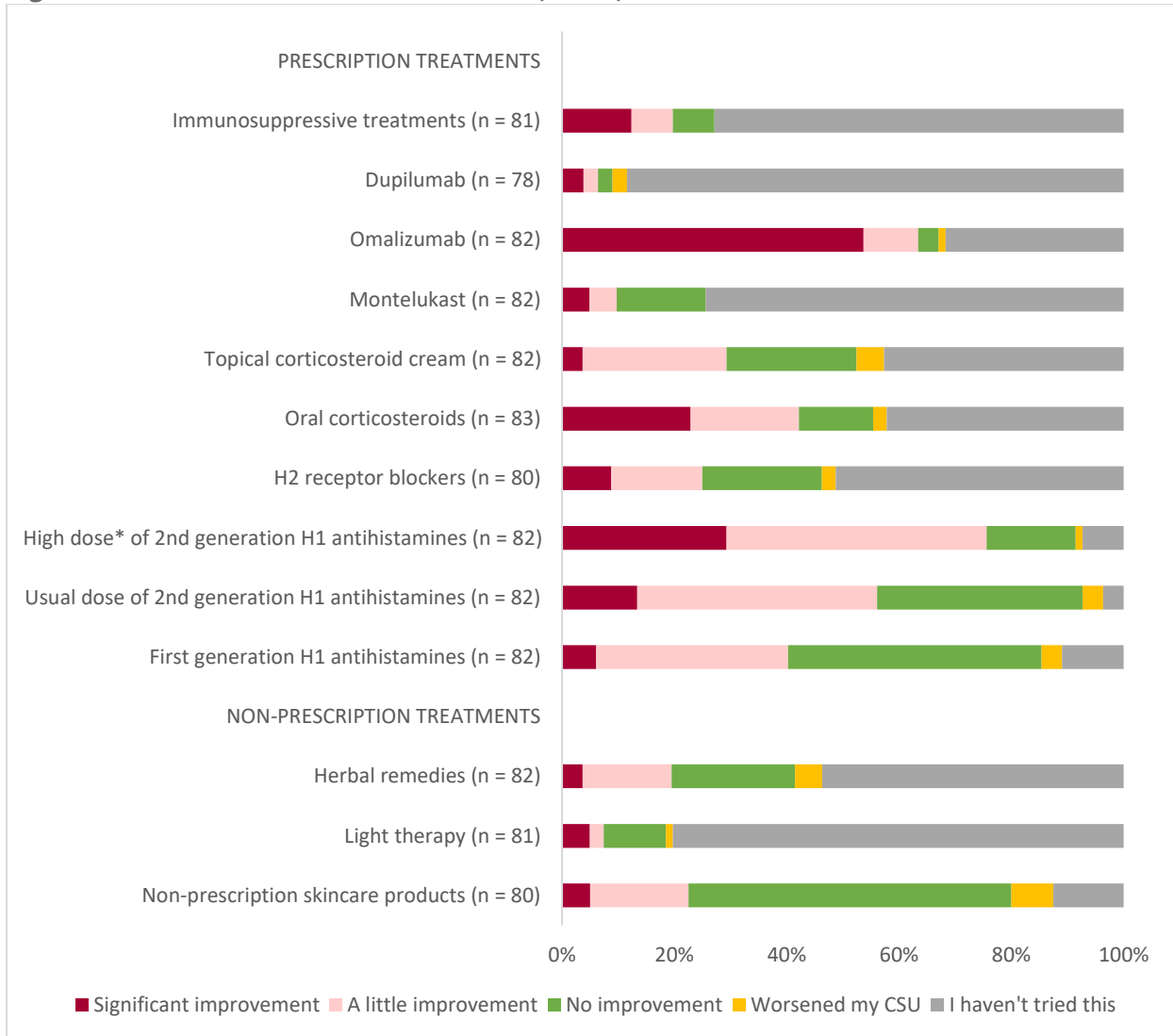
ii. EFFECTIVENESS OF TREATMENTS

Respondents were asked to indicate their experiences with non-prescription and prescription treatments for CSU, and the findings indicate that respondents have tried multiple treatment, implying that relief is both needed and difficult to achieve (**Figure 19**). The majority of respondents (87%) have tried non-prescription skincare products such as moisturizers or emollients found on drugstore shelves, but only 5.7% have experienced a significant improvement from this option. Of respondents, 92.7% have used high-dose (up to four times the regular dose) of second-generation H1 antihistamines (such as cetirizine hydrochloride [Reactine™], rupatadine fumarate [Rupall™], loratadine [Claritin™], fexofenadine [Allegra™] and bilastine [Blexten™]) and 31.2% had a significant improvement. Omalizumab was the most successful treatment for respondents: 68.3% of respondents reported having tried this biologic, and of these, 78.6% experienced a significant improvement in their symptoms. However, it is unknown how long it took for these patients to derive benefits from this

"I think about how long I've lived with this, and how little healthcare professionals know and care about it."

treatment; prior literature indicates that for many patients, meaningful symptom improvement may not be evident until multiple injections have been administered over many months.³⁶ Additionally, for the more than 20% that did not experience significant improvement, long-term treatment options that are safe and effective are limited.

Figure 19. Effectiveness of CSU Treatments (n = 83)

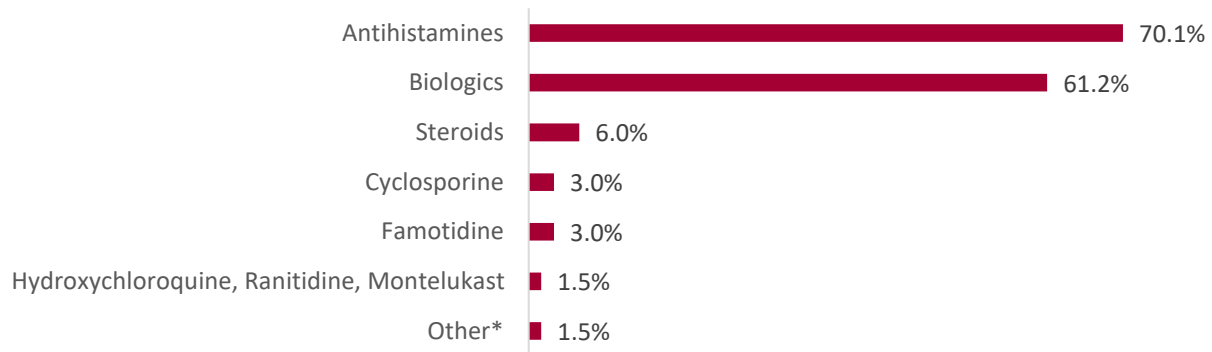


*More than 4 times the usual dose

iii. EXPERIENCES WITH AND PERCEPTIONS OF CURRENT CSU TREATMENTS

Of 82 respondents, 81.7% reported that they are currently receiving treatment for CSU (**Figure 20**). The most common treatments were antihistamines and biologics, each taken by more than 60% of respondents, indicating that patients are often using multiple treatments concurrently to manage their symptoms.

