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ORIGINAL RESEARCH

The Atopic Dermatitis Control Tool: Adaptation and Content Validation for Children and Caregivers of Children with Atopic Dermatitis

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ABSTRACT

Introduction: The Atopic Dermatitis Control Tool (ADCT) assesses six concepts regarding patient-perceived control of atopic dermatitis (AD) in adults and adolescents with AD. This study aimed to develop two modified ADCT versions, one for children with AD aged 8–11 years and another for caregivers of children with AD aged 6 months to 11 years.

Methods: Following the US Food and Drug Administration patient-reported outcomes guidance, the ADCT was modified to produce draft Child and Caregiver ADCT versions, maintaining the original six concepts. The instruments were refined and finalized through an iterative process using input from children with AD and caregivers of children with AD via qualitative interviews. Inclusion criteria were clinician diagnosis of AD, prescription treatment use in the past 3 months, and itching/scratching or rash in the past month. Interviews consisted of concept elicitation to identify perceptions of AD control and cognitive debriefing to test and refine the ADCT items.

Results: In total, 19 children (mean age 9.2 years, 74% male) and 17 caregivers (mean age 36.3 years, 100% female) were interviewed. During concept elicitation, children and caregivers reported similar symptoms and described the cycling and unpredictability of AD. Most participants reported that daily activities were impacted negatively by AD symptoms. The concept of AD control resonated with children and caregivers, and respondents were able to describe their experiences related to AD symptom severity. Children were unfamiliar with the term AD, so the Child ADCT version was named the Child Eczema Control Tool (ECT). Children and caregivers both reported that the instruments

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assessed relevant concepts, comprehensively measured AD control, and demonstrated content and face validity.
Conclusions: The Child ECT and Caregiver ADCT were developed and qualitatively validated for assessing AD control in patients aged 6 months to 11 years and may offer simple ways to assess disease control and optimize treatment decisions.

Keywords: Atopic dermatitis; Patient-reported outcomes; ADCT; Disease control; Pediatric AD patients

Key Summary Points

The Atopic Dermatitis Control Tool (ADCT) is validated for use by adults and adolescents with atopic dermatitis (AD) to assess patient-perceived control of AD; it has not been previously validated for use in children with AD aged less than 12 years.

The objectives of this study were to modify the ADCT to develop two new versions: one intended for self-completion by children with AD and one intended for caregivers of children with AD.

The original ADCT was modified to create draft Child and Caregiver versions of the ADCT; through an iterative process of qualitative interviews with children with AD and caregivers of children with AD, the draft versions were modified and finalized.

The Child version of the ADCT was named the Child Eczema Control Tool (ECT) as children were unfamiliar with the term AD.

The novel Child ECT and Caregiver ADCT versions were reported to measure relevant concepts in AD, and to comprehensively measure AD control.

This study describes the development and qualitative validation of the Child ECT and Caregiver ADCT, demonstrating that both have content and face validity for assessing symptom control in patients with AD aged less than 12 years and can be used in clinical practice to optimize treatment decisions.

DIGITAL FEATURES

This article is published with digital features, including a video abstract to facilitate understanding of the article. To view digital features for this article go to https://doi.org/10.6084/m9.figshare.26893381.

INTRODUCTION

Atopic dermatitis (AD), also frequently referred to as eczema, is one of the most common, chronic, relapsing skin disorders and can significantly impair the quality of life of both children and their parents/caregivers [1–3]. Despite the consensus that patient-reported disease control is an important part of the clinical evaluation of patients with AD [4–6], no validated instrument has been available for use in patients with AD aged under 12 years. Therefore, there is a need to develop validated instruments to better help children with AD, their caregivers, and their physicians assess AD control status to optimize their disease management [7].

