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ORIGINAL ARTICLE

# Development of a validated short-form of the Childhood Atopic Dermatitis Impact Scale, the CADIS-SF15

M. Gabes,[1,2,*] S.L. Chamlin,[3] J.-S. Lai,[4] D. Cella,[4] A.J. Mancini,[3] C.J. Apfelbacher[1]

[1]InsStitute of Social Medicine and Health Economics, Otto von Guericke University Magdeburg, Magdeburg, Germany
[2]Medical Sociology, Department of Epidemiology and Preventive Medicine, University of Regensburg, Regensburg, Germany
[3]Ann and Robert H. Lurie Children's Hospital of Chicago and Northwestern Feinberg School of Medicine, Chicago, IL, USA
[4]Department of Medical Social Sciences, Feinberg School of Medicine, Northwestern University, Chicago, IL, USA
*Correspondence: M. Gabes. E-mail: michaela.gabes@klinik.uni-regensburg.de

## Abstract

**Background** The Childhood Atopic Dermatitis Impact Scale (CADIS) with 45 items may be burdensome to complete. We therefore aimed to develop a CADIS short-form.

**Methods** Parents of 300 children completed the prototype CADIS. Exploratory factor analysis was conducted on the 45-item CADIS version. The most representative items were chosen. Confirmatory factor analysis was used to confirm the *a priori* factor structure. Content validity was assessed in a focus group of patients, parents, clinicians, methodologists and industry delegates. Internal consistency, 48-h test–retest reliability, construct validity and responsiveness of the newly developed short-form were assessed.

**Results** A total of 270 families provided data at baseline, 34 after 48 h and 228 after 4 weeks. Fourteen items of three different factors fulfilled the proposed eligibility criteria and were included in the draft short-form. After the content validity rating, one item relating to the child's sleep was added to further improve content validity. The confirmatory factor analyses showed good model fit, and a 15-item short-form was initiated, the CADIS-SF15. The total scale and the three domains showed good internal consistency and test–retest reliability. The correlation between SCORAD and other subjective measures was consistent with our hypotheses. Differences in scores between mild, moderate and severe AD patients were significant, and the CADIS-SF15 was able to detect changes in 'improving' patients over time.

**Conclusion** The CADIS-SF15 with 15 items in three domains is an internally consistent, reliable, valid, responsive and brief measure of QoL in children affected with AD and their parents. Further evaluation of clinical applicability is required.

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## Conflicts of interest

Christian Apfelbacher has received institutional funding and consultancy fees from Dr. Wolff GmbH and consultancy fees from Sanofi Genzyme. He is a member of the executive committee of the Harmonising Outcome Measures for Eczema (HOME) initiative.

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## Introduction

Atopic dermatitis (AD), also called eczema or atopic eczema, is a common skin disease that predominantly affects children often causing intense pruritus.[1] In the United States, AD is reported in 17% of schoolchildren,[2] and in Northern Europe, there is a similar prevalence of about 16%.[3] The lifetime prevalence of AD probably lies between 15 and 30% in children with an increasing incidence noted in industrialized countries during the last decades.[4] AD is often associated with other allergic diseases, such as food allergies, allergic rhinitis and asthma. For these reasons, AD is considered to be a significant public health problem.[5]

Notably, children with AD are affected by significant pruritus often resulting in sleep disturbances and other behavioural issues. School performance and more difficulties with concentration at school are reported.[6] It is indisputable that AD negatively affects the quality of life (QoL) of the affected children and their families.[7,8] As AD severity worsens, the negative impact on QoL also worsens.[9] In addition, the QoL of parents of children with

AD, especially mothers, is impaired. Caring for a child with AD requires extra work including additional skincare, medical treatment and housework. Parental sleep disturbance is also well-reported.[10]

