	Comment	Response
Editorial comments		
1	How often was the intervention used? 92% of parents said they used it "every time" but what does that mean? How often were the children bathed? With topical treatments we would expect daily or near-daily use is needed to obtain benefit, yet we could not find any description of how frequently baths were supposed to be taken. This seems a major limitation.	We have added the following on p11: *Parent/carer report regarding frequency of bathing were: 31.2% (124/397) fewer than three baths per week; 32.7% (130/397) three or four baths per week; 36.0% (143/397) 5 or more baths per week.* We have added a table to make this clearer (Table 2: Adherence to allocated treatment and frequency of bathing during the 16-week primary outcome period) It is important to point out that we were testing the effectiveness of GPs prescribing bath additives, rather than an efficacy trial of closely controlled adherence to use of bath emollient. This was the pragmatic question that our funders sought an answer to and that we believe will be most useful to prescribers.
2	Conversely, are these additives available without prescription? And could this have led to contamination, so that both group used these?	Although bath additives are available without prescription they are rarely purchased as prescriptions for children are free in the UK. This was a pragmatic trial so some contamination is always possible (as will happen in daily practice). However, data on contamination suggests good group differentiation, as shown in Table 2
3	We are not sure bath emollients do not work, based on this trial, only that they don't work when baths are intermittent. At a minimum we think we need information about the frequency of bathing in each group and a discussion of this matter.	Please see response to editorial comment 1 and 7.
4	Likewise, as some reviewers point out, it remains possible additives are effective in some subgroups such as those with more severe disease. You need to defend pooling patients with varying degrees of disease severity.	We have added text and table reporting subgroup analyses (Table 4: POEM scores during the 16-week primary outcome period, by group and subgroup) We have added the following comment in the discussion: *While we cannot exclude the possibility that children aged less than 5 years who bath frequently might benefit, this is unlikely to be a clinically meaningful benefit.*
5	We agree with reviewer who says we need a better description of what emollient bath additives are.	We have added to the Background that emollient bath additives are thought to leave a film of oil over the skin that helps it to stop losing moisture.
6	More information on how adverse events (AEs) were collected would be useful. It is unclear, from the AE table, how many individual participants experienced an AE. You report 44 slips, for example, but in how many people?	This is 44 slips occurring in unique participants over the 16 week period. We have added the n to the table 5 to make this clearer.
7	What does "pragmatic" mean? The patient reviewer makes a good point about this.	We have added the following sentence to the Methods: *We chose a pragmatic design (Loudon et al, BMJ 2015) that aimed to test whether bath additives offer additional benefit in real life eczema care rather than in ideal experimental conditions.* In the protocol paper for this trial, published in BMJ Open and referred to in the manuscript, we explained