The Atopic Dermatitis Control Tool (ADCT) facilitates patient/physician discussion about long-term disease control and has been validated for use in adults and adolescents [7, 8]. Its utility and content validity were recognized by the Harmonizing Outcome Measures in Eczema (HOME) initiative as a preferred instrument to measure AD control in both clinical trials and clinical practice [9]. The ADCT was designed to be brief, easily completed via paper, website, or a handheld device and consists of six items (each with five response options) to assess six concepts related to patient-perceived control of AD over a 7-day recall period [8]: (1) overall severity

of symptoms, (2) frequency of intense periods of itching, (3) degree of bother, (4) frequency of sleep impact, (5) impact on daily activities, and (6) impact on mood or emotions. Each of the six ADCT items has a score range from 0 (no problem) to 4 (worst), rating the severity of each concept; the total score ranges from 0 to 24, which is the summation of the responses to all the items. A score of ≥ 7 points was derived as the threshold to identify patients "not in control," on the basis of optimal sensitivity/specificity values [8]. Despite widespread use of the ADCT to measure disease control in adults and adolescents with AD [7, 8, 10], the ADCT has not previously been validated for use in children with AD aged 11 years or younger.

The objectives of this study were to modify the ADCT to develop Child ADCT (intended for self-completion by children with AD) and Caregiver ADCT (intended for caregivers of children with AD) versions. In line with the US Food and Drug Administration (FDA) guidance on patient-reported outcomes [11, 12], development of the modified versions of the ADCT was informed through the conduct of individual qualitative interviews with pediatric patients with AD and caregivers of pediatric patients with AD to ensure content validity and ease of completion.

METHODS

Participant Recruitment and Inclusion Criteria

Interview participants from the US were recruited in collaboration with Global Parents for Eczema Research, a patient advocacy organization that maintains a large database of caregivers of children with AD. The following inclusion criteria were applied at screening, based on caregiver self-reporting on behalf of their child: a clinician-confirmed diagnosis of AD, use of a prescription treatment for AD in the past 3 months, itching/scratching or rash within the past month, and the respondent aged 8 to 11 years (Child version of the ADCT) or a caregiver of a child aged 6 months to 11 years (Caregiver version of the ADCT). Prior to starting each interview an informed consent (for adult participants) or assent (for child participants) discussion took place and informed consent/assent forms were completed, which included consent to publish. This study was conducted in accordance with the ethical principles of the Declaration of Helsinki of 1964 (including its later amendments) and the International Council for Harmonization Good Clinical Practice guideline. This study received Research Triangle Institute institutional review board approval.

Stage 1: Development of Draft Child and Caregiver ADCT Versions

The items in the original US English ADCT (available at https://www.adcontroltool.com/) were adapted to facilitate self-completion by children aged 8–11 years in the draft Child version of the ADCT. Specifically, the language used in response options was simplified, and the number of response options for each item was reduced from 5 to 4. Separately, the ADCT also was modified to produce the draft Caregiver ADCT to be completed by caregivers of children with AD aged 6 months to 11 years. This stage included changing response options to relate to the observation of symptoms rather than direct experience of AD. For several concepts in both the draft Child and Caregiver ADCT versions, multiple item options were presented at the initial interview to determine preference.

Stage 2: Qualitative Interviews and Iterative Instrument Modification

Qualitative interviews were conducted remotely by two experienced interviewers using the Zoom online video conference platform. Some interviews included both the child and caregiver together while others were conducted with individual participants. All interviews consisted of two parts, concept elicitation and cognitive debriefing. For concept elicitation, participants were asked to describe their (or their child's) experiences with AD, including symptoms and impact, and their understanding of "AD control." More targeted questioning then was

conducted to ensure that all key symptoms and impacts were discussed (if not raised first by the participant). For cognitive debriefing, participants were asked for feedback on instructions, questions, and response scales while they completed the draft ADCT instrument. Participants also were asked to "think aloud" and to describe their thought processes as they responded to modified items. This process was intended to identify any issues with content relevance or clarity of the items and to determine if the item set was comprehensive enough to fully capture each concept within the ADCT.

For interviews that included both the child and their caregiver, the concept elicitation exercise was designed to elicit input from the child followed by additional or contrary information from the child's caregiver. The child and caregiver then each completed their respective draft ADCT instrument. After each item on the draft Child version of the ADCT was debriefed with the child, caregivers were asked for their response on the corresponding item on the draft Child version of the ADCT, and the similarities and differences between their responses were discussed.

Modifications were made to the draft instruments on the basis of the results of the qualitative interviews, with further interviews conducted as required. Cognitive debriefing was used to assess modifications made to the instruments and to determine whether further modifications were required. Once no further refinements were required, the draft Child and Caregiver versions of the ADCT were finalized. This iterative interview and instrument modification process is shown in Fig. 1.

