Weekly versus daily bathing for people with eczema: results of the Eczema Bathing online randomised controlled trial

Running head: Bathing frequency and eczema trial

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Data availability: Data underlying the results will be available from the Nottingham Research Data Management Repository (https://rdmc.nottingham.ac.uk/). Any data shared will be pseudonymised which may impact on the reproducibility of published analyses. The protocol and statistical analysis plan are freely available on the trial registry (ISRCTN12016473).

Ethics statement: The trial received ethical approval by the London - Surrey Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom) on 11/10/2023 (approval number: 23/PR/0899).

Patient consent: Not applicable

What is already known on this topic?

- Questions about bathing practices are important to people with eczema but are rarely the focus of randomised controlled trials.
- International eczema guidelines vary in their recommendations for frequency of bathing due to the poor evidence base.
- Efficient trials about the self-management of eczema are helpful in generating reliable evidence in a way that is timely, relevant and cost-effective.

What does this study add?

- The Eczema Bathing Study found no important differences in eczema symptoms for people who bathed/showered weekly compared to daily over 4 weeks
- These results give people with eczema the freedom to choose how often to bathe – whatever suits them.
- This innovative citizen science approach to delivering high-quality, co-produced trials was successful and can be used to answer other important questions about the self-management of eczema and other chronic health conditions

Abstract

Background Questions about washing are a high priority for people with eczema (syn. atopic dermatitis, atopic eczema) but are rarely the focus of randomised controlled trials (RCTs).

Objectives To assess the impact of weekly bathing compared to daily bathing in people with eczema in the first of a series of eczema citizen science online trials in the United Kingdom.

Methods Pragmatic, two-arm, parallel-group superiority RCT. People with self-reported eczema aged ≥1 were eligible, excluding those with very mild eczema (Patient Orientated Eczema Measure (POEM) score ≤ 2). Participants were allocated (1:1) using minimisation, balancing on eczema severity (POEM), age and usual method of bathing, to either the weekly bathing group (bath or shower once or twice a week) or the daily bathing group (≥6 times a week) for 4 weeks. Participants were not blinded to their allocation. Primary outcome was participant reported eczema symptoms collected weekly over four weeks using POEM (range 0 to 28, higher scores more severe).

Results 438 people with eczema (108 aged <16 years) were randomised between 29th January and 8th July 2024: 218 to daily bathing and 220 to weekly bathing. The primary analysis included 195 participants (89%) allocated to daily bathing and 193 (88%) to weekly bathing who completed at least one follow-up questionnaire. Mean POEM scores at baseline, 1, 2, 3 and 4 weeks, were 14.5 [standard deviation 5.7], 11.7 [5.9], 12.2 [5.9], 11.7 [6.7] and 11.6 [6.5], respectively, in the daily bathing group, and 14.9 [6.3], 12.1 [6.8], 11.3 [6.7], 10.5 [7.0] and 10.6 [7.2] in the weekly bathing group. The adjusted difference in mean POEM score over 4 weeks for weekly versus daily bathing was -0.4 (95% confidence interval -1.3 to 0.4, p = 0.30). Process evaluation data highlighted participants' experiences of making changes to bathing routines, including barriers to following the allocated routine. No serious unintended effects or harms were reported.

Conclusions The trial found no evidence of a difference in eczema symptoms between bathing or showering weekly compared to daily. These results are helpful for people with eczema, giving them the freedom to choose what suits them best.

Trial registration ISRCTN12016473 (Registered 22-Nov-2023)

Introduction

Randomised controlled trials (RCTs) are the cornerstone of evidence-based medicine but are expensive and time consuming to conduct. Questions about everyday self-management that are important to patients are often not addressed in RCTs due to the lack of financial drivers to health services to answer them. Eczema (syn. atopic dermatitis, atopic eczema[1]) is an example of this. Fourteen priorities were identified in a James Lind Alliance Priority Setting Partnership (PSP) exercise in 2011 on how best to manage eczema[2]. Many of these have begun to be addressed, however very little research has been conducted to address the five patient and carer priorities around self-management[3]. An alternative approach to delivering RCTs is needed to address such questions in a robust and efficient manner and to share new knowledge directly with those who need it.

