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SYSTEMATIC REVIEW

Measurement properties of patient-reported outcome measures for eczema control: a systematic review

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Abstract

Atopic eczema (herein referred to as 'eczema') is a skin disease characterized by remitting and relapsing symptoms. The Harmonising Outcome Measures for Eczema (HOME) initiative was developed to establish a core outcome set (COS) for eczema to be measured for all future eczema trials. The core outcome set for atopic eczema clinical trials includes the domain for patient-reported eczema control, but a review of the validation of available eczema control instruments was lacking. We aimed to review the literature and systematically assess the measurement properties of validated patient-reported outcome instruments that capture eczema control. PubMed and Ovid EMBASE were searched up to 24 January 2020 for any study that reported on PROM instrument development or validation. The COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) criteria were used to assess the quality of eligible studies. We screened 12 036 titles and abstracts and 58 full texts. A total of 12 papers were included, reporting on seven PROMS. These were assessed with respect to development, reliability, construct validity and responsiveness. Two instruments, Recap of Atopic Eczema (RECAP) and the Atopic Dermatitis Control Tool (ADCT), have been developed and validated to a sufficient standard to support their recommendation as patient-reported outcome instruments for measuring control of atopic eczema as part of the HOME Core Outcome Set.

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Conflicts of Interest

LH, KST, NKR and JRC contributed to development of the Recap of Atopic Eczema (RECAP) measurement instrument. ES contributed to development of the Atopic Dermatitis Control Test (ADCT). ES reports grants, personal fees and other from Lilly, Incyte, Kyowa Hakko Kirin, Leo Pharmaceutical, Pfizer, Regeneron, Sanofi-Genzyme, grants from Merck, personal fees Abbvie, Dermira, Forte Bio Rx and Janssen, all outside the submitted work. LH reports a PhD Studentship from the British Skin Foundation during the conduct of the study. BLS, LH, JRC, NKR, ES and KST are all members of the HOME initiative. DG, EG and TP have no conflicts to declare.

Funding source

No funding was received for this work.

Introduction

Rationale

Atopic eczema (herein referred to as 'eczema') is a common chronic, inflammatory skin disease characterized by itching and dry skin. It typically develops in children aged two years or under, but adult onset may also occur.

Many people experience relapsing and remitting symptoms, with periods of 'flare', during which their eczema worsens.[1] Given this episodic nature, it is important to capture whether patients are able to get and maintain control of their disease.

The Harmonising Outcome Measures in Eczema (HOME) initiative aims to create a Core Outcome Set to be used in all eczema clinical trials. During the HOME II consensus meeting in Amsterdam in 2011, long-term control of eczema was included through consensus vote as one of the four domains deemed important to measure in all trials of eczema. Additional domains included clinician-reported signs, patient-reported

symptoms and quality of life.[2] Multiple HOME meetings subsequently took place, but challenges arose regarding how eczema control should be defined.

An international qualitative study including patients, parents and clinicians suggests eczema control is a multifaceted construct involving changes in disease activity, the treatment and management of the condition and psychological, social and physical functioning.[3] It was agreed by consensus at *HOME V that the long-term control domain represents something in addition to repeated measures of signs, symptoms, quality of life and recommended addition of a patient-reported global instrument that captures eczema control.*[4] *This review sought to identify suitable instruments for capturing 'eczema control'. The HOME domain of long-term control is conceptualized as repeated measurement of eczema control over time, in addition to the other core outcome set domains.*

A previous systematic review was conducted to explore which strategies were available for measuring the HOME domain of long-term control.[5] However, that review was not specific to eczema control and did not assess the methodological qualities of the included measurement tools. *The current review was designed to identify instruments suitable for capturing the construct of 'global eczema control' as recommended at the HOME V meeting and evaluated the measurement properties of the identified instruments.*

Objectives

1 To identify all validated patient-reported outcome instruments that capture control of eczema.
2 To systematically assess the measurement properties of those instruments with respect to validity, consistency, reliability, responsiveness and measurement error, guided by the COSMIN guidelines.
3 To provide an evidence base for future recommendations by HOME for instruments measuring long-term control of eczema in clinical trials to be included in a Core Outcome Set.

Methods

Protocol and registration

The study was both conducted and reported in line with the PRISMA guidelines and was preregistered on 26 May 2020 on PROSPERO (CRD42020162312).

