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Development and initial testing of a new instrument to measure the experience of eczema control in adults and children: Recap of atopic eczema (RECAP)

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What's already known about this topic?

- Eczema control has been identified as an important outcome by key stakeholders in eczema research (including patients, carers, healthcare professionals, and researchers).
- Qualitative studies suggest eczema control is a multifaceted and individual experience and no instrument has been identified that captures eczema control in this way.

What does this study add?

- We have developed Recap of atopic eczema (RECAP), a seven-item questionnaire to capture the experience of eczema control in all ages and eczema severities. There are two versions: a self-reported version for adults/older children with eczema, and a caregiver-reported version for younger children with eczema.
- Designed with input from people with eczema, caregivers, and healthcare professionals to ensure good content validity.
- Initial testing of score distributions and construct validity suggests good measurement properties.

What are the clinical implications of the work?

- The RECAP instrument is appropriate and feasible for measuring eczema control in clinical trials and may also be useful in routine practice.

Abstract

Background: Eczema control has been identified as an important outcome by key stakeholders in eczema research (including patients, carers, healthcare professionals, and researchers) but no validated instruments for the domain have been identified.

*Objective: t*o develop a measurement instrument to capture a patient's perspective of eczema control that is suitable for use in eczema clinical trials.

Methods: Best practice for development of a patient-reported outcome was followed. A mixed-methods approach was used to develop and refine a conceptual framework, generate, refine and

select items and to test the distribution and construct validity of the final scale. The mixed-methods approach involved expert panel meetings (including patient representatives, healthcare professionals and methodologists), and data collection using a focus group, cognitive interviews and an online survey with people with eczema/caregivers. Multivariable linear regression was used in the item selection process.

Results: Fourteen expert panel members co-produced the instrument; with input from people with eczema/caregivers via a focus group (n=6), cognitive interviews (n=13) and an online survey (n=330). The resulting instrument, Recap of atopic eczema (RECAP), is a seven-item questionnaire that captures eczema control via self or caregiver report. The development process aimed to ensure good content validity and feasibility. Initial testing suggested no floor or ceiling effects and good construct validity. Hypothesised correlation with the Patient-Oriented Eczema Measure was confirmed ($r(258) = 0.83$, $p < 0.001$).

Conclusion: RECAP has the potential to improve reporting of eczema control in research and clinical practice. Further exploration of measurement properties is required.

Key words: patient-reported outcome, measurement instrument, atopic eczema, atopic dermatitis, long-term control of eczema

Main body text: 3133 words

Introduction

Atopic eczema (syn. eczema, atopic dermatitis) is a common, chronic condition that is characterised by itchy, dry skin that can become cracked and score and often has a relapsing and remitting disease course. The Harmonising Outcome Measures in Eczema (HOME) initiative recommends 'long-term control of eczema' as a core outcome domain that should be measured in every clinical trial over 3 months in duration, indicating that it is an important outcome for a range of stakeholders (including patients, carers, healthcare professionals and researchers) (1).

Consensus voting at the HOME V meeting in June 2017 identified the need for a patient global assessment of eczema control (2).

Qualitative research involving people with eczema, their caregivers and healthcare professionals suggests that 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, 4). Measuring such a complex construct over time can be challenging, but instruments to capture long-term control have been developed in other chronic diseases such as asthma and urticaria (5, 6).

This study aimed to develop a new outcome measurement instrument to capture a patient's perspective of eczema control for use in research and clinical practice. The study objectives were to: 1) develop an instrument to capture eczema control that is suitable for use in both adults and children with eczema and 2) conduct preliminary validation of the new instrument (including assessment of floor and ceiling effects and construct validity).

Methods

Study Design

This mixed-methods study included five stages of instrument development as summarised in Figure 1. Methodological guidance for instrument development were followed (7-11). The development process was guided by an international expert panel consisting of three dermatologists, a dermatology nurse, a general practitioner, two adults with eczema, two caregivers of children with eczema, four methodologists, and a psychologist. Five countries (UK, Germany, Sweden, The Netherlands, and Australia) were represented on the expert panel. This project has been approved by the University of Nottingham's Faculty of Medicine & Health Sciences Research Ethics Committee (Refs: 18-1805 and F14062016 SoM ROD). Both the protocol and data analysis plan were uploaded to the Centre of Evidence Based Dermatology's registration portal *a priori* and can be referred to for further methodological details of the study: https://www.nottingham.ac.uk/research/groups/cebd/resources/protocol-registration.aspx.

Stages of Instrument Development

STAGE 1: Develop and refine the conceptual framework

Box 1 outlines the intended purpose of the instrument. The qualitative studies, and HOME V meeting discussions, suggest that the focus of this instrument should be individual 'perceptions' of eczema control. It also is worth noting that this construct as defined is not related to perceptions about the 'controllability of eczema', which might relate to what an individual thinks they can do, or what their treatment can do, to control their eczema, but about the attainment of control perceived when reflecting on their experience. The details of what are 'indicators of control' are presented in the conceptual framework (Figure 2). The conceptual framework was drafted by LMH, JC, CA and KT through synthesising findings from an international qualitative study (3, 4), an international patient survey (12), and a systematic literature review (13) relating to the construct of interest.

A 2 hour face-to-face focus group involving people with eczema and caregivers of children with eczema was conducted to confirm the conceptual framework and to ensure that key items had not been overlooked. This focus group was moderated by CA, who has experience moderating groups and training in qualitative research. The focus group followed a topic guide that included open discussion about the construct of interest, followed by discussion focused on the conceptual framework (Appendix A). The focus group was recorded and transcribed verbatim. The findings from the focus group were discussed by the expert panel who used this conceptual framework as a starting point to begin item design. The conceptual framework developed suggests this instrument requires a formative measurement model, which has impacted the methodology choices later in the development process.

