

Are accelerometers a useful tool for measuring disease activity in children with eczema? Validity, responsiveness to change, and acceptability of use in a clinical trial setting

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Summary

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Conflicts of interest

None declared.

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Background Actigraphy, which uses accelerometers to record movement, has been proposed as an objective method of itch assessment in eczema. Previous studies have found strong correlations with actigraphy and video surveillance, disease severity and biological markers in patients with eczema.

Objectives To assess the validity of accelerometer data, its responsiveness to change and the practicality and acceptability of accelerometers when used as an outcome measure in a clinical trial.

Methods This study used data collected from 336 participants of the Softened Water Eczema Trial (SWET). Accelerometer data were compared with three standardized scales: Six Area, Six Sign Atopic Dermatitis (SASSAD) severity score, Patient Oriented Eczema Measure (POEM) and Dermatitis Family Impact (DFI). Spearman's rank testing was used for correlations.

Results Only 70% of trial participants had complete data, compared with 96% for the primary outcome (eczema severity – SASSAD). The convergent validity of accelerometer data with other measures of eczema severity was poor: correlation with SASSAD 0.15 ($P = 0.02$) and POEM 0.10 ($P = 0.13$). Assessing for divergent validity against quality of life measures, the correlation with the DFI was low ($r = 0.29$, $P < 0.0001$). Comparing the change scores from baseline to week 12 for SASSAD, POEM and DFI with the change in accelerometer scores we found low, negative correlations ($r = -0.02$, $P = 0.77$; $r = -0.12$, $P = 0.06$; and $r = -0.01$, $P = 0.87$, respectively). In general, the units were well tolerated but suggestions were made that could improve their usability in children.

Conclusions Actigraphy did not correlate well with disease severity or quality of life when used as an objective outcome measure in a multicentre clinical trial, and was not responsive to change over time. Further work is needed to establish why this might be, and to establish improved methods of distinguishing between eczema-related and eczema-nonrelated movements.

Eczema is a chronic inflammatory skin condition that is characterized by intense itching.¹ Despite being a defining feature of eczema,² itching is difficult to assess in a reliable way.³ Previous studies have used self-reported itch as an outcome measure for eczema treatments,^{4,5} but itch (or scratching) is a difficult concept to quantify in a clinical trial setting. Visual, verbal and numerical rating scales have been used to assess itch severity^{6,7} in eczema as well as other pruritic skin condi-

tions; however, these are subjective measures and require the patient to understand the concept of the rating scale, making them difficult to use in young children.

Patients with eczema often scratch without being aware of their actions, and self-reported itch has been shown to correlate poorly with observed behaviour.^{8,9} In trials involving young children, self-reported itch is often captured by proxy (usually by the primary care giver), making assessment of the

degree and duration of itching almost impossible. In order to overcome some of these methodological difficulties, actigraphy has been proposed as an objective tool for capturing scratch behaviour in inflammatory skin diseases research.^{3,10,11} Actigraphy is the recording of movement using portable devices known as accelerometers (scratch meters), and can be used to record movement over an extended period. This method of assessing scratching behaviour has been used in various pruritic disease settings, such as liver disease¹² and pruritic dermatoses,¹³ in addition to eczema. Previous studies in eczema have reported strong correlations between night-time movement (actigraphy) and video surveillance,⁸ disease severity,¹¹ and biological markers.¹⁰ However, these studies were all cross-sectional, and involved limited numbers of participants. Only one previous study¹¹ has used actigraphy to assess response to treatment in eczema, making further exploration of the association between actigraphy scores and long-term disease control of interest.

This paper reports our practical experiences of using accelerometers (Actiwatch Mini™; CamNtech Ltd, Cambridge, U.K.) as an outcome in a pragmatic clinical trial. We assess the practicality, validity, responsiveness to change, and acceptability of using accelerometers in this setting.

Materials and methods

Objectives

These were: (i) to assess the construct validity (convergent and divergent) of accelerometer data; (ii) to assess the responsiveness to change of accelerometer data over a 12-week period; and (iii) to assess the practicality and acceptability of accelerometers in a clinical trial setting.