To measure QoL, self- or proxy-reported patient-reported outcome measures (PROMs) are used in clinical trials to capture the patient's perspective.[11] Until now, several PROMs have been developed for children with AD and their parents. In 2016, Heinl *et al*.[12] published a systematic review on the measurement properties of quality of life measurement instruments for children with AD. These were as follows: the Children's Dermatology Life Quality Index (CDLQI),[13] the Childhood Impact of Atopic Dermatitis (CIAD),[14] the DISABKIDS Atopic Dermatitis Module (DISABKIDS-ADM),[15] the Infant's Dermatitis Quality of Life Index (IDQoL)[16] and the Childhood Atopic Dermatitis Impact Scale (CADIS).[17] Of these instruments, the CADIS was the only instrument that had the potential to be recommended for use in the future depending on the results of further validation studies. All other instruments lacked significant validation data. The CADIS was developed in 2005 for use in children with AD under 6 years of age. The development was based on the hypothesis that previous measurement instruments did not cover the emotional impact of AD on child and family well-being that are important for the promotion of appropriate care.[7,17] The CADIS items were developed after directed focus sessions with expert clinicians and parents of young children affected with AD, and its conceptual framework is based on this and a review of the literature.[17] It is an internally consistent, reliable and responsive questionnaire with adequate construct validity.[18]

However, though comprehensive, it can be challenging for families to complete all 45 CADIS item during their clinical visits. At the Harmonising Outcome Measures for Eczema (HOME) V Meeting in Nantes, the CADIS was considered too lengthy by the participants and therefore as not feasible for the use in clinical trials.[19] Therefore, we aimed to develop a brief version of the CADIS to make this instrument more feasible and to provide a well-validated instrument that can be recommended for future use.

## Patients and methods

The current data have already been analysed in three previous manuscripts and were used with permission of the developer, Dr. Sarah L. Chamlin.[17,18,20]

### Participants and study design

The sample population consisted of the parents or primary caregivers of 300 young children from birth to 6 years of age with AD. The recruitment took place at two paediatric dermatology practices in the United States (Ann & Robert H. Lurie Children's Hospital of Chicago, formerly Children's Memorial Hospital, Chicago, Illinois; and University of California, San Francisco, California). One family refused to participate. All parents or primary caregivers gave written informed consent. The Institutional Review Boards at the participating institutions approved the study protocol. The study was conducted in accordance with guidelines established by the Declaration of Helsinki. Participants were required to be able to read and understand English.[9,10]

The original Childhood Atopic Dermatitis Scale (CADIS) is an instrument measuring the impact of AD on the QoL of affected children younger than 6 years and their families. The 45 items are explained by two dimensions with five domains: child dimensions (symptoms and activity limitation/behaviour) and parent dimensions (family/social function, sleep and emotions). Each item has five response options relating to frequency ('never' to 'all the time'). A response of 'never' is scored with zero points, and a response with 'all the time' with 4 points. Scores range from 0 to 180. The CADIS is a proxy-reported instrument completed by the patient's parents. The recall period takes the last 4 weeks into account.[17,18]

Data collection included the CADIS, sociodemographic items, other subjective measures, a global question on the child's skin condition and two open-ended questions about bother. Disease severity was examined by a physician using the Severity Scoring of Atopic Dermatitis (SCORAD) index during the clinic visit.

After 48 h, 41 parents were asked again to complete the CADIS to assess test–retest reliability. This short time period was selected because childhood AD can change quickly with a few days of therapy.

Four weeks after enrolment, all participants received a copy of the CADIS and were asked again to rate their child's skin condition with the same global question as during initial enrolment.

### Analyses

We performed an exploratory factor analysis on the 45 items of the CADIS and correlated each item with the CADIS total score and the corresponding domain score to identify the most representative items of the original CADIS. Items of the short-form were chosen if they met at least two of the following criteria:

1 An item should have a significant factor loading (>0.3) on the corresponding factor and no significant loading (<0.3) on another factor.
2 An item should have a high correlation with the corresponding domain score (>0.7) and no high correlation on any other domain score (<0.7).
3 An item should have a high correlation with the overall CADIS score (>0.7).

All selection criteria were recorded in an *a priori* determined analysis plan. The analysis plan was reviewed and accepted by all authors.

In a second step, confirmatory factor analysis (CFA) was performed on the most representative items to verify the *a priori* scales of the CADIS. The goodness of fit of the CFA model was

evaluated utilizing the following indices and cut-off levels: comparative fit index (CFI) $\geq 0.95$, root mean square error of approximation (RMSEA) $< 0.08$, standardized root mean square residual (SRMR) $< 0.08$ and chi-square/df ration ($\chi^2$/df) $< 3$.