RESULTS

Participants

For the draft Child version of the ADCT, 19 children were interviewed. The mean age of child participants was 9.2 years (range 8–11 years), 74% were male, 68% were white, 90% had received topical treatment in the previous 3 months, and 37% had received biologic treatment for AD (Table 1). For the draft Caregiver ADCT, 17 caregivers were interviewed. The mean age of these participants was 36.3 years (range 29–43 years), 53% were white, 65% had a college degree or higher qualification, and all caregivers were female. The mean age of children for whom the Caregiver ADCT was completed was 5.5 years (range 0.7–11 years), and 77% of these children were male. There were 12 paired child and caregiver interviews conducted. Additional information on the characteristics of child and caregiver

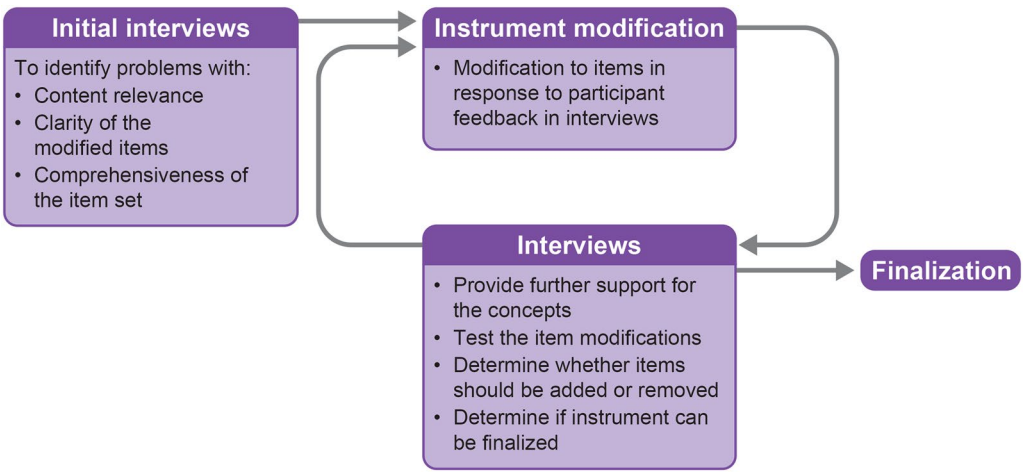

Fig. 1 Overview of the cognitive debriefing iterative review process

Table 1 Demographic of study participants

Characteristics	Child participants, Child ADCT ($N=19$)	Paired caregivers,[a] Child ADCT ($N=12$)	Caregiver participants, Caregiver ADCT ($N=17$)
Age, mean (range), years	9.2 (8–11)	39.3 (33–46)	36.3 (29–43)
Sex			
Male	14 (73.7)	–	–
Female	5 (26.3)	12 (100)	17 (100)
Race/ethnicity, *n* (%)			
White	13 (68.4)	10 (83.3)	9 (52.9)
Black	–	–	3 (17.6)
Hispanic	2 (10.5)	1 (8.3)	1 (5.9)
Asian	–	–	3 (17.6)
Other	4 (21.1)	1 (8.3)	1 (5.9)
Education			
Some college/technical school	–	2 (16.7)	6 (35.3)
College degree	–	6 (50.0)	4 (23.5)
Graduate/professional degree	–	4 (33.3)	7 (41.2)

ADCT Atopic Dermatitis Control Tool

[a]The caregivers who participated in the paired child/caregiver interviews to review the Child ADCT were not the same as those who participated in reviewing the Caregiver ADCT

participants per interview round is provided in Table 2.

First Round of Qualitative Interviews

Concept Elicitation

Following development of the draft ADCT instruments, an initial round of qualitative interviews was conducted with children ($n=8$) and with caregivers ($n=11$). Participants' experiences with AD, including terminology, symptoms, disease impacts, and understanding of AD control are summarized in Fig. 2. Some caregivers reported that they would use the term "atopic dermatitis" rather than "eczema" when speaking to peers because the average person does not consider the potential seriousness of "eczema." All children commented on their familiarity with and use of the word "eczema" to describe their skin condition; some were completely unaware of the term "atopic dermatitis." Both children and caregivers reported a broad range of AD symptoms and associated negative impacts. Caregivers cited the negative impacts AD had on their child's education and development, sleep, socialization and mood, and day-to-day activities; they also cited the burden of AD treatments (Fig. 2). Similarly, children reported that their AD symptoms impacted their schoolwork and resulted in negative feelings, including frustration and embarrassment.

