

How to use the Harmonising Outcome Measures for Eczema Core Outcome Set for atopic dermatitis trials: a users' guide

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Abstract

Background The Harmonising Outcome Measures for Eczema (HOME) initiative has agreed upon the Core Outcome Set (COS) for use in atopic dermatitis (AD) clinical trials, but additional guidance is needed to maximize its uptake.

Objectives To provide answers to some of the commonly asked questions about using the HOME COS; to provide data to help with the interpretation of trial results; and to support sample size calculations for future trials.

Methods and results We provide practical guidance on the use of the HOME COS for investigators planning clinical trials in patients with AD. It answers some of the common questions about using the HOME COS, how to access the outcome measurement instruments, what training/resources are needed to use them appropriately and clarifies when the COS is applicable. We also provide exemplar data to inform sample size calculations for eczema trials and encourage standardized data collection and reporting of the COS.

Conclusions By encouraging adoption of the COS and facilitating consistent reporting of outcome data, it is hoped that the results of eczema trials will be more comprehensive and readily combined in meta-analyses and that patient care will subsequently be improved.

What is already known about this topic?

- The Harmonising Outcome Measures for Eczema (HOME) initiative has recommended core domains and outcome instruments that should be included and reported in all intervention trials of atopic dermatitis treatments.
- Use of the Core Outcome Set (COS) in trials and systematic reviews is currently low.
- Guidance is needed on how to access the HOME core instruments, how to use them and how to report trial findings.

What does this study add?

- This paper provides a 'how-to' guide to promote use of the HOME COS.
- It addresses common questions that people ask when trying to use the core instruments and provides data to support sample size calculations and the interpretation of results.

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What are the clinical implications of this work?

- By increasing uptake of the HOME COS, clinical practice will be improved as data from published trials will be more easily combined in meta-analyses, thus improving clinical decision making.
- Improving the reporting of trial data in a consistent way for defined subgroups (e.g. children/adults) can boost the power of subgroup analyses in systematic reviews and help make informed personalized medicine decisions.

The Harmonising Outcome Measures for Eczema (HOME) initiative has published an agreed Core Outcome Set (COS) for use in atopic dermatitis (AD; also referred to as atopic eczema and eczema) trials.¹

While it is hoped that the COS will be widely adopted, this will not happen without broad awareness, ownership and acceptance of the COS throughout the eczema research community. Uptake of COS across medicine is known to be variable,^{1,2} and guidance on how best to support the uptake of COS suggests a need for recommendations on how to measure outcomes.^{3,4} Tracking use of the HOME COS has shown that uptake of the core domains and outcome instruments is increasing over time, but there is still much room for improvement.^{5,6}

Herein, we provide practical guidance on the use of the HOME COS for investigators planning clinical trials in patients with AD. It answers some of the common questions about using the HOME COS, how to access the outcome measurement instruments, what training/resources are needed to use them appropriately and clarifies when the COS is applicable. We also provide exemplar data to inform sample size calculations for eczema trials and encourage standardized data collection and reporting of the COS.

Which trials does the Core Outcome Set apply to?

The HOME COS is recommended for use in all trials testing AD interventions, if they are asking a question for which clinical outcomes are relevant. This includes drug and non-drug trials.

The HOME COS is not relevant for early-phase dose-finding studies or mechanistic studies (e.g. capturing biomarkers); primary prevention trials (when the incidence of eczema may be a more appropriate outcome); or trials of other types of eczema (e.g. for hand eczema there is a separate COS initiative: <https://www.c3outcomes.org/hecos>).

The domain of long-term control is only required if a trial is of 3 months' duration or longer.

If a trial includes people with a range of skin conditions (e.g. people with both AD and psoriasis), we recommend that the HOME core outcome instruments be considered for the trial where possible, but adherence to the COS would not be mandated as this might result in an undue data-collection burden. If data collected are of relevance to the HOME COS [e.g. quality of life (QoL) using the Dermatology Life Quality Index (DLQI) family of instruments], then – ideally – data should be presented separately for participants with AD. This could be provided as [supplementary material](#).

Is the Core Outcome Set suitable for all people?