Eligibility criteria

We included any study that reported on patient-reported outcome measurement (PROM) instrument development or validation. The instruments had to be designed to capture patient-reported control of eczema of any severity in either adults or children. *The papers had to either explicitly state that the instrument measured eczema control or both reviewers had to agree that the instrument met the following definition of eczema control* 'a multifaceted construct involving changes in the signs and symptoms of eczema, psychological, social and physical functioning, and the treatment and management of the condition'.[3] Only instruments pertaining to atopic eczema were included.

This review was designed to inform HOME consensus decisions at the HOME VII meeting in Japan.[6] It was agreed at the HOME V meeting in France that eczema control should not be measured by flares or well-controlled weeks[4] Therefore, papers that sought to validate these measures were excluded. Quality of Life is a separate domain for HOME purposes and therefore papers which define control in terms of quality of life were excluded. Similarly, 'itch' is a subdomain of the symptoms domain, and so papers developing or validating measures of itch were not included. Finally, it is not possible to undertake The COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) assessment process (see below) where only an abstract is available. Therefore, conference abstracts were excluded.

Information sources and searches

Searches were run in Ovid Embase and PubMed on 24 January 2020 as these are the two databases for which the COSMIN filter is available for validation studies.[7] The search strategies (see Appendix S1) combine alternative free text terms and subject headings for three search concepts, to be combined using the Boolean operator AND: (1) atopic dermatitis, (2) disease control and (3) the relevant COSMIN filter for the database concerned. There were no language restrictions.

In addition to the search of the databases above, we undertook a survey of the membership of the HOME membership and contacted experts in the field to identify any relevant instruments that were in development.

Data collection and data items

The review followed the process set out in the COSMIN guidance for systematic reviews of PROMs.[8]

As per the COSMIN guidelines, we assessed the following measurement properties:

- Content validity
- Internal consistency
- Structural validity
- Hypotheses testing (construct validity)
- Cross-cultural validity
- Reliability
- Measurement error
- Responsiveness

Data were extracted in an Excel spreadsheet developed for the review. Data extraction was performed independently by two paired reviewers (BS, LH, RP, JC, EG, TP and ES) with adjudication by others in the study team, who had not reviewed the instrument, in case of disagreement (JC, KT and ES). Measurement properties were determined as sufficient, insufficient,

indeterminate, not assessed or not applicable as outlined in step two of the COSMIN assessment.[9] Measurements that had insufficient content validity were deemed not to capture the construct of interest and were therefore not assessed further.

PROMs can be developed based on a reflective or a formative model.[10] Internal consistency and structural validity are not appropriate assessments for multi-item scales developed using a formative model.[8,11] Therefore, these have not been assessed for PROMs developed using this approach.

Extracted information for each paper included:

- Study characteristics including author, year, country of origin and study design.
- Characteristics of the PROM including construct being measured, the target population, the number of items and response categories.
- Measurement properties of the instruments including content validity, ease and usefulness of interpretation and item fit statistics.

Risk of bias

The COSMIN checklist was used to evaluate the methodological quality of included studies. This is undertaken first for each study individually using the COSMIN Risk of Bias checklist.[9,12]

For each of the measurement properties, the COSMIN checklist consists of 5–18 items covering methodological standards (organized in nine boxes for the nine measurement properties). In addition, each item can be scored on a four-point scale (i.e. 'inadequate', 'doubtful', 'adequate' and 'very good'). Taking the lowest rating for each item in one box, an overall score is obtained for each measurement property separately.

Summary measures and strategy for data synthesis

Due to the measurement properties being assessed in this review, data have been synthesized qualitatively in accordance with the methodology outlined in the COSMIN guidelines.

For each included PROM, the data were combined into an overall score of sufficient, insufficient, indeterminate, not assessed or not applicable for the measurement property.[8]

Risk of bias across studies

An overall GRADE of quality for that instrument has been produced (High, Moderate, Low or Very Low).

Taking into account this rating, alongside issues of interpretability and feasibility, if relevant, a recommendation was then made on the PROM or PROMs with the best validity for use in measuring control in eczema patients. The criteria set out by COSMIN are[8] as follows:

- A – Evidence for sufficient content validity and at least low-quality evidence of sufficient internal validity if applicable (PROM can be recommended).
- B – PROMs that may have the potential to be recommended, but further validation studies are needed.
- C – High-quality evidence for an insufficient measurement property (PROM should not be recommended).

Results

Study selection

We identified 14 272 papers and after removing duplicates 12 036 were screened by two reviewers (BS and LH) for eligibility. One additional instrument was identified from the 106 responses received from the survey of HOME members. We obtained 58 full texts and identified 12 eligible papers reporting on seven instruments[3,13-23] (Fig. 1).

