

Exploring the content validity of the EQ-5D-5L and four bolt-ons (skin irritation, self-confidence, sleep, social relationships) in atopic dermatitis and chronic urticaria

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Objectives

- The EQ-5D-5L is a widely used generic preference-based measure of health-related quality of life (HRQoL). Additional dimensions (bolt-ons) may improve the instrument's content validity and responsiveness in certain patient populations.¹
- This study aimed to assess the content validity of the EQ-5D-5L and four existing bolt-ons for *Skin Irritation*, *Self-confidence*, *Social Relationships* and *Sleep*, in people with atopic dermatitis (AD) and chronic urticaria (CU).

Methods

- Interviews were conducted with 30 adults with AD or CU. Participants had varying levels of AD/CU severity and participated in online or in-person semi-structured interviews (~60 minutes long). A specialist recruitment agency recruited participants.
- Participants were eligible if they were 18 years or older, living in the UK, able to read and speak English, and had a self-reported diagnosis of AD or CU. Participants gave informed consent prior to participation.
- Interviews assessed participants' experiences with their skin condition, including symptoms and HRQoL impacts. Cognitive debriefing, using 'think-aloud' and retrospective probing, evaluated the EQ-5D-5L and the *Skin Irritation*, *Self-confidence*, *Social Relationships* and *Sleep* bolt-ons.
- Participants also completed a brief socio-demographic and clinical questionnaire, which included the patient-oriented eczema measure (POEM) for AD or the urticaria control test (UCT) for CU, condition-specific validated measures for severity or control.
- Interviews were recorded, transcribed, then analysed using content and thematic analysis. Quantitative data were analysed with descriptive statistics.

Results

Sample Characteristics

Table 1. Participant clinical demographics

	Chronic urticaria (CU)	Atopic dermatitis (AD)
	N = 15	N = 15
Age (years)	Mean (SD)	39.6 (12.1)
	Range	23, 62
11 (73%)	11 (73%)	
Gender: Female	n (%)	12 (80%)
Ethnicity: White	n (%)	10 (67%)
Time since diagnosis (years)	Mean (SD)	8.3 (8.3)
	Range	0.4, 27.0
19.4 (13.5)	2.1, 41.6	

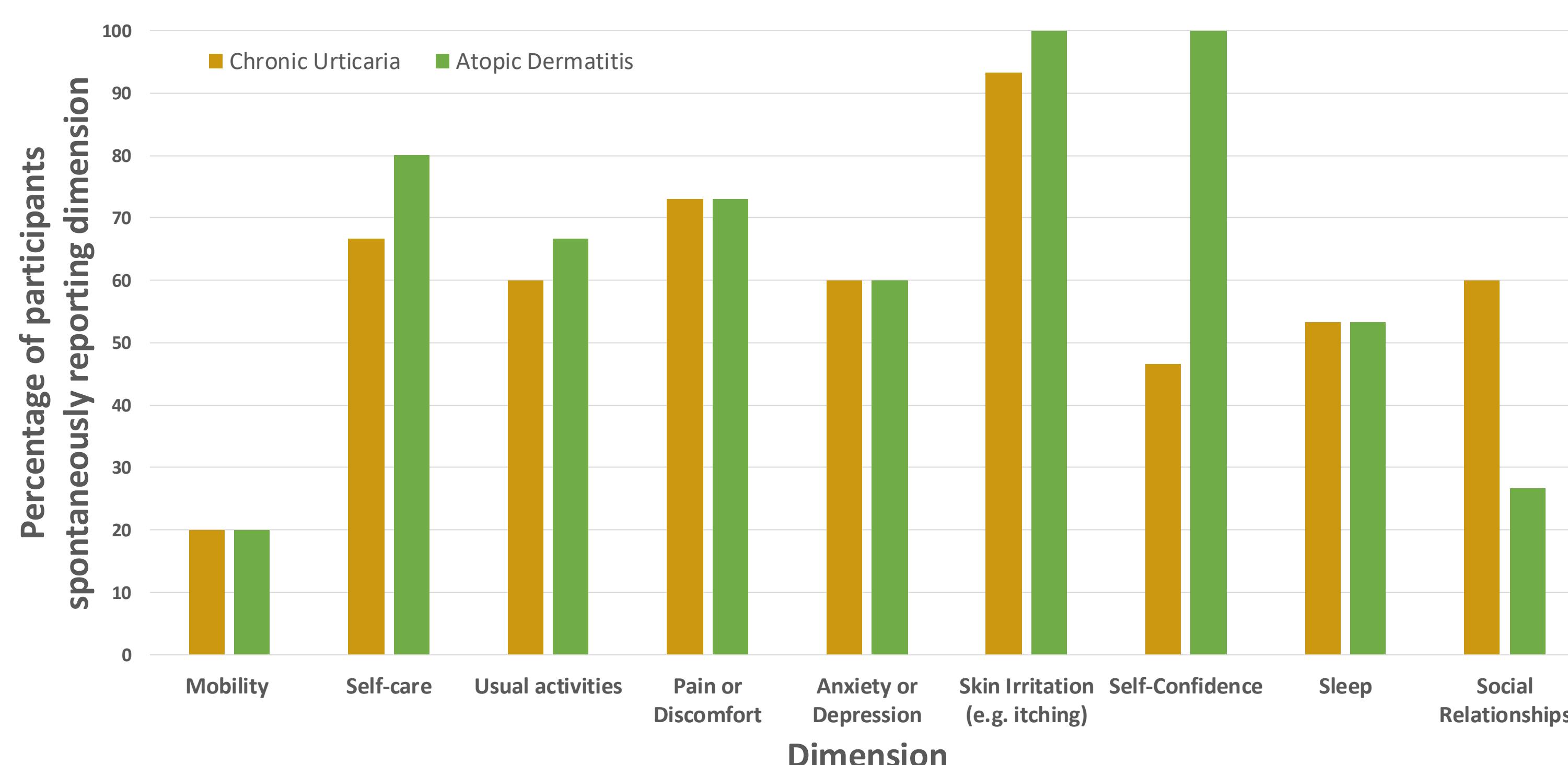
- Most CU participants had chronic spontaneous urticaria (80%; n=12). UCT scores indicated that 73% of participants (n=11) had urticaria that were not well controlled (UCT scores less than 12/16).²
- Most AD participants' POEM scores categorised their AD as moderate (60%; n=9; POEM 8-18/28) or severe (33%; n=5; POEM 17-24/28).³