The COS has been chosen to be relevant for all severities of AD, all ages and all ethnic groups, although some of the recommended instruments are age specific (Figure 1). Training for assessors may be needed to ensure applicability across all skin tones (particularly for the assessment of clinical signs in people with dark skin tones).^{7,8} There is a need for ongoing validation work to test the suitability of all instruments in different cultures, ethnicities and ages, but current evidence supports their wide use and applicability.

How can the Core Outcome Set instruments be accessed?

Details of how to access the recommended core outcome instruments are available on the HOME website (www.homeforeczema.org). All instruments are freely available for use in noncommercial studies and for academic purposes, but copyright is usually retained by the developer and so permission for use should be obtained (see the individual instruments' websites for details of how this can be obtained). Some instruments may charge for commercial use.

Many of the preferred outcome instruments have been translated (and checked for quality of translation) and these translations are made available via the instrument's individual websites where possible. To reduce research waste and ensure consistency, the HOME initiative encourages sharing of validated versions of the translated instruments.

If a specific language version of the outcome instruments has not yet been made available, best-practice guidance on how to translate the instrument and ensure that the translated version is fit for purpose is available on the HOME website. Alternatively, various commercial companies offer suitable translation services and accreditation certificates.

The patient-reported outcomes included in the HOME COS are simple to use and all take < 2 min to complete. Specific instructions for completion are included within the instruments. For the assessment of clinical signs with the Eczema Area and Severity Index (EASI), a practical guide on how to complete the instrument is available,⁹ and training materials for clinicians or researchers making the assessments are available on the HOME website.

How should the Core Outcome Set outcomes be collected?

There is currently no agreed consensus from HOME as to the preferred timing of outcome data collection, although

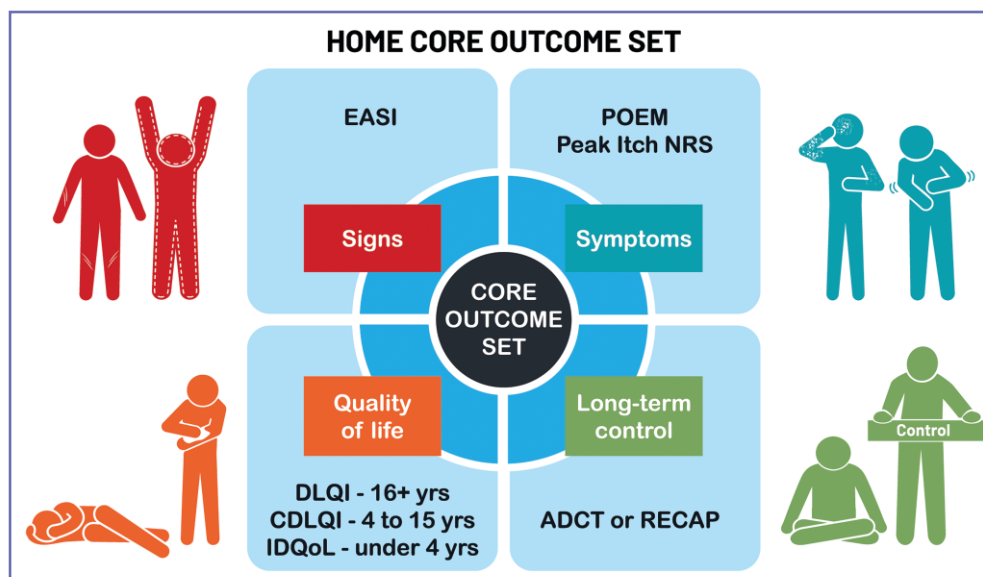


Figure 1 The Harmonising Outcome Measures for Eczema Core Outcome Set. Copyright: University of Nottingham 2023. ADCT, Atopic Dermatitis Control Tool; CDLQI, Children's Dermatology Life Quality Index; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IDQoL, Infants' Dermatitis Quality of Life Index; NRS, Numeric Rating Scale; POEM, Patient Oriented Eczema Measure; RECAP, Recap of atopic eczema. (Copyright University of Nottingham, 2023).

the TREATment of ATopic eczema (TREAT) Taskforce has published a consensus statement for use in clinical registries suggesting that outcomes should be collected at 'a minimum follow-up frequency of initially 4 weeks after commencing treatment, then every 3 months while on treatment and every 6 months while off treatment'.¹⁰ It has been reported that collecting outcomes for at least 4–5 timepoints during a trial is most efficient,¹¹ but the exact timing of these assessments still lacks consensus agreement. Collecting outcomes very frequently throughout a trial (e.g. weekly) may lead to nonspecific trial effects for both groups that could mask small treatment effects.¹²

How should the Core Outcome Set outcomes be reported?

