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Capturing and reporting topical treatment use in childhood eczema: lessons for data collection in eczema trials

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Abstract

Background Emollients and topical corticosteroids (TCS) prevent and treat flares in eczema. However, topical treatment use is poorly recorded and reported in clinical trials. There is no clear consensus of how best to capture and summarize topical treatment use.

Objectives To explore different ways of capturing and reporting topical treatment use in childhood eczema.

Methods This was a secondary data analysis using 450 participants from the Best Emollients for Eczema (BEE) trial. Participants were allocated to use one type of emollient (lotion, cream, gel or ointment) 'twice daily and when required' for 16 weeks. Otherwise, clinical management remained unchanged. Parents completed weekly questions about topical therapy use and eczema symptoms. Two versions of topical treatment use questionnaires were used. The first ($n=202$, 44.9%) asked parents to report treatment use on days 1–7, starting completion on the day they were randomized. The second ($n=248$, 55.1%) reported use by day of the week (Monday to Sunday), starting completion the first Monday after randomization. Both underwent patient and public involvement review but the second version was tested more thoroughly using cognitive interviewing techniques, following parent feedback that questions on the first version were confusing. Descriptive statistics compared questionnaire completion and differences in emollient and TCS use.

Results Overall, questionnaire completion for both emollient and TCS use decreased with time, but at weeks 1 and 16, it was 84.7% (381/450) and 58.9% (265/450) for emollient use, and 94.2% (424/450) and 80.4% (362/450) for TCS use, respectively. Fewer emollient use questionnaires were completed with the first (33.5%, 1082/3232 patient-weeks) than the second (87.9%, 3489/3968 patient-weeks) version ($P<0.001$). TCS use questionnaire completion were similar for both (84.9%, 2744/3232 patient-weeks and 87.4%, 3468/3968 patient-weeks, $P=0.002$). We present different ways of summarizing topical treatment use.

Conclusions Although questionnaire completion was similar for TCS use, emollient-use data completeness was higher in the second version. When designing questionnaires, balancing the detail and complexity of questions is important, especially if being collected as a secondary outcome measure. Numerous ways of summarizing the same data can provide different information. Future collection and reporting of treatment use should reflect specific trial aims.

What is already known about this topic?

- Long-term topical therapy use is the mainstay treatment for eczema; however, adherence to topical therapies is generally considered poor and their use is underreported in clinical trials.
- Within the 2017 Cochrane Review of 'Emollients and moisturisers for eczema', only 11 of 77 included studies reported on topical treatment use during trials.
- There are different ways to measure and report topical treatment use but no consensus on which is best.

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What does this study add?

- If questionnaires are used to collect topical treatment use, they should be appropriate for the population completing them and the outcomes of interest.
- Question detail and complexity must be balanced against respondent burden, especially if being collected as a secondary outcome measure.
- This paper offers key learning points for investigators designing or reporting surveys or trials where topical therapy use is examined.

Eczema, also known as atopic dermatitis, is a chronic relapsing inflammatory condition affecting ~20% of children.[1] Long-term topical therapy includes emollients and topical corticosteroids (TCS) to prevent and treat flares.[2] Low adherence, where adherence is defined as how much a person's health-related behaviours coincide with agreed recommendations,[3] is a main cause of treatment failure.[4]

Although topical treatments are not effective if they are not applied correctly or adequately, their use remains underreported in eczema research. Of the 77 studies included in the 2017 Cochrane Review of 'Emollients and moisturisers for eczema',[5] only 11 of the included studies reported on treatment use. Insufficient collection and reporting of topical treatment use may be because of challenges in collecting these data and uncertainties of how to summarize or interpret findings in a meaningful way.

We sought to explore different ways of capturing and reporting emollient and TCS use for children with eczema using parent-completed questionnaires with recommendations for future research in this area.

Materials and methods

Data source

Data were from the Best Emollient for Eczema (BEE) trial.[6,7] In summary, BEE was a pragmatic randomized, superiority trial comparing effectiveness and safety of four different emollient types (lotion, cream, gel or ointment) for 550 children with eczema. Recruitment started in January 2018, and the last participant completed their 16-week primary outcome period in February 2020. Participants were allocated to a study-approved emollient type to use 'twice daily and when required' as their main leave-on moisturizer. Parents were asked to complete weekly questionnaires on topical therapy use and eczema symptoms [Patient-Orientated Eczema Measure (POEM)].[8] Otherwise, clinical management was unchanged.

For this secondary data analysis study, data were restricted to participants with data on emollient and TCS use for at least one timepoint and at least one consecutive paired POEM (allowing for calculation if a flare occurred).

Eczema symptoms

POEM is a seven-item parent-reported measure asking about the frequency of seven symptoms over the previous week on a five-point scale, providing a total score of 0–28 (a higher score indicates worse disease).[8] Charman *et al*. have published the following cutoffs for categorizing eczema severity: 0–2 (clear/almost clear); 3–7 (mild); 8–16 (moderate); 17–24 (severe); and 25–28 (very severe).[9]

Emollient and topical corticosteroid steroid use

Each week, parents were asked to retrospectively report on which days (if any) their allocated emollient had been used, other types of leave-on emollient had been used, and/or TCS. Questionnaires were completed online (415/450, 92.2%) or paper (35/450, 7.8%).

Two versions of the topical therapy use questionnaires were used (Figure S1; see Supporting Information), and each participant only completed one version. The first version (January 2018 to February 2019; $n=289$) asked participants to start reporting topical treatment use on days 1 through to 7, from the day of randomization. Because of concerns about data completeness, a second version of the questionnaire was introduced (March 2019 to February 2020; $n=261$), which asked participants to start completing it by day of the week (Monday through to Sunday), starting on the first Monday after randomization.

Data have been aggregated based on how many days topical treatments were used in each week, from 0 (did not use) to 7 (used every day), rather than on which specific days of the week. Emollient use was categorized as any emollient (allocated or other), allocated emollient only, allocated and nonallocated, and nonallocated only. Missing data were weekly questionnaires that were not returned or were returned but not completed (e.g. no responses to any questions, including 'did not use' option).