Figure 20. CSU Treatment Currently Being Taken by Respondents (n = 67)

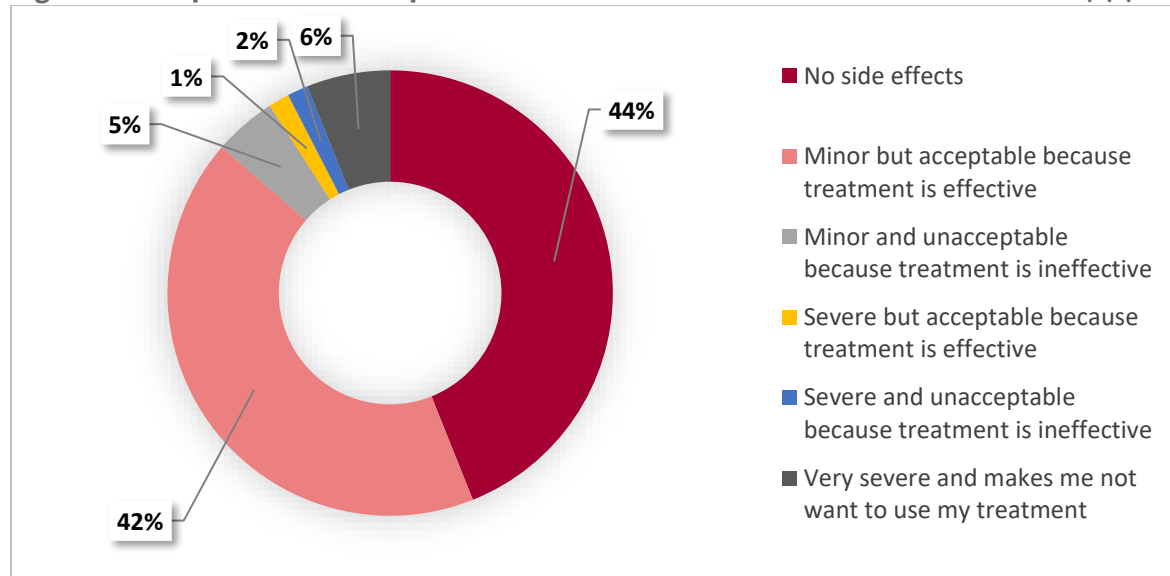


*Nasal rinse

Respondents currently being treated for CSU were asked to describe the side effects of their treatments (**Figure 21**); 43.9% reported not experiencing side effects, while side effects were present for another 42.4%, but deemed acceptable due to the treatment’s effectiveness. Of note, 6% of respondents indicated that they were taking treatment(s) that was ineffective, yet undergoing side effects, while over 9% were experiencing severe or very severe side effects with their treatment. This is suggestive of a desperate patient subset that is incurring difficult adverse events in the hopes of some relief from the symptoms of this condition.

“Before Xolair, I had no life. It was impossible for me to imagine a future for myself if a solution couldn't be found to alleviate my suffering.”

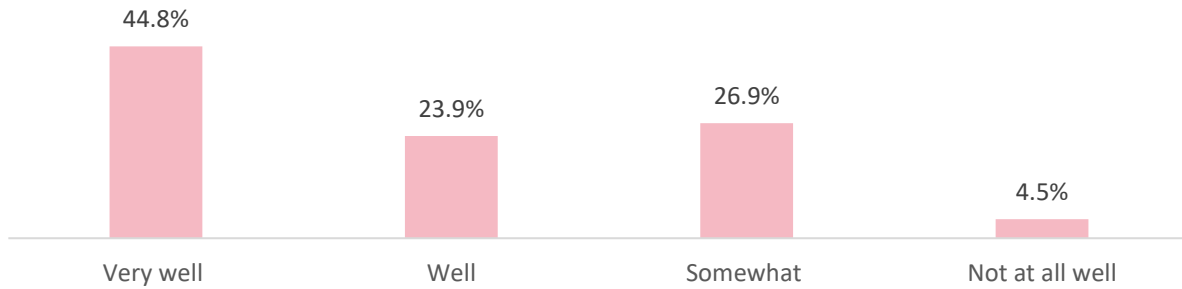
Figure 21. Respondents’ Description of Side Effects of Their Current CSU Treatment(s) (n = 66)



iv. PERCEPTIONS OF SYMPTOM CONTROL WITH CURRENT CSU TREATMENTS

Of respondents, 68.7% reported that they considered their CSU to be well-controlled or very well-controlled by their current treatments (**Figure 22**).

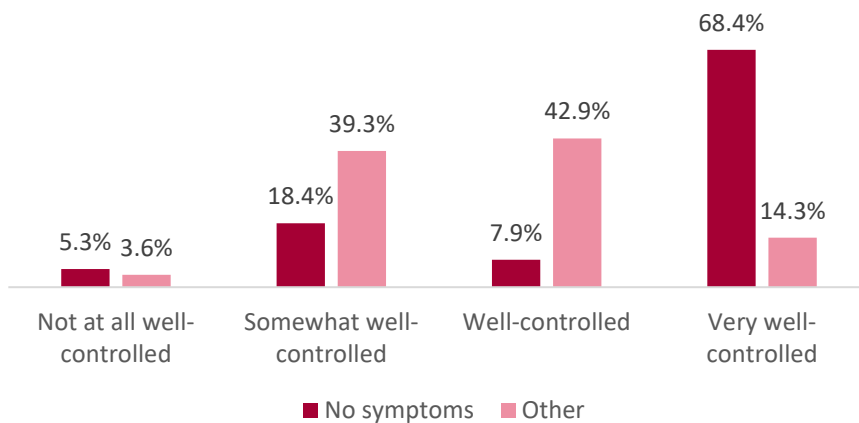
Figure 22. Respondents’ Perceptions of How Well Their CSU is Controlled on Treatment (n = 67)



“Before I had the condition under control, it was terrifying. My doctor doesn’t know what causes it, and I didn’t know what to do to help it. So I felt like I had no control. I was in pain, couldn’t go about my life, didn’t know when it would stop, or how.”