The Rapid Eczema Trials research programme aims to improve the lives of people with eczema by working with citizen scientists to deliver multiple, efficient online clinical trials about self-management[4]. The project has established an Eczema Citizen Science Community people with lived experience of eczema who are willing to co-produce, run and help disseminate findings from the RCTs.

The first question prioritised by the group was "How often should people with eczema have a bath or shower?". Only two small RCTs ($n < 50$) have previously addressed this, both for children over a two-week period, with conflicting results[5, 6]. This lack of evidence has led to variation in recommendations on frequency of bathing across international eczema guidelines[7]. The Eczema Bathing Study was designed to compare weekly bathing (once/twice per week) to daily bathing (≥ six times per week) in people with eczema.

Methods

Study design and objectives

This was an online, two-arm (1:1), parallel group, superiority RCT to compare weekly bathing to daily bathing over four weeks on eczema symptoms, quality of life and disease control in children and adults with eczema. A nested, qualitative study (reported separately) was conducted as part of a process evaluation to explore barriers and facilitators to changing bathing practices and to understand the impact of trial processes on participation. The protocol has been previously published[8]. No changes were made during the trial.

Patient and Public Involvement

This trial was co-produced in partnership with members of the public with experience of eczema (citizen scientists), as previously described[9]. In brief, a series of co-production groups took place, involving 21 citizens scientists. The groups worked on prioritising the topic, designing the intervention materials, designing the trial, ensuring inclusivity and knowledge mobilisation. The trial design group determined the eligibility criteria, selected the outcome measures, determined the study duration, developed the recruitment strategy and planned the process evaluation. Two citizen scientists were members of the Trial Management Group, providing input on recruitment and retention including suggesting changes to follow-up reminder wording to improve completion. The trial design and knowledge mobilisation co-production discussed ways to disseminate the results prior to the end of recruitment. Citizen scientists provided input into the results webpage, video summary and participant newsletter. Two trial participants talked about their experiences during two online results webinars.

Setting and participants

People aged ≥1 year living in the UK with self-reported eczema were eligible. Potential participants were excluded if they had mild eczema symptoms (Patient Orientated Eczema Measure[10] (POEM) score ≤ 2); unlikely to have atopic eczema (e.g. eczema only present on hands/around varicose veins, limited to where skin exposed to nickel); had started a new eczema treatment (other than emollients) in the last 4 weeks; were participating in another eczema intervention trial, were unable/unwilling to change bathing practices for 4 weeks, planned to swim more than twice weekly in next 4 weeks or if another household member was already a trial participant. The recruitment strategy included social media adverts, publicity via existing networks (e.g. eczema support organisations) and invitation letters or text messages from General Practices (GPs). Potential participants were guided to the trial website (www.RapidEczemaTrials.org), with the trial information. Following initial self-reported eligibility screening, electronic consent (e-consent) was gained prior to completion of baseline questionnaires. For children (<16 years), e-consent was provided by the parent/carer. Adverts and invitations from GPs continued until the target sample size had been met.

Randomisation

Randomisation was conducted online by the participant after confirmation of eligibility and completion of baseline questionnaires using a randomisation system provided by the Nottingham Clinical Trials Unit (NCTU) on REDcap (Research Electronic Data Capture [11, 12]). Participants were randomised to either the weekly bathing or daily bathing group using a minimisation algorithm with a probabilistic element balancing on: eczema severity (POEM 3-7 mild, 8-16 moderate, 17-28 severe), age (<4 years, 4-11, 12-15, 16-25, 26-55, >55 years) and usual method of bathing (bath or not bath).

It was not possible to mask participants to their allocation. However, prior belief about the impact of frequency of bathing on eczema symptoms was collected before randomisation. The TMG (excluding the data/IT team) remained blinded to allocation until database lock for analysis.

Interventions

Participants were informed of their allocated bathing frequency immediately after randomisation. Information was provided as weblink, downloadable pdf and animated video to aid inclusivity[13].