Patient and public involvement

Parents of children with eczema were invited to review and comment on trial study materials, including the first topical treatment questionnaire, prior to the BEE trial commencement. Following feedback, four volunteers from within this advisory group were shown two potential amended versions and worked through questions using 'think aloud' and verbal probing techniques, aiding the second version creation.

Sample size

For the original trial, a sample size of 520 was determined to detect a clinically important difference in POEM scores (≥ 3) between treatment arms. This cohort study is an exploratory secondary analysis of these data; therefore, a sample size estimate was not done.

Statistical methods

All analyses were performed using Stata v17.0, including Sankey graph formulation (code by Naqvi Asjad, v1.73).[10] Descriptive analyses were undertaken for baseline characteristics. Continuous data were summarized as mean (SD) unless skewed, in which case median [interquartile range

(IQR)] was used. Categorical data were presented as proportion (percentage). Differences were tested using χ^2 distribution for categorical data, Mann–Whitney *U*-test for nonparametric data, and paired *t*-test for parametric data. Sankey graphs were used to present patterns of emollient use across weeks.

Results

Study sample and participant characteristics

As shown in Figure 1, 100/550 (18.2%) participants were excluded because 23 did not return their weekly questionnaire at any timepoint and 77 did not provide any paired POEM scores (allowing for flare calculation) and/or no TCS or emollient use data. Questionnaires were administered weekly for 16 weeks, so that a total of 7200 questionnaires were sought from the 450 participants in the cohort.

Of the 450 participants, there were 47.3% females ($n=213$), 87.1% of White ethnicity ($n=392$) and a median age of 4 years (IQR 2–8) with a mean baseline POEM score of 9.2 (SD 5.5) (Table 1), similar to those in the main trial. Of those who were excluded, there were a greater number from a lower socioeconomic background and who had completed the first version of topical therapy questionnaires (i.e. those given the first version were more likely to not answer it at all).

Completion of emollient and topical corticosteroid use questionnaires

Completion of emollient use questionnaires decreased from 84.7% (381/450) at week 1 to 58.9% (265/450) at week 16 (Table 2). TCS use questionnaire completion was better for week 1 (94.2%, 424/450), and although it decreased, it remained higher by week 16 (80.4%, 362/450).

Fewer emollient use questionnaires were completed in total over 16 weeks if provided with the first version (33.5%, 1082/3232 patient-weeks) compared with if provided with the second (87.9%, 3489/3968 patient-weeks, $P<0.001$). There was no difference in TCS use questionnaires completed in total over 16 weeks if provided the first version (84.9%, 2744/3232 patient-weeks) or if provided the second (87.4%, 3468/3968 patient-weeks, $P=0.002$). Completion by version is provided in Figures S2 and S3; see Supporting Information.

Reported topical therapy use over time

Table 2 presents emollient and TCS use as the proportion of days used at five timepoints and overall within the trial. Inclusive of weeks 1–16, overall topical therapy use, presented as median, were: 7 (IQR 4–7) days of use for any emollient, 6 (IQR 0–7) days of use for allocated emollient, 0 (IQR 0–3) days of use for nonallocated emollient types

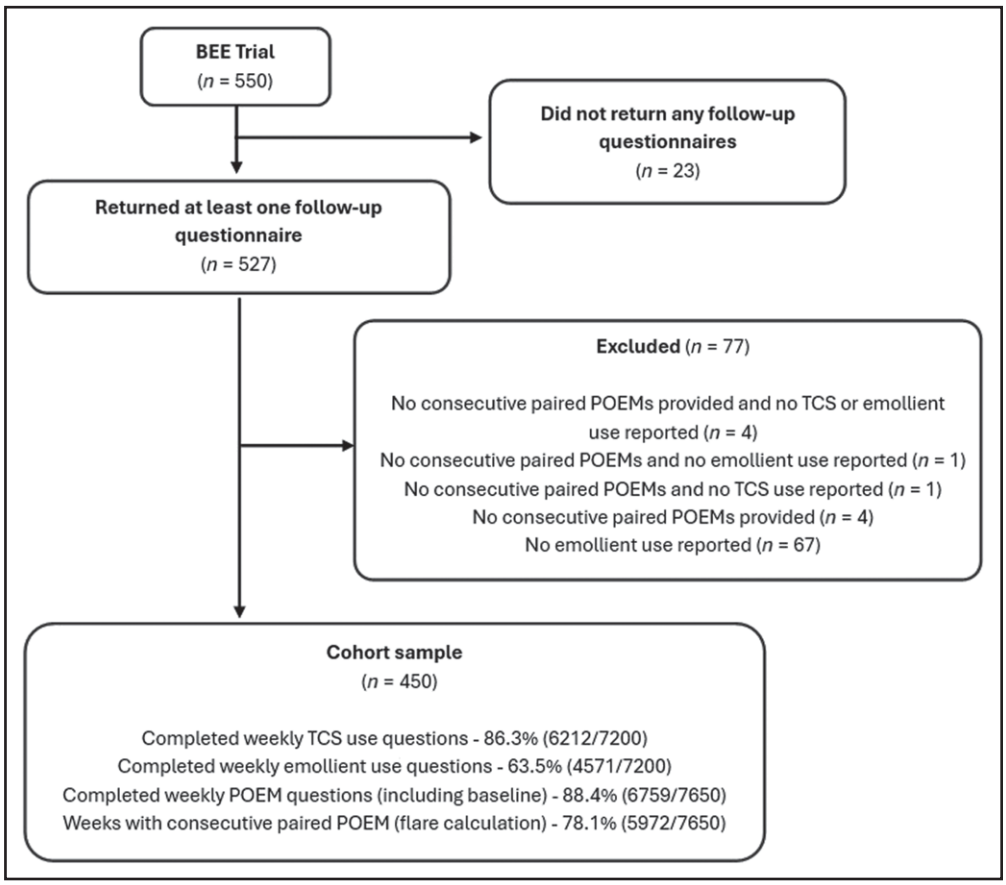

Figure 1 Study sample. Flowchart displaying inclusion criteria, sample size and percentage (number) of weekly completed questionnaires from weeks 1 to 16 for this cohort. Topical treatment questionnaires were considered completed if there was a response to at least one treatment use question per week. Note: two consecutive weekly paired POEM scores allow for calculation whether a flare occurred. BEE trial, Best Emollients for Eczema trial; POEM, Patient-Orientated Eczema Measure; TCS, topical corticosteroids.