However, when respondents were asked about how they define “well-controlled” CSU symptoms, 38.2% indicated that they would still consider their CSU to be well-controlled if they had some symptoms, such as having swelling only in the morning, or some hives daily that were either not itchy or with a manageable itch. Such responses indicate that some patients have likely had a difficult and impactful journey with their CSU symptoms, and are relieved for any improvement even if it is not complete.

Figure 23. Respondents’ Perceptions of How Well Their CSU is Controlled, Stratified by Their Definitions of “Well-Controlled” (n =67)

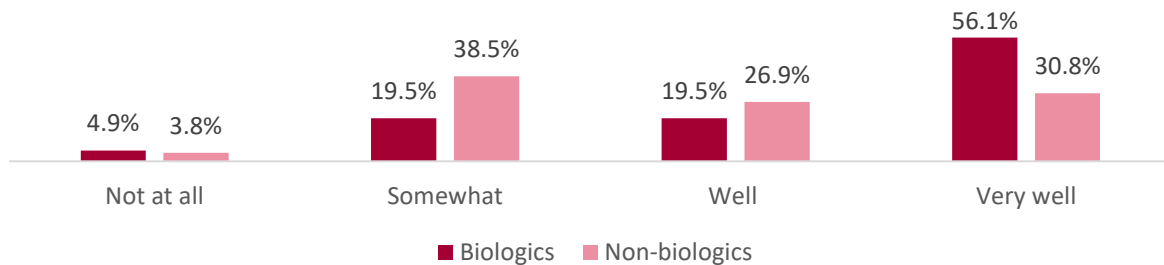


Respondents that reported their CSU as not at all controlled or very-well controlled were more likely to define “well-controlled” as being free from symptoms, compared to those who considered their condition to be somewhat well-

controlled or well-controlled (**Figure 23**). This further implies that there is a sizable subset of patients who are using CSU treatments, experiencing some improvement, and perhaps view this symptomatic state as bearable compared to what they have previously experienced so have lowered expectations about best achievable health state.

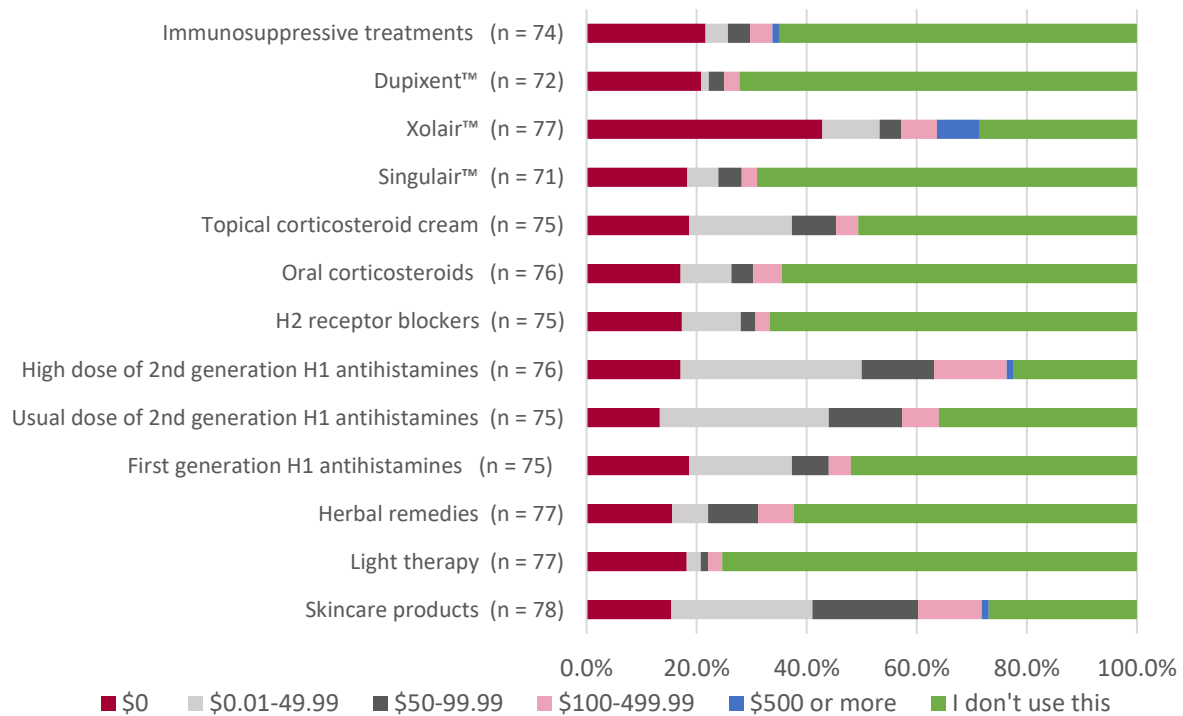
Those currently taking biologics (**Figure 24**) were more likely to report that their CSU was well-controlled or very well-controlled compared to those taking other treatments.

Figure 24. Respondents' Perceptions of Symptom Control Based on Whether they are Taking Biologics (n = 67)



v. COSTS OF CSU TREATMENTS

Figure 25. Average Monthly Out-of-Pocket Costs (CDN) on Treatments



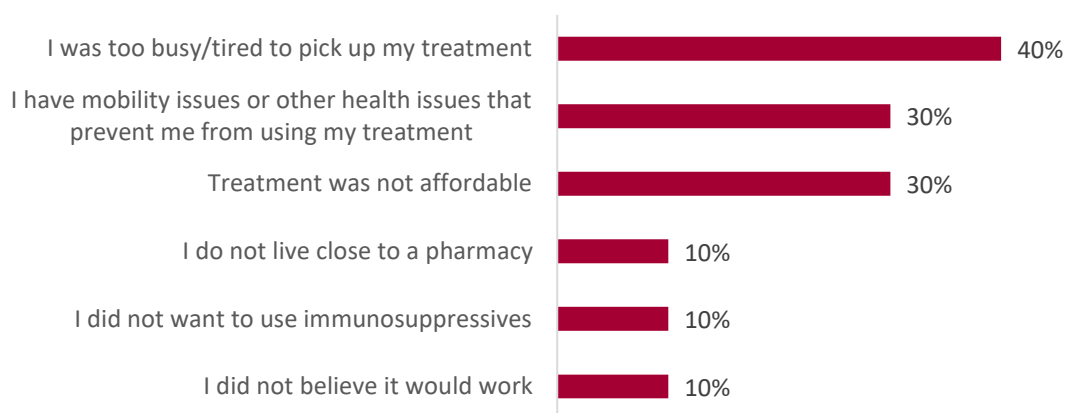
Respondents were asked about their monthly out-of-pocket costs related to CSU, and the findings indicate that 55% patients are paying for two or more products each month to manage their symptoms (**Figure 25**). The majority of respondents indicate that they use high

