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STUDY PROTOCOL

Assessing the need of overlapping itch assessments in the HOME core outcome set for eczema clinical trials

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Lay summary

Eczema is a chronic skin condition affecting around 1 in 10 people; it is more common in early childhood. There are usually periods when the eczema is less noticeable followed by periods of flare-ups where the symptoms become worse. People living with eczema can experience very itchy skin, leading to more issues such as sleep disturbance, anxiety, and depression. The condition not only affects the person with eczema, but their family too, especially due to its impact on daily activity.

While there is no cure for eczema, it can be treated with moisturisers, steroid creams or by avoiding triggers such as allergens, heat, or certain soaps. With eczema being a common condition, there are still gaps in our knowledge about how to best manage and treat it. These gaps can be filled by conducting high quality trials that measure the same outcomes across each trial, so there is improved evidence to decide treatments and management strategies.

Core outcome sets are a set of key aspects of a disease that should be measured in every clinical trial of a given condition. This project will focus on the Harmonising Outcome Measures for Eczema (HOME) core outcome set that measures the following aspects of eczema: clinical signs, patient-reported symptoms, long-term disease control and quality of life. Within these core outcomes, participants of trials are asked to fill out multiple questionnaires. However, there are overlaps of the same questions surrounding the trial participants' experience of itch. This repetition can be time-consuming or frustrating for participants, which reduces the quality of data and efficiency of the trial.

To explore the best ways of minimising repetition within the HOME core outcome set, we will be using an existing eczema trial dataset to evaluate whether the responses to the identical questions from the two questionnaires called: POEM and RECAP are similar enough to only ask once. We will also compare the agreement within the 'frequency of itch' questions and 'intensity of itch' questions from different questionnaires to assess whether they add value to the core outcome set.

The results of this project will fill an important gap in our understanding of how to best collect the HOME core outcome set. In addition, this work will help to minimise the burden of using the HOME core outcome set and thus can potentially improve uptake. This will provide a better evidence base for patient care.

Study synopsis

Title	Assessing the redundancy of itch assessments in the HOME core outcome set for eczema clinical trials

Aims & objectives	**Aim:**
	To explore the relationship between the different itch questions contained in the HOME core outcome set and understand the implications for implementation of the core set.
	Objectives:
	• To assess the level of agreement between the POEM and RECAP 'frequency of itch' questions (Note: these questions are identical but administered within the context of different questionnaires)
	• To explore the impact of using the 'first collected answer' to the frequency of itch question on the EMO trial results.
	• To assess the correlation between all available itch measurements:
	  ○ Frequency of itch (POEM and RECAP)
	  ○ Intensity of itch (RECAP and NRS itch)

Study Design	Secondary data analysis, using existing data collected in a previously completed online trial (EMO). Ethics approval was granted for the EMO trial. This study does not require ethical approval.
Research questions	Research question 1: Are the identical questions included in the POEM and RECAP questionnaires (frequency of itch) sufficiently similar to enable collection only once? Research question 2: Is there redundancy in the HOME core outcome set itch questions or do they all add value?
Eligibility (data source)	EMO trial dataset accessible from: https://rdmc.nottingham.ac.uk/handle/internal/10456
Outcomes	This work will help to minimise the burden of using the HOME core outcome set and thus improve uptake which will in turn provide better evidence base for patient care. The results of this project will fill some of the gaps in our understanding of how to best collect the HOME core outcome set.
Sample size	296 participants in the EMO randomised controlled trial. Self-completed data with available measurements for RECAP, POEM and NRS Itch will be used in this project.
Analysis	• Exploratory analysis using descriptive statistics (analysed using STATA version 18) • Levels of agreement calculated using weighted kappa and kappa statistic. • Correlations reported using Pearson's correlation

Background

What is eczema?