Table 1 Baseline characteristics[a]

Characteristics	BEE trial (*n* = 550)	Cohort sample (*n* = 450)	Excluded (*n* = 100)	*P*-value
Sex				
Female	295 (53.6)	213 (47.3)	42 (42.0)	0.33
Male	255 (46.4)	237 (52.6)	58 (58.0)	
Ethnicity				
White	473 (86.0)	392 (87.1)	81 (81.0)	0.28
African, Caribbean or Black	18 (3.3)	12 (2.7)	6 (6.0)	
Asian or Asian British	16 (2.9)	13 (2.9)	3 (3.0)	
Mixed	43 (7.8)	33 (7.3)	10 (10.0)	
Age (years), median (IQR)	4 (2–8)	4 (2–8)	4 (2–7)	0.65
Socioeconomic background (IMD quintiles)[b]				
IMD 1 (most deprived)	62 (11.3)	46 (10.2)	16 (16.0)	0.02
IMD 2	55 (10.0)	39 (8.7)	16 (16.0)	
IMD 3	102 (18.5)	81 (18.0)	21 (21.0)	
IMD 4	111 (20.2)	90 (20.0)	21 (21.0)	
IMD 5 (least deprived)	173 (31.5)	154 (34.2)	19 (19.0)	
Missing	47 (8.5)	40 (8.9)	7 (7.0)	
Met UK diagnostic criteria for eczema	447 (81.3)	367 (81.6)	80 (80.0)	0.72
Baseline POEM,[c] mean (SD)	9.3 (5.5)	9.2 (5.5)	9.7 (5.1)	0.45
Baseline eczema severity				
Clear/almost clear (POEM 0–2)	40 (7.3)	37 (8.2)	3 (3.0)	0.34
Mild (POEM 3–7)	185 (33.6)	152 (33.8)	33 (33.0)	
Moderate (POEM 8–16)	266 (48.4)	210 (46.7)	56 (56.0)	
Severe (POEM 17–24)	53 (9.6)	46 (10.2)	7 (7.0)	
Very severe (POEM 25–28)	5 (0.9)	4 (0.9)	1 (1.0)	
Missing	1 (0.2)	1 (0.2)	0 (0.0)	
Treatment arm				
Lotion	137 (24.9)	114 (25.3)	23 (23.0)	0.91
Cream	140 (25.5)	116 (25.8)	24 (24.0)	
Gel	135 (24.5)	109 (24.2)	26 (26.0)	
Ointment	138 (25.1)	111 (24.7)	27 (27.0)	
Questionnaire version				< 0.001
First	289 (52.5)	202 (44.9)	87 (87.0)	
Second	261 (47.5)	248 (55.1)	13 (13.0)	

Data are *n* (%) unless otherwise specified. IMD, Index of Multiple Deprivation; IQR, interquartile range; POEM, Patient-Orientated Eczema Measure; TCS, topical corticosteroids. [a]Baseline characteristics of the Best Emollient for Eczema (BEE) trial, this cohort sample and excluded participants. Cohort sample was derived from BEE participants (Figure S1). In total, 100 participants were excluded because 23 did not return their weekly questionnaire at any timepoint and 77 did not provide any paired POEM scores and/or no TCS or emollient use data, from weeks 1 to 16. Statistical analysis: χ^2 test for categorical data and Mann–Whitney *U*-test for nonparametric data, *t*-test for parametric data. [b]*n* = 503 for BEE study, *n* = 410 for cohort sample, *n* = 93 for excluded participants. [c]*n* = 549 for BEE study, *n* = 449 for cohort sample, *n* = 100 for excluded participants.

and 0 (IQR 0–2) days of use for TCS. Where co-use was reported, allocated emollients were applied more often than nonallocated types.

Table 3 presents the proportion (percentage) of participants who reported only using their allocated emollient for all 16 weeks. We found 100% use of allocated emollient was most reported by those allocated to cream (*n* = 43/116; 37.1%) and 0% use was most reported by those allocated to gel (*n* = 52/109; 47.7%).

Figure 2 graphically presents the median days topical therapy combinations were used, by week and allocated treatment arm. Data were presented this way in the original BEE paper.[7] Participants allocated to lotion and cream appeared to have generally high emollient use. For those allocated to ointment, use of allocated and any emollient decreased over time. TCS use remained minimal for each treatment arm across all weeks.

Emollient use by individual trajectories

Table 4 shows the proportion (percentage) of participants reporting different emollient use combinations at individual timepoints (weeks 8 and 16) and throughout timepoints (weeks 1–8 and weeks 9–16), separated by allocated arm. Inclusive of weeks 1–16, total allocated emollient use ranged from 29.8% (ointment, 530/1776) to 47.7% (cream, 886/1856). These figures include all from each allocated arm (e.g. including those who did not complete their questionnaire within each week).

Sankey graphs visually depict participant use of the same or different emollients over different weeks (Figure 3). Participants generally used what they were allocated, but some used combinations of emollients or nonallocated types. The proportion of individuals within each allocated treatment arm who did not complete their questionnaire each week was similar. As some data in Table 4 were used when formulating our Sankey graph, the following conclusions can be drawn: at week 8, 29–52% used only their allocated emollient and 9–23% used nonallocated types only. At week 16, use of only allocated emollient was lower at 23–40%.