Concept elicitation

Symptoms and impacts:

- Analysis showed that 76-95% of symptoms and impacts of CU and AD were reported in the first five interviews of each sample, indicating that data saturation was reached.
- Itch was the most reported symptom for both AD (100%) and CU (93%) (see Figure 1).
- Other impacts that were frequently spontaneously reported included impacted self-confidence (AD: 100%, CU: 93%), sleep (AD: 53%, CU: 53%), and social relationships (AD: 27%, CU: 60%)

Figure 1. Proportion of participants spontaneously reporting impacts relating to the EQ-5D-5L and bolt-on dimensions



Cognitive debrief

EQ-5D-5L:

- CU and AD participants found both the EQ-5D-5L and EQ-5D-5L with *Skin Irritation* and *Self-confidence* bolt-ons easy to complete and comprehensive. All participants stated that the version with the two bolt-ons better reflected the impacts of their condition.
- In both samples, there was variation in how participants interpreted the dimensions, with some responding based on general health, and others focusing only on AD/CU-specific experiences.
 - In CU this was especially true for the *Pain/discomfort*, *Anxiety/depression*, and *Self-confidence* dimensions.
 - Two AD participants requested clarification on whether the instrument refers to AD or overall health. For example, interpretation of the *Usual Activities* dimension was mixed, interpreted by several as skin irritation caused by activities such as swimming in sea water and sweating at the gym.

- For each bolt-on, a majority of participants determined them to be relevant (Table 2).
- The *Skin Irritation* bolt-on was the most relevant or important dimension for 60% of AD and 73% of CU participants.
- Social Relationships* was considered the least relevant or important bolt-on by the majority of those asked (22/30 were asked).

Table 2. Summary of the cognitive debrief of the bolt-ons.