Setting

This study used data collected as part of a pragmatic randomized controlled trial of water softeners for the treatment for eczema in children (Softened Water Eczema Trial: SWET).¹⁴ Recruitment into the trial took place in eight centres throughout the U.K. Participants were identified through secondary care, primary care, and by direct advertising. The trial compared installation of a water softener (plus usual eczema care) vs. usual eczema care alone, over a period of 12 weeks. Due to the nature of the intervention, blinding was particularly difficult to achieve, and so an objective outcome was used as the primary outcome [eczema severity measured using the Six Area, Six Sign Atopic Dermatitis (SASSAD) severity score].¹⁵

Data on the acceptability and use of the accelerometers were also collected during pilot work conducted in Nottingham prior to starting the trial.¹⁶

Ethics approval for the main study was obtained from the North West Multicentre Research Ethics Committee (06/MRE08/77), and for the pilot study from Nottingham Research Ethics Committee 1 (05/Q2403/169).

Participants

Three hundred and thirty-six children aged between 6 months and 16 years, with a diagnosis of eczema, were enrolled into the SWET trial. The diagnosis of eczema was standardized using the U.K. working party's diagnostic criteria for eczema,² and the term eczema (rather than atopic eczema, or atopic dermatitis) has been used throughout the paper as specific IgE testing was not conducted. This is in line with recommendations by the World Allergy Organization.¹⁷ All participants had an eczema severity score (SASSAD) of 10 points or more.

Data collection

Data were collected at baseline (week 0), week 4 and week 12. Outcomes included: (i) eczema severity (primary outcome); (ii) percentage of the night spent moving (measured using accelerometers); (iii) amount of topical treatments used (topical steroids and calcineurin inhibitors); (iv) proportion of participants showing good or excellent improvement at 12 weeks (based on SASSAD data); (v) patient-reported disease severity (Patient Oriented Eczema Measure, POEM¹⁸); (vi) number of totally controlled and well-controlled weeks;¹⁹ and (vii) quality of life – Dermatitis Family Impact (DFI) scale²⁰ and EuroQol EQ-5D.^{21,22}

For the purposes of this study, we chose to compare accelerometer data (mean percentage of the night spent moving) with three of the published scales (SASSAD, POEM and DFI). SASSAD scores were performed by research nurses who were blinded to the treatment allocation. The POEM and DFI questionnaires were completed by the participant and/or their carer at each study visit.

We anticipated a high correlation between SASSAD scores and the proportion of the night spent moving, as strong correlations had been reported previously (using a similar eczema severity scale – SCORAD¹⁰), and because both were objective outcomes that were likely to be free of information bias.

Accelerometer recordings were taken for a period of 7 days at baseline and then again at week 12. In order to capture periods when the children were asleep, data were analysed for the period from 22:00 h until 06:00 h each day. This time period has been used successfully by others.⁸ Participants were advised to wear the Actiwatch Mini™ on their dominant arm if possible, and to wear the watches over other clothing (or to use tubular bandaging), to protect the area of skin around the wrist.

The Actiwatch units contain a uniaxial accelerometer which produces constant data on activity intensity. The intensity of movement is converted into a digital value for each second. The recording time is broken down into epochs, 1-min time periods, and the activity counts for each second summed together to give the activity for each epoch. Adding together epochs demonstrating activity across the recording period indicates the proportion of the night spent moving.

The units were programmed by the research nurse at the initial study visit. At the next visit, data from the units were

uploaded on to a laptop as a digital file. This was then transferred electronically to the coordinating centre.

Performance criteria

Practicality is an assessment of how useful an instrument is when used in a research setting. This was assessed using the proportion of participants with complete and useable accelerometer data at baseline and at 12 weeks, along with a summary of reasons for loss of data.

Convergent validity is a measure of how closely related two outcomes are that aim to capture the same concept or trait.²³ We hypothesized that there was likely to be a reasonable correlation between the SASSAD, POEM and accelerometer scores, as all three capture elements of eczema severity.