Discussion

Questionnaire completion for both emollient and TCS use decreased with time. Fewer questions about emollient use

Table 2 Number of participants reporting different combinations of emollient use

Treatment	Baseline	Week 1	Week 4	Week 8	Week 12	Week 16	Weekly use across weeks 1–16, median (IQR)[a]
Emollient use							
Completed questionnaires (% total)	450	381 (84.7)	283 (62.9)	292 (64.9)	269 (59.8)	265 (58.9)	
First version (% total)	202	143 (70.8)	56 (27.7)	71 (35.1)	58 (28.7)	65 (32.2)	
Second version (% total)	248	238 (96.0)	227 (91.5)	221 (89.1)	211 (85.1)	200 (80.6)	
Any emollient (% completed)		369 (96.9)	275 (97.2)	282 (96.6)	254 (94.4)	251 (94.7)	
Median (IQR) days any use		6 (4–7)	7 (5–7)	7 (4–7)	7 (5–7)	7 (4–7)	7 (4–7)
Allocated emollient use only (% completed)		202 (53.0)	185 (65.4)	169 (57.9)	156 (58.0)	149 (56.2)	
Median (IQR) days allocated use		5 (0–7)	6 (2–7)	6 (0–7)	6 (0–7)	5 (0–7)	6 (0–7)
Co-use of allocated & nonallocated (% completed)[b]		71 (18.6)	40 (14.1)	40 (13.7)	30 (11.2)	29 (10.9)	
Median (IQR) days allocated use		5 (3–6)	6 (2–7)	7 (4–7)	6 (4–7)	7 (4–7)	6 (4–7)
Median (IQR) days nonallocated use		3 (2–5)	4 (2–7)	4 (2–7)	3 (2–7)	2 (2–6)	3 (2–7)
Nonallocated use only (% completed)		96 (25.2)	50 (17.7)	73 (25.0)	68 (25.3)	73 (27.5)	
Median (IQR) days nonallocated use		0 (0–3)	0 (0–2)	0 (0–3)	0 (0–3)	0 (0–4)	0 (0–3)
TCS use							
Completed questionnaires (% total)	450	424 (94.2)	403 (89.6)	389 (86.4)	372 (82.7)	362 (80.4)	
First version (% total)	202	190 (94.1)	179 (88.6)	170 (84.2)	161 (79.7)	162 (80.2)	
Second version (% total)	248	234 (94.4)	224 (90.3)	219 (88.3)	211 (85.1)	200 (80.6)	
Any TCS use reported (% completed)		169 (39.9)	168 (41.7)	155 (39.8)	141 (37.9)	126 (34.8)	
Median (IQR) days TCS use		0 (0–2)	0 (0–3)	0 (0–2)	0 (0–2)	0 (0–2)	0 (0–2)
Emollient and TCS use							
Any emollient and any TCS use (% total)	450	376 (83.6)	278 (61.8)	290 (64.4)	267 (59.3)	263 (58.4)	
First version (% total)	202	142 (70.3)	54 (26.7)	71 (35.1)	56 (27.7)	63 (31.2)	
Second version (% total)	248	234 (94.4)	224 (90.3)	219 (88.3)	211 (85.1)	200 (80.6)	
Median (IQR) days both used		0 (0–2)	0 (0–2)	0 (0–2)	0 (0–2)	0 (0–2)	0 (0–2)

Data are *n* (%) of participants who returned questionnaires in total and those reporting different emollient use categories by week for weeks 1, 4, 8, 12 and 16, unless otherwise specified. IQR, interquartile range; TCS, topical corticosteroids. [a]Median (IQR) days of use during each week displayed by category, for individuals who returned their topical therapy use questionnaire. [b]Median (IQR) of co-use includes only those individuals who reported at least 1 day of allocated and nonallocated emollient use during the specified week.

were completed with the first version of the treatment use questionnaire, whereas there was no difference in the completion rates for the two versions for TCS use.

Summary tables provided detailed numerical information but quickly became complex and hard to interpret. In comparison, figures can help overcome this problem, but often a textual summary is needed, for example, for scientific abstracts. It is difficult to succinctly present both type and frequency of use, and so no one way to best report topical treatment use exists. Therefore, a combination of different tables and figures may be the only way to provide a detailed understanding of use.

We have shown that different numerical and graphical ways of summarizing topical treatment use, at individual timepoints and across trajectories, can lead to differences in how data are interpreted and the conclusions that can be drawn.

For example, the median (IQR) days of allocated emollient use (Table 2) appeared to remain consistently high at different timepoints [e.g. allocated use at weeks 1 and 16 were both 5 (0–7) days]. However, when presented graphically and considered by week and treatment group (Figure 2), it can be seen that median use of allocated emollients was consistently high for lotion and cream but decreased for

Table 3 Proportion (percentage) of respondents reporting allocated emollient use only[a]

Reported use of allocated emollient only, %	Allocated emollient, *n* (%)			
	Lotion (*n* = 114)	Cream (*n* = 116)	Gel (*n* = 109)	Ointment (*n* = 111)
100	20 (17.5)	43 (37.1)	25 (22.9)	17 (15.3)
90–99	12 (10.5)	14 (12.1)	4 (3.7)	11 (9.9)
80–89	13 (11.4)	13 (11.2)	8 (7.3)	6 (5.4)
70–79	5 (4.4)	2 (1.7)	1 (0.9)	2 (1.8)
60–69	3 (2.6)	1 (0.9)	5 (4.6)	7 (6.3)
50–59	2 (1.8)	6 (5.2)	3 (2.8)	6 (5.4)
40–49	2 (1.8)	1 (0.9)	3 (2.8)	4 (3.6)
30–39	5 (4.4)	1 (0.9)	2 (1.8)	2 (1.8)
20–29	3 (2.6)	7 (6.0)	2 (1.8)	3 (2.7)
10–19	5 (4.4)	4 (3.4)	1 (0.9)	6 (5.4)
1–9	5 (4.4)	0 (0)	3 (2.8)	7 (6.3)
0	39 (34.2)	24 (20.7)	52 (47.7)	40 (36.0)

[a]Number of participants reporting use of their allocated emollient only during the trial. Calculated by the total number of weeks only allocated emollient use reported, divided by the total number of completed questionnaires.