Cognitive Debriefing

For the draft Child version of the ADCT, all children correctly interpreted the instructions in the first round of interviews. Several children

Table 2 Additional Characteristics of Child Participants (Child ADCT)

Characteristic	Round 1 ($n = 8$)	Round 2 ($n = 11$)	Total ($n = 19$)
Symptoms (past month), *n* (%)			
Itching/scratching[a]	8 (100)	11 (100)	19 (100)
Skin rash (patches, flaky, scaly)	8 (100)	10 (90.9)	18 (94.7)
Redness	7 (87.5)	11 (100)	18 (94.7)
Dryness	7 (87.5)	11 (100)	18 (94.7)
Cracking	6 (75.0)	9 (81.8)	15 (78.9)
Pain/soreness	6 (75.0)	6 (54.5)	12 (63.2)
Bleeding	5 (62.5)	7 (63.6)	12 (63.2)
Oozing, runny, wet, weeping	2 (25.0)	5 (45.5)	7 (36.8)
AD treatments (past 3 months), *n* (%)			
Topical cream or ointment	7 (87.5)	10 (90.9)	17 (89.5)
Biologic	4 (50.0)	3 (27.3)	7 (36.8)
Antibiotic	2 (25.0)	–	2 (10.5)
Antihistamines	4 (50.0)	4 (36.4)	8 (42.1)
Oral (pill)	–	1 (9.1)	1 (5.3)
Phototherapy	1 (12.5)	–	1 (5.3)

[a]Study inclusion criteria (i.e., child must have experienced AD-related itching or skin rash in the past month)

AD atopic dermatitis, *ADCT* Atopic Dermatitis Control Tool

reported being unfamiliar with the term "atopic dermatitis." Using a mixture of terms on time-based concepts was found to lead to confusion, as participants varied in their accuracy and consistency when referencing the past week in addition to the "current" time period. For example, some items included the time-based recall period "over the last week," and others assessed the generalized frequency of symptoms "how often?" Older children (aged 10–11 years) often interpreted "how often?" as referring to either the present moment, or their last meaningful related experience (i.e., "I was really itchy last month"). When given a choice between item options that investigated the same disease concept, children preferred the item that used simpler language. For instance, two item options were tested in the first round of interviews for the concept of disease severity, and children preferred "over the last week, how bad was your eczema?" to "how bad are your eczema symptoms (such as itching, dry skin, and skin rash)?" as they found the word "symptoms" to be complex and challenging to understand. For the concept of impact on mood and emotions (item 6), children felt that the term "grouchy" was not relevant in both options: (A) "over the last week, how often did your eczema make you feel sad or grouchy?" and (B) "how often does your eczema make you feel sad or grouchy?" When children were given two response option sets for the items covering the concept of itching (item 2), bother (item 3), impact on sleep (item 4), impact on daily activities (item 5), and impact on mood and emotions (item 6), the shorter, simpler four-option set "never," "sometimes," "often," and "always" was preferred by the participants over the longer, more complex four-option set "none of the time," "some of the time," "most of the time," and "all of the time."