Participants in the weekly bathing group were asked to have a bath or shower 1 or 2 times per week for the 4-week period. A bath or shower was defined as any way of washing that soaks the body in water. Participants in the daily bathing group were asked to have a bath or shower 6 or more times per week. Daily bathing was considered as the comparator as this was most commonly reported practice in a survey conducted to inform the study design[14]. Participants were asked not to change anything else about the way they washed or managed their eczema and asked, if possible, not to start any new eczema treatments during the trial.

People could request financial assistance (£20) if they were concerned about any additional costs associated with participation.

Outcomes

Follow-up was conducted via online questionnaires at 1, 2, 3 and 4 weeks after randomisation. The four-week duration was chosen during co-production to be acceptable to participants to persevere with a change in bathing habits whilst long enough to detect changes in the skin (as observed in study by Andrew et al[15]).

Proxy reporting by parent/carer was accepted for children unable to complete the questionnaires themselves. Up to two automated reminders were sent to non-responders, with an additional phone call at 4 weeks for non-responders.

Outcomes included the Harmonizing Outcomes Measures for Eczema (HOME) initiative's recommended core outcome set, except for eczema signs, which requires clinical assessment of the skin[16]. The primary outcome was eczema symptoms assessed weekly over 4 weeks by POEM[10]. POEM includes 7 items and has a total score from 0 to 28 with higher scores representing more severe eczema.

Secondary outcomes were skin specific quality of life, eczema control, itch severity, use of usual eczema treatments, improvement in POEM of ≥3 points and global change in eczema (defined in full in Table S1). Change in eczema treatments and whether participants had sought advice from a healthcare provider due to worsening of the eczema were collected as safety outcomes. As part of the process evaluation, to explore participants' experiences and to identify any unintended consequences, participants were asked about changes to their normal bathing routine and anything that helped or made it more difficult to bathe as they were asked to.

Sample size

The trial was designed to detect a difference of 2.2 between the two groups in mean POEM scores assessed weekly for 4 weeks. This was felt to be a small, but potentially important difference to people with eczema, for this non-pharmacological intervention[17]. Assuming a standard deviation (SD) of 6.5 and a correlation between repeated measurements of 0.8, 156 participants per group were required to detect this difference with 90% power and 5% two-sided significance level. Allowing for 20% loss to follow-up, a total sample size of 390 participants was required.

Statistical methods

Analysis was conducted using Stata© (StataCorp LLC) version 18 according to a statistical analysis plan (SAP) finalised prior to database lock (available on ISRCTN12016473). Analyses were conducted according to randomised allocation regardless of actual frequency of bathing.

The primary outcome was analysed using a linear mixed effects model with random effects used to allow for observations nested within participants over time and included participants with at least one weekly follow-up POEM score. The model adjusted for the minimisation variables as well as frequency of bathing, whether participants usually wash their hair in the bath/shower, use of emollient wash

products, use of moisturisers after bathing, diagnosis of eczema (UK Diagnostic Criteria[18]) and use of systemic treatments. The difference in mean POEM score averaged over 4-weeks is reported as there was no strong evidence of a differential effect over time when an interaction term between time and allocated group was included in the model. Sensitivity analysis for missing data, supplementary analyses and subgroup analyses are described in the Supporting Information.

Between-group comparison of secondary outcomes used an appropriate regression model for the outcome (linear for continuous outcomes, logistic for binary) with adjustment as described above and included the baseline outcome measure for continuous variables if available. Further details of all analyses, including specification of alternative methods if assumptions were violated, are provided in the SAP.

The responses to questions on experiences of changing bathing routine and barriers to sticking to the allocated intervention were analysed by organising into themes.

Results

Recruitment and retention

Between 29th January and 8th July 2024, 885 people expressed interest through pre-screening on the trial website of which 457 were eligible. The most common reason for exclusion was incomplete consent (Figure 1). 438 were randomised: 218 allocated to daily bathing and 220 to weekly bathing. Overall, 388 participants (89%) who completed at least one follow-up questionnaire were included in the primary analysis.