Eczema is a chronic, inflammatory skin condition characterised by itchiness and dry skin (Weidinger and Novak, 2016). It affects 1 in 5 children and 1 in 10 adults (Association, 2023). There are remitting and relapsing cycles with eczema, also known as flare-ups. During flare-ups, people can experience severe itching, weeping, swelling and bleeding (NHS, 2019). In eczema, the skin barrier (epidermis) is compromised, allowing moisture to leave the skin making it prone to allergens entering through the epidermis. Despite it being such a common condition, the cause is still not fully understood but it is thought to be a complex interplay of genetic and environmental factors, such as genetic predisposition, stress, dust, temperature extremes and wash products. People can experience mild, moderate, or severe eczema but all severities have a significant impact on quality of life affecting self-confidence and causing sleeplessness, anxiety, and depression. It is important to consider the itching associated with eczema can be intense, which does exacerbate the symptoms of eczema in many people.

Treatments for eczema can ease symptoms, but there is no cure. The mainstay of eczema treatments are emollients and topical corticosteroids (NICE, 2023). Alternatively, reducing scratching by wearing gloves or keeping short nails and avoiding triggers for flare-ups as preventative measures (NHS, 2019). Itching is the main symptom and an essential criterion for diagnosis of eczema according to the UK Diagnostic Criteria for Eczema ((NICE), 2023)

Core outcome sets

Core outcome sets (COS) are a consensus-based set of outcomes that should be measured and reported in all clinical trials for a particular disease (Williamson et al., 2012). Core outcomes are not restrictive but are the expected minimum outcomes that should be reported in all the clinical trials of a certain condition. The Core Outcome Measures in Effectiveness Trials (COMET) Initiative was established to overcome the issue of outcome heterogeneity, which makes it difficult to compare results from several trials about the same condition. The COMET initiative promotes COS development, by bringing researchers, the public and methodologists together and collate ideas and combine to form COS for certain conditions (COMET, 2023). Measuring the same set of outcomes allows study results to be combined in systematic reviews and meta-analyses (Williamson et al., 2012). They improve the quality of evidence-based knowledge, so it is more useful to make clinical decisions and reducing research waste. Without COSs, important outcomes will not be investigated, which could exclude many participants who have given their time to contribute to research (Williams et al., 2022).

HOME Initiative Core Outcomes

The Harmonising Outcomes Measures for Eczema (HOME) initiative have created a COS minimum that should be measured in all eczema clinical trials. In the past, there have been a lot of unvalidated outcome measures for eczema which leads to clinical trials being incomparable, inconsistent and

failure to come up with an effective intervention (Charman et al., 2003). The core outcome sets ensure there is a standardised framework to assess the effectiveness of interventions of eczema. The HOME initiative focuses on four outcome measures: clinical signs, patient-reported symptoms, long-term control, and quality of life (Williams et al., 2022). For clinical signs, the Eczema Area and Severity Index (EASI) is used (Hanifin et al., 2001). It is a scoring system used by clinicians for grading physical signs of eczema. The patient-reported symptoms core domain includes the Patient-Oriented Eczema Measure (POEM) instrument (Charman et al., 2004) that measures eczema symptoms from the patient perspective and the Numerical Rating Scale (NRS) 11-point measures for itch intensity over last 24 hours. The quality-of-life outcome domain contains three questionnaires for different age groups: the Dermatology Life Quality Index (DLQI) for individuals aged 16 years and above (Finlay and Khan, 1994), the Children DLQI (CDLQI) for children aged 4 to 15 years (Lewis-Jones and Finlay, 1995) and Infant DLQI (IDQoL) for the age 4 and below (Lewis-Jones et al., 2001). For the long-term control domain, the RECAP of Atopic Eczema (RECAP) (Howells et al., 2020) and Atopic Dermatitis Control Tool (ADCT) instruments are used to assess eczema control (Simpson et al., 2019).