doses of second-generation H1 antihistamines (77.6%); 27.6% reported that they pay \$50 or more monthly on these medications. Omalizumab was the next most commonly used treatment (71.4%), with 18.2% of respondent spending more than \$50 monthly on this biologic, and 7.8% reporting costs of \$500 or more. Even non-prescription skincare products such as moisturizers and emollients from drugstores or online store leads to significant costs for respondents; 32.1% of respondents reported spending \$50 or more every month on this category of products specifically for their CSU, while 12.8% are paying at least \$100 monthly.

vi. REASONS FOR NOT USING A PRESCRIBED TREATMENT FOR CSU

Of 77 respondents, 13% reported that they had previously been prescribed a treatment for CSU that they did not use. When asked about their reasons, the most common response was that they were too busy or tired to pick up their treatment from a pharmacy (40%); further probing would be required to understand whether this may be related to fatigue from the condition itself. Additionally, 30% each reported that they had health issues that hindered them for using the treatment and the treatment was not affordable (**Figure 26**).

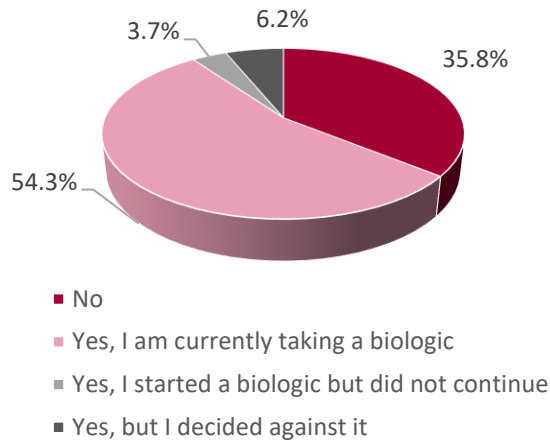
Figure 26. Reasons for Not Using a Prescribed CSU Treatment (n = 10)



vii. EXPERIENCES WITH BIOLOGICS

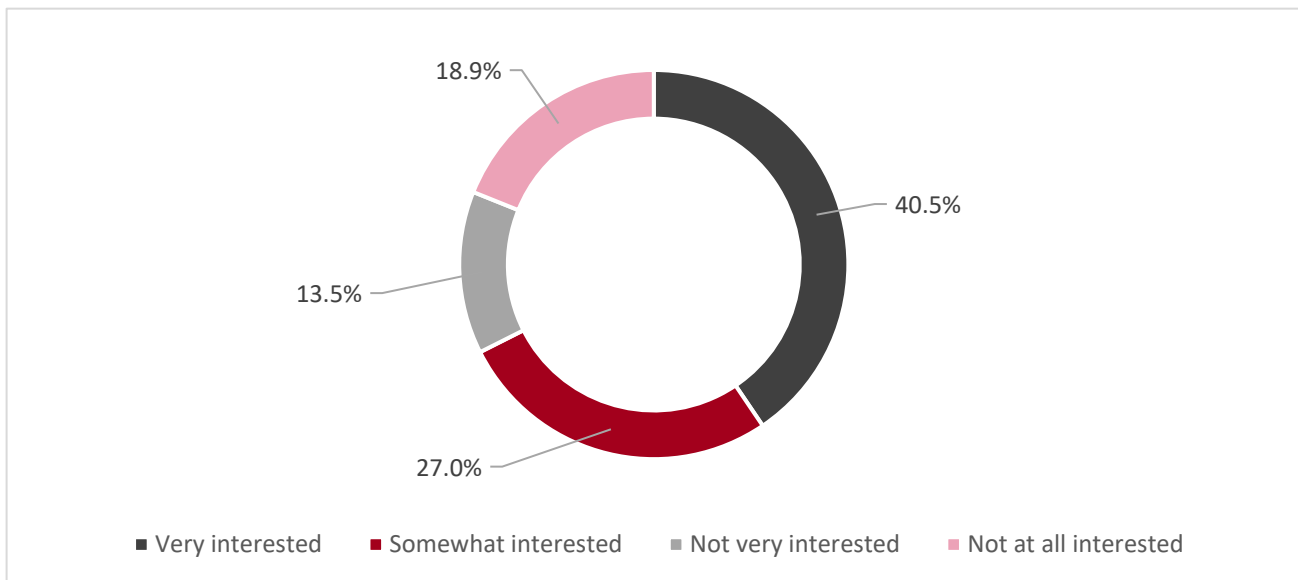
Patients were asked about prior experiences with biologics, and specifically, whether an HCP had ever recommended that they take one (**Figure 27**).

Figure 27. Did HCP Recommend that the Respondent Use a Biologic? (n = 81)



Of 81 respondents, more than half are currently taking a biologic. Of the 37 respondents that are not currently taking a biologic, 67.5% reported being somewhat or very interested in doing so if it was available to them (**Figure 28**). This may indicate that awareness, funding and access may be larger barriers to the use of biologics rather than patients' disinterest.