Divergent validity assesses the degree to which scales measure different concepts.²³ We used the DFI scale to assess divergent validity, on the basis that this scale captures wider quality of life issues for the whole family.

Responsiveness to change is an assessment of the degree to which clinically meaningful changes in disease status are captured by the instrument.²³ We assessed whether change scores for each of the outcomes (week 12 minus baseline) were correlated.

Acceptability to trial participants was assessed on the basis of feedback from trial participants and research nurses, and during pilot work for the trial.

Statistical methods

Formal sample size calculations were not performed for this study as the available sample size was dictated by the number of participants enrolled in the SWET trial.

The mean percentage of the night spent moving was calculated by taking the mean of the first 3 nights of usable data at baseline and the last 3 nights of usable data at week 12. Usable data were defined as values between 5% and 95% of the night spent moving, to exclude outliers. The mean of the 3 days of usable data from each 7-day period was chosen in order to minimize the incidence of missing data, as pilot work

for the trial suggested that complete data for the full 7-day period were rare.

Validity and responsiveness to change were assessed using Spearman's rank tests. A moderate correlation was defined as having an *r* score of ≥ 0.6 , and a strong correlation was defined as ≥ 0.8 .²⁴ Acceptability and practicality of the accelerometers is presented descriptively.

Only participants with complete data at both baseline and week 12 have been included in the analysis.

Data were stored in a dedicated Access database, and analysed using Stata 10.1 (Stata, College Station, TX, U.S.A.).

Results

In total, 336 participants were randomized into the study from 14 May 2007 to 4 June 2009. A summary of their demographic details and outcome scores from the SWET trial are summarized in Table 1.

The SWET trial¹⁴ reported a 20% improvement in SASSAD scores at 12 weeks in the group using water softeners, but over the same time period a 22% improvement in SASSAD scores was recorded in the control group; the mean change in disease severity between the groups was 0.66 at 12 weeks ($P = 0.53$) in favour of the control group. No statistically significant differences were noted between the groups for any of the objective secondary outcomes [grouped eczema severity scores, time spent moving during the night (actigraphy) and use of topical medication]. Small but statistically significant differences in favour of the intervention were observed in three of the four unblinded secondary outcomes: POEM scores ($P = 0.009$), number of well-controlled weeks ($P = 0.04$) and DFI score ($P = 0.05$).

Practicality

Of the 336 participants enrolled in the trial, 301 (90%) had complete and useable Actiwatch data at baseline, and 240 (71%) had complete Actiwatch data at week 12. Only 235 (70%) had complete data at baseline and week 12. A sum-

Table 1 Demographic and outcome data for included participants

	Baseline (week 0)	Week 12	Difference week 12 – week 0
n with complete data for Actiwatch and eczema severity	235		
Age (years), mean $\pm$ SD	5.7 $\pm$ 4.1		
Sex (M/F) n (%)	135 (57)/100 (43)		
Ethnicity, n (%)			
White	184 (78)		
Nonwhite	49 (21)		
Not stated/unknown	2 (1)		
Eczema severity (SASSAD) (n = 235), mean $\pm$ SD	25.4 $\pm$ 13.5	20.3 $\pm$ 13.8	-5.2 $\pm$ 9.6
% of the night spent moving (Actiwatch data) (n = 235), mean $\pm$ SD	21.8 $\pm$ 8.8	25.6 $\pm$ 16.9	3.8 $\pm$ 15.7
Self-reported eczema severity (POEM) (n = 234), mean $\pm$ SD	16.5 $\pm$ 5.9	12.1 $\pm$ 6.9	-4.4 $\pm$ 7.2
Dermatology Family Impact score (n = 226), mean $\pm$ SD	10.4 $\pm$ 6.9	8.0 $\pm$ 6.8	-2.4 $\pm$ 5.7

SASSAD, Six Area, Six Sign Atopic Dermatitis severity score; POEM, Patient Oriented Eczema Measure score.

mary of their demographic details and outcome scores from the SWET trial are summarized in Table 1. By contrast, completeness of data for the SASSAD score, which was assessed by the research nurses during study visits, was extremely high (323; 96% had complete data at both baseline and week 12).