Table 1 sets out the key characteristics of all included scales. All scales were developed and validated in English, with the exception of the Patient Benefit Index (PBI) 2.0 which also had a German version. The English version of the PBI 2.0 was the one assessed in this review. There was one single-item patient global severity measure and five multi-item instruments. Only RECAP, ADCT and Atopic Dermatitis Score 7 (ADS7) specified a recall period. RECAP and ADCT were validated over a 1-week period. ADS7 has two questions which are completed daily for 7 days and then a total score calculated for the 7-day period based on the daily recall. RECAP and ADS7 were validated for use in both adults and children whilst the others were for use in adults only. Review authors involved in the development/validation of an eligible control scale were not permitted to assess their own instruments.

Risk of bias

We judged all PROMs to have been developed using a formative model, and therefore, structural validity and internal consistency were not assessed. None of the studies assessed measurement error or cross-cultural validity. Table 2 sets out the ratings.

The quality of the validation studies of the Atopic Eczema Score of Emotional Consequences (AESEC) scored as doubtful and ADS7 and the Impact of Chronic Skin Disease on Daily Life (ISDL) as inadequate, on the PROM development. These were downgraded due to the concept elicitation aspect. The methods used to explore the relevance and the comprehensiveness of the included questions were not conducted in a manner consistent with the COSMIN recommendations on qualitative interviewing.

The quality of the RECAP and ADCT validation studies were rated as 'very good' across all assessed domains.

Methodological quality and quality of evidence across studies

The methodological quality, rated as sufficient, insufficient or inconsistent and the GRADE rating (high/moderate/low/very low) for each instrument is set out in Table 3.

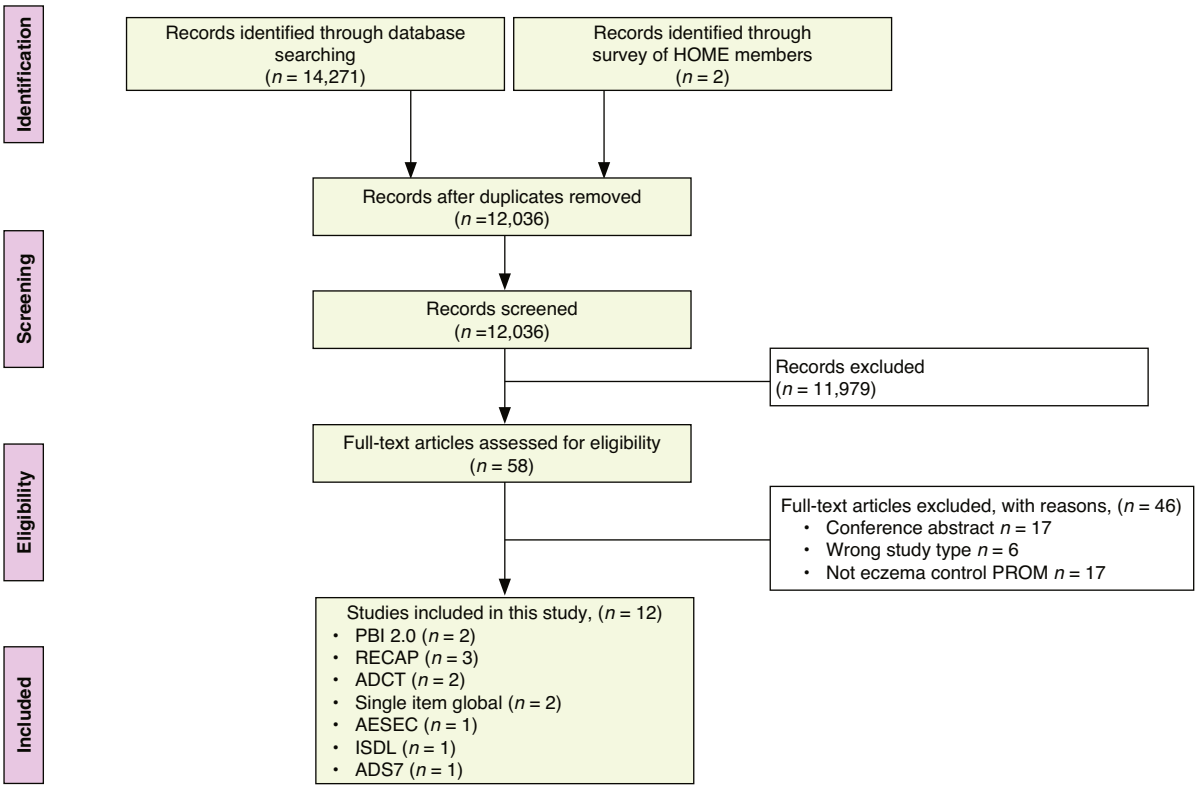

Figure 1 PRISMA Flow Diagram.

