



**Title** A Multicentre Randomized Controlled Trial and Economic Evaluation of Ion-Exchange Water Softeners for the Treatment of Eczema in Children: The Softened Water Eczema Trial (SWET)

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## Aim

To determine whether installing an ion-exchange water softener in the home could improve atopic eczema in children and, if so, to establish its likely cost and cost effectiveness.

## Conclusions and results

Target recruitment was achieved (n=336). The analyzed population included 323 children who had complete data. The mean change in primary outcome (Six Area, Six Sign Atopic Dermatitis [SASSAD]) at 12 weeks was -5.0 (standard deviation [SD] 8.8) for the water softener group (group A) and -5.7 (SD 9.8) for the usual care group (group B) (mean difference 0.66, 95% confidence interval [CI] -1.37 to 2.69, p=0.53). Per-protocol analysis supported the main analysis. No evidence showed that the treatment effect varied between children with and without mutations in the filaggrin gene. No between-group differences were found in the 3 secondary outcomes that were assessed blindly (use of topical medications; night-time movement; proportion showing reasonable, good, or excellent improvement). Small, but statistically significant, differences favoring the water softener were found in 3 of the secondary outcomes assessed by participants (Patient-Oriented Eczema Measure; well-controlled weeks; Dermatitis Family Index). Results of the economic evaluation suggest that from an NHS perspective ion-exchange water softeners are unlikely to be a cost-effective intervention for children with atopic eczema. Water softeners provided no additional benefit to usual care in this study population. Small, but statistically significant, differences were found in some secondary outcomes reported by parents, but such improvements were likely the result of response bias. Whether or not the wider benefits of installing a water softener in the home are sufficient to justify purchasing a softener is something for individual householders to consider on a case-by-case basis. This trial demonstrated overwhelming demand for nonpharmacological interventions in treating eczema, which should be considered when prioritizing future research.

## Recommendations

See Executive Summary link [www.hta.ac.uk/project/1520.asp](http://www.hta.ac.uk/project/1520.asp).

## Methods

The Softened Water Eczema Trial (SWET) was a pragmatic, randomized controlled trial (RCT) of children aged 6 months to 16 years with moderate or severe atopic eczema. All lived in hard water areas ( $\geq 200$  mg/l calcium carbonate) in England. Participants were randomized to receive either immediate installation of an ion-exchange water softener plus their normal eczema care for 12 weeks (group A), or normal eczema care alone for 12 weeks (group B). At 12 weeks the primary outcome was assessed, after which water softeners were removed for participants in group A, or installed for a period of 4 weeks for those in group B. Additional data were collected between weeks 12 and 16 to conduct within-group comparisons to determine the possible duration of benefit effects in group A and speed of onset of possible benefit in group B. The primary outcome of change in eczema severity at 12 weeks was measured using the SASSAD score, which records 6 signs of eczema in 6 areas of the body. Research nurses who were unaware of treatment allocation measured the SASSAD score. Pilot work had demonstrated that blinding participants with a sham unit was only partially successful. Hence, participants and their families were not blinded to allocation group in the main SWET study.

## Further research/reviews required

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