Encouraging all trials to report outcomes at consistent timepoints can facilitate meta-analysis in systematic reviews.¹⁰ In the absence of consensus from the HOME initiative over the timing of outcome assessments, we would propose a pragmatic solution of trialists reporting outcome data at 4 weeks after starting treatment (to demonstrate short-term effect) and between 12 and 16 weeks (to capture medium term effects). In so doing, these recommendations reflect the consensus recommendation by the TREAT Taskforce,⁷ and systematic review teams would be able to combine data from these two timepoints with relative confidence. Data for these timepoints could be made available as [supplementary data](#) files, if necessary.

Trial reports should include the mean and standard deviation for each timepoint (or median and interquartile range, depending on the distribution of the data) to facilitate inclusion in meta-analyses.¹³ Presenting data as a categorized outcome (e.g. the proportion achieving a clinically significant improvement) can help with the interpretation of trial

findings but is insufficient for reporting of the COS without also including summary data for the continuous data.

To facilitate meta-analyses, we would advise the sharing of trial datasets so that important subgroup effects can be explored with combined datasets. If full data sharing is not possible, then it can be helpful to provide summary data for key characteristics separately from the main trial effects (e.g. age, sex, ethnicity and eczema severity). Such comparisons are generally underpowered in most trials, but by reporting these data separately, subsequent meta-analyses may be able to explore important subgroup effects and better inform clinical practice.

A template data table for use when reporting the HOME COS is provided (Table S1; see [Supporting Information](#)) and is available on the HOME website. If trialists routinely use this and provide it as supplementary information alongside trial reports, this could significantly enhance the speed and reliability of conducting meta-analyses in systematic reviews and inform subgroup analyses for specific patient groups.

How should data from the core outcome instruments be interpreted?

When reporting changes in scores for the HOME core outcome instruments, it is useful to understand the clinical relevance of any observed changes.

Many of the HOME core outcome instruments have been mapped to severity bandings to aid interpretation (Table 1), which can be helpful when characterizing a study population.

The minimum important change (MIC) is often described as the smallest within-person change that is important to patients.¹⁴ This can be an important concept to aid interpretation of trial results. For example, it can be used to report the proportion of people responding to treatment (i.e. achieving the MIC) for each of the compared treatments.¹⁵

Table 2 Data used to inform sample size calculations: clinical signs (Eczema Area and Severity Index)

Trial (setting)	No. of participants	Eligibility for trial	Age group	Baseline, mean (SD)	12 weeks, mean (SD)	16 weeks, mean (SD)	Correlations between timepoints (if repeated measures)
BEE trial (primary care, UK) ⁴¹	550	Mild/moderate AD	Children	Intervention (cream): 3.2 (IQR 2.0–6.3) Control (lotion): 3.3 (IQR 2.0–7.2)	NA	Intervention (cream): 2.3 (IQR 0.9–5.2) Control (lotion): 2.2 (IQR 0.6–3.6)	–
CLOTHES trial (primary and secondary care, UK) ^{42,a}	300	Moderate/severe AD	Children	Intervention: geometric mean 9.6 (7.8) Control: geometric mean 11.4 (10.6)	NA	Intervention: geometric mean 7.7 (10.1) Control: geometric mean 7.7 (8.7)	Correlation between baseline and 16 weeks: 0.65
Dupilumab trial (secondary care, USA and Canada) ⁴³	251	Moderate/severe AD	Adolescents (12–18 years)	Intervention: 35.8 (14.8) Control: 35.5 (14.0)	–	Intervention: 12.3 (11.1) Control: 24.1 (15.5)	–

AD, atopic dermatitis; BEE, Best Emollients for Eczema; CLOTHES, clothing for the relief of eczema symptoms; IQR, interquartile range; NA, not available. ^aData in the CLOTHES trial were skewed and so the geometric mean was used for analysis.