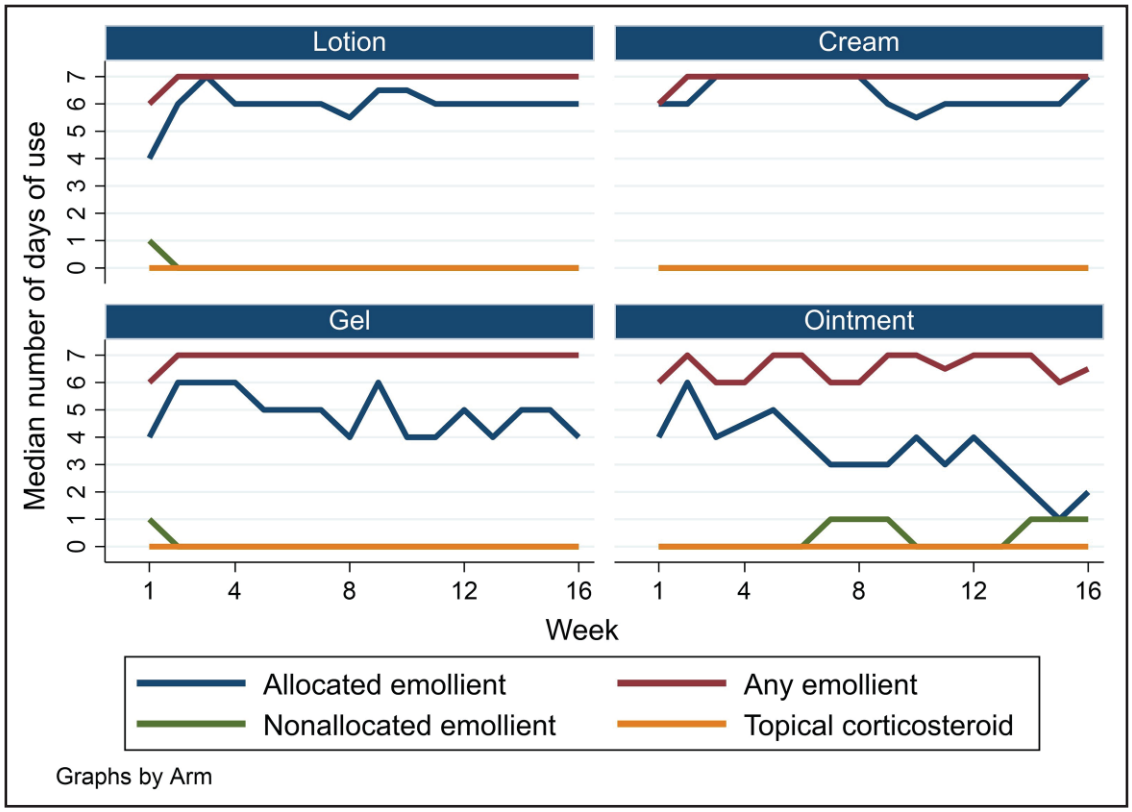

Figure 2 Median days emollient and topical corticosteroid (TCS) use reported by treatment arm. Emollient use displayed as median reported use of allocated emollient type, any emollient (allocated and other), and nonallocated emollient type only.

ointment with time. Depending on the research question and study design, this suggests that data like these should be presented in tabular and graphical formats, both for overall use but also by time and type of emollient.

Additionally, Table 2 and Figure 2 present TCS use as median days for all participants with completed questionnaires and use generally appeared low; overall median 0 (IQR 0–2) days. However, current National Institute for Health and Care Excellence guidelines generally recommend TCS use only during flares for 7–14 days,[11] and so this may not be the best way to present TCS use (i.e. TCS use should only be considered when flares occur).

Presenting use of particular topical treatments as proportions (Table 3 and Table 4) provides an overall summary but has limitations. Summarizing use as the proportion of people reporting use of a specific emollient type (Table 3) does not tell us anything about how often that emollient was used, and summarizing co-use of emollients (Table 4) does not reflect use at an individual level. For example, 29–52% and 23–40% used their allocated emollient at weeks 8 and 16, respectively (Table 4), but this does not tell us if the same children are using a particular emollient at these timepoints. By contrast, the Sankey graph shows how some individuals used different emollient combinations at different weeks, but most generally only used their allocated emollient type (Figure 3). This further supports our suggestion to use different but complementary methods to present findings.

Strengths of the study include that it provides novel insights into how to collect and report topical therapy use in childhood eczema, which could be applied to other age groups and dermatological conditions. This sample was a large and diverse cohort of children with different eczema severities who were representative of the original trial population, who in turn reflect UK community populations. More participants with a lower socioeconomic background were excluded, perhaps because a lack of literacy provides a barrier to answering the questionnaires.[12]

Weaknesses of the study include that although changes to the treatment use questions midtrial provided an opportunity for us to compare their completion, this was not planned as a study within the trial and participants were not randomized to one version or the other. Patients were invited to comment on version 1 of the topical treatment use questionnaires before they were used, but despite this, some parents confused the day of the week on which emollients were used with the number of days of emollient use and reported being uncertain which questions to answer if use deviated from allocation. The second version was tested more thoroughly, using 'think aloud' techniques. The large difference in completion for emollient use supports the suggestion that the problem was confusion over the questions rather than lack of willingness to engage.

Weekly collection of topical therapy use and eczema severity allowed for small changes in trends to be detected. However, self-report questionnaires may over-report use.[13,14] The questionnaires did not ask about the frequency, quantity applied each day or type of TCS, as this would have made the questionnaire too complex. We did not measure treatment use by asking participants to return tubs to clinics

Table 4 Proportion (percentage) of participants reporting different combinations of use by treatment arm, at and through timepoints

