Assessing itch severity: content validity and psychometric properties of a patient-reported Pruritus Numeric Rating Scale in atopic dermatitis

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Supplementary material

Measures

Sleep-Loss Scale

The Sleep-Loss Scale is a novel scale that measures patient-reported sleep-interference due to itch. It consists of a single question "To what extent did your itching interfere with your sleep last night?" Response options range from 0 ("Not at all") to 4 ("Unable to sleep at all").

Patient-Oriented Eczema Measure (POEM)

The Patient-Oriented Eczema Measure (POEM) is a patient- or observer-reported measure used to monitor disease activity in children and adults with AD. It consists of 7 items about some symptoms and impacts of AD, with each item scored on a 5-pt scale ranging from "No Days" to "Every Day". A total score out of 28 points is calculated based on item responses. The POEM has been evaluated for use in clinical practice and clinical trial settings [1].

Dermatology Life Quality Index (DLQI)

The Dermatology Life Quality Index (DLQI) is a PRO measure that aims to capture the quality-of-life impact of dermatological conditions on patients. It consists of 10 items about the impact of skin problems over the last week, with a 4-pt response scale ranging from "Very much" to "Not at all". The DLQI has been evaluated for use in clinical settings for various dermatological conditions, including AD [2].

Hospital Anxiety and Depression Scale (HADS)

The Hospital Anxiety and Depression Scale (HADS) is a PRO used to detect and evaluate levels of anxiety and depression [3]. It has been widely used, and has been evaluated in adult and adolescent populations [4, 5]. The HADS has subscales for depression and anxiety, each with 7 items. Each item is scored on a 4-pt scale, ranging from 0 to 3, with 3 denoting the highest level of anxiety or depression. A total score of ≥8 out of 21 points on each subscale marks a significant level of anxiety or depressive symptoms.

Global Assessment of Change for AD (GAC-AD)

The Global Assessment of Change for AD (GAC-AD) is a single-item PRO. Patients were asked at the end of the clinical trial about their impression of the overall change in their AD.

Investigator Global Assessment (IGA)

The Investigator Global Assessment (IGA) is an instrument used in clinical settings to rate the overall severity of the patient's AD. IGA ratings are based on a 5-point scale, ranging from 0 (clear) to 4 (severe). The IGA must be conducted prior to conducting the EASI assessment.

Body Surface Area (BSA)

Body surface area (BSA) is a clinical tool for measuring the amount skin involvement in patients with AD. BSA is estimated based on sections of the body (e.g., head and neck, each arm, legs, and trunk). BSA can also be estimated based on patients' "handprints", with each palm-sized area reflecting approximately 1% of patient's BSA [6].

Eczema Area and Severity Index (EASI)

The Eczema Area and Severity Index (EASI) is a clinician-reported tool used to evaluate the severity and extent of AD. A composite score from 0 to 72 is given, based on body area and severity sub-scores. The EASI has been evaluated as a comprehensive, fit-for-purpose tool for both adult and adolescent populations [7].

Conceptual saturation - Symptom and sleep impacts in AD (total sample n=21)

Group 1 (n=4)	Group 2 (n=4)	Group 3 (n=4)	Group 4 (n=4)	Group 5 (n=4)
Burning	Pain			--
Itch	Red spots			
Rash	Stinging			
Redness	Tingling			
Skin cracked				
Skin dry				
Skin feels tight				
Skin flaky				
Skin irritation				
Skin oozing or weeping				
Skin peeling				
Skin sensitive				
Sleep: difficulty falling asleep				
Sleep: difficulty staying asleep				
Sleep: restless sleep				
Sleep: tired next day				
Sleep: unable to sleep				
Soreness				
18 concepts	4 concepts	0 concepts	0 concepts	0 concepts

Participant-reported impact of AD (total sample n=21)

n ≥ 5 participants	n=4 participants	n=3 participants	n=2 participants	n=1 participant
Modifications to mitigate symptoms (n=16)	Bleeding	Anxiety	Mess from shed skin	Open wounds
Scratch: need to (n=11)	Distraction	Stress	Range of motion	Appearance
Concentration (n=9)	Embarrassment	Self-confidence	Conversation	Brushing teeth
Scratch: until bleeding (n=7)	Exercise	Scratch: redness from	Inconvenience	Doing dishes
Socializing (n=7)	Annoyance	Studying	Infection	Dressing
Work (n=7)	Sadness			Family impact
Outdoor activities (n=6)				Handwashing
Scratch: in public (n=6)				Irritation (emotional)
Self-conscious (n=5)				Isolation
Clothing choice (n=5)				Mood
Comments from others (n=5)				School impact
Daily activity interference (n=5)				Using cleaning products
Frustration (n=5)				