Challenge of Implementing COS

A COS is only useful if it is used and widely implemented. The insufficient uptake of a COS is a common problem across most trials. The main reasons for the limited uptake of the HOME COS might be due to the lack of stakeholder awareness and engagement, universal applicability, and the administrative burden associated with its use (Leshem et al., 2023). Once a COS has been established, it can be many years before the full benefits are realised and it requires all stakeholders to be aware and supportive. It is important to involve the main stakeholder in COS development to form a credible COS. Involving stakeholders in decisions has proven an increase in uptake of HOME COS by the research community (Vincent et al., 2020). The HOME initiative includes members of the public, clinicians, methodologists, researchers, regulator. To ensure there is also continued global intake, consensus meetings should be held in countries around the world to inform the results and updates of these COS. The HOME stakeholders suggest there should be a maximum of four outcome measures to make it accessible to participants. Other ways to make sure COS is easy to use on a large scale is the time to complete the COS, avoiding overlapping questions, the cost, and the availability of instruments. The uptake will also improve if you decrease uncertainty in the COS. It is recommended that each COS should make it clear how to measure and report each outcome using which instruments. The HOME initiative, for example, published on how to report answers from the EASI and POEM questionnaires in a standardised way (Leshem et al., 2023).

This project will focus on how HOME can reduce burden for participants by assessing the effect of the overlapping questions contained in the COS.

Itch Questions in HOME COS

Questions about itch is assessed five times by four patient-reported instruments in the HOME COS (POEM, RECAP, NRS Itch, DLQI). Some of the itch questions are overlapping. Each scale was developed and validated separately, so it is not possible to simply remove overlapping questions. This could mean unnecessary responder burden, meaning participants could find partaking time-consuming, stressful, and difficult (Williams et al., 2022). This questions the feasibility of the HOME COS which in turn affects implementation. The ‘frequency of itch’ and ‘intensity of itch’ questions are repeated in individual questionnaires. Questions about the patient’s frequency of itch is asked

three times within the COS by POEM, RECAP and in the three variations of DLQI. The questions about patient's itch intensity are asked twice in the HOME COS by RECAP and the NRS itch questionnaire. While some repetition can be useful to ensure the consistency of responses, excessive repetitions of a question can reduce the accuracy of the data collected due to the burden on participants. There needs to be a balance between collecting the necessary data to analyse and respecting the participant's time and effort. Based on the results, recommendations will be made to HOME on how to best collect data about patient-reported itch.

Filling Validation Gaps

This project will explore whether all itch questions are required to be included in the HOME COS. This will be the first step to inform future HOME consensus discussions on this topic. If avoidable redundancy is identified, this could help the uptake of the COS by minimising the burden of data collection when using the HOME COS (Williams et al., 2022).

This will be done by exploring the relationship between the responses of the itch questions from different questionnaires, using various statistical methods. This project is a secondary data analysis project using the Eczema Monitoring Online (EMO) trial dataset. The EMO dataset includes data from the RECAP, POEM, and NRS-11 questionnaires. Since the EMO trial did not assess the quality of life the itch questions from the quality-of-life instruments will not be assessed in this project.

Methods

Aim:

To explore the relationship between the different itch questions contained in the HOME core outcome set and understand the implications for implementation of the core set.

Research question 1:

Are the identical questions included in the POEM and RECAP questionnaires (frequency of itch) sufficiently similar to enable collection only once?

Research question 2:

Is there redundancy in the HOME core outcome set itch questions or do they all add value?

Study design

This will be a secondary data analysis project using existing data collected in a previously conducted online trial (EMO). Ethical approval for the EMO trial was obtained from the University of Nottingham Research Ethics Committee (reference number: 239-0421). This study does not require ethical approval because it uses the already existing EMO dataset for secondary analysis.

Data sources

Eczema Monitoring Online (EMO) trial dataset is accessible from https://rdmc.nottingham.ac.uk/handle/internal/10456. The dataset contains patient-reported outcome assessments collected at baseline and week 8, assessed by the EMO trial dataset includes a

total of four itch questions from POEM, RECAP and NRS Itch as shown in Table 1. The DLQI is not part of the database so it will not be included.