Emollient use combinations per allocated type	Allocation to each arm	Individual timepoints			Throughout timepoints		
		Week 8	Week 16	Weeks 8 and 16	Weeks 1–8	Weeks 9–16	Weeks 1–16
Lotion							
Lotion only	114	42 (36.8)	40 (35.1)	32 (28.1)	357 (39.1)	326 (35.7)	683 (37.4)
Lotion and one other emollient type		13 (11.4)	4 (3.5)	2 (1.8)	93 (10.2)	53 (5.8)	146 (8.0)
Other emollient type only		14 (12.3)	14 (12.3)	6 (5.3)	113 (12.4)	105 (11.5)	218 (12.0)
Other combination of emollient types		2 (1.8)	4 (3.5)	1 (0.9)	32 (3.5)	33 (3.6)	65 (3.6)
No emollient use		1 (0.9)	3 (2.6)	1 (0.9)	16 (1.8)	26 (2.9)	42 (2.3)
Questionnaires not completed		42 (36.8)	49 (43.0)	72 (63.2)	301 (33.0)	369 (40.5)	670 (36.7)
Subtotal		114	114	114	912	912	1824
Cream							
Cream only	116	60 (51.7)	46 (39.7)	39 (33.6)	481 (51.8)	405 (43.6)	886 (47.7)
Cream and one other emollient type		12 (10.3)	11 (9.5)	6 (5.2)	88 (9.5)	66 (7.1)	154 (8.3)
Other emollient type only		10 (8.6)	12 (10.3)	7 (6.0)	77 (8.3)	88 (9.5)	165 (8.9)
Other combination of emollient types		0 (0)	0 (0)	0 (0.0)	4 (0.4)	7 (0.8)	11 (0.6)
No emollient use		2 (1.7)	2 (1.7)	0 (0.0)	13 (1.4)	21 (2.3)	34 (1.8)
Questionnaires not completed		32 (27.6)	45 (38.8)	64 (55.2)	265 (28.6)	341 (36.7)	606 (32.7)
Subtotal		116	116	116	928	928	1856
Gel							
Gel only	109	35 (32.1)	37 (33.9)	29 (26.6)	309 (35.4)	287 (32.9)	596 (34.2)
Gel and one other emollient type		6 (5.5)	6 (5.5)	3 (2.8)	86 (9.9)	47 (5.4)	143 (8.2)
Other emollient type only		19 (17.4)	14 (12.8)	8 (7.3)	132 (15.1)	121 (13.9)	253 (14.5)
Other combination of emollient types		2 (1.8)	3 (2.8)	1 (0.9)	18 (2.1)	23 (2.6)	41 (2.4)
No emollient use		5 (4.6)	5 (4.8)	2 (1.8)	33 (3.8)	49 (5.6)	82 (4.7)
Questionnaires not completed		42 (38.5)	44 (40.4)	66 (60.6)	294 (33.7)	345 (39.6)	639 (36.6)
Subtotal		109	109	109	872	872	1744
Ointment							
Ointment only	111	32 (28.8)	26 (23.4)	22 (19.8)	300 (33.8)	230 (25.9)	530 (29.8)
Ointment and one other emollient type		9 (8.1)	8 (7.2)	4 (3.6)	68 (7.7)	61 (6.9)	129 (7.3)
Other emollient type only		26 (23.4)	25 (22.5)	15 (13.5)	163 (18.4)	179 (20.2)	342 (19.3)
Other combination of emollient types		0 (0)	1 (0.9)	0 (0.0)	5 (0.6)	11 (1.2)	16 (0.9)
No emollient use		2 (1.8)	4 (3.6)	0 (0.0)	21 (2.4)	25 (2.8)	46 (2.6)
Questionnaires not completed		42 (37.8)	47 (42.3)	70 (63.1)	331 (37.3)	382 (43.0)	713 (40.2)
Subtotal		111	111	111	888	888	1776

Data are *n* (%). [a]Number of participants who reported using different emollients and combinations from baseline allocation at individual timepoints (week 8 and 16) and throughout timepoints (weeks 1–8 and weeks 9–16) per allocated treatment arm.

or by having electronic lids because this was a pragmatic clinical trial.

It is common in trials to observe questionnaire completion rates declining over time, and a reduction in topical treatment use question completion specifically has been previously reported in the Barrier Enhancement for Eczema Prevention (BEEP) and Bath Additives in the Treatment of cHildhood Eczema (BATHE) trials. In BEEP, which explored whether daily emollient use reduced the risk of developing eczema in infants,[15] emollient use questions completion were 76.8% (532/693) at 3 months, 74.9% (519/693) at 6 months and 73.0% (506/693) at 12 months, with 63.8% (442/693) completing at all 3 timepoints. In the BATHE trial, where the effectiveness of bath additives for childhood eczema was evaluated,[16] 92.0% (424/461) and 86.1% (397/461) answered questions on the use of bath additives and frequency of baths per week, respectively. Like BEE, both trials collected data remotely (online, paper questionnaire or over the phone with researcher). Similar adherence in dermatology trials did not report on completion (e.g. their number of returned and/or completed questionnaires).[17–19] Our completion rate will be an underestimation as, for the purpose of other planned analyses, we excluded those without at least one paired POEM score from our analyses. Completion rates may also be affected by the frequency of questionnaires; weekly for 16 weeks in the BEE study compared with 3-monthly in BEEP for 12 months and once at 16 weeks in BATHE, for example. Asking participants to complete the questionnaire itself may constitute an intervention; for example, methodological work on POEM has demonstrated that completion is associated with improved eczema severity.[20]

Many trials exploring adherence in dermatology have only presented treatment use numerically as proportions (percentage) or mean (SD) of days of reported daily use.[16,17,21,22] We found that where our tables contained complex granular data, graphs complemented them visually to contextualize the data. Some adherence trials have similarly copresented both graphical and numerical data (either in tables or textually) to describe treatment use using line graphs[23–25] or bar charts[26,27] to display differences between treatment arms or trends over time. We are not aware of other studies utilizing Sankey graphs in this research area.