Figure 28. Interest in Taking a Biologic for CSU (n = 37)



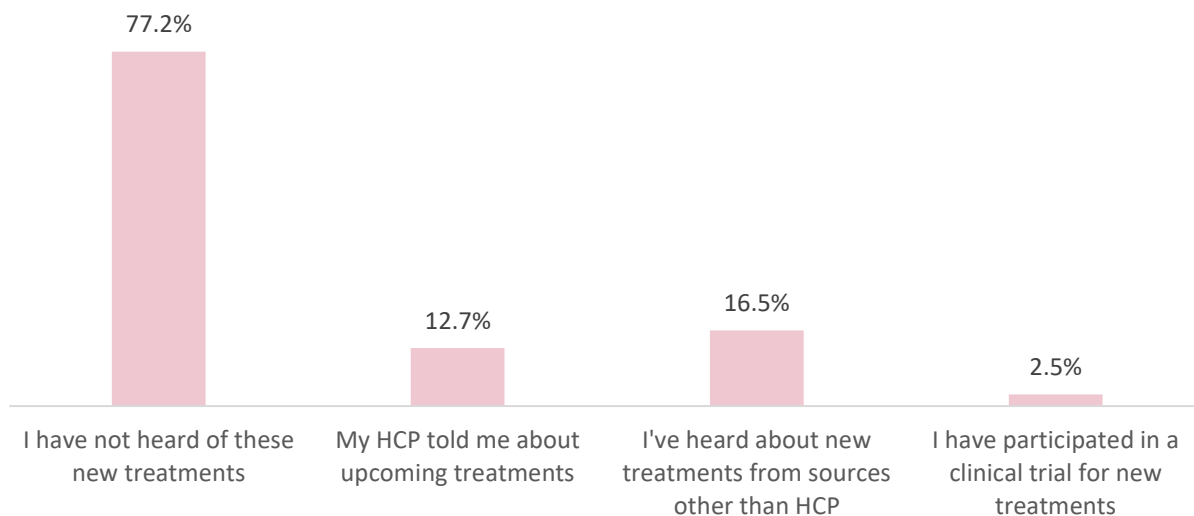
viii. SATISFACTION WITH CURRENT CSU TREATMENTS

The majority of respondents expressed satisfaction (72.2%) in the ability of prescription CSU treatments that they have used to achieve their treatment goals. This high percentage may be reflective of the majority of this sample currently taking a biologic for CSU. However, it may also be influenced by patient expectations, and indicative of patients having become accustomed to feeling satisfied with incomplete relief of this condition: of the 55 patients that indicated they were satisfied or very satisfied with their current CSU treatments, 36.4% reported that they would still consider their CSU to be well-controlled if they were symptomatic.

ix. KNOWLEDGE OF AND INTEREST IN NEW CSU TREATMENTS

New treatments for CSU (including Bruton’s tyrosine kinase [BTK] inhibitors) are expected to be approved for use in Canada in upcoming years. Respondents were asked about their awareness of pipeline treatments, and more than three-quarters had not heard of them at the time of survey completion (**Figure 29**) while 2.5% had been a clinical trial participant for one or more of the new treatments. Only 12.7% of respondents had been told about upcoming treatments by one of their HCPs, indicating a gap in information flow from trusted resources, as well as a potential need for HCPs that treat patients with CSU to have improved knowledge and awareness of pipeline treatments for this condition.

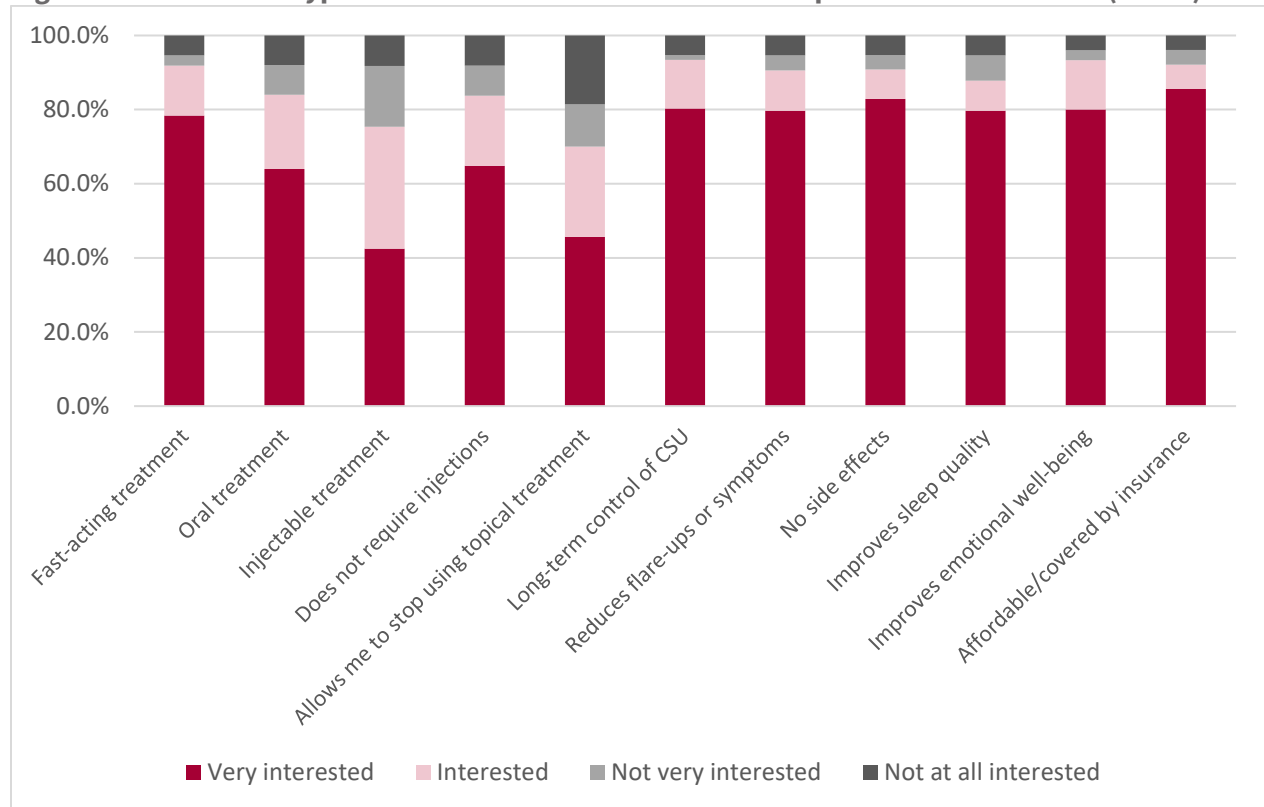
Figure 29. Respondents’ Knowledge about New Treatments for CSU (n = 79)



When asked about their interest in specific CSU treatment characteristics, the highest percentage of respondents indicated strong interest in treatment affordability or coverage by insurance (85.5%), lack of side effects (82.9%), the treatment providing long-term control of CSU symptoms (80.3%) and improvement in emotional well-being (80.0%) (**Figure 30**). This indicates that patients’ preferences with respect to CSU treatments may be closely aligned with which treatments are publicly funded or covered by their private insurance, though a product that offers a low level of risk but continuous, effective CSU management to minimize impact of mental health is ideal.