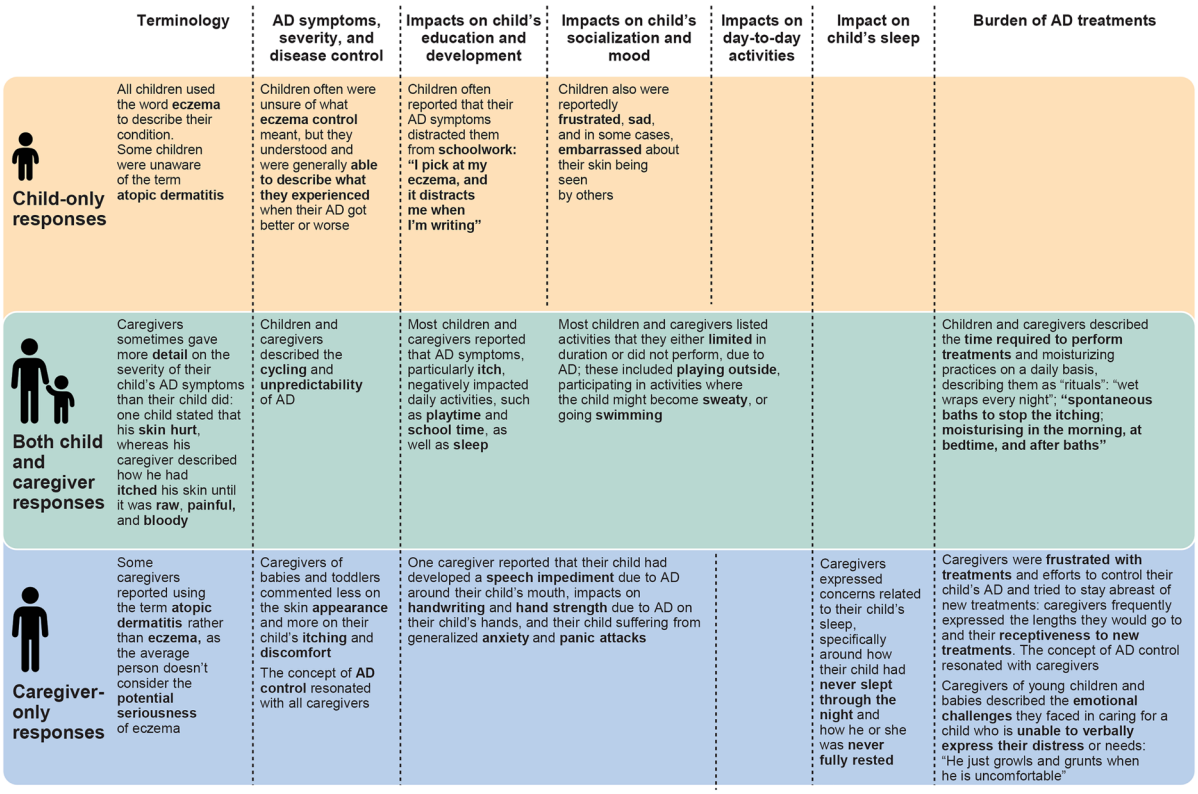

Fig. 2 Caregiver and child experiences with AD. *AD* atopic dermatitis

For the Caregiver ADCT, a single draft item was tested with caregivers in the first round of interviews for disease severity (item 1), impact on sleep (item 4), impact on daily activities (item 5), and impact on mood and emotions (item 6). Two draft item options were tested in the first round of interviews for the concept of itching (item 2) and bother (item 3). For itching, caregivers preferred item option (A) "over the last week, how many days did your child have intense episodes of itching because of his or her eczema?" to item option (B) "over the last week, how many days did your child scratch a lot because of his or her eczema?", as they felt that "intense episodes of itching" better described their child's symptoms. For bother, caregivers preferred item option (B) "over the last week, how much did your child seem bothered by eczema?" to item option (A) "over the last week, how bothered did your child seem to be by eczema?", as they felt that the wording of item option B made more sense. The time-based recall period "over the last week" tested well among caregivers during the first round of interviews, with all participants able to recall their child's symptoms, experiences, and behaviors over the previous 7 days.

Instrument Refinement

The Child ADCT version was named the Child Eczema Control Tool (ECT), as the children had reported they were unfamiliar with the term "atopic dermatitis". For each of the six ADCT concepts in the Child ECT, the two modified item options that were tested in the first round of interviews were reduced to one item per concept on the basis of participant feedback. For the concept of disease severity, item option (A) "over the last week, how bad was your eczema?" was retained over item option (B) "how bad are your eczema symptoms (such as itching, dry skin, and skin rash)?". The four-option response set "not bad at all," "a little bad," "pretty bad," and

"very bad" was retained for all items covering the concept of itching (item 2), bother (item 3), impact on sleep (item 4), impact on daily activities (item 5), and impact on mood and emotions (item 6). Additional changes to the draft Child ECT following the initial round of interviews included removal of "atopic dermatitis" from the interview instructions, retaining "over the last week" for all items when asking children to recall symptoms, and removal of the term "grouchy" from the item regarding the concept of impact on mood and emotions (item 6).