Table 1 Characteristics of included studies

Author/Year	Instrument	Country/language	Recall period	Target population	Number of items	Sample size
Howells *et al*. 2019 Howells *et al*. 2020 Bhanot *et al*. 2020	Recap of Atopic Eczema (RECAP)	UK/English	1 week	Adults and children	7	97 330
Simpson *et al*. 2019 Pariser *et al*. 2020	Atopic Dermatitis Control Tool (ADCT)	United States/ English	1 week	Adults	6	1010 270
Blome *et al*. 2016 Topp *et al*. 2019	Patient Benefit Index (PBI) 2.0	English, German	N/A	Adults	24	16 64
Vakharia *et al*. 2018 Silverberg *et al*. 2018	Single-item	United States/ English	N/A	Adults	1	265 602
Arents *et al*. 2019	Atopic Eczema Score of Emotional Consequences (AESEC)	9 European countries (Czech Republic, Denmark, France, Germany, Italy, Netherlands, Spain, Sweden, UK)/English	N/A	Adults	28	1189
Evers *et al*. 2008	Impact of Chronic Skin Disease on Daily Life (ISDL)	Netherlands/English	N/A	Adults	16	128
Darrigade *et al*. 2019	Atopic Dermatitis Score 7 (ADS7)	Belgium/English	1 day	Adults and children	2	81

The AESEC was assessed as insufficient with respect to content validity. AESEC was in part developed using free-text responses to a question via a social media platform. It is unclear whether this approach to PROM development would elicit all the key aspects of eczema control, nor that the final questionnaire items had been tested with the population of interest for

Table 2 COSMIN Risk of bias checklist (Very good, adequate, doubtful and inadequate)

Instrument	PROM development	Reliability	Hypothesis testing/ construct validity	Responsiveness
RECAP	Very good	Very good	Very good	Very good
ADCT	Very good	Very good	Very good	Very good
PBI 2.0	Adequate	Not assessed	Very good	Very good
Single-item	Adequate	Not assessed	Very good	Very good
AESEC	Doubtful	Not assessed	Very good	Not assessed
ISDL	Inadequate	Not assessed	Very good	Very good
ADS7	Inadequate	Not assessed	Very good	Not assessed

comprehensibility. As such, it was not further assessed. While lacking content validity for eczema control, it may have adequate content for emotional consequence of the disease – its intended purpose.

Similarly, the ADS7 was assessed as insufficient with respect to content validity, as it was not clear how the PROM content had been developed or validated. As such, it was also not further assessed.

The ISDL was inconsistent with respect to content validity. The relevance and the comprehensiveness were very good, but it was unclear whether the response options matched the question or were clearly understood by the intended population. The overall PROM development was rated as inadequate, and therefore, the GRADE rating of the evidence was low.

The single-item patient global severity measure asks 'Would you describe your AD or eczema as mild, moderate or severe?'[19,20] was similarly downgraded for content validity to inconsistent because it was unclear whether the response options were appropriate to the concept of control. This instrument may have appropriate content validity for patient-reported disease severity.

The study assessing responsiveness for PBI 2.0 reported that not all hypotheses for testing responsiveness were met; therefore, responsiveness is scored 'inconsistent'.

Where they were reported, reliability, responsiveness and hypothesis testing tended to be sufficient for all instruments, with moderate to high-quality evidence.

Recommendations

Based on the risk of bias, the overall rating and the quality of the evidence, the RECAP and ADCT scored 'A', suggesting that they could be recommended for the Core Outcome Set The single-item measure, PBI 2.0, AESEC, ISDL and ADS7 scored 'B', as there was no high-quality evidence of insufficient measurement properties, which would be the requirement for a score of C.

Discussion

The review suggests that the RECAP and ADCT were of moderate to high quality and had sufficient evidence of good measurement properties. Both scales are well validated by COSMIN standards and scored an 'A' for the overall evidence, suggesting that they could be considered for inclusion in the core outcome set. The two instruments were developed independently but are similar; both multi-items scales with a recall period of one week, validated in English only. The questionnaires cover similar domains with similar response values scored 0-4, though RECAP has an additional question separating itch from intense itch. Whilst RECAP is validated for use in adults and children, ADCT is currently validated only for use in adults. Recommended cut-offs for defining eczema control are available for ADCT but not for RECAP.