Baseline characteristics

Participant characteristics were balanced at baseline (Table 1 and Table S2). Of the 438 participants, 108 were children, and 101/330 adults were aged 56 years or more. 66% identified as female and 87% were white (Table 2). The mean POEM score was 14.7 (SD 6.0). Participants reported having a bath or shower 4.3 times (SD 2.3) in a typical week and using a range of products including emollients, soap, shower gel or water alone (Table S2). 55% of participants reported no prior belief about whether bathing frequency affected eczema symptoms (Table 1).

Participant reported frequency of bathing

Adherence to the allocated frequency of bathing was between 80-90% each week in both groups (Table S3). Frequency of bathing/showering as allocated in all 4 weeks for participants completing all questionnaires was 72% (daily) and 73% (weekly). Using conservative assumptions about frequency when questionnaires were not completed (see Supporting Information), frequency of bathing/showering as requested in all 4 weeks was estimated to be 62% (daily) and 61% (weekly).

Primary outcome

There was no evidence of a difference between groups in weekly participant reported eczema symptoms (Table 2 and Figure S1). The adjusted difference in mean POEM score over 4 weeks for weekly bathing compared to daily bathing was -0.4 (95% confidence interval -1.3 to 0.4, p-value 0.30).

Sensitivity analysis using multiple imputation for missing weekly POEM scores was consistent with the primary analysis (Table S4). Similarly, the analysis exploring the impact of adherence for weekly bathing was supportive of the primary analysis (Table S5).

In subgroup analyses, there was evidence that eczema symptoms were improved for those allocated to a group that matched their prior beliefs about the impact of bathing frequency whereas for those with no prior belief there was no evidence of a difference as in the primary analysis (Figure 2 and Table S6 for all subgroup analyses).

Secondary outcomes

An improvement in POEM of ≥ 3 points compared to baseline, itch intensity, eczema control, global change in eczema and quality of life scores were similar in the two groups at 4 weeks (Table 3 and Table S7).

Median participant reported moisturiser use was 7 days in both groups in all 4 weeks (Table 4). Reported use of flare control creams was slightly lower in the weekly bathing group (Table 4): the adjusted difference in mean number of days flare control creams were used each week for weekly compared to daily bathing was -0.5 (95% CI -0.8 to -0.1). Safety outcomes were similar in the two groups (Table 3).

Process evaluation

There were 394 responses to the questions exploring experiences of changing bathing routines. In addition to frequency, a small number of participants reported making other changes, most commonly including products used (n=31); shorter duration (n=25); and reduced water temperature (n=11).

In terms of what helped bathe as asked, some daily bathing participants reported that toys, games or music (n=10) were helpful for them/their child. In the weekly bathing group, the most common aid was sink/flannel washing (n=10).

In total, 142 barriers to bathing as allocated were reported (Table S8). In the daily group, the most common were lack of time (n=21), itching/worsening of eczema (n=17), change in routine (n=12) and tiredness/lack of energy (n=6). Reported barriers in the weekly group included feeling unclean (n=25), itching/worsening of eczema (n=17), weather (n=11), lack of time (n=8), change in routine (n=8) and sports/exercise (n=6).

Discussion

Main findings

This trial found no evidence of a clinically important difference in eczema symptoms between weekly and daily bathing. The 95% confidence interval for the difference was narrow and did not include the small difference of 2.2 on POEM that the trial was designed to detect. The secondary outcomes for itch, eczema control and quality of life were consistent with the primary outcome. Participants in both groups continued to use moisturisers with a similar frequency to baseline throughout the trial. There was some evidence of a reduction in topical steroid use in the weekly bathing group equivalent to half a day less a week. No serious unintended effects or harms were reported.

Strengths and limitations

This was a large trial co-designed by people with a lived experience of eczema. A diverse population participated with regards to age, geographical location (urban/peri-urban/rural), socio-economic status and ethnicity. However only 6 people of black ethnicity took part, potentially due to strong cultural beliefs about bathing in this community highlighted by citizen scientists during the trial development. Recruitment was completed in less than six months, follow-up completion was good and, where questionnaires were completed, most participants reported bathing/showering as requested. Only a small number of participants reported making other changes to their bathing routines. This demonstrates the interest in the research question to people with eczema and the acceptability of the trial design and procedures achieved through the co-production process.