STAGE 2: Item generation

Driven by the conceptual framework and a short guidance document on constructing questions the expert panel members submitted ideas for items to include in the instrument (9, 14). The items were then categorised and discussed by the panel. The items were either discarded, kept or amended to produce an initial working list of items.

STAGE 3: Item refinement

Cognitive interviews, which used a range of think-aloud and probing techniques, were used with the aim to improve the comprehension, comprehensibility and relevance of the questionnaire. The target population were adults (16+ years) with eczema or caregivers of children with eczema living in the UK. Children under 16 years could take part if their caregiver was present. Participants were recruited using existing mailing lists held at the Centre of Evidence Based Dermatology (CEBD) in Nottingham of people interested in eczema-related research and through social media. All participants had to be proficient in English language. There was no exclusion of participants based on age, eczema severity, sex or ethnicity and purposeful sampling aimed to achieve a diverse range of participants based on these characteristics.

Cognitive interviews lasting approximately one hour each took place either face-to-face, on the telephone, or video call depending on participant preference. All interviews were conducted by LMH, who has experience and training in qualitative research and the team received further support from a methodological advisor (PL). Interviews followed a semi-structured interview guide (Appendix B). The participants were asked to answer the items using think-aloud methods (15). The interviewer planned breaks to summarise and use pre-planned probes to encourage elaboration by participants. Once the think-aloud process was applied to all items, the interviewer then probed the participants about the items as a global set. Interviews took place in rounds, with the expert panel refining the content in between rounds, and subsequent rounds assessing if the changes had addressed the initial problems. It was planned that rounds would be continued until no further refinements were required. All interviews were recorded and transcribed verbatim.

STAGE 4: Item selection

An online survey was used to conduct an impact analysis, which uses information about frequency of occurrence and the importance of the experiences to assess relevance of each item. The aim of impact analysis is to assess the importance of each item, as formative models require that the most important items are represented. The survey was also used to conduct a backward stepwise regression analysis. The aim of regression analysis is to reduce the number of items and

ensure each item adds unique information about the experience of eczema control. The target population was the same as stage 3 as were the recruitment methods, although the latter was supplemented with the use of posters in various public settings (shops, cafes, libraries, universities, healthcare centres).

Variables included in the survey were age, sex, ethnicity, 'bother caused by the eczema' global eczema severity, the Patient-Oriented Eczema Measure (POEM), and items being considered for inclusion following the item refinement stage. Participants also indicated if that experience had occurred for them/their child over the past year and how important this experience is when thinking about their/their child's eczema.

STAGE 5: Instrument scoring and preliminary validation

The online survey described in stage 4 was also used to collect data on the final items chosen for inclusion so that these could be scored and tested. Overall scores for the final items were generated using scoring rules determined by the expert panel. These scores were then tested for distribution of scores. The aim was to ensure that the items did not produce a score with a floor or ceiling effect, which is where a high proportion of the total population has a score at the lower or upper end of the scale, respectively (7). They were also tested for construct validity, which aims to assess the degree to which the scores of the instrument are consistent with hypotheses that are based on the assumption that the instrument validly measures the construct to be measured (16).

Analysis

Focus group for stage 1: develop and refine the conceptual model

Experiences of eczema control were mapped onto the theoretical framework used in previous concept elicitation studies (3, 17). LMH and PL independently coded the data and met to discuss any discrepancies in coding. A qualitative descriptive approach was used to analyse the participants' responses to the conceptual framework (18).

Cognitive interviews for stage 3: item refinement

Data were analysed using a top-down coding approach, and refined with inductive coding (Table S1). All data were analysed by LMH, with secondary coding on selected transcripts by JC or AS. As it was not possible with resources available for all transcripts to be coded, transcripts for secondary coding were selected to include both early and final interviews, interviews containing a variety of problems across the coding framework, and selected transcripts with difficult to code problems. Discrepancies in coding were discussed and resolved via discussion. SR, KT, LMH and JC were all involved in ongoing discussions about the coding and between each round of interviews, any problems that were identified and potential solutions were fed back to the expert panel for their input. Based on a saturation model, interview rounds continued to test if problems from previous interview rounds were resolved until the authors were satisfied that there were no major problems that could be resolved via further cognitive interviewing. The final round tested items in the final wording that was then used in the online survey for further item reduction.

Online survey for stages 4 and 5: item selection, instrument scoring and preliminary validation

Data were analysed using STATA 15.

Impact analysis: For each item concept, the proportion of individuals who had experienced that in the past year was multiplied by the mean score of the importance rating (1 = not important, 5=extremely important) to give an impact score ranging from 0 to 5. Whole sample analysis and sub-group analysis by age of person with eczema (0-4 years, 5-15 years, 16+ years) were decided *a priori*. It was predefined that an impact score of less than 2 in any group analysed indicated that an item should not be considered for inclusion in the instrument, as was used in the development of the Urticaria Control Test (5).

Multivariable regression analysis: The potential items were entered as independent variables into multivariable linear regression models. The dependent variable was 'bother caused by eczema' (0-10 points). This dependent variable was chosen because there was no 'gold standard'

measure of 'eczema control' that could be used. 'Bother' caused by the eczema' was agreed by the expert panel to be the most closely aligned measure available (it has been used in previous eczema research) with the concept of 'eczema control' as defined for the development of RECAP. Sample size was calculated as at least 10 cases per independent variable. The backward elimination variable selection technique was used to determine which items remained in the model. The stopping criteria for this process was p=0.157, which is recommended for sample sizes with between 10 and 25 events per parameter (19). The assumptions of multicollinearity, linearity, normality of residuals and homoscedasticity of residuals were met.

Scoring: The expert panel agreed scoring rules resulted in all RECAP items being scored from 0-4 and weighed equally and added together (total scores ranging from 0-28), with a higher score indicating less eczema control.

Distribution of scores: Assessment of histograms. A floor or ceiling effect was defined prior to data collection as more than 15% of participants achieving the highest or lowest possible score (20).

