

BMJ - Decision on
Manuscript ID
BMJ.2017.042841.R
1

Body:

12-Mar-2018

Dear Dr. Santer

Manuscript ID BMJ.2017.042841.R1 entitled "Emollient bath additives for the treatment of childhood eczema (BATHE): multi-centre pragmatic parallel group randomised controlled trial of clinical and cost-effectiveness"

Thank you for sending us your paper. We sent it for external peer review and discussed it at our manuscript committee meeting. We recognise its potential importance and relevance to general medical readers, but I am afraid that we have not yet been able to reach a final decision on it because several important aspects of the work still need clarifying.

We hope very much that you will be willing and able to revise your paper as explained below, so that we will be in a better position to understand your study and decide whether the BMJ is the right journal for it. We are looking forward to reading the revised version and, we hope, reaching a decision.

Yours sincerely,

dr. Wim Weber
European editor, The BMJ
wweber@bmj.com

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Thank you for reporting additional secondary outcomes. However, there are still discrepancies between register and the present paper:

Register mentions:

3. Disease-specific QoL at baseline, 16 weeks and 1 year, measured by DFI (Dermatitis Family Impact), IDQoL (Infants Dermatitis Quality of Life index) and CDLQI (Childrens Dermatology Life Quality Index).
4. Generic QoL as measured by the Child Health Utility 9D (CHU 9D), a paediatric health related quality of life measure for use in economic evaluations, and the Health Utility Index II (HUI2), a utility measure that has been widely used in paediatric research (the UK valuation tariff will be used).

The paper mentions (p. 6-7) the following outcomes, that are not given in Table 3:

Disease-specific quality of life at 16 weeks and 1 year, measured by Dermatitis Family Impact(18),
Generic quality of life at 16 weeks and 1 year, measured by Child Health Utility 9D(19),
Resource use from GP notes review and parent/carer questionnaires,
Adherence to treatment allocation (parent/carer report).

Preferably all data for the secondary outcomes as listed in the register should be given in the paper. However, if you want to report these elsewhere (As these are part of the cost-effectiveness analysis that we have asked you to shorten), please add a sentence informing the reader where these can be found. We would appreciate data in Table 3, for the secondary outcomes you mention on p.6-7.

First, please revise your paper to respond to all of the comments by the reviewers. Their reports are available at the end of this letter, below.

In your response please provide, point by point, your replies to the comments made by the reviewers and the editors, explaining how you have dealt with them in the paper.

**** Comments from the external peer reviewers****

Reviewer: 1

Recommendation:

Comments:

This paper has been revised to take account of many of the previous statistical issues.

1. More information is provided on the treatment of missing values, the randomisation method and the sample size calculation.
2. Frequency of bathing data is now presented (new Table 2).
3. Additional subgroup analyses have been carried out and reported in detail (new Table 4) which includes the comparison for the subgroup who bathed more frequently.
4. Acknowledgement of the low response rate is included in the Discussion.

There is just one remaining point related to the interpretation of the results. The significant effect for those children who bathed 5 or more times per week is reported in the text (but not in the Abstract) and is simply interpreted as, "...there may be a small clinically meaningful benefit to bath additives in this group" (Page 13). I would have thought that a little more should be made of this result, particularly in relation to the idea that very frequent use may be needed to receive any benefit of the treatment..

Additional Questions:

Please enter your name: Julie Morris

Job Title: Head of Medical Statistics

Institution: UHSM

Reimbursement for attending a symposium?: No

A fee for speaking?: No

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Funds for research?: No

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