Table 1. Itch questions available in the EMO trial dataset

Questionnaire	Question	Frequency or Intensity
RECAP	Over the last week, on how many days has your **skin been itchy** because of your eczema?	Frequency
POEM	Over the last week, on how many days has your skin been itchy because of the eczema?	Frequency
RECAP	Over the last week, on how many days has your **skin been intensely itchy** because of your eczema?	Intensity
NRS Itch	On a scale of 0 to 10, with 0 being 'no itch' and 10 being 'worst itch imaginable', how would you rate your itch at the worst moment during the previous 24 hours?	Intensity

The kappa and correlation will only use the data from baseline (not week 8 after the intervention) The main variables that will be investigated from the database are the POEM frequency of itch, RECAP frequency of itch, RECAP intensity of itch, NRS intensity of itch questions. The variables used will also include all questions from baseline and follow-up in POEM and all baseline questions in RECAP (*see Appendix*).

Statistical analysis and sample size

Analysis methods

This is an exploratory secondary project and is not formally testing a hypothesis. Analyses will use STATA (version 18) and will focus on descriptive statistics. Statistics will be presented with 95% confidence intervals (CI) where appropriate.

Objective 1: To assess the level of agreement between the POEM and RECAP 'frequency of itch' questions

Levels of agreement between the identically worded frequency of itch questions in the POEM and RECAP will be evaluated using both a weighted kappa (primary method) and kappa.

The itch question is an ordinal scale from 0 to 4 (ranging from no days to every day). Kappa weightings will be applied using a quadratic approach as follows (Sim and Wright, 2005):

- Difference of 0 between the POEM and RECAP questions = 1.00
- Difference of 1 between the POEM and RECAP questions = 0.89
- Difference of 2 between the POEM and RECAP questions = 0.56
- Difference of 3+ between the POEM and RECAP questions = 0.00

A high level of agreement (suggesting that the item may not need to be asked twice) is defined as being a correlation ≥ 0.8.

Objective 2: To explore the impact of using the 'first collected answer' to the frequency of itch question on the EMO trial results.

For the analysis exploring impact on the EMO trial results, the original syntax from the trial analysis will be used. The trial results will be re-calculated using the total POEM scores at baseline and week 8, which have been calculated in two ways:

- Using the original POEM scores (7-items, range from 0 to 28)
- Using 6 items from the original POEM score, plus the frequency of itch question from the RECAP outcome instrument (7 items, range 0 to 28)

Trial results will be presented with mean between group difference and 95% CIs to explore the likely impact on the trial conclusions of collecting the frequency of itch questions only once.

Objective 3: To assess the correlation between all available itch measurements:

The association between frequency of itch questions (POEM and RECAP) and intensity of itch questions (RECAP and NRS-itch) will be explored using Pearson's correlation coefficients and 95% confidence intervals.

A high level of agreement (suggesting that the item may not need to be asked twice) is defined as being a correlation ≥ 0.8.

Results of this project will help provide the evidence for HOME to resolve any uncertainties in the assessment of itch in the current COS. In turn, this will improve the accuracy and feasibility of the HOME COS and help to enhance its uptake.

Sample size

The sample size was determined by the availability of required data in the EMO trial.

Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) helps researchers evaluate the psychometric properties of outcome measurement instruments. For studies assessing construct validity, COSMIN recommends that a sample size of over 100 is appropriate to use (Prinsen et al., 2016); the EMO trial has a sample size of >200. Only data from self-completers will be used, data from parents of children will be excluded due to the low number of participants (*n* =15).

Patient and Public Involvement

This research project will be utilising a secondary dataset, so there will be no direct patient and public involvement (PPI). However, in the EMO trial dataset six members of the entre of Evidence Based Dermatology Patient Panel were involved in the design of the secondary outcome measures. The PPI members also provided feedback on the patient facing materials, including participant information sheet, consent form and social media adverts for recruitment.

Study Management

I will be the project manager for this dissertation under the supervision of Prof Kim Thomas, Ms Arabella Baker, and Prof Beth Stuart. Under the University of Nottingham policy, we are required to store research data securely. The data will be stored in our restricted access Microsoft Teams file, where it will only be accessible to the people assisting in this project.