Construct validity: Convergent validity assesses if instruments that are theoretically measuring similar constructs are related. POEM measures the construct of 'eczema-related morbidity' by monitoring eczema symptoms over the last week. A systematic review that included studies looking at the measurement properties of POEM concluded that there was limited evidence for good internal consistency, moderate evidence for good construct validity, good responsiveness and good content validity, and unclear evidence of test-retest reliability and measurement error (21-24). Interpretation of POEM has been assessed in the form of the minimally important change and severity bandings (22, 25-27). Pearson's correlation coefficients were used to assess the relationship between POEM (measuring patient-reported symptoms) and the newly developed instrument. It was hypothesised that correlations would be at least 0.3 (moderately correlated). Discriminative validity is where a measurement instrument is able to distinguish between subgroups of patients. This can be done by comparing the mean scores on the measurement instrument for the subgroups (7). Subgroups of participants were categorised based on scores from a global eczema severity measure and POEM severity categories (26). It

was hypothesised that there would be a linear trend of higher mean RECAP scores for each subgroup of participants categorised with more severe eczema on the global eczema severity measure and the POEM severity categories.

Patient and Public involvement

As expert panel members, two patients and two caregivers took part in face-to-face/video meetings, teleconferences and email feedback to co-design items and input into decisions throughout the process. All reviewed the wording and design of materials (including information sheets, consent forms, advertisement/posters, the online survey). NR and TB piloted the cognitive interview process to give the interviewer feedback on the process. The CEBD Patient Panel day (a patient and public involvement day at the University of Nottingham) provided input during item refinement process with some key, targeted queries to aid finding solutions to a problem exposed in the cognitive interviews.

Results

Participant characteristics

Number of participants, sex and self-reported ethnicity (where available) is reported for the focus group (stage 1) and the cognitive interviews (stage 3) in Table 1. Self-reported eczema severity ranged from mild to very severe in both the focus group and cognitive interviews. For the interviews, age of adults with eczema ranged from 37 to 64 years and all reported onset of eczema as young children. Age of children of the caregivers taking part ranged from 2 years and 8 months to 14 years. Onset of eczema was reported from 8 weeks old to 2 years and 6 months old. A total of 330 took part in the online survey (stage 4 and 5), but 6 of these participants only completed demographic variables. Table 2 provides the participant characteristics for the online survey.

Key stages of instrument development

STAGE 1: Develop and refine the conceptual framework

Figure 2 shows the initial conceptual framework that was presented to members of the focus group (although more detail was included relating to each concept). Mapping to the thematic framework indicated that data saturation for concept elicitation was reached. Participants confirmed that the framework represented an accurate model of 'eczema control' and that the conceptual framework was comprehensive. Nevertheless, some minor refinements were suggested, as summarised in Table 3. The final conceptual framework for the RECAP instrument, after refinement based on all stages of instrument design is presented in Figure 3. The conceptual framework suggests that a formative model is the best approach to developing the measurement model for this construct of interest as multiple unique factors are relevant to the experience, which when combined together, form the latent variable (7).

STAGE 2: Item generation

Fourteen expert panel members were each asked to submit questions that could be used to capture the key elements of eczema control as outlined in the conceptual framework. This process resulted in an initial list of 154 ideas, although many of the ideas gave multiple alternate options to capture the same concept. Using these as a starting point, the expert panel worked together to group, discard and amend items and make key decisions on how to present the items (e.g. number of response options). On the basis of this discussion, the lead researcher compiled a list of 25 items that were then revised and approved by the expert panel to be tested in the next phase of the development process.

STAGE 3: Item refinement

Thirteen interviews over four rounds took place (round 1: n=5, round 2: n=3, round 3: n=4, and round 4: n=1). The changes that took place over four rounds of cognitive interviews were; the recall period was changed from 4 weeks to 1 week; the number of response options was increased from 4 to 5; the items were changed from statements to questions; wording was changed to provide clarity; and language was amended to reflect terms respondents felt had

greater resonance and that increased the confidence of respondents in their ability to answer the questions. By the end of the interviews 15 items remained for further testing. Detailed results of this analysis are presented in Appendix C. However, only 14 items were included in subsequent analysis as the expert panel made the decision to remove the remaining treatment-related item, having reflected on the HOME V meeting decisions about the feasibility of treatment-related measures, the cognitive interview findings and the conceptual framework refinements.

STAGE 4: Item selection

Impact analysis: Data on frequency, importance and impact scores from the online survey are presented in Table 4. 'Feeling self-conscious' scored less than 2 in the age group 0-4 years and 'feeling isolated' scored less than 2 across all ages, in the age group 0-4 years and the age group 16+ years. It was pre-defined that any item with an impact score of less than 2 for any of our target groups was considered not relevant and therefore these two items were excluded from the subsequent regression analysis. Items on the 'acceptability', 'overall individual perception', and 'treatment been enough' were not included in the impact analysis due to the expert panel appraising that it was not appropriate to assess the frequency and importance of these items.

Multivariable linear regression analysis:

Two models were developed. The first model contained all 12 items that were still under consideration for inclusion in the final set of items as predictor variables. 'Bother caused by the eczema' was used as the outcome variable. Five predictor variables were removed from the model following a backward elimination item reduction technique with a stopping criterion of p = .157. These included items 'being unable to stop scratching' (p = .809), 'stopped from doing something wanted or needed to do' (p = .438), 'having flares' (p = .314), 'having any symptoms' (p = .809) and 'painful or sore skin' (p = .612). The results of the regression indicated that the seven remaining predictor variables explained 71.1% of the variance in 'bother caused by the eczema', R^2 = .718, adjusted R^2 = .711, $F(7, 256) = 93.19$, $p < .001$. Table 5 shows the predictor variables that remained in the model.