Bolt-on	Chronic urticaria (CU)	Atopic dermatitis (AD)
Skin Irritation	<ul style="list-style-type: none">All CU participants reported that <i>Skin Irritation</i> was relevant. It was the most relevant or important bolt-on dimension for 11 people.Skin irritation was defined as itching, redness, raised skin, pain, hives and burning. Two people suggested changes to the wording.All of those asked, reported <i>Skin Irritation</i> should be added to the core EQ-5D-5L.	<ul style="list-style-type: none">All AD participants reported that <i>Skin Irritation</i> was relevant. It was the most relevant or important dimension for nine people.Skin irritation was defined as itching, dryness and redness. One person suggested rewording it as it only mentions itching.All of those asked, reported <i>Skin Irritation</i> should be added to the core EQ-5D-5L.
Self-confidence	<ul style="list-style-type: none">All CU participants described <i>Self-confidence</i> as relevant. However, it was the most relevant or important bolt-on dimension for only one person.When asked which of the four bolt-ons should be added to the core EQ-5D-5L, nine people said <i>Self-confidence</i> should be added.	<ul style="list-style-type: none">All AD participants described <i>Self-confidence</i> as relevant. It was the most relevant or important bolt-on dimension for two people.When asked which of the four bolt-ons should be added to the core EQ-5D-5L, nine people said <i>Self-confidence</i> should be added.
Sleep	<ul style="list-style-type: none">Eleven CU participants reported <i>Sleep</i> to be relevant, however it was the most relevant or important bolt-on dimension for only one person.When asked which of the four bolt-ons should be added to the core EQ-5D-5L, 10 people said <i>Sleep</i> should be added.	<ul style="list-style-type: none">Ten AD participants reported <i>Sleep</i> to be relevant. It was the most relevant or important bolt-on dimension for two people.When asked which of the four bolt-ons should be added to the core EQ-5D-5L, nine people said <i>Sleep</i> should be added.
Social Relationships	<ul style="list-style-type: none">Ten CU participants described <i>Social Relationships</i> as relevant.When asked which of the four bolt-ons should be added to the core EQ-5D-5L, six people said <i>Social Relationships</i> should be added.<i>Social Relationships</i> was most often ranked as the least relevant or important dimension (Seven people).	<ul style="list-style-type: none">Eight AD participants described <i>Social Relationships</i> as relevant.When asked which of the four bolt-ons should be added to the core EQ-5D-5L, seven people said <i>Social Relationships</i> should be added.<i>Social Relationships</i> was most often ranked as the least relevant or important dimension (Seven people).

Skin Irritation:

"I think this [skin irritation] is probably what affects me most because it affects me every single day and it's unavoidable, I will have skin irritation every day so for me it's pretty important." – C009

Self-confidence:

"Usually on a bad day I don't leave the house, I don't see anyone, I don't do anything and that's partly because it's painful and partly because I'm just, when it looks really bad on my face, I'm so self-conscious that I don't want to do anything and also, it makes me feel anxious and depressed I would say." – A013

Sleep:

"It's like a whole-body reaction for days on end, because I can't sleep, I get more mentally affected by it mostly from the chronic sleep deprivation that comes." – C014

Social Relationships:

"When my eczema was at its worst, it was difficult for me to enter into a new relationship because I was worried about what they'd think about my skin." – A001

Missing concepts:

- Before seeing any bolt-ons, n=6 with AD and n=1 with CU reported self-confidence as missing from the EQ-5D-5L. Skin irritation was not reported at this stage.
- After reviewing the EQ-5D-5L with *Skin Irritation* and *Self-confidence* bolt-ons, CU participants reported eight missing concepts, including social relationships and sleep by n=1 each. Similarly, n=6 AD participants reported six missing concepts including social relationships (n=2) and sleep (n=1).

Related dimensions:

- Some participants considered some dimensions to be linked, including *Skin Irritation* and *Pain/discomfort* (AD n=10, CU n=6), and *Self-confidence* and *Anxiety/depression* (AD n=11, CU n=5).

Conclusions

- This is the first study to use the EQ-5D-5L bolt-ons in CU and its findings are consistent with other recent studies on using skin irritation and self-confidence bolt-ons in AD.⁴
- Skin Irritation* and *Self-confidence* bolt-ons showed good evidence of content validity for people with AD and CU.
- Preliminary support was found for the addition of the *Sleep* bolt-on, however the evidence for the *Social Relationships* bolt-on is less clear.
- Quantitative psychometric research is recommended to further support the use of EQ-5D-5L bolt-ons in CU and AD.

References:

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The research was funded by a EuroQol Research Foundation grant (EQ Project 1475-RA). AKS, MG, AL and KG are all employees of Acaster Lloyd Consulting. AL and FR are members of the EuroQol group. Views expressed by the authors in the publication do not necessarily reflect the views of the EuroQol Foundation.