We provide a more detailed insight into patterns in use than the original BEE paper, while supporting their conclusion that most participants used their allocated emollient. We have purposefully not discussed use in terms of adherence (measuring use against a predetermined standard)[3] because it is not clear what constitutes good adherence beyond possibly daily emollient use. In BEE, adopting a definition of using an 'allocated emollient type at least one in every four weeks for at least 60% of days within this week', 28% of participants were deemed adherent. In other

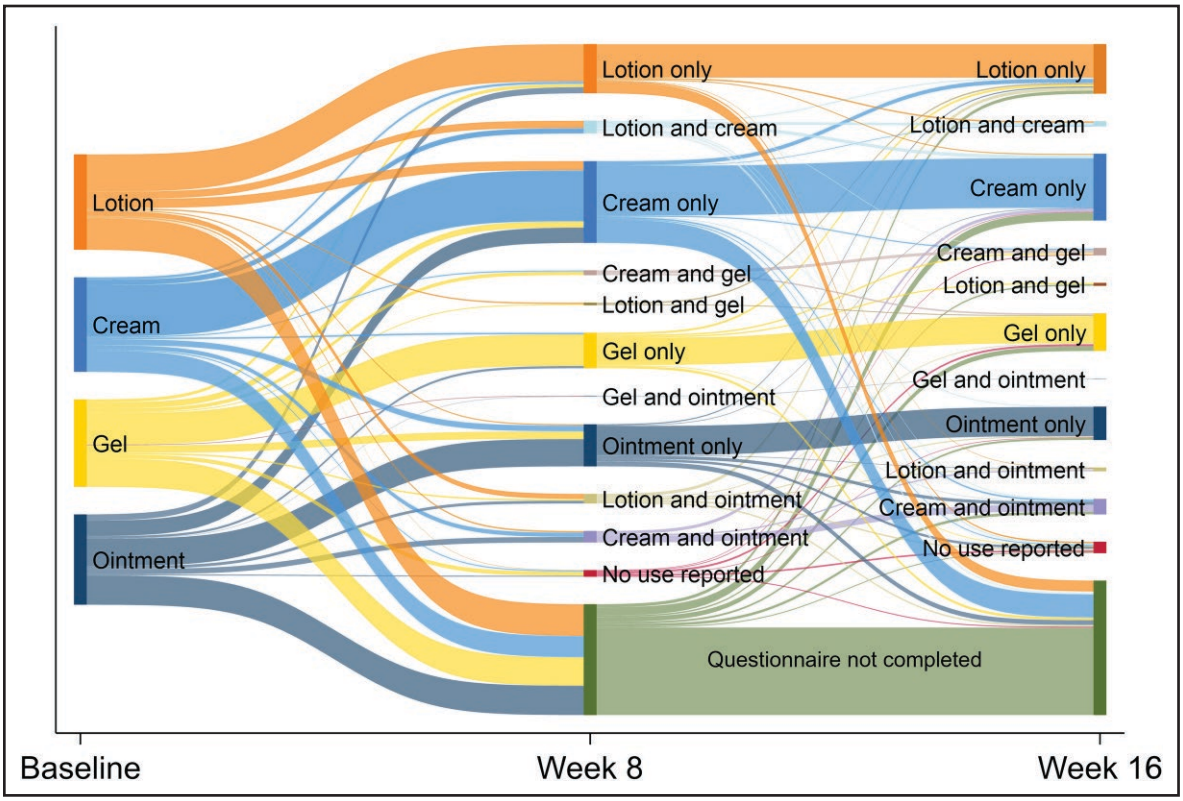

Figure 3 Sankey graph of reported emollient use at weeks 8 and 16 ($n=450$). Width of bar represents proportion of individuals who did not report use or used that emollient type and/or combination per week.

clinical trials, an arbitrary >80% use of prescribed medication is often used, without clinical rationale,[28] as this figure was derived from trials of tablets for hypertension.[29] This threshold may not necessarily be relevant to skin conditions, where acceptable adherence should focus on each individual's symptom burden and depends on type of therapy and the patient's desired outcome (e.g. rash resolution or itch reduction).[30]

Although Harmonising Outcome for Eczema guidelines make recommendations about which outcomes to collect and report in trials of eczema treatments,[31] to the best of our knowledge there is no consensus about how best to collect and report use of topical treatments as a process or outcome measure.

Implications of this study include that if topical treatment use is to be measured using patient-completed questionnaires, the detail and complexity of questions must be balanced against respondent burden and ease of completion, especially if being collected as a secondary outcome measure. The importance of how questions are phrased and response options structured, is reinforced by the differences in responses seen between versions 1 and 2 of the BEE topical treatment use questions, at least for emollients. Novel questionnaires should be piloted, using approaches such as cognitive think aloud interviews,[32] before use in studies and future research should explore barriers to questionnaire completion in this population.

Resource-limited projects should plan data collection and analysis from the outset to ensure they do not gather more data than they need to present and that findings are reported thoughtfully. We recommend a combination of graphs and numerical data to complement each other. The level of detail we collected (e.g. allocated and nonallocated use) may not be required in other trials, depending on their design. Future research should explore how best to capture daily quantity and frequency of topical therapy use, as well as TCS potency used, and in turn, how best to summarize these data. Consideration of the frequency of this data collection is warranted to achieve a balance between granularity of data, response burden and any 'treatment effect' that continually asking about the use of topical treatments might have.

In summary, there are many ways to collect and report treatment use data. Self-report questionnaires should be designed and tested according to the intended outcomes, balancing complexity and accessibility. Greater transparency on how topical treatment use is collected is warranted.

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Conflicts of interest

The authors declare no conflicts of interest.

Data availability

The authors will support any reasonable request for the data that underpins the findings of this study in line with the original BEE trial data sharing agreement.

Ethics statement

The original BEE trial was granted approval by the NHS REC (South West – Central Bristol Research Ethics Committee 17/SW/0089).

Patient consent

Participants gave written consent for their anonymized data to be used in subsequent future research.

Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's website.