Publication and dissemination

This project is a part of my BMedSci. Following completion, I will be required to create a poster and present it twice. There is potential for publishing in a peer reviewed journal. The results will be presented at the next HOME meeting and be used to inform consensus recommendations around the bast ways of using the HOME core outcome set.

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Appendix

Variable Codebook:

Variables	**Field Label**
poem_a_10	Over the last week, on how many days has your skin been itchy because of your eczema? (Week 0)
poem_a_20	Over the last week, on how many nights has your sleep been disturbed because of your eczema? (Week 0)
poem_a_30	Over the last week, on how many days has your skin been bleeding because of your eczema? (Week 0)
poem_a_40	Over the last week, on how many days has your skin been weeping or oozing because of your eczema? (Week 0)
poem_a_50	Over the last week, on how many days has your skin been cracked because of your eczema? (Week 0)
poem_a_60	Over the last week, on how many days has your skin been flaking off because of your eczema? (Week 0)
poem_a_70	Over the last week, on how many days has your skin felt dry or rough because of your eczema? (Week 0)
poemmisa0	Number of missing values (Week 0)
poemscra0	POEM score (Week 0)
poem_a_18	Over the last week, on how many days has your skin been itchy because of your eczema? (Week 8)
poem_a_28	Over the last week, on how many nights has your sleep been disturbed because of your eczema? (Week 8)
poem_a_38	Over the last week, on how many days has your skin been bleeding because of your eczema? (Week 8)
poem_a_48	Over the last week, on how many days has your skin been weeping or oozing because of your eczema? (Week 8)
poem_a_58	Over the last week, on how many days has your skin been cracked because of your eczema? (Week 8)
poem_a_68	Over the last week, on how many days has your skin been flaking off because of your eczema? (Week 8)
poem_a_78	Over the last week, on how many days has your skin felt dry or rough because of your eczema? (Week 8)
poemmisa8	Number of missing values (Week 8)
poemscra8	POEM score (Week 8)

nrs_itch0	On a scale of 0 to 10, with 0 being 'no itch' and 10 being 'worst itch imaginable', how would you rate your itch at the worst moment during the previous 24 hours?
nrs_itch8	On a scale of 0 to 10, with 0 being 'no itch' and 10 being 'worst itch imaginable', how would you rate your itch at the worst moment during the previous 24 hours?
recap_a_10	Over the last week, how has your eczema been? (Week 0)
recap_a_20	Over the last week, on how many days has your skin been itchy because of your eczema? (Week 0)
recap_a_30	Over the last week, on how many days has your skin been intensely itchy because of your eczema? (Week 0)
recap_a_40	Over the last week, how much has your sleep been disturbed because of your eczema? (Week 0)
recap_a_50	Over the last week, how much has your eczema been getting in the way of day-to-day activities? (Week 0)
recap_a_60	Over the last week, on how many days has your eczema affected how you have been feeling? (Week 0)
recap_a_70	Over the last week, how acceptable has your eczema been to you? (Week 0)
recapmisa0	Number of missing values (Week 0)
recapscra0	RECAP score (Week 0)
recap_a_18	Over the last week, how has your eczema been? (Week 8)
recap_a_28	Over the last week, on how many days has your skin been itchy because of your eczema? (Week 8)
recap_a_38	Over the last week, on how many days has your skin been intensely itchy because of your eczema? (Week 8)
recap_a_48	Over the last week, how much has your sleep been disturbed because of your eczema? (Week 8)
recap_a_58	Over the last week, how much has your eczema been getting in the way of day-to-day activities? (Week 8)
recap_a_68	Over the last week, on how many days has your eczema affected how you have been feeling? (Week 8)
recap_a_78	Over the last week, how acceptable has your eczema been to you? (Week 8)
recapmisa8	Number of missing values (Week 8)
recapscra8	RECAP score (Week 8)
trtarm	Randomised allocation of X or Y
arm	X = intervention POEM every week for 8 weeks Y = Control Only baseline and week 8