Content validity of the draft short-form was assessed at the HOME VII Meeting in Tokyo, April 2019, by a focus group of 10 people. The group consisted of patients or parents of patients, clinicians, methodologists and pharmaceutical industry delegates and was led by a skilled facilitator, a member of the HOME executive committee (Dr. Eric Simpson). The group moderator was instructed before the group session and familiarized with the COSMIN guidance for giving a sufficient rating for the 10 criteria for good content validity (see user manual,[21] pages 54–57). Content validity was assessed with the COSMIN criteria guidance for evaluating content validity of patient-reported outcome measures (PROMs).[21] Notes were made during the group meeting, and data were analysed using the COSMIN guidance (see user manual,[21] pages 58–59). At least two researchers were involved when summarizing the results. All patients were asked about relevance, comprehensiveness and comprehensibility of the CADIS short-form.

According to the results of the content validity rating, confirmatory factor analysis was performed again with the adapted short-form.

After the confirmation of the final item set and the distinct domains, several measurement properties of the new short-form were determined. Internal consistency of the CADIS total score and each domain score was assessed through the calculation of Cronbach's alpha. Test–retest reliability was assessed after 48 h using intraclass correlation coefficients (ICCs). Concurrent validity was calculated using Spearman rank correlations with SCORAD and two other subjective criteria (ratings of pruritus and sleep loss, range 0–10). We formulated *a priori* hypotheses in order to test the results against. Since the total scale and the domains 'Family and Social Function' and 'Emotions' are measuring dissimilar, but related constructs, we expected correlations between 0.3 and 0.5 with the SCORAD and the two subjective measures. The 'Symptoms' domain should have a correlation >0.5 with the SCORAD and the subjective questions on pruritus and sleep since they measure similar constructs. In order to determine discriminant validity, patients were grouped according to their SCORAD clinical severity into patients with mild (scores < 15), moderate (scores of 15–40) and severe AD (scores > 40).[22] A Kruskal–Wallis test over all severity groups was performed, and single Wilcoxon tests were used to determine which severity groups significantly differed from each other. To assess responsiveness, the change in the single global question on the child's skin condition was used as an anchor. Spearman rank correlation between the anchor and the total score and all domain scores were calculated to determine the appropriateness of the anchor. Patients were grouped according to this anchor into three groups: patients improving (−1), patients experiencing no change (0) and patients worsening (1). A Kruskal–Wallis test was used to find differences over the three groups. Single Wilcoxon tests were calculated to identify in which group changes were significant.

All data analyses were conducted via IBM SPSS Statistics 25, Mplus software (Muthen & Muthen, Los Angeles, CA) and MS Excel.

## Results

The CADIS and sociodemographic items were completed by 270 of 300 enrolled families (90%) at baseline and by 34 of 41 families (82.9%) after 48 h. 55% of the participating children were male, and 52% were identified as Caucasian by the parent. The child's mean age was 23.3 months. 86% of the parents were married or living with a partner, 81% were privately insured, and 56% had an annual family income >$75 000.

Fourteen items fulfilled at least two of the proposed criteria, five items of the 'Symptoms' domain, four items of the 'Family and Social Function' domain and five items of the 'Emotions' domain. Confirmatory factor analysis showed acceptable goodness-of-fit indices (see Table 1).

The content validity of this 14-item draft short-form was rated at the HOME VII Meeting in Tokyo. Comprehensibility was rated as sufficient since items were considered as appropriately worded by the group members and response options matched the questions. Regarding the relevance rating, items were considered to be relevant for the population of interest and the context of use and response options were considered to be appropriate. The recall period and the relevance of the items for the construct of interest were rated as insufficient, resulting in an inconsistent relevance rating. Comprehensiveness was rated as insufficient since one key concept, namely the child's sleep, was missing. The overall content validity rating was therefore inconsistent.

In order to fill this content gap, further analyses were conducted by including sleep items from the original CADIS. 'This skin condition affects how well my child sleeps' (part of the 'Symptoms' domain) was selected unanimously after content and data review of originally excluded items. Originally, this item was excluded since it significantly loaded on the

**Table 1** Goodness-of-fit indices obtained by the confirmatory factor analyses

| Goodness-of-fit indices | Draft 14-item short-form | 15-item short-form (sleep included) |
|---|---|---|
| **CFI** | 0.944 | 0.945 |
| **RMSEA** | 0.073 | 0.071 |
| **SRMR** | 0.055 | 0.055 |
| **$\chi^2$/df** | 2.424 | 2.358 |

CFI, comparative fit index; df, degrees of freedom; RMSEA, root mean square error of approximation; SRMR, standardized root mean square residual.