		why we chose a pragmatic question and how this influenced trial design: *Pragmatic clinical trials aim to test the effectiveness of an intervention in a real-life setting in order to recruit a study population that is as similar as possible to the population on which the intervention is meant to be used. Whereas an explanatory clinical trial aims to answer the question, 'Can this intervention work under ideal conditions?' a pragmatic approach seeks to answer the question, 'Does this intervention work under usual conditions?' (Thorpe 2009, Loudon 2015). Features of pragmatic trials include: that they use clinically important outcomes, commonly participant-reported outcomes; that they include longer term follow-up; and that participants are encouraged to adhere to the intervention only to the extent that would be anticipated in usual care.* The following paragraph then explains in further detail how this influenced trial design. In order to keep the outcomes paper concise, we did not repeat this discussion
8	Flow diagram says 265 were in the intervention group, but Table 1 says 264. Is this flow diagram up to Consort standards?	Thank you for highlighting this – we have revised the Consort diagram to show the additional information.
9	You assert this is an ITT analysis but the flow diagram doesn't have explicit numbers for the final analysis, just reports how many filled out forms at various points. Can you add this information?	In order to contribute to a mixed model, a participant has to have at least 1 post baseline measure. Ideally, they have more, but 1 is the minimum. So 461/482 (95.6%) participants contributed to the final analysis. We have added detail to the CONSORT diagram to make this clearer.
10	A very small proportion of eligible participants decided to participate in the trial. This doesn't seem a particularly burdensome study, so what is the reason for the reluctance? Is the trial population representative of the wider population of children with eczema or is there something unusual about those who agreed to participate? Can you comment?	The response rate to letters of invitation from practices, although in keeping with similar studies, (Ridd 2016) was relatively low. However, of those who replied that they did not wish to participate, by far the most common reason for this was that their child's eczema was no longer a problem. It seems likely that many who did not respond would have not returned the reply slip for this reason. We have added acknowledgement of the response rate to the second paragraph of the discussion on p13.
11	We probably do not need an extended Cost-effectiveness analysis, when intervention was not effective.	We have left a brief paragraph on cost-effectiveness in the manuscript, as we feel some readers may be interested in this, but would be happy to remove this.
12	There are differences in secondary outcomes as listed in the trial registry vs. protocol vs. paper. Within the paper there are differences between the list on p. 6-7 and Tables 2-3. See attached list.	Apologies for the differences, which are accounted for by discrepancies in whether the economic evaluation and adverse effects are listed with 'secondary outcomes' or 'other outcomes'. All listed outcomes are included in the paper, except that cost-effectiveness and resource use are presented very briefly. We could add further data if needed.
Reviewer 1		
1	More detail and explanation about co-interventions- both groups continued standard eczema management- topical (leave on) emollients and steroids when	We apologise for the use of acronyms and have added a footnote to table 2 explaining that TCS/TCI denotes topical corticosteroid or topical calcineurin inhibitor.

	required. Table 2 reports on TCS and TCI- I am unsure what TCI stands for (topical emollient). Was there a differential use of these co-interventions in the proportion of children using them during the course of the RCT? Did adjustment for topical emollient and/or steroid have any impact on the primary and/or secondary outcomes when measured as a continuous variable and/or categorical variable?	As set out in the statistical analysis plan, we controlled for TCS/TCI use at baseline in the adjusted analyses. We didn't control for TCS/TCI use at each time point because we only asked at baseline, 16 weeks and 52 weeks.
2	Formatting issues- Table 1, last column is redundant;	We are happy to remove this column if this is preferable to the Editors
3	Figure 1, abbreviation for "BA" and "No BA" is needed.	We apologise and have removed these abbreviations from Figure 2. (They do not appear in Figure 1)
Reviewer 2		
1	I hope the research group continues to answer pragmatic primary care research questions	Thank you and we in intend to.
Reviewer 3		
1	Data from the 3 emollient bath additives in the study were pooled despite that they differ in composition. A few additional comments/information would be helpful to a reader interested in understanding the contribution of non-drug interventions in eczema management: a. Please provide the numbers of subjects that used the various bath additives, b. Provide a few words about the composition of each (Aveeno (oatmeal bath) varies significantly from Balneol). c. Assuming no between-treatment subanalysis of the various interventions was conducted (or possible?), please mention why. It's possible that there could be influences/differences related to composition, which should be at least mentioned in the discussion.	We have added detail of proportion of participants using each bath additive to the manuscript on p16. There are no published efficacy trials or other rationale suggesting that any emollient bath additives are superior to each other, except that those with antimicrobial properties may be more irritant, which is why the latter were excluded. Although the postulated 'emollient effect' mechanism for bath additives are the same, they vary in constituent ingredients. We included the three mostly widely prescribed in the UK: Oilatum (Light Liquid paraffin 63%); Balneum (85% soya oil). As Aveeno does not have a pharmaceutical license (it is listed as ACBS in the British National Formulary), there is no Summary of Product Characteristics. However the main constituents listed on their website are water and glycerine. We would prefer not to carry out post hoc analyses f the different bath additives as this wasn't a trial to compare the effectiveness of different products, but to find any evidence of benefit as currently used in a pragmatic trial. No subgroup analysis comparing different bath additives was included in the statistical analysis plan for this reason. Carrying out this post hoc analysis would be complicated by the finding that some families used more than one bath additive product.
2	The manuscript mentions the range of possible scores for the POEM evaluation. However I could not find a similar range for the DFQI. The median values are fairly low at baseline and unchanged, but without the range the reader has no idea of how impacted the patients were.	We apologies and have added the ranges for POEM, DFIQ and NESS to Table 1
3	The study included mostly patients with mild and moderate eczema, but also some with	Please see our response to Editorial comment 4.