It was not possible to mask participants due to the online nature of the trial, potentially leading to bias in the participant reported primary outcome. To explore this, prior belief about frequency of bathing/showering on eczema symptoms was collected. Subgroup analysis did show differences in effect in those with a prior belief on the frequency of bathing/showering on eczema in the direction consistent with belief. This does not necessarily indicate detection bias as it could reflect a genuine differential effect based on a lifetime of experimentation of bathing practices in individuals with a range of skin dryness associated with eczema.

Eczema was self-reported, however 87% met the UK working party criteria for atopic dermatitis and 50% participated following invitations from their GP due to a recorded eczema diagnosis and a prescription for emollient or topical corticosteroids in the previous 2 years. Recruitment was mostly during winter and spring, generalising to warmer more humid countries where sweat contributes to itching[19] and where daily bathing might be the norm is limited. The four-week duration was a pragmatic decision after extensive discussion during co-production to balance maximising participation and retention with allowing sufficient time for any differences between groups to be detected. An extended trial duration would be needed to explore the longer-term effects.

Comparison with other studies

Very few studies have been conducted to explore the effect of frequency of bathing on eczema, particularly in adults. In a systematic review (13 studies with 9 RCTs and 4 observational studies[20]), only two RCTs were specifically designed to answer questions about bathing frequency. The review found no evidence of a difference between eczema severity for bathing/showering >7 times compared to ≤7 times per week. The two RCTs were conducted in children with a two-week follow-up period. They had conflicting results: one (n=28) did not find any difference between eczema severity for twice weekly bathing compared to daily bathing[6], whilst the other cross-over trial (n=42) found a reduction in eczema severity for twice daily bathing compared to twice weekly bathing[5]. No further RCTs on this topic have been conducted since the publication of the systematic review.

Implications for practice and future research

Members of the Rapid Eczema Citizen Science community have fed back that the results are helpful for people with eczema, giving them the freedom to choose a frequency which suits them best. The results

have been included in the evidence-based Eczema Care Online behavioural intervention resource (www.eczemacareonline.org.uk) to support the self-management of eczema. In line with NICE guidance to signpost to quality information, the many different healthcare professionals who are involved in the care of people with eczema can now signpost to this study and Eczema Care Online to give a consistent message with respect to frequency of bathing i.e. do whatever suits them best.

This trial has started to address one of the evidence gaps for the patient/carer priorities from the PSP for eczema, however there are still other unanswered questions about the best way to wash[21]. There is interest in the community in the effect of weekly bathing in older adults (i.e. >65 years) as a difference in effect is plausible due to losing natural skin lipids as people get older[22] and there was insufficient data to explore this in this trial. The Rapid Eczema Community have prioritised two further questions about the self-management which will be developed and conducted using the methods and infrastructure set-up for this trial. We are currently testing the use of a severity assessment app based on photos of eczema[23] to address concerns over participant self-reporting and to include an assessment of clinical signs as per the HOME core outcome set initiative.

Conclusion

This is the first large trial to explore the effect of frequency of bathing on eczema symptoms and has begun to address one of the many questions patients and carers have around self-management of eczema. The finding of no clinically important difference in eczema symptoms between weekly and daily bathing gives people with eczema the freedom to choose how often to bathe, and provides evidence to healthcare professionals in order to give a consistent messages about frequency of bathing.

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Figure legends

Figure 1: Participant flow through the trial

Figure 2: Forest plot for adjusted difference in mean POEM score between weekly bathing and daily bathing over 4 weeks in each subgroup