Conversely, respondents reported that the new product being administered via injection vs. other mode of delivery was of less interest, as was the ability of the treatment to eliminate the need for the use of topical treatments.

Figure 30. Interest in Hypothetical CSU Treatments Based on Specific Characteristics (n = 79)

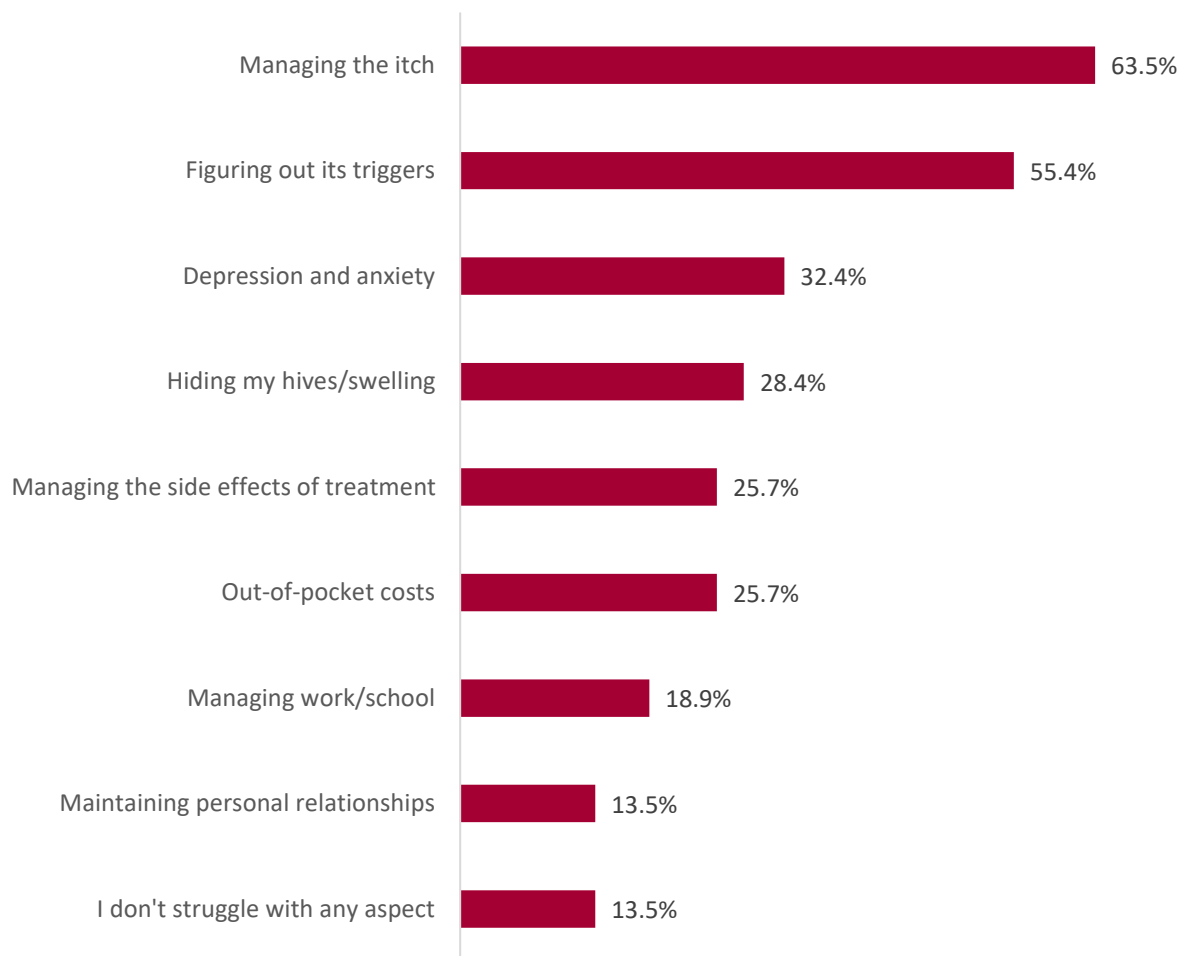


Section IV: CSU Struggles and Triggers

i. AREAS OF STRUGGLE

When asked where they struggle when managing their CSU, only 13.5% reported that they do not have any particular area of concern, further suggesting that patients have a difficult journey with this condition despite that they may indicate that their symptoms are well-controlled. The majority of respondents indicated that both managing the itch of their condition and determining what the triggers are challenges, while close to one-third of respondents reported that they struggled with the mental health ramifications of CSU (Figure 31).

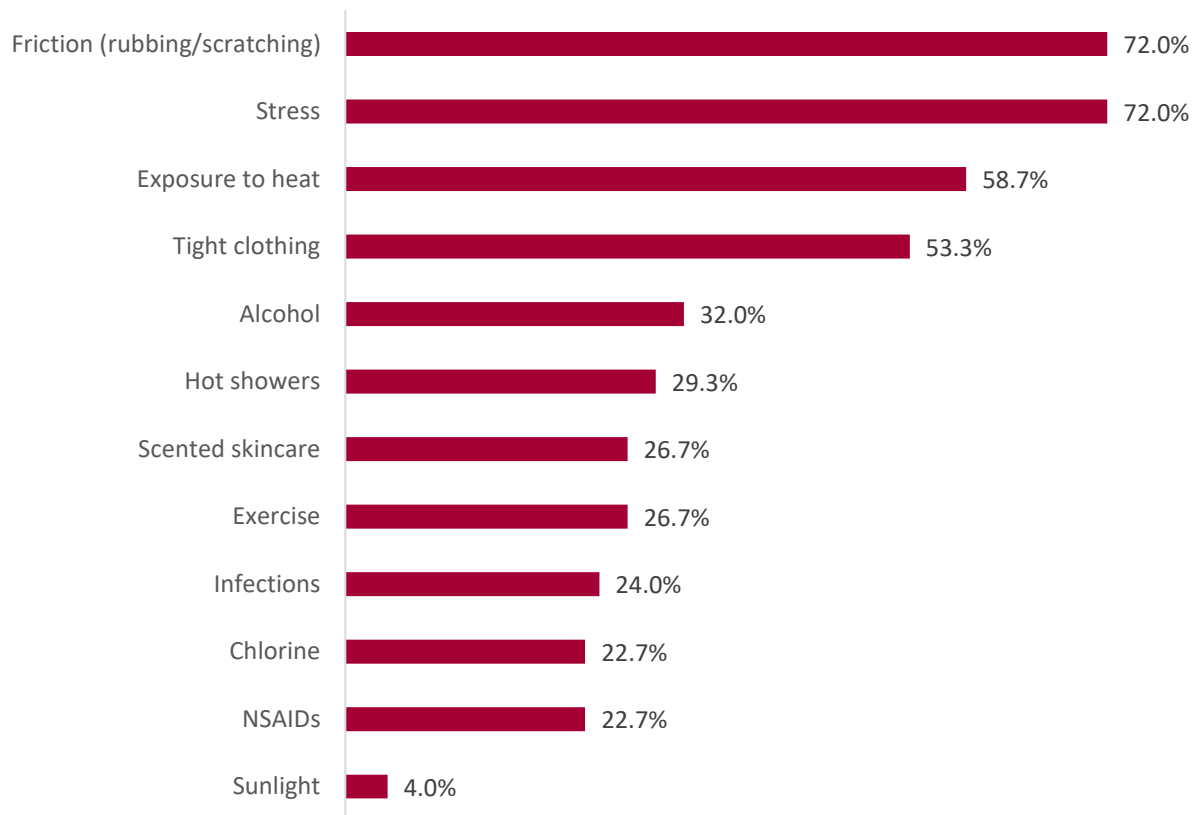
Figure 31. Areas of Struggle Regarding Management of CSU (n = 74)