For concepts for which several item options were included in the first round of interviews in the Caregiver ADCT, the favored item option on the basis of caregiver feedback was retained. For the concept of itching, item option (A) "over the last week, how many days did your child have intense episodes of itching because of his or her eczema?" was retained over item option (B) "over the last week, how many days did your child scratch a lot because of his or her eczema?". For the concept of bother, item option (B) "over the last week, how much did your child seem bothered by eczema?" was retained over item option (A) "over the last week, how bothered did your child seem to be by eczema?". No changes were required for the interview instructions, as these were well understood by caregivers during the initial interviews. On the basis of participant feedback, "over the last week" was retained across all items in the Caregiver ADCT. The response scales used in the original ADCT were found to be appropriate during the initial round of interviews and were retained in the draft Caregiver ADCT.

Second Round of Qualitative Interviews and Instrument Finalization

Following refinement of the ADCT instruments, a second round of qualitative interviews was conducted with children ($n = 11$) and with caregivers ($n = 6$). For the Child ECT, participants found all items to be relevant, clear, and easy to answer, allowing for finalization of the instrument with no additional modifications (final version available at https://www.adcontroltool.com/accessadct). Although children were easily able to answer all items, some, as in the initial round of interviews were unable to think back a full 7 days. For the Caregiver ADCT, all participants found the instrument items to be relevant, clear, and easy to answer, so the instrument was finalized with no additional modifications (final version available at https://www.adcontroltool.com/accessadct).

Alignment Between the Child ECT and the Caregiver ADCT

Responses to the Child ECT and Caregiver ADCT instruments were generally well aligned. Children and caregivers both reported that the ADCT measured relevant concepts and reported that they believed it to be comprehensive for the measurement of AD control. Some caregivers also stated that additional concepts may be important to consider when evaluating AD control, including impacts on developmental delays and mental health ($n = 3$) and the role of triggers and allergies ($n = 2$).

Questions relating to the impact of AD on sleep (item 4), impact on daily activities (item 5), and impact on mood and emotions (item 6) sometimes generated a more frequent response from caregivers than children. For example, some caregivers stated that they were sometimes more aware of the impact of AD on their child's sleep than their child and that they could easily detect the impact of AD on their child's sleep on the basis of their child's behavior or mood in the morning. Regarding daily activities, while children tended to think about the impact of AD on school and play activities, caregivers often considered the impact of AD on a wider range of daily activities, including those affected by daily treatments and moisturizing, such as morning or bedtime routines, and the frequency or duration of baths. Children also were found to have a more limited insight into the impacts of AD on their mood and emotions, with caregivers discussing the broader impact of AD on their child's personality, such as their self-confidence and anxiety. Caregivers also commented on the importance of capturing the impact of AD on their child's

mood and emotions, as these impacts can be overlooked during clinical AD assessments.

DISCUSSION

The ADCT is an established instrument for measuring disease control in adult and adolescent patients with AD. In this study, we developed two modified versions of the original ADCT, for use by children and/or their caregivers. The Child ECT and Caregiver ADCT instruments were found to have content and face validity in their target populations. Our methods followed the US FDA guidance on patient-reported outcome measurement instruments [11]. These novel versions of the ADCT will allow the assessment of AD control in patients under 12 years of age in clinical trials and clinical practice.

Although child and caregiver responses were well aligned, some differences relating to the impacts of AD on their child's sleep, daily activities, and mood and emotions were observed, with caregivers having a broader perspective. This finding supports the importance of children aged 8–11 years completing the ADCT instrument in conjunction with their caregivers, when possible, to ensure that the full impact of AD on the patient is captured. It may be that some children aged 8–11 years are unable to independently complete the Child ECT reliably and consistently owing to difficulties in recalling the previous 7 days. Healthcare providers and caregivers should therefore decide whether to use the Child ECT, Caregiver ADCT, or both instruments in each case on the basis of a given child's needs and development level.

