



Softened Water Eczema Trial

RESULTS



More information at: www.swet-trial.co.uk

Overall surprise findings:

The study showed that softening the water in the homes of children with moderate to severe eczema had no clear benefit for their eczema.

Eczema is very common, affecting around 20% of school children in developed countries, and appears to be on the increase worldwide.

Evidence linking increased water hardness with an increase in the numbers of people with eczema has been reported in primary school children living in the UK, Spain and Japan. In addition, there are widespread reports of the benefits of water softeners for the treatment of eczema. The SWET study was the first large randomised controlled trial in the world to try and answer the question “does installing a water softener in the home improve eczema in children?” The study took place across seven hard-water areas in England, UK (Boston/Lincoln, Nottingham, Leicester, Cambridge, London, Portsmouth, Isle of Wight) and was funded by the UK National Institute for Health Research Health Technology Assessment programme.

What did the study involve?

Children were put into one of two groups, decided at random. There was an equal chance of being randomised into either group. **Group A** had an ion-exchange water softener in their home for the first 12 weeks. **Group B** continued with their usual eczema care for the first 12 weeks and then had a water softener installed for 4 weeks. Data collected between weeks 0 to 12 was used to answer the main question (i.e. whether there was any overall benefit or not), with Group A being the water softener group and Group B acting as a control group. Data collected between weeks 12 to 16 was to show possible speed of onset of benefit, and any after-effects. Research nurses measured eczema severity (and other indicators) at recruitment, 4 weeks, 12 weeks and 16 weeks. The nurses did not know whether the families they were seeing were in Group A or Group B. As it was impossible to hide which group those who took part in the study (children and their families) belonged to, we made every effort to make sure that nurses didn't know who had the water softener when they made their eczema assessments so that they remained “blinded” to treatment group.

	0 to 12 weeks	12 to 16 weeks
Group A 170 children	Water softener installed + usual eczema care	Unit switched off and/or removed
Group B 166 children	Usual eczema care	Water softener installed

Who took part in SWET?

Children aged 6 months to 16 years with moderate to severe eczema. All lived in hard water areas of England (UK) (water contained ≥ 200 mg/L calcium carbonate). The study recruited from May 2007 to May 2009, and exceeded its original target (310) to reach a final total of **336 participants**.

Appreciation:

The SWET Study Team would like to thank all the families who took part.

SWET RESULTS—page 2

What type of water softener did SWET use?

An ion-exchange water softener was produced specially for the SWET study. This type of water softener removes calcium and magnesium ions from household hard water, replacing them with sodium ions (from common salt). All units met regulatory standards and were installed by qualified water engineers. Units were usually installed under the kitchen sink. Hardness levels were reduced from over 200 mg/L calcium carbonate to ≤ 20 mg/L and weekly water samples were sent for testing to check that the unit was working properly. An extra tap at the kitchen sink supplied mains (hard) water for drinking and cooking.



How similar were the two groups to start with?

Children in the water softener group (Group A) were very similar to those in the control group (Group B) in terms of age, sex, eczema severity, bathing/showering frequency, and water hardness. This meant a fair comparison between groups could be made of the possible effects of the softener. Children were recruited from eight UK centres, and included families of different socio-economic backgrounds living in a mixture of housing (owned outright, being bought with the help of a mortgage or rented from private landlords or housing associations). Very few families dropped out of the study. Of the 336 children randomised into the study 314 (93%) attended their final assessment at 16 weeks.

How were any changes in eczema measured?



The severity of the eczema was recorded by the research nurse using a scoring system called SASSAD (Six Area Six Sign Atopic Dermatitis). This gives a value to six different physical features of eczema (e.g. redness) at six different parts of the body (head & neck, trunk, hands, arms, legs and feet). Each sign is scored between 0 to 3 and all the individual scores added up. The maximum SASSAD score is 108; in practical terms moderate to severe eczema scores lie in the range 10 to 70.

A reduction in total score represents an improvement in eczema. To measure the possible benefit of having a water softener the average improvement in SASSAD eczema score was compared over the first 12 weeks between the water softener group (Group A) and the control group (Group B).

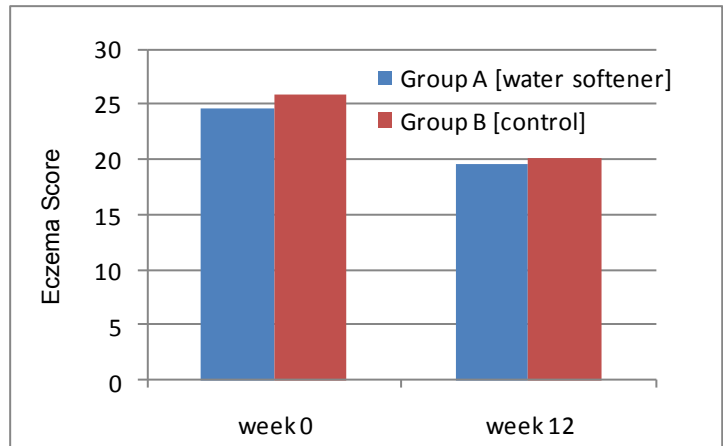


SWET RESULTS—page 3

What was the main result ?

Both groups showed an improvement in eczema severity over the 12 week main study period. However, to our surprise, the improvement in eczema severity was *very similar* in those receiving the water softener (Group A) compared with those in the control group (Group B).

The average eczema score reduction in the water softener group was 20% (5 points improvement on SASSAD) compared with a 22% eczema score reduction in the control group (5.7 points improvement on SASSAD).