'Symptoms' and the 'Sleep' domain and significantly correlated with both domains as well. With the inclusion of this item, the goodness-of-fit indices were slightly improved in comparison with the draft 14-item version (see Table 1). All indices indicated an acceptable model fit with the CFI on the borderline (criterion: 0.95).

The final CADIS short-form has 15 items in three domains, 'Symptoms', 'Family and Social Function' and 'Emotions' (see Fig. 1) and is named CADIS-SF15 (see Appendix 1).

Internal consistency of the total scale and all three subscales was calculated using Cronbach's alpha coefficient. Cronbach's alpha was 0.92 for the total scale and 0.91, 0.88 and 0.82 for the scales of 'Symptoms', 'Family and Social Function', and 'Emotions', respectively.

Only 34 families completed and returned the CADIS after 48 h. Due to the short time interval, disease severity was assumed to be stable. Test–retest reliability was measured using ICCs. We found an ICC of 0.97 for the total scale and ICCs of 0.97, 0.92 and 0.93 for 'Symptoms', 'Family and Social Function', and 'Emotions', respectively.

Spearman rank correlations with SCORAD and two subjective measures (pruritus and sleep loss) were used to assess convergent validity. The correlations with SCORAD and the two subjective measures are presented in Table 2. Our results were mostly and consistently in line with our hypotheses.

According to their SCORAD, patients were classified as having mild, moderate or severe AD. There were significant differences over all severity groups ($P < 0.001$). We carried out single Wilcoxon tests to compare patients with mild AD with patients with moderate AD and to compare patients with moderate AD with patients with severe AD. There were significant differences in the CADIS total score and all domain scores between patients with mild and moderate AD ($P \leq 0.015$) and between patients with moderate and severe AD ($P < 0.001$).

Improved skin condition was noted in 146 (64.0%)patients, 61 (26.8%) patients experienced no change, and 21 (9.2%) patients worsened after 4 weeks. The skin change score had a correlation of −0.517 with the CADIS total change score, of −0.538, −0.247 and −0.359 with the 'Symptoms', 'Family and Social Function', and 'Emotions' change scores, respectively, and is considered appropriate. The Kruskal–Wallis test showed

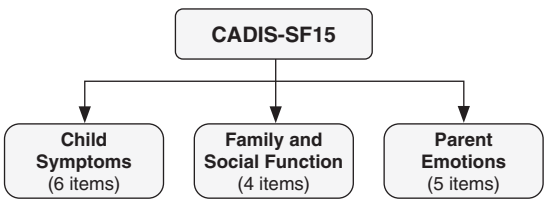


**Figure 1** Composition of the CADIS-SF15.

**Table 2** Spearman rank correlations of different measures with the CADIS-SF15 total scale and all domains

| | Total scale | 'Symptoms' | 'Family and Social Function' | 'Emotions' |
|---|---|---|---|---|
| **SCORAD** | 0.570 | 0.607 | 0.364 | 0.411 |
| **Rating of pruritus** | 0.593 | 0.623 | 0.350 | 0.454 |
| **Rating of sleep loss** | 0.591 | 0.673 | 0.395 | 0.366 |

significant differences in the total score and all domain scores over all three groups ($P \leq 0.002$). In the 'worsening' and the 'no change' groups, there were no significant differences in the total score and all domain scores between baseline and four-week follow-up ($P \geq 0.084$). Only the 'Emotions' domain significantly improved in parents experiencing no change in their child's skin condition ($P = 0.010$, see Table 3). This can be possibly explained by the fact that the parents somehow learned to live with the disease of their child over time. Their frustration, helplessness, disappointment, anger and worries decreased although the skin condition of their child did not. This decrease could be due to greater knowledge about the disease, due to social support or medical help. In our opinion, strong feelings such as anger or frustration can quickly evaporate over time since they are influenced by many environmental factors. In the 'improving' condition, we found significant differences in the total score and all domain scores between baseline and four-week follow-up ($P < 0.001$).

