

Impact case study (REF3b)

Institution: University of Portsmouth
Unit of Assessment: 2 Public Health, Health Services and Primary Care
<p>Title of case study: Demonstration of the ineffectiveness of water softeners in reducing symptoms of eczema in children</p>
<p>1. Summary of the impact</p> <p>Our research has shown that water softeners are not effective in reducing the symptoms of moderate to severe eczema in children, and that their use provides no additional benefit over usual care. This finding has had an impact on Healthcare practitioners ensuring they are now able to offer the evidence-based advice to patients that the use of water softeners will not alleviate the symptoms of eczema. This advice not only eliminates false hope in patient groups but also results in significant cost savings for families of children with moderate to severe eczema who might otherwise have purchased water softeners.</p>
<p>2. Underpinning research</p> <p>Atopic eczema (AE), that has a varied clinical spectrum, is the most common of the chronic inflammatory skin diseases, with a life time prevalence of 15-30% in children and 2-10% in adults (WAO, White Book on Allergy, 2011). AE represents an important public health issue due to its impact on quality of life and its socio-economic burden. The economic burden of AE in UK is high, with an estimated total annual expenditure of £465million in 1996. Treatment options for childhood eczema have focused on topical medications, with corticosteroids being the mainstay of treatment, along with the regular use of emollients. Many parents, however, worry about the side effects of the medications. Although side effects such as skin thinning and growth retardation, have not been supported by long-term studies, it is important to recognise these concerns and to look for other ways of treating eczema. Options that avoid these possible side effects would be a welcome addition to the management of eczema.</p> <p>There have been widespread anecdotal reports of skin improvement of people with eczema when moving from a hard- to a soft-water area, but a previous systematic review of eczema treatments (Hoare et al HTA Systematic Review 2000) failed to identify any relevant trials evaluating the potential benefit of water softeners for eczema. In view of the limited evidence, the high public interest in their potential benefit, and low risk of adverse effects, the UK NIHR Health Technology Assessment programme prioritised and commissioned us ⁽¹⁾ to conduct the Softened Water Eczema Trial (SWET). The study for which Professor Dean was a Principal Investigator, took place during 2007-2010, in collaboration with Professor Hywel Williams and Dr Kim Thomas (Centre of Evidence Based Dermatology, University of Nottingham). Professor Dean has significant experience of carrying out complex multi-centre clinical trials in the area of asthma and allergy and was pivotal in securing the funding needed to conduct the study.</p> <p>The SWET had two main objectives: (1) to assess whether water softeners reduce the severity of eczema in children with moderate to severe eczema, and, if so, (2) to establish the likely cost and cost-effectiveness of the intervention. This was an observer-blind randomised trial involving 336 children (aged 6 months-16 years) with moderate/severe atopic eczema. This sample size was needed to provide 90% power, assuming a significance level of 5%. Participants, living in hard water areas, were randomly allocated into one of two groups: installation of an ion-exchange water softener plus usual eczema care, or usual eczema care alone². The primary assessment was change in eczema severity (Six Area Six Sign Atopic Dermatitis Score, SASSAD) at 12 weeks, measured by research nurses (blinded to treatment allocation). The mean change in SASSAD at 12 weeks was 25.0 (20% improvement) for the water softener group, and 25.7 (22% improvement) for the usual care group (mean difference 0.66, 95% CI 21.37 to 2.69, p = 0.53). The research provided conclusive evidence that the use of water softeners provides no additional benefit to usual care in this study population^{3,4}.</p>

3. References to the research

- 1) Williams H, Thomas K, **Dean T**, Brown N, Pollock I. Randomised controlled trial of ion-exchange water softeners for the treatment of atopic eczema in children, Department of Health Research & Development, HTA Programme. Grant period: 2006-2009, value: £980,000.
- 2) Thomas, K. and Sach, T.* on behalf of **the SWET Trial Investigators including Professor Dean**. (2008) *A multicentre randomized controlled trial of ion-exchange water softeners for the treatment of eczema in children: protocol for the Softened Water Eczema Trial (SWET)* (ISRCTN: 71423189). *British Journal of Dermatology*, 159: 561-566.
DOI: [10.1111/j.1365-2133.2008.08704.x](https://doi.org/10.1111/j.1365-2133.2008.08704.x) Impact factor: 3.759
- 3) Thomas K., Koller K., **Dean T.**, O'Leary C., Sach T., Frost A., et al. (2011) *A multicentre randomised controlled trial and economic evaluation of ion-exchange water softeners for the treatment of eczema in children: the Softened Water Eczema Trial (SWET)*. *Health Technology Assessment*, 15(8): 5-156.
DOI: [10.3310/hta15080](https://doi.org/10.3310/hta15080) Web: <http://www.hta.ac.uk/fullmono/mon1508.pdf>
Impact factor: 4.02
- 4) Thomas KS, **Dean T**, O'Leary C, Sach TH, Koller K, et al. (2011) *A Randomised Controlled Trial of Ion-Exchange Water Softeners for the Treatment of Eczema in Children*. *PLoS Med* 8(2): e1000395.
DOI: [10.1371/journal.pmed.1000395](https://doi.org/10.1371/journal.pmed.1000395) Impact factor: 15.253
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4. Details of the impact

