A study of ion-exchange water softeners for the treatment of eczema in children: SWET

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)

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Executive summary

Health Technology Assessment 2011; Vol. 15: No. 8
DOI: 10.3310/hta15080

Health Technology Assessment
NIHR HTA programme
www.hta.ac.uk

Executive summary

Background

Atopic eczema (also known as atopic dermatitis, or eczema) is a chronic, itchy, inflammatory skin condition that mainly affects young children.

Eczema is very common, affecting around 20% of school children in developed countries, and appears to be on the increase worldwide. Eczema can cause intractable itching, leading to thickened skin, bleeding, secondary infection, sleep loss, poor concentration and psychological distress to the child and the entire family. The cost of treating eczema is substantial, both for the health provider and for families.

Evidence linking increased water hardness with increased prevalence of eczema was first reported in a large study of primary school children living around Nottingham, UK. Similar results have since been reported in Japan and Spain. In addition, there are widespread anecdotal reports of the benefits of water softeners for the treatment of eczema. However, reviews of eczema treatments have failed to identify any relevant clinical trials looking at the potential benefits of water softeners for eczema sufferers. In view of the limited evidence for water softeners in eczema and the high public interest in their potential benefit, along with the added benefits of protecting against scale deposition in household appliances and the low risk of adverse events, the UK National Institute for Health Research Health Technology Assessment programme commissioned the Softened Water Eczema Trial (SWET).

Objectives

The aim of SWET was to test whether installation of an ion-exchange water softener in the home could reduce the severity of eczema in children and, if so, to establish its likely cost and cost-effectiveness.

Methods

The Softened Water Eczema Trial (SWET) was a pragmatic randomised controlled trial (RCT) of children aged 6 months to 16 years with moderate or severe atopic eczema. All lived in hard water areas (≥ 200 mg/l calcium carbonate) in England. Participants were randomised 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 main (primary) outcome was assessed, after which time 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 in order 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 Six Area, Six Sign Atopic Dermatitis (SASSAD) score, which, as the name suggests, records six physical

signs of eczema in six areas of the body. The SASSAD scale ranges from 0 to 108, with high scores representing more severe eczema. SASSAD score was measured by research nurses who were unaware of treatment allocation (blinded). Previous pilot work had demonstrated that blinding participants with a sham unit was only partially successful, owing to the different feel of softened water and the amount of soap suds generated. As a result, participants and their families were not blinded to allocation group in the main SWET study.

Three hundred and thirty-six children aged 6 months to 16 years were enrolled into the trial. All had a diagnosis of eczema, according to the UK working party's diagnostic criteria, and a minimum eczema severity score of 10 points using SASSAD. Outcomes were collected by the research nurse during clinic assessments at baseline and 4, 12 and 16 weeks.

Secondary outcomes were (i) the proportion of time spent moving during the night (captured using wrist accelerometers); (ii) the amount of topical medications used (corticosteroids and calcineurin inhibitors); (iii) Patient-Oriented Eczema Measure (POEM) score; (iv) Dermatitis Family Impact (DFI) score; (v) European Quality of Life-5 Dimensions (EQ-5D); (vi) the proportion of children who had a no change or reasonable, good or excellent improvement in SASSAD score; and (vi) how well the child's eczema was controlled on a week-to-week basis (captured from symptom diaries kept by the participants). In addition, saliva samples were taken from consenting participants and screened for mutations of the gene coding for filaggrin – a protein in the skin that is thought to be important for normal skin barrier function. A planned subgroup analysis was based on participants with at least one mutation in the gene coding for filaggrin.

The intervention was a standard ion-exchange water softener that was assembled specifically for the trial and carried the SWET logo. Ion-exchange water softeners use a synthetic resin to remove calcium and magnesium ions from household hard water, replacing them with sodium ions. The resin becomes depleted of sodium and is recharged using sodium chloride (common salt). Sufficient salt was supplied for the duration of the installation.

For those allocated to group A, a water softener unit was installed in the child's main residence as soon as possible after randomisation into the trial. All water entering the home was softened, with the exception of a drinking water tap at the side of the kitchen sink. Participants continued with their usual eczema treatments and were asked to bathe and wash their clothes in the usual way. Participants were encouraged to reduce their soap use in line with general advice on the use of water softeners in the home. Participants allocated to group B (delayed installation) received an active unit after the primary outcome had been collected at 12 weeks.

Both groups continued to receive their usual eczema care throughout the trial. 'Usual care' was defined as any treatment that the child was currently using in order to control his or her eczema (e.g. topical corticosteroids, emollients, contacts with health professionals). In order to minimise performance bias, participants in both groups had the same amount of contact with trial personnel, including a support telephone call from the co-ordinating centre at 8 weeks.

Results

Of the 336 children enrolled into the trial, 323 (96%) had complete data at baseline and 12 weeks (159 in group A and 164 in group B). Participants were recruited from eight UK centres, and included families of diverse socioeconomic backgrounds. The groups were broadly balanced at baseline in both clinical and demographic characteristics.