The second model contained 10 items as it excluded 'acceptability' and 'overall individual perception' due to expert panel concerns that the more global nature of these items may remove important but more specific items. Appendix D shows full results of model 2. The expert panel agreed model 1 as the final set of items using the evidence from all previous stages of development. Model 1 was considered to be comprehensive and explained a larger proportion of the variance than model 2 (Model 2: R^2 = .627, adjusted R^2 = .615, $F(8, 256) = 53.74$, $p < .001$). The final RECAP instrument can be found in Figure 4.

STAGE 5: Instrument scoring and preliminary validation

Each of the seven questions in RECAP carries equal weight and is scored from 0 to 4 (total score of 0-28) (Full scoring details in Appendix E). Figure 5 shows a normal distribution of scores and no floor or ceiling effects are present. The scores for the final instrument were significantly positively correlated with POEM scores, $r(258) = 0.83$, $p < 0.001$, which is in line with the hypothesis about convergence validity (construct validity). Table 6 illustrates how each increase in severity banding according to established POEM severity bandings and a single item global severity measure corresponded with a larger mean RECAP score for those scoring within that severity category (26), which is in line with hypotheses about discriminative validity (construct validity).

Discussion

RECAP is a patient or caregiver reported instrument to capture 'an individual's experience of eczema control' intended for use in clinical trials and routine care. RECAP, comprising of just seven questions, represents a practical and feasible approach to capturing a patient/caregiver's perspective of eczema control. The development process was designed to maximise the comprehensiveness, comprehensibility and relevance of the items to patients and caregivers whilst producing a tool that was feasible (16).

How eczema control is conceptualised has implications for the most appropriate measurement model to use in developing RECAP. The study team engaged in multiple discussions about whether the construct of interest for RECAP was best considered a reflective or a formative

model. It was considered that each item was tapping into a different characteristic, and contributing part of the construct, and when considered together they form the whole construct. Therefore, it was decided that a formative model was most appropriate. Furthermore, eczema control is a complex construct and therefore it was considered difficult to capture using only a single question, particularly as the term 'control' has multiple meanings in everyday language and can be interpreted in different ways (28).

Given that eczema control includes a dimension of time, it was considered important to ask about experiences of eczema during a defined period rather than "at the moment". It was initially felt that a 4-week recall period may be a better indicator of 'long-term' control. However the 4-week period used at the start of the study was found to affect the ability of patients to calculate a response due to difficulties with recall and if their eczema had varied greatly over that period of time, averaging out their experience (29). The chosen recall period of "the last week" is in line with FDA guidance, which states a preference for items that ask patients to describe their current or recent state (8).

Strengths and limitations

The instrument was purposefully developed so that it could be applied across all age groups and a self-report and caregiver-report version have been developed simultaneously to create a measure that will work across all trial populations. This quick to complete instrument could be easily transferred to online / smartphone application platforms. The questionnaire is free to access and use.

It may be that there are some differences in the way individuals who have eczema and caregivers perceive eczema control, which further research should explore. The initial development phase involved testing of the instrument in a UK population and English language only due to resources available. However, involvement of stakeholders across different countries in the development team was utilised to try and anticipate any difficulties in adaptation and translation that could be foreseen by the team. The recruitment methods were varied to try and reach different audiences. However, it is possible that there are potential biases in the types of people who would be willing to take part in focus groups, interviews, and online surveys voluntarily.

Conclusion

RECAP is a new instrument to capture 'eczema control' over the past week. It was developed according to best practice for the development of patient-reported outcome measures. Further studies are now required to confirm the psychometric properties of the RECAP instrument in different populations and confirm the suitability of RECAP for use in research studies and clinical practice.

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Figure-1 Study design for developing RECAP

Table 1 Focus group and cognitive interview participant characteristics

Participant characteristics	Focus group, N	Cognitive interviews, N
Total N	6	13
Adults	5	8
Sex:		
Male	2	0
Female	3	8
Ethnicity:*		
White-British		5
White-Scottish		2
Sikh		1
Caregivers	1**	
Child's Sex:		
Male	1	3
Female	0	2
Child's ethnicity:*		
White-British		5
Welsh/Maltese		1

**Note.* Ethnicity stated have been preserved as participant's reported. **Although only one person took part primarily as a caregiver, there were an additional two participants who are classified as adults with eczema in this table, but they also had experiences of caring for their children with eczema.

Table 2 Online survey participant characteristics

	N	%	Mean (SD)	Range
Age	324	-	22.71	0-66
Under 5 years*	62	19.14	-	-
5-15 years*	77	23.77	-	-
16+ years	185	57.10	-	-
Sex	322	-	-	-
Male	110	34.16	-	-
Female	211	65.52	-	-
Non-binary	2	0.62	-	-
Rather not say	1	0.31	-	-
Ethnicity	321	-	-	-
White	300	93.46	-	-
Bangladeshi	1	0.31	-	-
Black Caribbean	2	0.62	-	-
Chinese	6	1.87	-	-
Indian	6	1.87	-	-
Mixed Race	5	1.56	-	-
Other Asian (non-Chinese)	1	0.31	-	-
Sikh	1	0.31	-	-
Total POEM score	263	-	15.12 (7.37)	0-28
POEM severity banding	263	-	-	-
Clear-Almost clear	13	4.94	-	-
Mild	33	12.55	-	-
Moderate	95	36.12	-	-
Severe	96	36.50	-	-
Very severe	26	9.89	-	-
Global severity	266	-	-	-
Clear	6	2.26	-	-
Almost clear	34	12.78	-	-
Mild	65	24.44	-	-
Moderate	121	45.49	-	-
Severe	40	15.04	-	-
Bother caused by the eczema**	324	-	5.65 (2.56)	0-10

*For under 16-year olds the survey was completed by a caregiver in 95% of cases (n=132)

**How much bother has your/your child's eczema been over the past week?

Responses from 0 (No bother at all) to 10 (as much bother as you can imagine)

Box 1 Defining the purpose of the instrument (stage 1)

Intended purpose:	**Decision:**
Intended construct of interest:	The experience of eczema control. This was defined in this study as "the extent to which the various manifestations of eczema and the impact that these have for an individual are removed or meaningfully reduced."
Intended target population:	Individuals with eczema of all ages. However, for younger children who do not have the cognitive abilities to answer the questionnaire alone, it is intended that the information will be provided by caregivers or with the assistance of caregivers. The questionnaire is not intended to be exclusive to use in a single disease severity, disease duration, sex or ethnicity.
Intended context for use:	Primarily designed for use in clinical trials assessing any type of intervention in people with eczema. As a secondary aim, it was also anticipated that the instrument should be appropriate for use in clinical settings.