Table 3 Data used to inform sample size calculations: patient-reported symptoms (Patient Oriented Eczema Measure)

Trial (setting)	No. of participants	Eligibility for trial	Age group	Baseline, mean (SD)	12 weeks, mean (SD)	16 weeks, mean (SD)	Correlations between timepoints (if repeated measures)
BATHE trial (primary care, UK) ⁴⁴	482	Mild/moderate AD	Children	Intervention: 9.5 (5.7) Control: 10.1 (5.8)	Intervention: 7.7 (6.2) Control: 7.9 (5.9)	Intervention: 7.1 (6.1) Control: 8.2 (6.3)	Correlation between baseline and 12 weeks: 0.52; correlation between baseline and 16 weeks: 0.48
ECO trial (primary care, UK) ⁴⁵	337	All severities	Young people (13–25 years)	Intervention: 15.1 (5.3) Control: 15.3 (5.5)	Intervention: 11.1 (5.9) Control: 14.0 (6.0)	Intervention: 11.2 (5.9) Control: 14.4 (6.3)	Correlation between baseline and 12 weeks: 0.57; correlation between baseline at 16 weeks: 0.56
ECO trial (primary care, UK) ⁴⁵	340	All severities	Children	Intervention: 12.9 (5.2) Control: 12.8 (5.4)	Intervention: 9.6 (6.1) Control: 10.0 (6.1)	Intervention: 9.7 (6.1) Control: 10.0 (6.0)	Correlation between baseline and 12 weeks: 0.61; correlation between baseline at 16 weeks: 0.61
CLOTHES trial (primary and secondary care, UK) ⁴²	330	Moderate/severe AD	Children	Intervention: 15 (6.0) Control: 15.8 (5.6)	Intervention: 11.5 (7) Control: 13.4 (6.7)	Intervention: 10.9 (6.6) Control: 13.3 (7.2)	Correlation between baseline and 16 weeks: 0.64
Dupilumab trial (secondary care, USA and Canada) ⁴³	251	Moderate/severe	Adolescents (12–18 years)	Intervention: 21.1 (5.5) Control: 21.1 (5.4)	–	Intervention: 11.2 (7.4) Control: 16.2 (8.3)	–
EMO trial (online, UK) ¹²	296	Mild-to-severe	Mostly adults (93%)	Intervention: 15.42 (6.02) Control: 14.28 (6.06)	Intervention (8 weeks): 12.00 (6.08) Control: 12.94 (6.47)	–	–

AD, atopic dermatitis; BATHE, emollient bath additives for the treatment of childhood eczema; CLOTHES, clothing for the relief of eczema symptoms; ECO, Eczema Care Online; EMO, Eczema Monitoring Online.

Table 4 Data used to inform sample size calculations: itch intensity (NRS-11 peak itch)

Trial (setting)	No. of participants	Eligibility for trial	Age group	Baseline, mean (SD)	12 weeks, mean (SD)	16 weeks, mean (SD)	Correlations between timepoints (if repeated measures)
ECO trial (primary care, UK) ⁴⁵	337	Mild/moderate	Young people	Intervention: 5.7 (2.2) Control: 5.6 (2.4)	Intervention: 5.0 (2.6) Control: 5.0 (2.5)	Intervention: 4.5 (2.6) Control: 4.7 (2.7)	NA
Dupilumab trial (secondary care, USA and Canada) ⁴³	251	Moderate/severe	Adolescents (12–18 years)	Weekly average intervention: 7.5 (1.8) Control: 7.7 (1.6)	–	Weekly average intervention: 4.0 (2.7) Control: 6.0 (2.3)	NA

ECO, Eczema Care Online; NA, not available; NRS-11, 11-point Numeric Rating Scale.