The primary outcome was the difference in mean change in eczema severity between groups A and B at 12 weeks, as measured using SASSAD. A reduction in the SASSAD score represents a reduction in the severity of eczema. There was no difference in baseline SASSAD score between groups [group A: 25.3 (standard deviation, SD, 13.4) and group B: 26.0 (SD 13.9)]. We found no difference between the groups in the primary outcome of change in disease severity. The mean change in the SASSAD score at 12 weeks compared with baseline was –5.0 (SD 8.8) in group A and –5.7 (SD 9.8) in group B. The difference between the two groups in mean reduction in disease severity at 12 weeks was small and not significant. The mean difference in score in favour of the control group was 0.66 [95% confidence interval, (CI) –1.37 to 2.69, $p = 0.53$].

Overall, there were no statistically significant differences between the groups for any of the objective (blinded) secondary outcomes. These included time spent moving during the night, the amount of topical medications used, and the eczema severity scores, grouped into no change (or worse), or reasonable, good or excellent improvement. Small, but statistically significant, differences in favour of water softeners were observed in three of the four unblinded secondary outcomes that were reported by the participants or their carers (POEM, number of well-controlled weeks and the DFI score).

Subgroup analyses including the 92 patients with at least one mutation on the gene coding for filaggrin showed no additional benefits for this group. The difference in mean change in disease severity between the two groups at 12 weeks in the subgroup was 1.05 in favour of the control group (95% CI –2.36 to 4.47, $p = 0.54$).

Analyses exploring speed of onset of benefit and duration of effects were not conducted as there was no overall treatment effect.

The results of the economic evaluation, and the uncertainty surrounding them, suggest that ion-exchange water softeners are unlikely to be a cost-effective intervention for children with atopic eczema from an NHS perspective.

Conclusions

Main findings

The SWET study found no benefit of using an ion-exchange water softener in addition to usual care in this study population. There were no clinically important differences between the treatment groups for any of the objective (blinded) outcomes. Furthermore, the 95% CIs around the primary efficacy estimates were narrow. An improvement of 1.37 points in favour of water softeners (the lower 95% CI) to 2.69 points in favour of usual care (the upper 95% CI) makes it unlikely that a clinically useful benefit has been excluded by chance.

Even though there was no change in disease severity, it is possible that water softeners could have proved beneficial if they resulted in reduced use of the topical medications needed to control the eczema (e.g. a steroid-sparing effect). However, measurement of the amount of topical steroid creams or calcineurin inhibitor creams applied showed that both groups used approximately equivalent amounts throughout the 12-week study period.

Of the four unblinded secondary outcomes, all except EQ-5D showed small, but statistically significant, differences in favour of the water softener group. However, the improvements seen were small and unlikely to be clinically significant. It is most likely that these differences were a result of response bias.

Of the children involved in the study, just under 30% had at least one filaggrin mutation. There was no difference in response between those with and without the mutation.

We believe that this pragmatic study has good external validity because participants were recruited from eight UK centres, and included families of diverse socioeconomic backgrounds. Every effort was made to include participants who lived in rented accommodation as well as owned homes. Nevertheless, the results are applicable only to children aged 6 months to 16 years with moderate or severe eczema. It is possible that water softening is beneficial for milder forms of eczema, or in adults with other eczema types such as asteatotic or seborrhoeic types. We are not able to comment on the impact of other types of water-softening devices such as physical water devices.

This trial demonstrated overwhelming demand for non-pharmacological interventions for the treatment of eczema, and this is something that should be considered when prioritising future research in the field.

Strengths and weaknesses

The Softened Water Eczema Trial (SWET) was an RCT with sufficient recruits to detect clinically important differences in eczema improvement between the groups. The motivation of families who participated in the study was high, as shown by the low number of dropouts (96% follow-up to 12 weeks; 94% follow-up to 16 weeks). Particular emphasis was placed on objective outcome measures to minimise observer bias, given that it was not possible to blind participants to the intervention. It is possible that our emphasis on objective outcomes meant that some important potential benefits were not captured in the primary analysis. Other factors, such as improvements in quality of life, or a reduction in symptoms (e.g. dry skin), may be important in determining whether or not parents choose to buy a water softener. Indeed, many parents in the trial reported small health benefits, and 55% from group A and 55% from group B chose to buy the water softener at the end of the trial. The reasons people gave for purchasing the units were perceived health benefits and the wider benefits of using softened water in the home.

It is also possible that small treatment effects were concealed by the usual eczema care that the children received, or that the moderate duration of the trial was insufficient to capture any longer-term treatment effect. However, there is no suggestion that either of these is the case from the data collected.

The continued use of soap and soap products during the trial may have limited the observed benefits if families were using too much soap in conjunction with the water softener. However, this was a pragmatic study that aimed to capture the effects of water softeners as they are normally used, according to standard advice. Evidence of how much soap was actually used was not collected, as we did not want to change participants' behaviour by intensive monitoring.

Interpretation

The primary end point results of this study are clear. We found no evidence of an objective benefit of ion-exchange water softeners for the treatment of moderate or severe eczema in children. Whether or not the wider benefits of installing a water softener in the home are sufficient to justify the purchase of one is something for individual householders to consider on a case-by-case basis.

Trial registration

This trial is registered as ISRCTN71423189.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Publication

Thomas KS, Koller K, Dean T, O'Leary CJ, Sach TH, Frost A, et al. 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 Technol Assess* 2011;**15**(8).

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 05/16/01. The contractual start date was in September 2006. The draft report began editorial review in June 2010 and was accepted for publication in October 2010. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA programme or the Department of Health.

ISSN 1366-5278

Published by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk), on behalf of NETSCC, HTA.
Printed on acid-free paper in the UK by the Charlesworth Group.