Convergent validity

The correlation between eczema severity (SASSAD score) at baseline and the mean percentage of the night spent moving (Actiwatch scores) at baseline was 0.15 ($P = 0.02$), suggesting evidence of a weak correlation. In view of this low correlation, an exploratory sensitivity analysis was conducted excluding participants if the data had been collected using different units for the two time points (thus minimizing variability in the dataset), and where the number of sleep bouts was < 5 (which could indicate that the units were not used for the entire night), and where the patient diary indicated they had not used the unit. This sensitivity analysis did not alter the main conclusion, and the correlation remained low (0.11, $P = 0.20$).

Similar findings were observed for the self-reported symptoms (POEM scores). The correlation between the POEM scores at baseline and the mean percentage of the night spent moving was 0.10 ($P = 0.13$), suggesting no evidence of a correlation.

Divergent validity

The correlation between the DFI score at baseline and the percentage of the night spent moving (Actiwatch scores) was 0.29 ($P < 0.0001$), suggesting a statistically significant, but weak association.

In order to explore the potential impact of age on actigraphy data, *post-hoc* analyses were performed splitting the data into groups by age [< 5 years of age ($n = 109$), and 5 years of age and older ($n = 126$)]. For older children, the correlation between the actigraphy data and SASSAD, POEM and DFI scores at baseline and 12 weeks ranged from 0.20 to 0.44, and were statistically significant. However, for the younger age group, these significant correlations were lost (range -0.05 to 0.15), suggesting that actigraphy data collected between 22:00 h and 06:00 h may be more suitable for use in children over the age of 5 years, who are potentially more consistent in their sleep patterns.

Responsiveness to change

Over the 12-week period of the trial, the primary outcome of eczema severity improved by 20% (mean for both groups). Likewise, there was a 27% reduction in POEM scores and a 23% reduction in DFI scores. By contrast, the percentage of the night spent moving increased by 18% over the same period. This is reflected in the negative values for the Spearman rank statistics, because as the SASSAD, POEM and DFI scores improved (i.e. decreased), the percentage of the night spent

moving worsened (i.e. increased). Comparing the change scores from baseline to week 12 for SASSAD, POEM and DFI with the change in the percentage of the night spent moving from the Actiwatch gave correlations of -0.02 ($P = 0.77$) for SASSAD, -0.12 ($P = 0.06$) for POEM and -0.01 ($P = 0.87$) for DFI, showing no evidence of any correlation (Fig. 1a–c). Analysis by age category also showed no difference in responsiveness to change for children aged over 5 years.

Acceptability

The accelerometers were generally well accepted by the study participants. The novelty factor made the children feel special and the ease of use and lightweight nature of the units were appreciated. Comments were made regarding the strap which attaches the accelerometer to the participant's wrist; in some cases it was felt to be too rough and there was concern it may exacerbate the child's eczema. It was suggested that changing the colour from black to a more interesting colour would increase the appeal of the units. Concerns were also raised regarding whether or not the unit was working, as there is no indicator light or switch on the unit. Reasons for not wearing included the child being distressed or irritated by wearing the accelerometer and the parent or child forgetting to use the unit (Table 2).

Discussion

These data suggest that the percentage of the night spent moving is a poor measure of disease severity as measured in this multicentre trial. Very low correlations were observed between the mean percentage of the night spent moving and all three of the validated scales used to assess disease severity and family impact. More importantly, this is the first study to examine responsiveness to change in a large-scale clinical trial setting, and in this regard the data were in conflict with all of the other outcome measures used in the trial. This would suggest a fundamental problem in using these units as a useful tool for measuring scratching in children with eczema in the setting of a pragmatic randomized controlled trial.