Table 1: Baseline characteristics

		Daily bathing group (n = 218)	Weekly bathing group (n = 220)	Total (n = 438)
Age (years)				
	Mean[sd]	35.1 [23]	34.7 [22.2]	34.9 [22.6]
	Median [25th, 75th centile]	32 [16, 53]	32 [16, 52.5]	32 [16, 53]
	Min, max	1, 82	1, 89	1, 89
	Children (<16)	53 (24%)	55 (25%)	108 (25%)
	Adult (16-55)	115 (53%)	114 (52%)	229 (52%)
	Older adults (>55)	50 (23%)	51 (23%)	101 (23%)
Gender				
	Male	73 (33%)	72 (33%)	145 (33%)
	Female	143 (66%)	147 (67%)	290 (66%)
	Other	2 (1%)	1 (<1%)	3 (1%)
Ethnicity				
	White British	176 (81%)	192 (87%)	368 (84%)
	White other	10 (5%)	3 (1%)	13 (3%)
	Black	6 (3%)	--	6 (1%)
	Asian	13 (6%)	14 (6%)	27 (6%)
	Mixed	10 (5%)	10 (5%)	20 (5%)

	Daily bathing group (n = 218)	Weekly bathing group (n = 220)	Total (n = 438)
Other ethnic group	3 (1%)	1 (<1%)	4 (1%)
Country of residence			
England	204 (94%)	215 (98%)	419 (96%)
Wales	8 (4%)	1 (<1%)	9 (2%)
Scotland	5 (2%)	4 (2%)	9 (2%)
Northern Ireland	1 (<1%)	--	1 (<1%)
Quintile of Index of Multiple Deprivation (derived from postcode)[1]			
Quintile 1 (most deprived)	33 (15%)	32 (15%)	65 (15%)
Quintile 2	32 (15%)	51 (23%)	83 (19%)
Quintile 3	35 (16%)	25 (11%)	60 (14%)
Quintile 4	43 (20%)	48 (22%)	91 (21%)
Quintile 5 (least deprived)	55 (25%)	53 (24%)	108 (25%)
Missing	20 (9%)	11 (5%)	31 (7%)
Urban/rural classification of postcode			
Urban (population >10K)	144 (66%)	141 (64%)	285 (65%)
Town and Fringe	19 (9%)	37 (17%)	56 (13%)
Village Hamlet & Isolated Dwellings	18 (8%)	18 (8%)	36 (8%)
Missing[2]	37 (17%)	24 (11%)	61 (14%)
English First Language	205 (94%)	210 (95%)	415 (95%)
Atopic eczema based on UK Working Party Diagnostic Criteria	188 (86%)	193 (88%)	381 (87%)
Eczema symptoms - POEM score			
Mild (3 to7)	27 (12%)	27 (12%)	54 (12%)
Moderate (8 to 16)	112 (51%)	111 (50%)	223 (51%)
Severe (17 to 24)	68 (31%)	62 (28%)	130 (30%)
Very severe (25 to 28)	11 (5%)	20 (9%)	31 (7%)
Usual method of bathing			
Bath	71 (33%)	74 (34%)	145 (33%)
Shower	144 (66%)	145 (66%)	289 (66%)
Other	3 (1%)	1 (<1%)	4 (1%)
Number of times take a bath or shower in a typical week			
Mean[sd]	4.3 [2.3]	4.3 [2.2]	4.3 [2.3]
Median [25th, 75th centile]	4 [2, 7]	4 [3, 7]	4 [2, 7]
Min, max	0, 14	0, 14	0, 14
n	218	218	436

	Daily bathing group (n = 218)	Weekly bathing group (n = 220)	Total (n = 438)
0 – 2	61 (28%)	52 (24%)	113 (26%)
3 – 5	77 (35%)	99 (45%)	176 (40%)
≥ 6	80 (37%)	68 (31%)	148 (34%)
Missing	--	2 (<1%)	2 (<1%)
Prior belief with respect to frequency of bathing and eczema			
Thinks bathing everyday is helpful for people with eczema	32 (15%)	25 (11%)	57 (13%)
Thinks bathing less often is helpful for people with eczema	57 (26%)	70 (32%)	127 (29%)
Does not know if frequency of bathing makes a difference	122 (56%)	120 (55%)	242 (55%)
Missing	7 (3%)	5 (2%)	12 (3%)

All data are N (%) unless otherwise indicated. Additional baseline data presented in Appendix Table S2.
Note 25 participants requested and received financial assistance (22 daily bathing, 3 weekly bathing).
1 - Index of Multiple Deprivation available only for participants living in England. Derived from postcode
2 – Rural/Urban classification available only for participants living in England and Wales. Some postcodes didn't match, and duplicate postcodes only give one result.

