

# 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.<sup>1</sup>
- 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
<b>Age (years)</b>	Mean (SD)	39.6 (12.1)	36.1 (11.5)
	Range	23, 62	23, 54
<b>Gender: Female</b>	n (%)	12 (80%)	11 (73%)
<b>Ethnicity: White</b>	n (%)	11 (73%)	10 (67%)
<b>Time since diagnosis (years)</b>	Mean (SD)	8.3 (8.3)	19.4 (13.5)
	Range	0.4, 27.0	2.1, 41.6

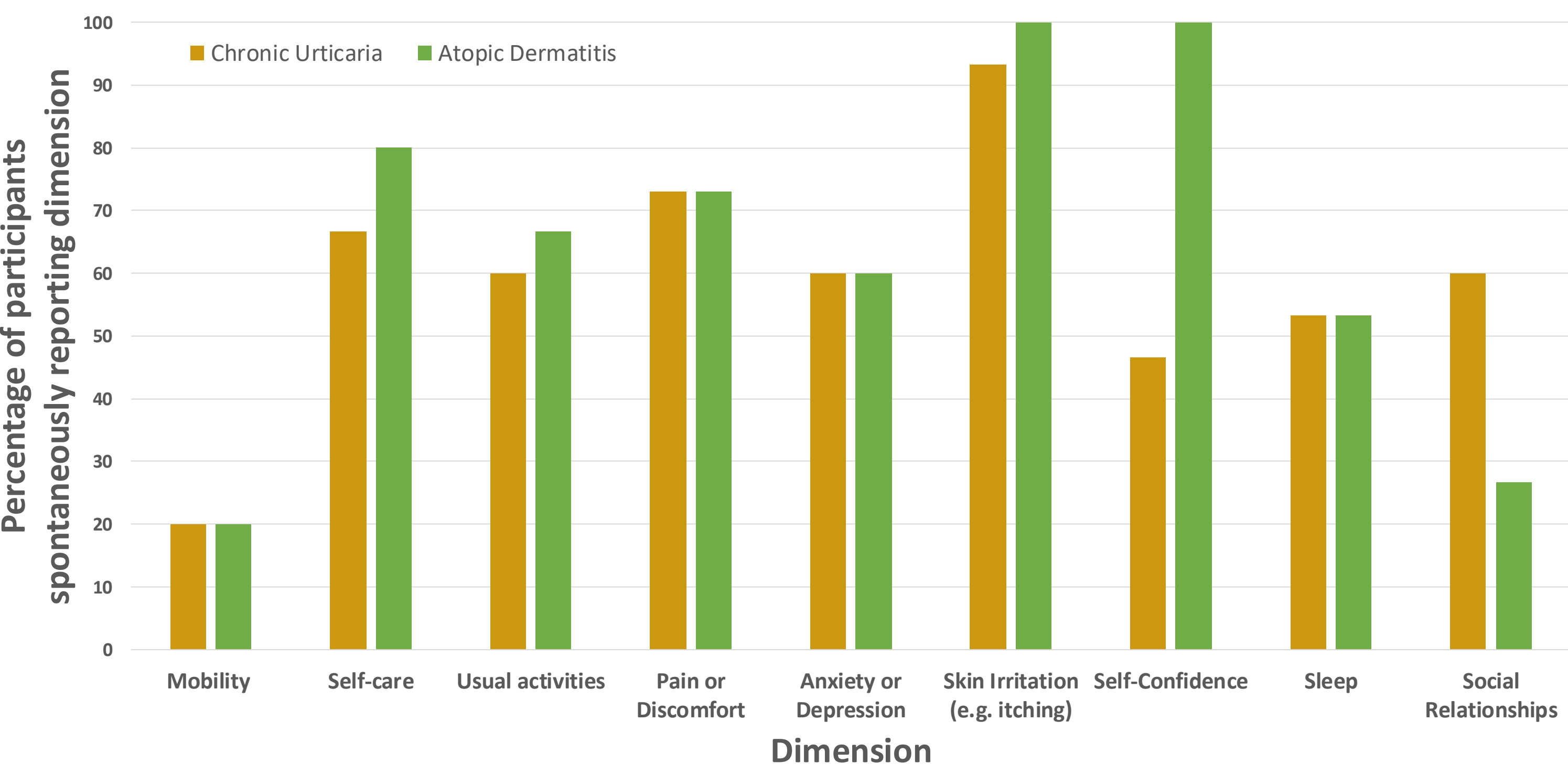
- Most CU participants had chronic spontaneous urticaria (80%; n=12). UCT scores indicated that 73% of participants (n=11) had urticaria that were not well controlled (UCT scores less than 12/16).<sup>2</sup>
- Most AD participants’ POEM scores categorised their AD as moderate (60%; n=9; POEM 8-18/28)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

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

#### *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.<sup>4</sup>
- 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.

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