	more severe eczema (POEM scores in Table 1). This begs the question as to whether there might be differences between those with low eczema impact, and those with a higher POEM scores. It might be worth commenting on this.	
4	The cost-effectiveness is important and nicely evaluated and discussed in the manuscript. Besides a potential for cost savings, omitting bath additives could be a welcome simplification in bath-time for care-givers, who bear additional burdens caring for children with eczema – another possible benefit.	We have not removed the cost-effectiveness analysis entirely because we agree that readers may be interested in this.
5	Under "What is already known on this subject" perhaps line 32 and 33 could be modified, e.g. "The efficacy of emollient bath additives for the treatment of childhood eczema has not been convincingly assessed due to a lack of adequately powered studies."	We have changed this accordingly.
6	Under "What this study adds" statement seems to be missing a word: "This is a large…"	We have changed this accordingly.
7	Also, page 8, line 37, should be "…additives with (not and) no difficulty"	We have changed this accordingly.
Reviewer 4		
1	There is no reference for "widespread clinical consensus around soap substitutes... ", which weakens the argument.	We apologise and have added the reference.
2	it is also described as a "Pragmatic randomised open-label superiority trial with two parallel groups" and referred to as pragmatic later in the text, which was confusing. Although, I have undertaken postgraduate study in research methods I was not completely clear how this differs from an RCT.	Please see our response to Editorial comment 7.
Reviewer 5		
1	The percentage of parents/carers who responded to the study invite was quite small (7%). Hence the study sample is select group of 'positive healthcare' families. This should be acknowledged.	Please see our response to Editorial comment 10.
2	The sample size statement relates to a repeated measures ANOVA, but insufficient information is given to be able to replicate the power calculation. More details should be provided about, for example, the assumed within and between subject variability.	We have added the assumed correlation between repeated measures on p7.
3	The disparity in the randomised group sizes (218 vs 264) seems rather large. Was a blocked randomisation method not used?	Randomisation was performed using LifeGuide software hosted by the University of Southampton and validated by Southampton Clinical Trials Unit. At the time of trial set-up, LifeGuide was unable to easily perform block randomisation, and the additional programming time

		would have resulted in delays to the trial. Simple randomisation was therefore used, stratified by centre. Although this can result in imbalances, it was felt that with strata over 100 participants each, the overall balance between groups would be preserved. Furthermore, simple randomisation may better preserve allocation concealment and be less subject to technical errors. (Hewitt 2006) Although simple randomisation can result in imbalances in the numbers recruited to each arm, in a large trial such as BATHE the overall balance between groups should be preserved. The baseline characteristics showed that, whilst there were more participants allocated to the bath additive arm than the no bath additive arm, the key characteristics were well balanced.
4	Exactly how were missing values dealt with in the statistical analysis?	We have added the following to the Methods section: *The model used all the observed data and made the assumption that missing POEM scores are missing at random given the observed data. The model included a random effect for centre (random intercept) and patient (random intercept and slope on time) to allow for between-patient and between-centre differences at baseline and between-patient differences in the rate of change over time (if a treatment/time interaction was significant), and fixed effects for baseline covariates. An unstructured covariance matrix was used.*
5	What was the frequency of use of the bath emollient? Adherence to using the emollient (every bath time) is not necessarily a good indicator of the effective use of the emollient if not all parents are bathing their child every day. It would seem more appropriate to measure frequency of use (every day, every two days?) and carry out a sensitivity analysis which takes account of this factor.	Please see response to Editorial comments 1 & 3.
6	Insufficient details of the economic analysis are reported. Perhaps this could be omitted from the paper?	We have left brief economic analysis in, but would be happy to remove.

References

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Ridd MJ, Garfield K, Gaunt DM, Hollinghurst S, Redmond NM, Powell K, et al. Choice of Moisturiser for Eczema Treatment (COMET): feasibility study of a randomised controlled parallel group trial in children recruited from primary care. BMJ Open 2016;6:e012021. http://dx.doi.org/10.1136/bmjopen-2016-012021

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