Table 5 Data used to inform sample size calculations: eczema control (RECAP)

Trial (setting)	No. of participants	Eligibility for trial	Age group	Baseline, mean (SD)	12 weeks, mean (SD)	16 weeks, mean (SD)	Correlations between timepoints (if repeated measures)
ECO trial (primary care, UK) ⁴⁵	340	Mild/moderate AD	Children	Intervention: 12.8 (5.4) Control: 12.3 (5.5)	Intervention: 9.0 (6.1) Control: 9.7 (6.3)	Intervention: 8.6 (6.0) Control: 9.4 (6.9)	NA
ECO trial (primary care, UK) ⁴⁵	337	Mild/moderate	Young people	Intervention: 13.0 (5.1) Control: 13.1 (5.6)	Intervention: 10.3 (6.0) Control: 11.5 (6.3)	Intervention: 9.2 (6.0) Control: 10.7 (6.6)	NA
EMO trial (community, UK) ¹²	232	All severities	Mostly adults	Intervention: 12.29 (6.14) Control: 11.79 (6.30)	Intervention (8 weeks): 10.67 (5.66) Control: 11.18 (5.86)	–	NA

ECO, Eczema Care Online; EMO, Eczema Monitoring Online; NA, not available; RECAP, Recap of atopic eczema.

Table 6 Data used to inform sample size calculations: eczema control (Atopic Dermatitis Control Tool)

Trial (setting)	No. of participants	Eligibility for trial	Age (years)	Baseline, mean (SD)	12 weeks, mean (SD)	16 weeks, mean (SD)	Correlations between timepoints (if repeated measures)
RELIEVE-AD registry real-world clinical practice (Strober <i>et al.</i> , 2022) ⁴⁶	699	Initiating dupilumab	≥ 18	15.8 (5.4)	5.6 (5.0)	6 months: 5.0 (4.9)	–
BioDay Registry (Oosterhaven <i>et al.</i> , 2022) ⁴⁷	104	On dupilumab for > 16 weeks and < 52 weeks	≥ 18	NA	NA	5.1 (3.7)	NA
CorEvita registry (data on file)	1738	Systemic eligible EASI ≥ 12 vIGA moderate-to-severe	≥ 18	13.2 (6.3)			NA

EASI, Eczema Area and Severity Index; NA, not available; RELIEVE, EaRly Real-WorLd Patient EValuation for DupixEnt in Atopic Dermatitis; vIGA, validated Investigator Global Assessment.

will consider whether all items are necessary and whether a more streamlined approach could be adopted. It is also unclear whether the HOME patient-reported outcomes should be administered in a consistent order or not.

Some of the instruments (POEM and DLQI family of instruments) were originally designed and validated using

paper questionnaires rather than online versions, but preliminary evidence suggests that use in either format is appropriate.²⁰ With the increasing use of online data-capture forms, it is tempting to make answering all items on the outcome instruments mandatory. We do not generally advise making electronic data items mandatory, as this does not

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least 17 weeks after treatment. Avoid use of bimekizumab during pregnancy. It is unknown whether bimekizumab is excreted in human milk, hence a risk to the newborn/infant cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Bimzelx therapy. No data available on human fertility. **Driving and use of machines:** No or negligible influence on ability to drive and use machines. **Adverse Effects:** Refer to SmPC for full information. Very Common ($\geq 1/10$): upper respiratory tract infection; Common ($\geq 1/100$ to $< 1/10$): oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis; headache, rash, dermatitis and eczema, acne, injection site reactions, fatigue; Uncommon ($\geq 1/1,000$ to $< 1/100$): mucosal and cutaneous candidiasis (including oesophageal candidiasis), conjunctivitis, neutropenia, inflammatory bowel disease. Storage precautions: Store in a refrigerator (2°C – 8°C), do not freeze. Keep in outer carton to protect from light. Bimzelx can be kept at up to 25°C for a single period of maximum 25 days with protection from light. Product should be discarded after this period or by the expiry date, whichever occurs first.

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Adverse events should be reported. Reporting forms and information can be found at <http://www.mhra.gov.uk/yellowcard>. Adverse events should also be reported to UCB Pharma Ltd at ucbcares.uk@ucb.com or 0800 2793177.

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