References

1 Langan SM, Irvine AD, Weidinger S. Atopic dermatitis. *Lancet* 2020; **396**:345–60.
2 National Institute for Health and Care Excellence. Clinical knowledge summaries (CKS). Eczema – atopic: summary. Available at: https://cks.nice.org.uk/topics/eczema-atopic/ (last accessed 14 September 2024).
3 Gupta G, Mallefet P, Kress DW *et al.* Adherence to topical dermatological therapy: lessons from oral drug treatment. *Br J Dermatol* 2009; **161**:221–7.
4 National Institute for Health and Care Excellence. Clinical Guidance. Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence (CG76). Available at: https://www.nice.org.uk/guidance/cg76 (last accessed 14 September 2024).
5 van Zuuren EJ, Fedorowicz Z, Christensen R *et al.* Emollients and moisturisers for eczema. *Cochrane Database Syst Rev* 2017; **2**:CD012119.
6 Ridd MJ, Wells S, Edwards L *et al.* Best emollients for eczema (BEE) – comparing four types of emollients in children with eczema: protocol for randomised trial and nested qualitative study. *BMJ Open* 2019; **9**:e033387.
7 Ridd MJ, Santer M, MacNeill SJ *et al.* Effectiveness and safety of lotion, cream, gel, and ointment emollients for childhood eczema: a pragmatic, randomised, phase 4, superiority trial. *Lancet Child Adolesc Health* 2022; **6**:522–32.
8 Charman CR, Venn AJ, Williams HC. The Patient-Oriented Eczema Measure: development and initial validation of a new tool for measuring atopic eczema severity from the patients' perspective. *Arch Dermatol* 2004; **140**:1513–19.
9 Charman CR, Venn AJ, Ravenscroft JC *et al.* Translating Patient-Oriented Eczema Measure (POEM) scores into clinical practice by suggesting severity strata derived using anchor-based methods. *Br J Dermatol* 2013; **169**:1326–32.
10 Naqvi A. Stata package 'sankey' 2024. 1.73. Available at: https://github.com/asjadnaqvi/stata-sankey (last accessed 14 September 2024).
11 National Institute for Health and Care Excellence. Clinical knowledge summaries (CKS). Eczema – topical corticosteroids. Available at: https://cks.nice.org.uk/topics/eczema-atopic/prescribing-information/topical-corticosteroids/ (last accessed 14 September 2024).
12 Bonevski B, Randell M, Paul C *et al.* Reaching the hard-to-reach: a systematic review of strategies for improving health and medical research with socially disadvantaged groups. *BMC Medical Res Methodol* 2014; **14**:42.
13 Stirratt MJ, Dunbar-Jacob J, Crane HM *et al.* Self-report measures of medication adherence behavior: recommendations on optimal use. *Transl Behav Med* 2015; **5**:470–82.
14 Ahn CS, Culp L, Huang WW *et al.* Adherence in dermatology. *J Dermatolog Treat* 2017; **28**:94–103.
15 Chalmers JR, Haines RH, Bradshaw LE *et al.* Daily emollient during infancy for prevention of eczema: the BEEP randomised controlled trial. *Lancet* 2020; **395**:962–72.
16 Santer M, Ridd MJ, Francis NA *et al.* Emollient bath additives for the treatment of childhood eczema (BATHE): multicentre pragmatic parallel group randomised controlled trial of clinical and cost effectiveness. *BMJ* 2018; **361**:k1332.
17 Pena-Robichaux V, Kvedar JC, Watson AJ. Text messages as a reminder aid and educational tool in adults and adolescents with atopic dermatitis: a pilot study. *Dermatol Res Pract* 2010; **2010**:894258.
18 Navarrete-Dechent C, Curi-Tuma M, Nicklas C *et al.* Oral and written counseling is a useful instrument to improve short-term adherence to treatment in acne patients: a randomized controlled trial. *Dermatol Pract Concept* 2015; **5**:13–16.
19 Balato N, Megna M, Di Costanzo L *et al.* Educational and motivational support service: a pilot study for mobile-phone-based interventions in patients with psoriasis. *Br J Dermatol* 2013; **168**:201–5.
20 Barrett A, Hahn-Pedersen J, Kragh N *et al.* Patient-reported outcome measures in atopic dermatitis and chronic hand eczema in adults. *Patient* 2019; **12**:445–59.
21 Techasatian L, Kiatchoosakun P. Effects of an emollient application on newborn skin from birth for prevention of atopic dermatitis: a randomized controlled study in Thai neonates. *J Eur Acad Dermatol Venereol* 2022; **36**:76–83.
22 Carr AJ, Patel RP, Jones M *et al.* A pilot study of a community pharmacist intervention to promote the effective use of emollients in childhood eczema. *Pharm J* 2007; **278**:319–22.
23 Staab D, Von Rueden U, Kehrt R *et al.* Evaluation of a parental training program for the management of childhood atopic dermatitis. *Pediatr Allergy Immunol* 2002; **13**:84–90.
24 Krejci-Manwaring J, Tusa MG, Carroll C *et al.* Stealth monitoring of adherence to topical medication: adherence is very poor in children with atopic dermatitis. *J Am Acad Dermatol* 2007; **56**:211–16.
25 Cork MJ, Britton J, Butler L *et al.* Comparison of parent knowledge, therapy utilization and severity of atopic eczema before and after explanation and demonstration of topical therapies by a specialist dermatology nurse. *Br J Dermatol* 2003; **149**:582–9.
26 Moore EJ, Williams A, Manias E *et al.* Eczema workshops reduce severity of childhood atopic eczema. *Australas J Dermatol* 2009; **50**:100–6.

27 Hix E, Gustafson CJ, O'Neill JL *et al.* Adherence to a five day treatment course of topical fluocinonide 0.1% cream in atopic dermatitis. *Dermatol Online J* 2013; **19**:20029.
28 Baumgartner PC, Haynes RB, Hersberger KE *et al.* A systematic review of medication adherence thresholds dependent of clinical outcomes. *Front Pharmacol* 2018; **9**:1290.
29 Haynes RB, Taylor DW, Sackett DL *et al.* Can simple clinical measurements detect patient noncompliance? *Hypertension* 1980; **2**:757–64.
30 Feldman SR, Vrijens B, Gieler U *et al.* Treatment adherence intervention studies in dermatology and guidance on how to support adherence. *Am J Clin Dermatol* 2017; **18**:253–71.
31 Williams HC, Schmitt J, Thomas KS *et al.* The HOME Core outcome set for clinical trials of atopic dermatitis. *J Allergy Clin Immunol* 2022; **149**:1899–911.
32 Van den Haak MJ, De Jong MD, Schellens PJ. Evaluation of an informational web site: three variants of the think-aloud method compared. *Tech Commun* 2007; **54**:58–71.