The development of both the Child ECT and Caregiver ADCT instruments is important for the management of pediatric AD, as clinical practice guidelines for the management of AD recommend that clinicians assess the impact of a patient's AD on daily activities [4], but until now there has been no validated instruments to assess overall disease control in this patient population. Indeed, the ADCT has now been included in the HOME outcome set for clinical practice [9]. By enabling the rapid assessment of self or caregiver-assessed AD control in patients under 12 years of age, the Child ECT and Caregiver ADCT instruments will likely be useful for physicians who manage AD in clinical practice. For instance, access to these validated instruments might facilitate a more standardized assessment of AD symptom control between patient visits, be incorporated into patient therapeutic monitoring, and provide clinicians with usable feedback on an individual's AD control, enabling enhanced clinical management when disease control is not attained. This study showed that the instruments can be completed using remote digital methods, which allows for triage of patient appointments and better monitoring and management of patients who are unable to access AD treatment face-to-face. The Child ECT and Caregiver ADCT instruments also may be useful in future clinical trials in this patient population, enabling investigators to capture the impact of novel therapies or treatment regimens on disease control in patients under 12 years.

While these results confirm the content validity of the novel Child ECT and Caregiver ADCT instruments, further studies will be required to assess the measurement properties of each instrument, such as the construct validity, known-groups validity, ability to detect change, internal consistency, and reliability through quantitative evaluation in different settings and to estimate disease control as well as clinically meaningful thresholds to define disease control status and contextualize the interpretation of scorings. The sample size was small for non-white children and caregivers, who may not perceive AD control in the same way as white patients. The study did not leverage FDA guidance for reporting of race and ethnicity and further information relating to other participant background characteristics, such as region, were not collected.

CONCLUSIONS

This study describes the development and qualitative validation of the Child ECT and Caregiver ADCT, demonstrating that both have content and face validity for assessing symptom control

in patients with AD aged less than 12 years. The findings highlight the importance of capturing perspectives on AD control from both children and their caregivers. The Child ECT and Caregiver ADCT can be used in clinical practice and research as additional tools to optimize AD treatment decisions.

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Data Availability. The datasets generated during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of Interest. E.S. received personal fees from AbbVie, Amgen, Arena Pharmaceuticals, Benevolent AI Bio Limited "BAI", BiomX Ltd, Bluefin Biomedicine, Boehringer Ingelheim, Boston Consulting Group, Collective Acumen LLC (CA), Coronado, Dermira, Eli Lilly, Evidera, Excerpta Medica, Forte Bio RX, Incyte, Janssen, Kyowa Kirin Pharmaceutical Development, LEO Pharma, Medscape LLC, Ortho Dermatologics, Pfizer, Regeneron, Sanofi, and SPARC India; and grants (or principal investigator role) from AbbVie, Amgen, Eli Lilly, Incyte, Kyowa Hakko Kirin, LEO Pharma, Merck, Novartis, Pfizer, Regeneron, Sanofi, and Tioga and Vanda Pharmaceuticals. D.M.P. was a consultant for Abbott Laboratories, Amgen, Asana BioSciences, LLC, Atacama Therapeutics, Bickel Biotechnology, Biofrontera AG, Celgene Corporation, Dermira, Dermavant Sciences, DUSA Pharmaceuticals, Inc, Eli Lilly and Company, LEO Pharma, US, Merck and Co, Inc, Novartis Pharmaceuticals Corp, Novo Nordisk A/S, Ortho Dermatologics, Peplin, Inc, Pfizer, Inc, Photocure ASA, Promius Pharma, LLC, Regeneron Pharmaceuticals, Inc, Sanofi, Stiefel (a GSK company), TDM SurgiTech, Inc, TheraVida, Inc, and Valeant Pharmaceuticals International. J.D., M.B., and S.F. received research funding for the current study from Research Triangle Institute Health Solutions. Z.W. is an employee and shareholder of Regeneron Pharmaceuticals, Inc. C.C.C. is an employee and may hold stock and/or stock options in Sanofi.

Ethical Approval. This study was conducted in accordance with the ethical principles of the Declaration of Helsinki of 1964 (including its later amendments) and the International Council for Harmonization Good Clinical Practice guideline. This study received Research Triangle Institute institutional review board approval.

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