Although the scratch meters were generally well tolerated by the children, the amount of missing data was high compared with other outcomes measures used in the trial. It is possible that with greater experience of using the technology, this could be improved; for example, some data were lost due to battery failure, which could have been avoided by more frequent replacement of the unit's batteries. However, most of the data were lost simply because the watches were not worn correctly, or were lost or damaged. Interestingly, analysis of the incomplete data demonstrated that the mean age of those with incomplete data was 1 year younger than those with complete accelerometer data.

From a practical viewpoint the units are reasonably straightforward to use. They are lightweight and portable and therefore easy for participants to use in their own homes. Children often reported liking the watches, and particularly enjoyed

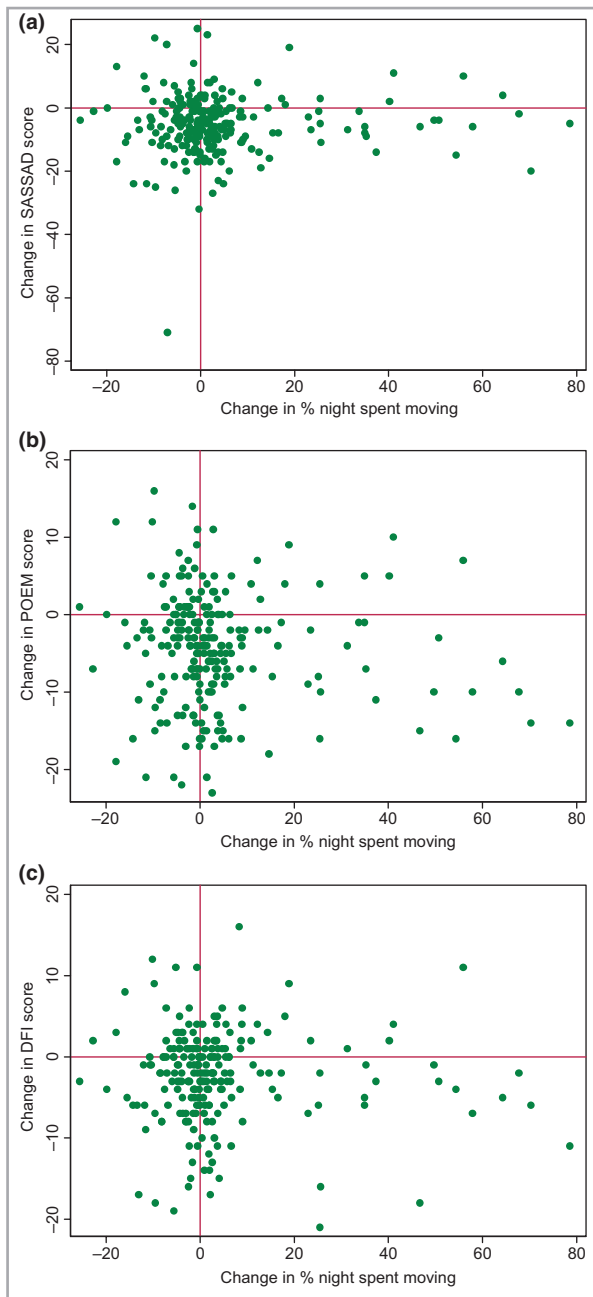


Fig 1. Scatter plots of correlations between the change in the proportion of the night spent moving and the change in (a) eczema severity [Six Area, Six Sign Atopic Dermatitis (SASSAD) severity score], (b) eczema symptoms [Patient Oriented Eczema Measure (POEM) score] and (c) quality of life [Dermatitis Family Impact (DFI) score] between baseline and week 12.

taking their sleep charts to school to show their friends and teachers.