ii. FACTORS THAT EXACERBATE CSU SYMPTOMS

Respondents reported multiple factors, environmental conditions, foods and drinks that worsen their hives (**Figure 32**). The most commonly selected factors were friction and stress, indicative of how difficult it is to avoid CSU triggers, particularly in the midst of a flare when both scratching the unbearable itch and feeling anxious about the condition are common and logical reactions.

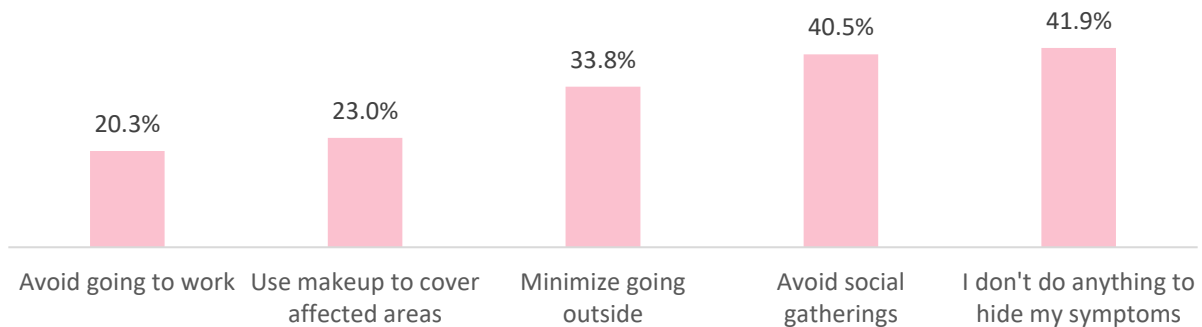
Figure 32. Factors that Exacerbate Hives for Respondents (n = 75)



iii. ENGAGEMENT IN BEHAVIOURS TO HIDE CSU

Nearly 60% of respondents reported that they engage in behaviours to hide the physical manifestations of CSU, most commonly involving avoiding social interactions, and staying indoors (**Figure 33**). These types of practices inevitably impact patient mental health as they are unable to participate in activities that they might like to or formerly enjoyed.

Figure 33. Behaviours that Respondents Engage in to Hide CSU Symptoms (n = 74)

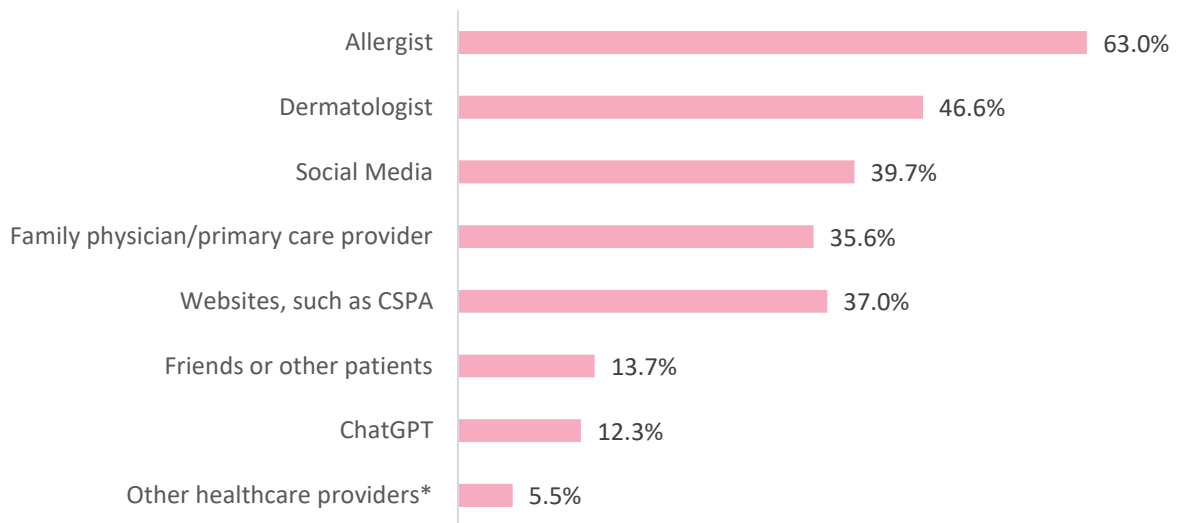


Section V: CSU-Related Information and Activities

i. SEEKING INFORMATION ABOUT CSU

Respondents were asked where they turn when seeking information about CSU (**Figure 34**). The two most common responses were both HCPs: allergists (63.0%) and dermatologists (46.6%). Online sources were also quite popular, such as the use of social media channels or website, which is likely reflective of the desire to obtain information in an immediate, readily accessible manner. However, it also speaks to the importance of ensuring that patients have easy access to accurate, medically sound information.