In April 2019, a preliminary version of these results, based on scoping searches, was presented at HOME VII and used to inform initial decisions about a recommended PROM for the long-term control domain.[6] Some results were amended following further independent COSMIN assessments and changes to reporting of some studies following peer review (See Appendix S1 for summary of changes). HOME provisionally included RECAP and ADCT in their core outcome set, subject to further research and assessment. This review supports that recommendation. Whilst the single-item patient global assessment also was considered, HOME decided that the response options did not adequately capture the concept of eczema control and so this could not be recommended as a global measure of eczema control.

The AESEC and ADS7 did not have sufficient content validity for further assessment. Based on the currently available published literature, they are not suitable measures for eczema control, though they may capture other important aspects of the patient's experience of eczema. Similarly, whilst the IDSL had some aspects that were sufficient, overall evidence was low for content validity, which made it unlikely to be suitable as a core measure of eczema control.

Strengths and limitations

This was a formal systematic review which followed the COSMIN methodology. This is a robust process that aims to provide the best evidence for decisions about the validation of measurement instruments.

However, we have only been able to assess those aspects of validation that have been reported in the published papers. It was not always reported whether a formative or reflective approach to development was used. We have had to use our

Table 3 Methodological quality and overall quality of evidence

	RECAP		ADCT		PBI 2.0		Single-item		AESEC		ISDL		ADS7	
	Overall rating	Quality of evidence	Overall rating	Quality of evidence	Overall rating	Quality of evidence	Overall rating	Quality of evidence	Overall rating	Quality of evidence	Overall rating	Quality of evidence	Overall rating	Quality of evidence
	+ / − / ±	High, moderate, low, very low	+ / − / ±	High, moderate, low, very low	+ / − / ±	High, moderate, low, very low	+ / − / ±	High, moderate, low, very low	+ / − / ±	High, moderate, low, very low	+ / − / ±	High, moderate, low, very low	+ / - / ±	High, moderate, low, very low
Content validity	+	High	+	High	±	Moderate	±	High	−	Very low	±	Low	−	Very low
Reliability	+	High	+	High	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed
Hypothesis testing/construct validity	+	High	+	High	+	High	+	High	Not assessed	Not assessed	+	High	Not assessed	Not assessed
Responsiveness	+	High	+	High	±	High	+	High	Not assessed	Not assessed	+	High	Not assessed	Not assessed

judgement to determine this. It is possible that PROMs we felt had taken a formative approach in fact used a reflective approach. Moreover, no papers assessed measurement error or cross-cultural validity, which are aspects that are likely to be important for PROMs that are included in a core outcome set. All PROMs would benefit from further validation work.

Clinical and research implications

Whilst further work is required to assess aspects of validity for the recommended instruments, HOME has now recommended a full Core Outcome Set, including two of the instruments assessed in this review.[6] The aim is for these to now be adopted in all clinical trials in eczema which measure eczema control.

This review suggests that the recommended instruments have been developed and validated in a robust process. Whilst a preliminary version of this review was presented to help the attendees at the HOME VII meeting reach a decision, this full review supports the decision made during the meeting. However, it also highlights a number of areas for each instrument that have not been fully validated. As these instruments become more widely used in clinical trials, researchers may wish to build in further validation work, for example on measurement error, cross-cultural validity and interpretability.

There is also further work to be done to understand how these PROMS relate to one another – we do not yet know whether a single-item patient global measure would perform as well as the multi-item scales or whether these multi-item scales ultimately are very similar and just one could be recommended or whether both tools need to remain in the Core Outcome Set to fully capture this domain. Similarly, we do not know to what extent these multi-item scales capture a construct that is truly distinct to repeated measures of signs/symptoms/quality of life. As studies adopt the Core Outcome Set, it may be useful to undertake secondary analyses of the collected data to explore the extent to which these domains are truly distinct underlying constructs. This may have the potential to reduce the Core Outcome Set instruments and therefore reduce participant burden in future trials.

Conclusion

RECAP and ADCT have been developed and validated to a sufficient standard to support their recommendation as PROMS for measuring control of atopic eczema.

Ethical approval

Not required.

Authorship statement

BS, LH, JC, DG, NKR and KT drafted the protocol and PROSPERO registration. DG developed the search terms with input from all authors and BS and LH acquired the data. BS, LH, RP, JC, EG, TP and ES extracted and evaluated the data. BS and LH

drafted the manuscript and all authors contributed to and approved the final version.

Data sharing

No additional data are available.

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Supporting information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. PROMs for eczema control -validation studies review.