Previous studies have generally shown stronger correlations between disease severity and night-time movement than those found in this study.^{8–10} Whether this is a reflection of the nature of the data collection, the study conduct or variability in the devices is unclear. Hon *et al.*¹⁰ demonstrated that wrist movements correlated closely with cytokine markers of atopic

Table 2 Typical problems associated with use of the scratch meters

Strap difficult to attach and secure
Watch strap irritating to skin of some patients
Children refusing to wear – some parents attached watches once child asleep
Child did not like the watch strap colour – changed to a pink ribbon
Forgetting to wear the Actiwatch
Forgetting to bring the Actiwatch to clinic appointments
Actiwatch put in washing machine
Actiwatch lost
Data lost due to battery failure

dermatitis and objective clinical scores but not with reported symptoms of sleep loss and pruritus. This group has since demonstrated a reduction in scratching activity in response to 2 weeks of treatment with tacrolimus.¹¹ Bringham *et al.*¹³ found a moderate correlation between the objective SCORAD and night-time movement, although there was considerable variation from night to night within the same individual. Benjamin *et al.*⁸ found a strong correlation between accelerometer recordings of scratching and video recordings of the participants, but no correlation between the parental assessment of itch severity and time spent scratching. This lack of association between accelerometer recordings and self-reported itch has also been reported in a recent study of 117 children and adults with itchy skin conditions.²⁵ Feuerstein *et al.*²⁶ recently described using k-means cluster analysis for accelerometer data to differentiate scratching from other movements, and reported that the technique provided 90% sensitivity for the detection of scratching. Being able to differentiate movement specifically due to scratching when analysing actigraphy measurements would be an important step forward and this method may warrant further investigation.

This is the first large, multicentre, randomized controlled trial to use accelerometers as an outcome measure for capturing night-time scratching in children with eczema. As such, it has explored the use of accelerometers in capturing change in eczema severity in response to a therapeutic intervention given over several months. Parents were given written and oral instructions on how to use the watches, but were not extensively monitored or reminded about their children wearing the watches each night. It is possible that by increasing the level of training and support, then a stronger correlation may have been observed.

It is possible that more frequent data collection throughout the 12 weeks of the study would have resulted in less variability and better correlations with disease severity. However, we did not want to overburden families with data collection, and felt that it was better to get accurate information at the beginning and end of the trial, than incomplete data throughout the trial period.

It is possible that relatively subtle effects of improvements in eczema severity were lost because there was too much 'noise' in the signal. Children are restless at night for many

reasons (e.g. illness, nightmares, anxiety), and it was difficult to control for these factors within the dataset.²⁶ Others have found wide variation from night to night in the amount of movement and temporal pattern of activity during the night.¹³

Depending on the type of accelerometer and software used, different summary statistics are provided by the units. Some accelerometers record the frequency of movement as well as duration of movement, and these have been reported to show positive correlations.¹⁰ It is possible that alternative statistics might be more discriminative; however, the proportion of the night spent moving was chosen as it was felt to be more intuitive and easier to understand in a clinical setting. It was also hoped that capturing movement in this way would include other motions associated with itch such as writhing or rubbing, as had been recommended by others.³

Movement was collected throughout the period of 22:00 h to 06:00 h on the grounds that the majority of children will be asleep during these hours. Hon *et al.*¹⁰ reported better correlations during the first 3 h of sleeping, but others have reported no evidence of a temporal pattern to night-time movement.¹³ It is possible that the majority of children were asleep well before 22:00 h, and that their period of peak activity (restlessness) was missed if it occurred within the first few hours of sleeping.

In conclusion, the use of actigraphy to measure night-time scratching activity as an objective surrogate for disease activity was found to be of limited use in this pragmatic, multicentre trial. This is disappointing as clinically meaningful, objective outcomes for the assessment of eczema in clinical studies are desperately needed. Further work is required to establish why the correlations seen in this trial dataset were so much lower than those reported by previous research teams, and to establish whether capturing frequency of movement as well as duration of movement is a possible way forward.

What's already known about this topic?

- Itch is a defining feature of eczema, but is difficult to measure.
- Objective outcome measures for use in eczema trials are urgently needed.
- Previous studies have suggested that scratching, as captured using actigraphy (scratch meters worn on the wrist), is a good measure of disease activity.

What does this study add?

- Proportion of the night spent scratching was a poor measure of disease activity in this randomized controlled trial.
- It did not correlate with previously validated eczema severity scales and was not responsive to change.
- We do not recommend the use of actigraphy as an outcome measure in clinical trials at this time.

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