Figure 2 **Initial conceptual framework discussed at focus group**

Table 3 Refinements to the conceptual framework

Refinement of conceptual framework	Reasons wh
Addition of concept predictability of eczema	Participants at the focus group expressed a concern that the predictability of eczema, which related to eczema control in their perception, was not included in the conceptual framework.
Removal of item on predictability	The cognitive interviews suggested that an item asking directly about the predictability of the eczema was not interpreted in line with the construct of interest. It may be that this concept is a related but distinct outcome to be measured.
Removal of concept impact on family	The expert panel meeting led to discussions about designing items on the impact on family and it was felt strongly amongst stakeholders including patients that this concept was not universal to all. It was also suggested to be a related but distinct construct.
Removal of treatment and management concepts	The cognitive interviews revealed issues regarding the applicability and relevance of treatment items. The expert panel discussed these findings and reviewed the inclusion of these concepts within the framework. Some members wanted these concepts to remain, whilst others felt they were not part of the construct of interest. The discussions at the HOME V consensus meeting were also referred to, which indicated that stakeholders did not think treatment-related items were feasible in all clinical trials. Issues that were considered when making this decision: 1. Treatment and management related questions are answered differently depending on disease severity and type of treatment used. For example, only people with more severe eczema will have access to systemic therapies. 2. There is difficulty in distinguishing between answers that relate to eczema control and answers that relate to personal choice (e.g. a patient who does not want to use a particular treatment but has low level of control may answer in a way that appears congruent with good control). 3. In many clinical trial situations it is not always possible for patients to change or step up / step down their treatment so these concepts are not always applicable, but were one of the main features of understanding level of control in a non-trial setting by stakeholders who inputted into the conceptual model.
Removal of items on social impact	The online survey revealed that the items regarding social impacts

	were not applicable and relevant to young children. This finding was discussed amongst the expert panel who approved removing this concept.
Change in way 'overall individual perception' and 'acceptability' were included in the framework	In the initial conceptual model, "an acceptable level of control is an individual experience" was an overarching concept that was considered important, but it was not initially clear how this fit within the design of the instrument. Through expert panel discussions when interpreting the findings from the face to face focus group and designing items, it was acknowledged that items about the 'acceptability of eczema' to an individual and the individual's personal overall perception of 'how the eczema had been' were unique perceptions about the experience of eczema control that could be included as items in the measure.

Figure 3 Final conceptual framework

Note. The direction of the arrows indicate that a formative measurement model is most appropriate to use.

Table 4 Results of impact analysis**

	Frequency (Proportion)				Importance (Mean score)				Impact score (Frequency x Importance)			
Age group (years)	All	0-4	5-15	16+	All	0-4	5-15	16+	All	0-4	5-15	16+
Itchy skin	1	1	1	1	4.77	4.89	4.82	4.7	4.77	4.89	4.82	4.70
Flare	0.9963	1	1	0.9935	4.6	4.81	4.64	4.5	4.58	4.81	4.64	4.47
Had any symptoms	0.9963	1	1	0.9935	4.57	4.63	4.54	4.55	4.55	4.63	4.54	4.52
Skin painful or sore	0.9925	1	0.965	1	4.63	4.74	4.73	4.56	4.60	4.74	4.57	4.56
Intensely itchy skin	0.9736	0.9811	0.9649	0.9742	4.55	4.74	4.66	4.45	4.43	4.65	4.50	4.34
Unable to stop scratching	0.9586	0.9444	0.9474	0.9677	4.58	4.7	4.79	4.46	4.39	4.44	4.54	4.32
Eczema affecting how been feeling	0.937	0.9259	0.9298	0.9419	4.4	4.5	4.59	4.29	4.12	4.17	4.27	4.04
Disturbed sleep	0.9023	0.9259	0.9483	0.8766	4.24	4.35	4.81	3.99	3.83	4.03	4.56	3.50
Eczema getting in the way of day to day activities	0.8647	0.8148	0.8966	0.8701	4.21	4.22	4.47	4.12	3.64	3.44	4.01	3.58
Stopped from doing something wanted or needed to do	0.7895	0.7222	0.8621	0.7806	4.14	4.17	4.38	4.04	3.27	3.01	3.78	3.15
Feeling self-conscious or embarrassed	0.7857	0.2778	0.8596	0.9355	4.3	3.61	4.59	4.39	3.38	1.00*	3.95	4.11
Feeling isolated	0.4906	0.1852	0.569	0.5677	3.5	3.54	4.28	3.15	1.72*	0.66*	2.44	1.79*

Note. *An impact score of <2 was defined a priori as indicating an experience was not relevant to include in the multivariable linear regression analysis. **Items on the 'acceptability, 'overall individual perception', and 'treatment been enough' were not considered appropriate for inclusion in the impact analysis

Table 5 Model 1 Final Output (all items included in the final RECAP instrument), N = 264

Predictor Variables	β	P-value	95% CI
Acceptability of eczema	0.30	0.017	0.05, 0.55
Itchy skin	0.19	0.053	-0.002, 0.38
Sleep disturbance	0.14	0.127	-0.04, 0.32
Getting in the way of day to day activities	0.32	0.01	0.08, 0.55
Affecting how been feeling	0.13	0.102	-0.03, 0.29
Intensely itchy skin	0.22	0.009	0.06, 0.39
Global	0.92	> 0.001	0.71, 1.24