Participant-reported impact of AD (total sample n=21)
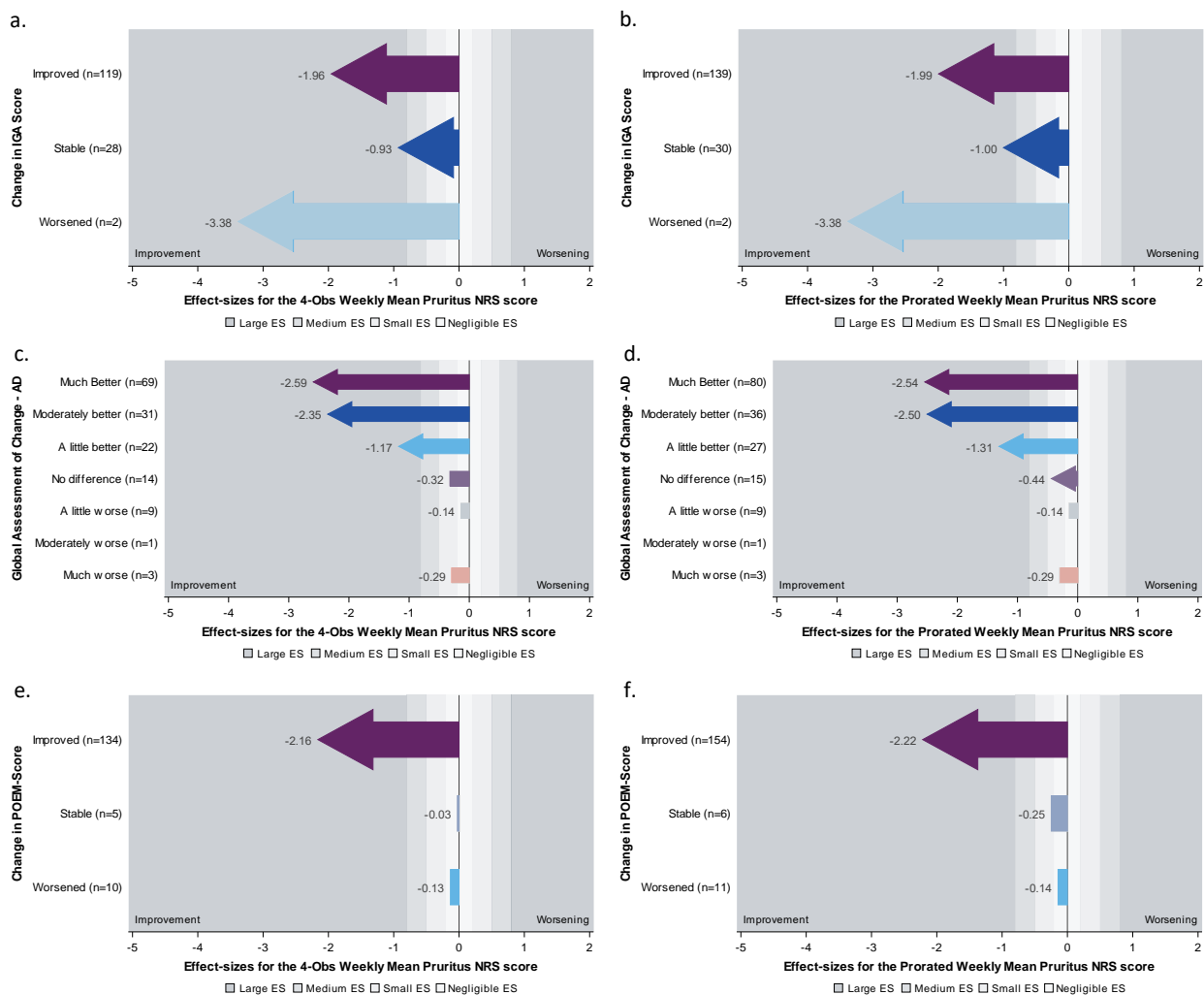
Summary results of meaningful change analyses

Method	Anchor	Improvement vs. all others	Improvement vs. no change	Moderate improvement vs. no change	Minimal improvement vs. no change	Range
ROC	IGA	-2.00	-2.00	-2.00	-2.00	
MEANS	IGA	-2.38	-2.38	-2.51	-1.85	
ROC	GAC-AD	-2.00	-2.00	-2.00	-2.00	
MEANS	GAC-AD	-3.55	-3.53	-2.49	-1.86	
Distribution-based						0.44 – 1.82

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on section #
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	2.1
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	n/a
Occupation	3	What was their occupation at the time of the study?	n/a
Gender	4	Was the researcher male or female?	n/a
Experience and training	5	What experience or training did the researcher have?	2.1
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	n/a
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	2.1
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	n/a
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	2.1.3
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	2.1
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	n/a
Sample size	12	How many participants were in the study?	3.1
Non-participation	13	How many people refused to participate or dropped out? Reasons?	n/a
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	2.1, 3.1
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	n/a
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	3.1, Table 1
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	2.1
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	n/a
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	2.1
Field notes	20	Were field notes made during and/or after the inter view or focus group?	2.1
Duration	21	What was the duration of the inter views or focus group?	2.1
Data saturation	22	Was data saturation discussed?	2.1, 3.1.1
Transcripts returned	23	Were transcripts returned to participants for comment and/or	n/a

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Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	2.1.3
Description of the coding tree	25	Did authors provide a description of the coding tree?	n/a
Derivation of themes	26	Were themes identified in advance or derived from the data?	2.1.3
Software	27	What software, if applicable, was used to manage the data?	2.1.3
Participant checking	28	Did participants provide feedback on the findings?	n/a
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	3.1.1, Table 2
Data and findings consistent	30	Was there consistency between the data presented and the findings?	3.1.1
Clarity of major themes	31	Were major themes clearly presented in the findings?	3.1.1
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	n/a

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

References

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