Figure 34. Sources of CSU Information (n = 73)

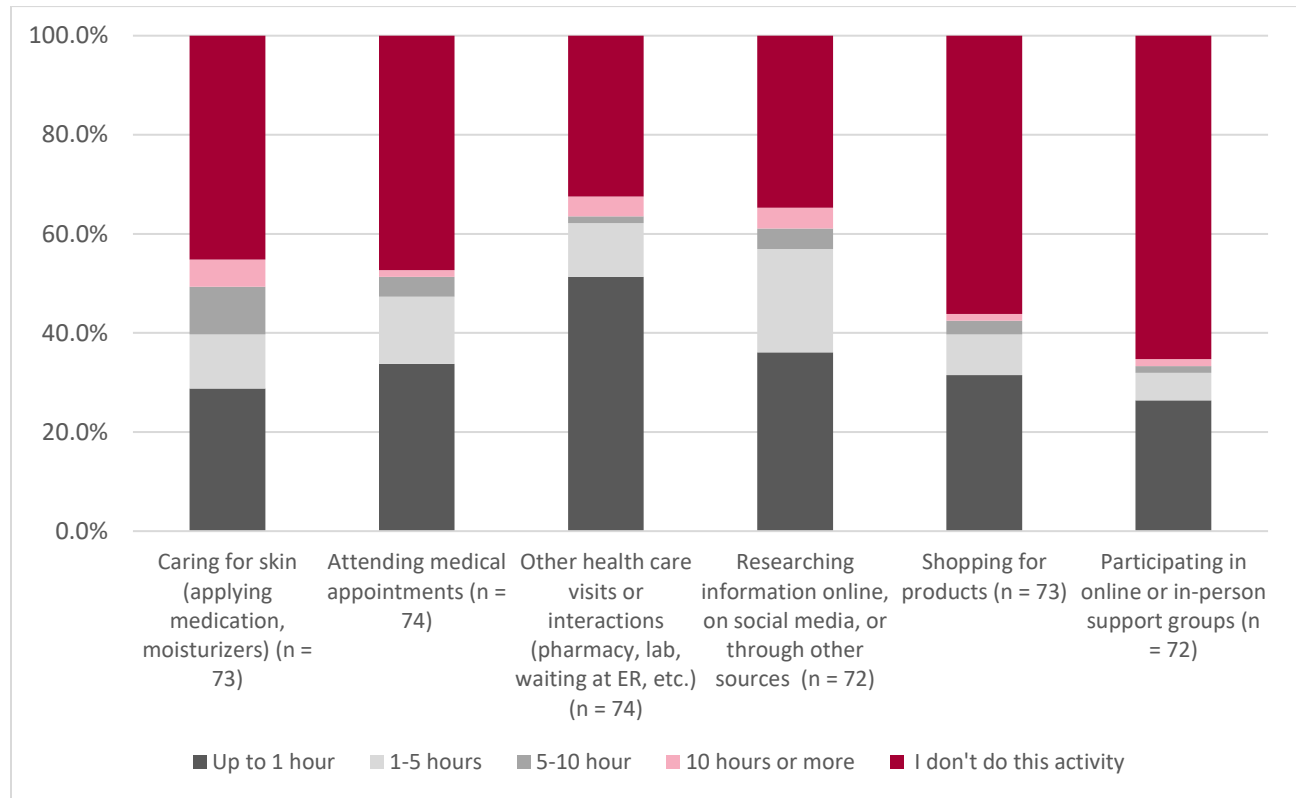


*Pharmacist, endocrinologist, naturopath

ii. TIME SPENT ON ACTIVITIES RELATED TO CSU

All respondents were asked how much time they spend on activities related to CSU (**Figure 35**) and the results demonstrate that managing CSU is time-consuming. For 43.8% of respondents, at least some time every month is devoted to shopping for products that may help them care for their condition. For 15.1% of respondents, a substantial amount of time (5 hours per month or more) is spent on self-administering medication or applying skincare treatment, while 8.4% spent 5 hours or more monthly researching their condition for more information. More than half of patients report some type of healthcare visit every month due to CSU. The results do not include additional time off work, school or personal activities due to CSU symptoms.

Figure 35. Percentage of Respondents Spending Time per Month on Activities Related to CSU



LIMITATIONS

When interpreting the findings of this survey, its limitations should be considered. Despite significant recruitment efforts, the sample size was fairly small, which may impact the representativeness of the results. As with all surveys, the findings of this survey may have been affected by response bias. Additionally, the survey’s sample includes both HCP-diagnosed and self-diagnosed participants, plus caregivers, which may have added heterogeneity to the study results. Finally, no verification of CSU diagnosis was conducted.

UNMET NEEDS OF PATIENTS WITH CSU

The findings of this survey of individuals in Canada with CSU indicate that the patient journey for this condition is a difficult one. Symptoms of CSU are challenging and stressful due to both their potential severity and their unpredictability; this combination causes patients to constantly worry that the cycle of wheals and intense itchiness will begin again. The impacts of CSU are far-reaching, and one of the most concerning effects is with regards to mental health, resulting in suicidal ideation for a sizable proportion of patients. Consequences of

CSU on sleep, career and education are also evident, increasing the patients' fatigue and limiting productivity.

Symptom management is a key focus for patients, and more than half of respondents reported that they are paying out-of-pocket every month for two different products. Many have not yet found a treatment that is effective, and for those that have, there are still concerns regarding the treatment no longer working or no longer being covered or affordable. Of concern, nearly 4 out of 10 respondents reported that they even if they were symptomatic while on treatment, they might still consider their CSU to be well-controlled. This suggests that many patients have been forced to become accustomed to treatments that provide some level of relief but cannot eliminate all symptoms, because they do not have a more effective alternative.

Survey findings indicate that CSU patients want safe and effective treatments that are affordable/covered by insurance, offer long-term symptom control, and allow them to experience the improvement in quality of life that accompanies full symptom control of this condition. These results corroborate the results of previous studies,^{37,38} which additionally identify rapid symptom control and convenient modes of treatment administration.

Given the prevalence of CSU combined with its detrimental consequences on all aspects of patients' lives, it is critical that patients are diagnosed quickly, that safe treatments that provide full symptom management are quickly approved, accessible and affordable, and that the clinicians conduct routine evaluation of their patients with CSU for mental health impacts and ensure that they are referred to support.

SURVEY TEAM

The survey team consisted of the following:

- Dana Gies (Canadian Skin Patient Alliance)
- Muna Chira (Patient representative)
- Dr. Gordon Sussman (Sussman Allergy and University of Toronto)
- Dr. Hermenio Lima (LEADER Research and McMaster University)
- Raquel Lazarowitz (McGill University)
- Dr. Jennifer Pereira (JRL Research & Consulting Inc.)

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