Figure 4 Self and caregiver reported versions of RECAP (copyright retained by authors)

Figure 5 Distribution of scores on final instrument, N=264

Table 6 Mean RECAP scores by severity categories

Severity Categories	N	Mean (SD)	Min-Max
POEM severity banding			
Clear – almost clear (0-2)	13	2.46 (2.67)	0-7
Mild (3-7)	33	7.15 (3.99)	0-19
Moderate (8-16)	94	12.64 (4.13)	4-22
Severe (17-24)	94	18.72 (4.25)	7-26
Very severe (25-28)	26	22.69 (3.18)	14-28
Global severity response option*			
Clear	6	0.67 (1.21)	0-3
Almost Clear	34	6.88 (4.94)	0-21
Mild	64	10.86 (4.10)	3-20
Moderate	120	17.24 (4.50)	6-26
Severe	39	22.15 (3.23)	14-28

*"How has your / your child's eczema been over the past week?"

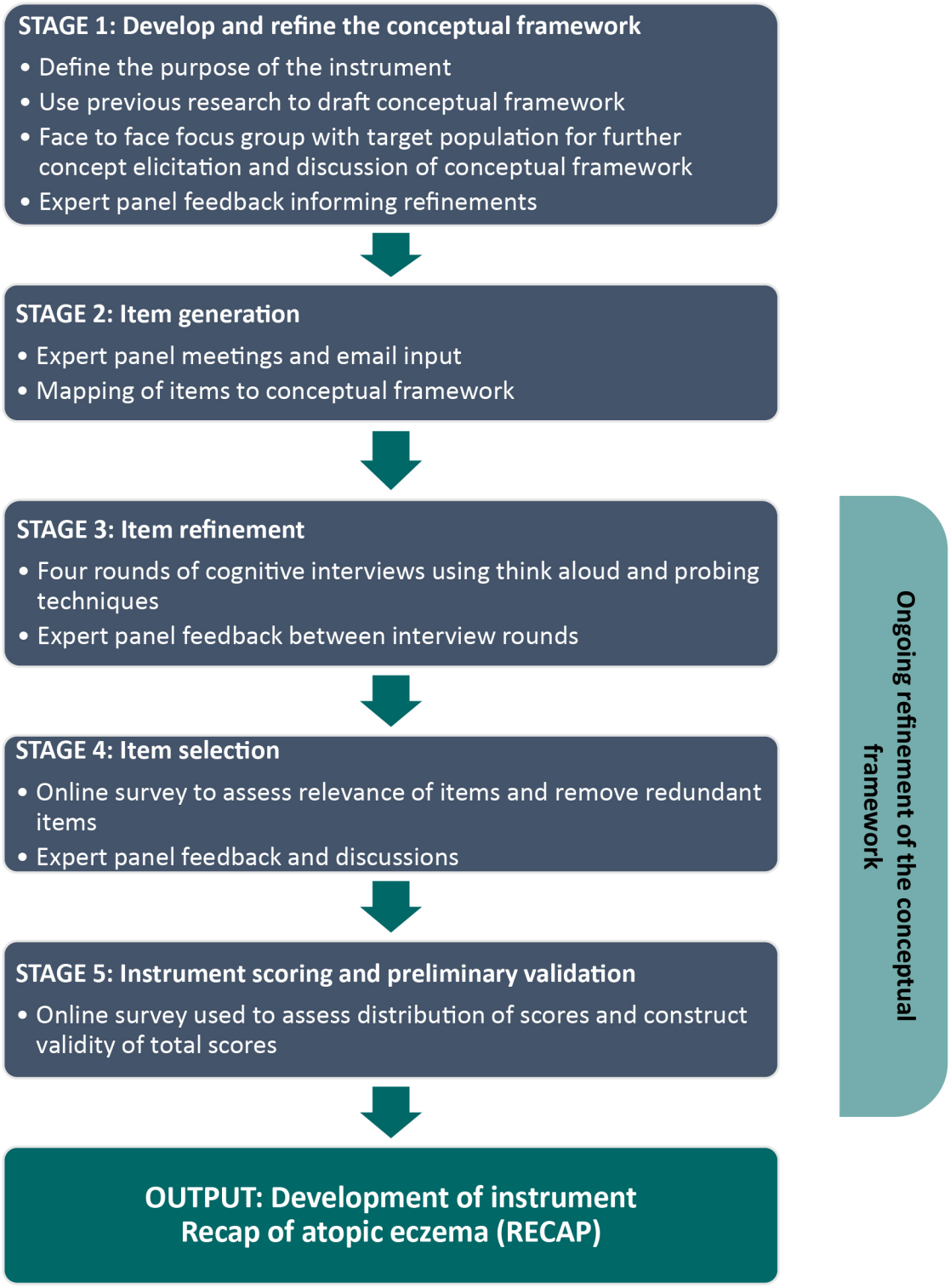
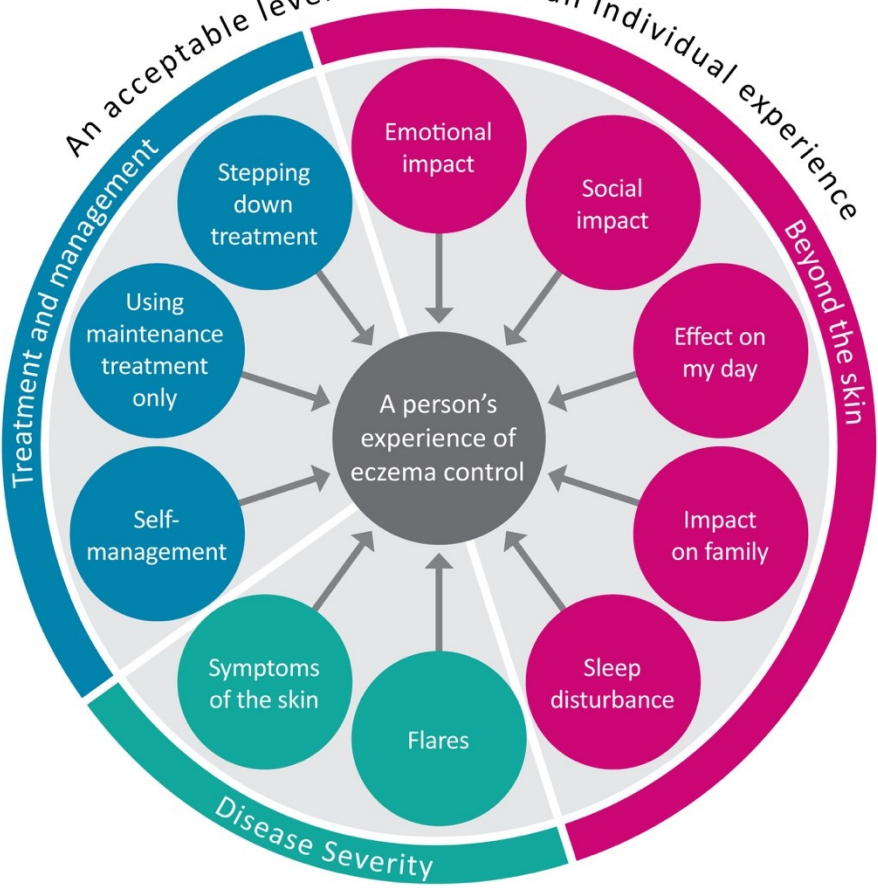
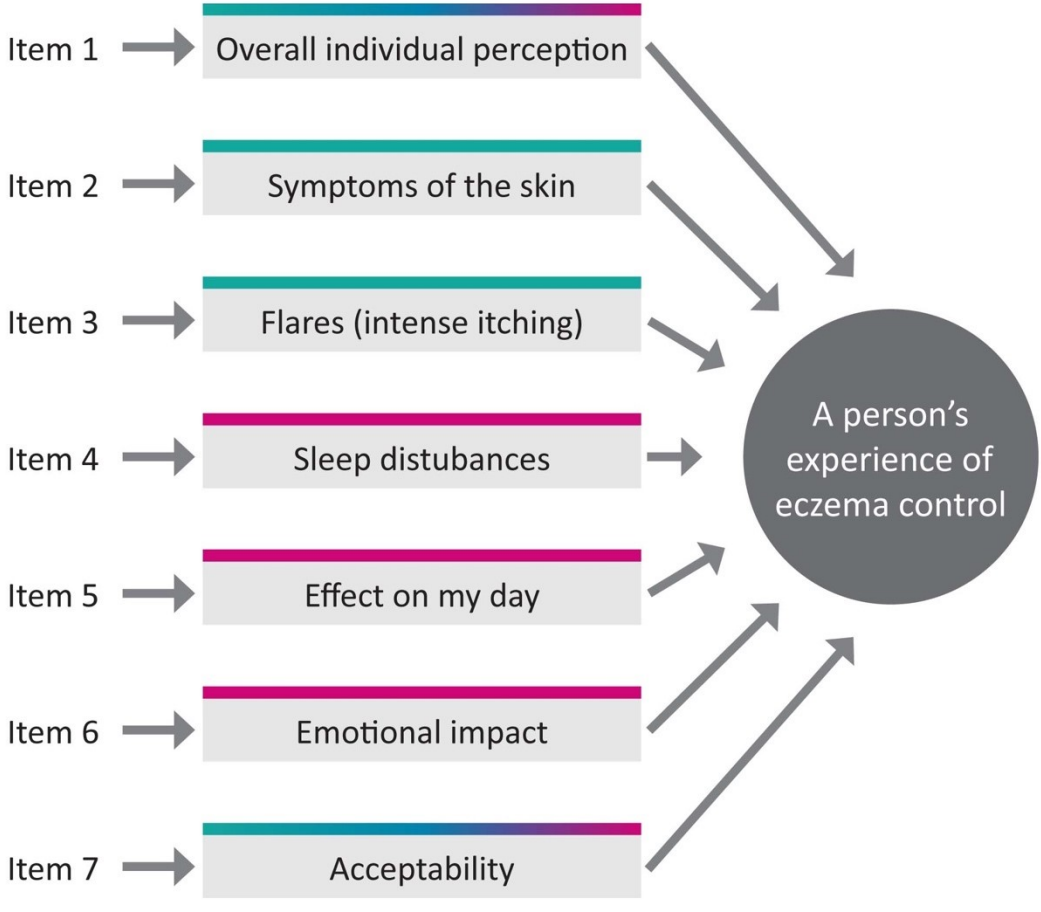