## Discussion

Atopic dermatitis has a measurable negative impact on patient and parent quality of life.[7–10] Several skin-specific and disease-specific instruments have been developed and validated to measure QoL in those affected by atopic dermatitis.[13–17]

The CADIS-SF15 is a newly developed, internally consistent, reliable, valid and responsive measure with confirmed structural validity. It contains child, family and parent aspects and is therefore

**Table 3** Results of the single Wilcoxon tests

| Patient group | *n* | Scale | *Z* | *P*-value |
|---|---|---|---|---|
| **Worsened** | 21 | Total score | −0.101 | 0.919 |
| | | 'Symptoms' | −0.086 | 0.931 |
| | | 'Family and Social Function' | −0.264 | 0.792 |
| | | 'Emotions' | −0.571 | 0.568 |
| **No change** | 61 | Total score | −1.725 | 0.084 |
| | | 'Symptoms' | −1.295 | 0.195 |
| | | 'Family and Social Function' | −0.651 | 0.515 |
| | | 'Emotions' | −2.5730 | 0.010* |
| **Improved** | 146 | Total score | −9.235 | <0.001* |
| | | 'Symptoms' | −9.259 | <0.001* |
| | | 'Family and Social Function' | −4.181 | <0.001* |
| | | 'Emotions' | −7.959 | <0.001* |

*means significant

unique. With the inclusion of the additional item relating to the child's sleep, not only the model fit of the CADIS-SF15 further improved, but also the scale should be now comprehensive regarding content. Furthermore, with only 15 items, the CADIS-SF15 is more feasible than the 45-item original CADIS.

According to the COSMIN group, a patient-reported outcome measure is placed in category A and therefore recommended for use if there is evidence for sufficient content validity and at least low-quality evidence for sufficient internal consistency. A sufficient internal consistency rating is only given if there is at least low evidence for sufficient structural validity. A sufficient structural validity rating is assigned if the CFI, the Tucker–Lewis index, or a comparable measure >0.95 or if the RMSEA <0.06 or if the SRMR is <0.08.[23] With a SRMR of 0.055, the CADIS-SF15 fulfils the criterion for sufficient structural validity. Since at least low evidence for sufficient structural validity is given and Cronbach's alpha ≥0.70 for each scale, one requirement for a placement in category A is met. With evidence for sufficient content validity with the addition of the sleep-item, the CADIS-SF15 fulfils both criteria for category A and could be therefore recommended for future use according to the COSMIN criteria.[24]

One strength of this study is the *a priori* developed, and author confirmed analysis plan for the development of the short-form. In addition, the iterative process of content review by the original authors, current authors and the HOME focus group strengthens the content validity. However, the HOME focus group was not recorded and transcribed verbatim and not all participants were English native speakers. Another strength of this study is the fact that the original CADIS is a well-developed instrument with good measurement properties and is currently available in two further validated language versions, Italian and Japanese.[30,31] It uniquely measures QoL in both of the affected children and their parents. Moreover, it was recommended for future validation by a systematic review of Heinl *et al.*[12] Future studies will focus on testing a shorter recall period since past criticism of CADIS includes that the four-week recall period was long.

The aim of future research will also include validation studies in different languages to replicate these findings and to disseminate the CADIS-SF15 internationally. Re-evaluation of the CADIS-SF15 by the HOME initiative as the core outcome instrument for quality of life in infants with AD is indicated.

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## Appendix 1

### The CADIS-SF15

These questions concern your feelings and your child's feelings about this skin condition over the past month. Check the answer that comes closest to the way you or your child have been feeling. If a question does not apply to you or your child, answer NEVER.

| How often during the past month do these statements describe you oryour child? | Never | Rarely | Sometimes | Often | All the time |
|---|---|---|---|---|---|
| 1. This skin condition affects how well my child sleeps | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| 2. I am bothered that this skin condition affects our vacation plans | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| 3. This skin condition affects our social life | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| 4. This skin condition makes my child fussy or irritable | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| 5. I am bothered that my family stays home more because of this skin condition | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| 6. My child scratches or rubs his/her skin | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| 7. This skin condition makes my child feel frustrated | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| 8. My child seems to cry more because of this skin condition | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| 9. I am frustrated with my child's skin condition | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| 10. My child seems to be restless or hyperactive because of this skin condition | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| 11. I feel helpless about my child's skin condition | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| 12. I am disappointed that my child has this skin condition | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| 13. I worry about the side effects from treatments for this skin condition | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| 14. I am angry that my child has this skin condition | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |
| 15. My child's skin condition makes it hard to do what I enjoy | ☐1 | ☐2 | ☐3 | ☐4 | ☐5 |

Have you answered every item? ○1 Yes ○2 No