Treating and living with eczema has large cost and quality of life implications for society and the individual families affected. In 1995–6 the total annual UK cost of eczema in children aged ≤ 5 years was estimated to be £47M (or £79.59 per child), of which 64% was accounted for by NHS health-care costs. A further UK study looking at a broader age range estimated the total annual cost to be in the order of £465M, of which £125M was incurred by the NHS, £297M by the patients and £42M by society. Childhood eczema has been shown to have a similar impact on health-related quality of life as other common childhood conditions, such as asthma and diabetes.

Current treatments consist predominantly of emollients, bath oils and topical corticosteroid creams, although some children may receive topical or oral antibiotics, or oral antihistamines. Many parents, however, worry about the side effects of conventional topical medications, particularly in relation to corticosteroids. Options that avoid the possible side effects of conventional pharmacological treatments, such as water softeners, wet wraps and special dietary products, have been welcomed by many parents and medical professionals as an additional way to manage eczema. Indeed hard water is identified as an environmental trigger in the NICE (2007) guidelines on atopic eczema in children 12 years and under.

It is likely that a number of families of children with eczema have purchased ion-exchange water softeners in the belief that their use would provide relief from the condition, although there was no robust scientific evidence to support this. Indeed, up until 2010 the National Eczema Society's Factsheet on the use of water softeners for healthcare professionals and eczema sufferers, indicated that the use of water softeners may be beneficial. The results of the SWET demonstrate that the use of water softeners does not alleviate the symptoms of eczema. The Chief Executive of National Eczema Society now states (CS1): "as a direct result of the research conducted by Professor Dean (University of Portsmouth) and Professor Williams and Dr Thomas (University of Nottingham) in their study, "Effectiveness of water softeners in the management of symptoms of moderate to severe eczema", which clearly demonstrated that water softeners do not provide any

Impact case study (REF3b)

additional benefit compared to standard eczema treatments, we decided to withdraw this Factsheet from our range”.

In May 2011, Drinking Water Inspectorate (who provide independent reassurance that public water supplies in England and Wales are safe and drinking water quality is acceptable to consumers) issued a guidance document on ‘Water Hardness’ which incorporated a section on ‘Should I use water softener?’. This document stated that our study ‘showed no objective difference in outcomes between the children whose homes were fitted with water softeners and those without’ (CS2), citing our PLOS paper (reference 4 in section 3) as the only reference.

As a direct result of our work clinical practitioners and healthcare professionals are now able to provide evidence-based advice that the use of water softeners will not alleviate the symptoms of eczema, thus managing expectations in patients and their families. An example of this is evidenced by a letter from a General Practitioner CS3.

Our work has also resulted in significant cost savings for families, who might otherwise have purchased water softeners, and the selection of more appropriate interventions for children with moderate to severe eczema. The typical cost of a water softener unit is £600 (range: £300-£1800). Our economic evaluation demonstrated that the additional mean total cost of eczema treatment per patient in the water-softener group compared with control group was £198 for the 12 weeks trial duration alone. . This significant cost difference was due to the cost of the intervention; all other resource categories (health professional visits, medications and other medical items) were not significantly different between groups. As our study conclusively demonstrated that ion-exchange water softeners were not found to be clinically effective or cost-effective over the trial horizon, it was not felt to be appropriate to model the longer term cost-effectiveness of water softeners.

This study is generalisable with significant reach. It was designed as a pragmatic study. Participants were recruited from UK centres across the primary and secondary care setting, and included families of diverse socioeconomic backgrounds. The main impact from this research is on the health of the population, with associated impacts on clinicians who can ensure that their practice (with respect to use of water softeners in patients with eczema) is based on robust high quality evidence.

A further, indirect, impact of the research is the potential cost saving offered to patients and their families, or to the health services that might pay for purchase and installation of a water softener.

5. Sources to corroborate the impact

CS1. Letter from CEO of National Eczema Society re. withdrawal of water softeners Factsheet

CS2. Water Regulatory Authority Guidance Document - <http://dwi.defra.gov.uk/consumers/advice-leaflets/hardness.pdf> Water Regulatory Authority Guidance Document –

CS3. Letter from a General Practitioner with an interest in Eczema