Figure-1 Study design for developing RECAP


An acceptable level of control is an individual experience
Treatment and management
Beyond the skin
Disease Severity
Stepping down treatment
Using maintenance treatment only
Self-management
Symptoms of the skin
Flares
Sleep disturbance
Impact on family
Effect on my day
Social impact
Emotional impact
A person's experience of eczema control


Item 1
Overall individual perception
Item 2
Symptoms of the skin
Item 3
Flares (intense itching)
Item 4
Sleep distubances
Item 5
Effect on my day
Item 6
Emotional impact
Item 7
Acceptability
A person's experience of eczema control

RECAP
recap · of · atopic · eczema

Recap of atopic eczema (RECAP)

The questions below provide a snapshot of how your eczema has been over the last week from your point of view. Please only select one response for each question. Try and respond to every question, but if you are unable to respond then leave it blank.

1. Over the last week, **how has your eczema been?**

Very good | Good | Ok | Bad | Very Bad

2. Over the last week, on how many days has your **skin been itchy** because of your eczema?

No days | 1-2 days | 3-4 days | 5-6 days | Every day

3. Over the last week, on how many days has your **skin been intensely itchy** because of your eczema?

No days | 1-2 days | 3-4 days | 5-6 days | Every day

4. Over the last week, how much has your **sleep been disturbed** because of your eczema?

Not at all | A little bit | Quite a bit | A huge amount | Completely

5. Over the last week, how much has your eczema been **getting in the way of day to day activities**?

Not at all | A little bit | Quite a bit | A huge amount | Completely

6. Over the last week, on how many days has your eczema **affected how you have been feeling**?

No days | 1-2 days | 3-4 days | 5-6 days | Every day

7. Over the last week, **how acceptable** has your eczema been to you?

Completely acceptable | Mostly acceptable | Quite acceptable | Not very acceptable | Not at all acceptable

RECAP
recap · of · atopic · eczema

Recap of atopic eczema (RECAP)

The questions below provide a snapshot of how your child's eczema has been over the last week from your point of view. Please only select one response for each question.
Try and respond to every question, but if you are unable to respond then leave it blank.

1. Over the last week, **how has your child's eczema been?**

Very good | Good | Ok | Bad | Very Bad

2. Over the last week, on how many days has your child's **skin been itchy** because of their eczema?

No days | 1-2 days | 3-4 days | 5-6 days | Every day

3. Over the last week, on how many days do you think your child's **skin been intensely itchy** because of their eczema?

No days | 1-2 days | 3-4 days | 5-6 days | Every day

4. Over the last week, how much do you think your child's **sleep has been disturbed** because of their eczema?

Not at all | A little bit | Quite a bit | A huge amount | Completely

5. Over the last week, how much has your child's eczema been **getting in the way of day to day activities**?

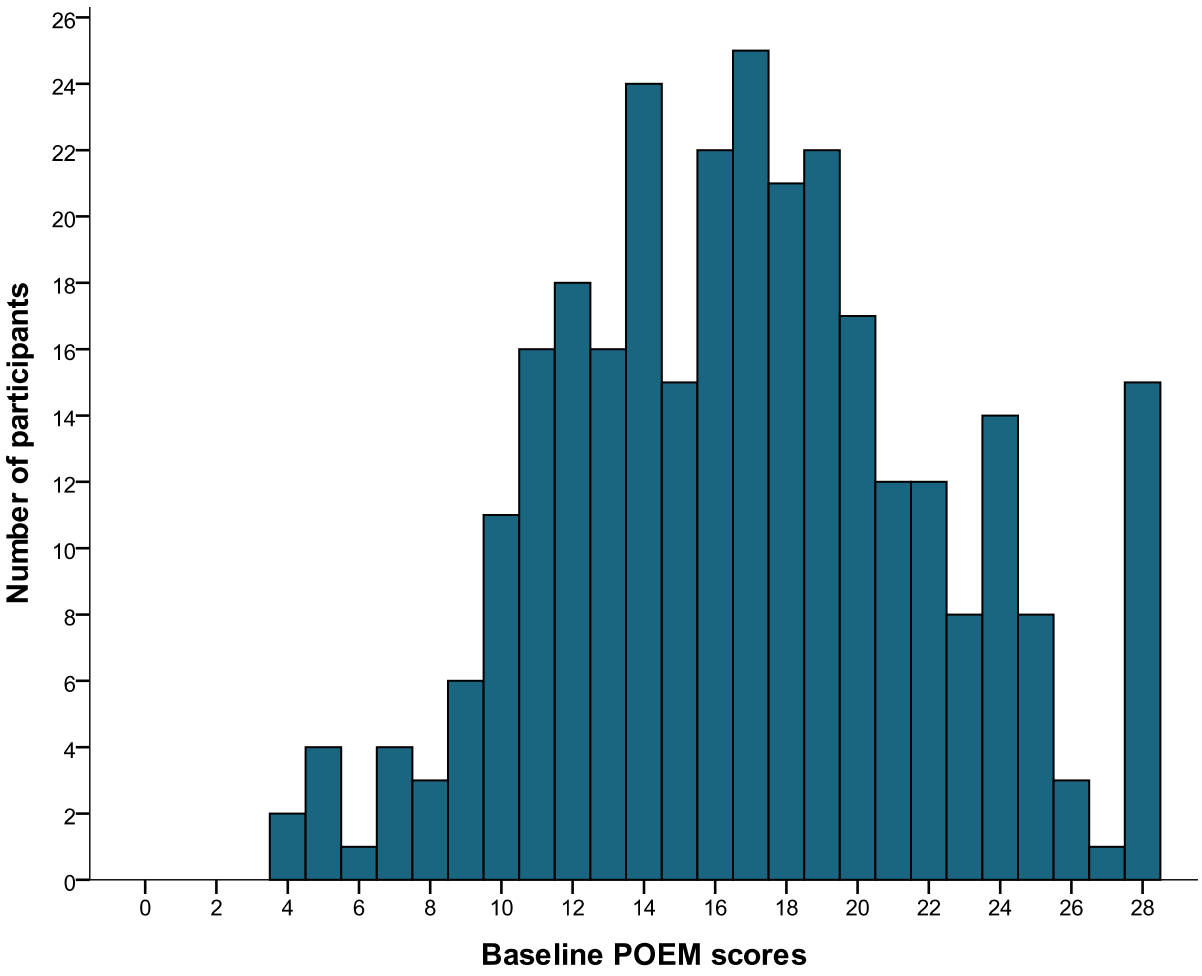
Not at all | A little bit | Quite a bit | A huge amount | Completely

6. Over the last week, on how many days do you think your child's eczema **affected how they have been feeling**?

No days | 1-2 days | 3-4 days | 5-6 days | Every day

7. Over the last week, **how acceptable** has your child's eczema been to you?

Completely acceptable | Mostly acceptable | Quite acceptable | Not very acceptable | Not at all acceptable


Number of participants
0
2
4
6
8
10
12
14
16
18
20
22
24
26
0
2
4
6
8
10
12
14
16
18
20
22
24
26
28
Baseline POEM scores