Editorial comments

Register mentions:

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).

Dermatitis Family Impact (DFIQ) appears in Table 3.

IDQoL (Infants Dermatitis Quality of Life index) and CDLQI (Childrens Dermatology Life Quality Index) were not measured. These appeared in the register as there was initial uncertainty regarding which disease-specific QoL we would use but, in order to minimise responder burden, we only included the DFIQ. Unfortunately we did not go back and change the registration.

In the published protocol paper we wrote that we would measure the DFIQ but did not mention the IDQoL and CDLQI (Santer et al 2015).

Register mentions:

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).

CHU-9D has been added to Table 3.

HUI2 was not measured. It appeared in the register as there was initial uncertainty regarding which generic QoL we would use but, in order to minimise responder burden, we only included the CHU-9D. The SPaCE pilot study in childhood eczema showed that the CHU-9D performed well (Santer et al 2014) so we used only this and unfortunately did not go back and change the registration.

In the published protocol paper we wrote that we would only measure the CHU-9D (Santer et al 2015).

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).

Dermatitis Family Impact (DFIQ) appears in Table 3.

Generic QoL (CHU-9D) has been added to Table 3.

Resource use from GP notes review and

parent/carer questionnaires are lengthy tables and appear in full in the HTA report, which has just been resubmitted. We have added the following sentence on p16:

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.

Full data on resource use (GP notes review and parent/carer report) and cost-effectiveness analysis will be published in the NIHR HTA journals library.

Adherence to treatment allocation appears in Table 2. We are happy to merge this with Table 3 if you prefer but feel the current layout of the tables allows more detail to be displayed.

Reviewer comments

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,

In addition to the comment cited by the reviewer on p13-14, we also reflect on this point in the discussion:

"....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.

We cannot exclude the possibility of a small benefit amongst children bathing more than 5 times per week or amongst children aged less than 5 years but differences are sufficiently small to be unlikely to be clinically useful. Furthermore, caution is needed in interpreting these underpowered subgroup analyses as statistically significant results may arise because the data has been tested multiple times rather than because a genuine difference exists between the groups.

We feel reluctant to flag up this underpowered exploratory analysis in the abstract, as it was one of a number of exploratory analyses mentioned in the paper, most of which were negative. As reported, within this subgroup the difference in POEM is only 2.27 (95% CI 0.63 to 3.91), which is small given the minimal clinical important difference of 3.

Santer M, Muller I, Yardley L, Burgess H, Selinger H, Stuart BL, Little P. Supporting self-care for families of children with eczema with a Web-based intervention plus health care professional support: pilot randomized controlled trial. Journal of medical Internet research. 2014 Mar;16(3).

Santer M, Rumsby K, Ridd MJ, Francis NA, Stuart B, Chorozoglou M, Wood W, Roberts A, Thomas KS, Williams HC, Little P. Bath additives for the treatment of childhood eczema (BATHE): protocol for multicentre parallel group randomised trial. BMJ open. 2015 Oct 1;5(10):e009575.