We were not surprised to find that the control group (Group B) had an improvement in eczema severity. It is well-known that being on a clinical trial can improve disease severity, even when the person is not receiving a new treatment. There are a number of reasons for this, and in SWET it is likely to have been because of increased monitoring of the child's eczema (parents completed an eczema symptom diary each day). This improvement in eczema was also seen in the water softener group (Group A). There were enough children in the study to have detected any *extra* improvement in the water softener group above this 'background' level of improvement, but SWET clearly showed no difference between the two groups.

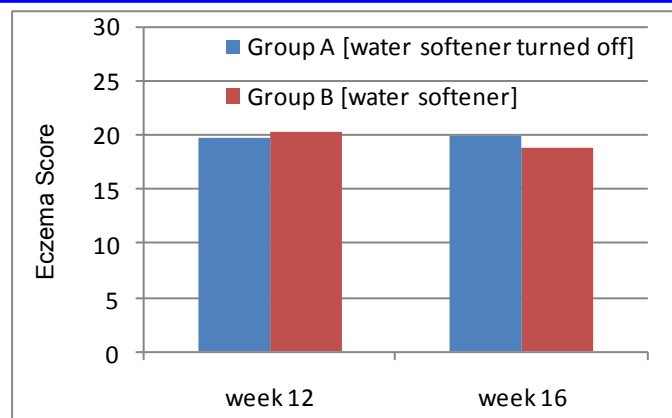
How confident can we be in this result?

The above results are eczema scores of all children who were assessed by the nurse at recruitment and week 12. A stricter way of analysing the data is to only include those children we were *completely* confident were exposed to fully softened water (in Group A) or hard water (in Group B) during the first 12 weeks of the study. The difference between these two groups was also not significant (reduction in score of 18% in Group A and 24% in Group B).

What happened between weeks 12 and 16?

Group A had their water softener removed (or switched off) for the last 4 weeks of the whole study period, while Group B had the opportunity to try the water softener for these last 4 weeks.

There was no significant difference in change in eczema severity (SASSAD) between groups during this final phase of the study. In other words, those that stopped using the water softener did not notice any significant deterioration, and those that started to use the water softener did not notice any significant improvement.



Did the water softener group have less itchiness?



Accelerometers (Actiwatch Mini™) were worn on the child's wrist every night for one week at the beginning of the study, and every night for the week just before their 12-week eczema assessment. These devices measure movement, and are believed to be a good way of measuring how itchy the eczema is. In the SWET study we found no significant difference between the water softener group and the control group in percent of the night spent moving during the 1st and 12th week.

SWET RESULTS—page 4

What about genetic aspects?



The filaggrin gene produces a protein called filaggrin which is normally found in large amounts in the outer layer of the skin, and helps prevent the skin from drying out (by keeping water in). Changes in the filaggrin gene are very common (10% of the population show changes) and a reduction (or absence) of filaggrin is thought to be associated with a dry, flaky skin and a greater chance of developing eczema. The majority of SWET participants (304 children) agreed to have their saliva tested, and we found filaggrin gene mutations in 30% (92 children); however, there was no difference in response between those with and without the filaggrin mutation.

Did the water softener group use less steroid cream?

Children brought their creams to each assessment visit with the nurse, and she weighed the different tubes. SWET measured steroid creams (Efcortelan, Betnovate, Elocon etc) and calcineurin inhibitors (Elidel, Protopic). We did not measure emollient use. Over the first 12 weeks children in the water softener group (Group A) used an average of 9 grams less cream in total than children in the control group (Group B). This tiny difference was not statistically significant. There was also no significant difference in the potency of creams used.



What was interesting was that both groups used very little cream overall (approximately 5 grams / week / child), which is much lower than doctors and nurses generally advise for controlling moderate to severe eczema.

What about feedback from families during SWET?

Parents (or their children if old enough) completed various questionnaires at each assessment visit to the nurse. They also completed a diary every day, recording eczema 'bother scores' and whether treatment was being stepped-up or not.

The Patient Oriented Eczema Measure (POEM) captured symptoms of importance to eczema sufferers (e.g. itchiness and bleeding). These symptoms were rated and added to give a total score. The water softener group had a significantly greater improvement in POEM score than the control group between recruitment and 12 weeks, although the amount of difference was small (2 points on a 28-point scale). A similar result was also found in the Dermatitis Family Impact questionnaire which measured how much the child's eczema affected the whole family over the previous week. The water softener group showed a 1.3 point improvement (on a 30-point scale) compared with the control group.

Information from diaries also showed that the water softener group had better overall and week-to-week control of the child's eczema, although the difference between groups was small (one more "well-controlled-week" and one more "totally-controlled-week" over the 12 weeks).

What does it mean?

The results of SWET are clear and we cannot recommend the use of ion-exchange water softeners for the treatment of eczema in children.

All the outcomes measured by nurses unaware of randomisation group showed no difference between the water softener group and the control group. Although the subjective outcomes showed small statistically significant differences in favour of the water softener group, these may be due to a slight over-reporting of benefit by some of the families who knew they were having the water softener (an indication of the hope these families placed in the treatment working). Overall 55% of SWET families bought the water softener at the end of the study (55% in Group A and 55% in Group B).

Contact details:
Dr Kim Thomas
Centre of Evidence Based Dermatology
University of Nottingham
Nottingham NG7 2NR

Results sheet compiled by
Karin Koller, SWET Trial Manager.

More information can be found at www.swet-trial.co.uk