Table 2: Primary outcome between group comparison – Eczema symptoms based on POEM assessed weekly

		Daily bathing group (n = 218)	Weekly bathing group (n = 220)	Adjusted[1] difference[2] in means (95% CI, p-value)
Baseline				
	Mean [sd]	14.5 [5.7]	14.9 [6.3]	
	n	218	220	
Week 1				
	Mean [sd]	11.7 [5.9]	12.1 [6.8]	
	n	183	184	
Week 2				
	Mean [sd]	12.2 [5.9]	11.3 [6.7]	
	n	165	162	-0.4 (-1.3 to 0.4), p = 0.30
Week 3				
	Mean [sd]	11.7 [6.7]	10.5 [7.0]	
	n	144	156	
Week 4				
	Mean [sd]	11.6 [6.5]	10.6 [7.2]	
	n	171	169	

1 – Adjusted by minimisation variables (age, baseline POEM score, and usual method of bathing) and other baseline variables as specified in the protocol (usual frequency of bathing, whether participants usually wash their hair in the bath/shower, whether they use emollient wash products, use of moisturisers after bathing, diagnosis of eczema according to the UK Diagnostic Criteria, whether participants are currently using systemic treatments).

2 – Difference for weekly bathing compared to daily bathing

1334 observations from 388 participants were included in the analysis model (663 observations from 195 participants in the Daily bathing group and 671 observations from 193 participants in the Weekly bathing group).

POEM score ranges from 0 to 28, higher scores indicating greater severity of eczema.

Table 3: Secondary outcomes at 4 weeks

	Baseline[1]	4 weeks[1]	Adjusted[2] difference (95% CI)
Improvement in POEM at week 4 of ≥ 3 points compared to baseline			
Daily bathing group (n = 171)	-	91 (53%)	
Weekly bathing group (n = 169)	-	97 (57%)	3.5% (-6.6% to 13.6%)
Itch intensity[3]			
Daily bathing group (n = 170)	6.1 [2.2]	5.4 [2.6]	
Weekly bathing group (n = 169)	6.3 [2.2]	5.1 [2.7]	-0.4 (-1.0 to 0.1)
Eczema control (RECAP)[4]			
Daily bathing group (n = 170)	13.0 [5.5]	11.0 [6.1]	
Weekly bathing group (n = 168)	13.3 [5.6]	10.7 [6.7]	-0.6 (-1.8 to 0.6)
Quality of life (according to age at randomisation)[5]			
IDQoL for participants aged < 4 years			
Daily bathing group (n = 14)	7.5 [5.3]	5.5 [5.1]	
Weekly bathing group (n = 12)[6]	8.5 [4.1]	5.8 [4.0]	0.4 (-4.1 to 4.8)
CDLQI for participants aged 4 to 15 years			
Daily bathing group (n = 28)	9.2 [6.5]	7.5 [6.1]	
Weekly bathing group (n = 28)[6]	8.0 [7.2]	6.6 [6.7]	-0.7 (-4.0 to 2.7)
DLQI for participants aged ≥ 16 years			
Daily bathing group (n = 126)[6]	8.4 [5.8]	7.7 [6.2]	
Weekly bathing group (n = 127)	8.1 [5.5]	7.0 [5.9]	-0.6 (-1.7 to 0.6)
Safety outcomes			
Changed eczema treatments during the study			
Daily bathing group (n = 168)	-	13 (8%)	
Weekly bathing group (n = 165)	-	17 (10%)	
Sought healthcare advice as a result of worsening eczema			
Daily bathing group (n = 170)	-	13 (8%)	
Weekly bathing group (n = 165)	-	20 (12%)	

1 - Mean [sd] presented unless otherwise indicated.

2 – Weekly bathing compared to daily bathing. Adjusted by minimisation variables and other baseline covariates as specified in Table 2. Risk difference presented for improvement in POEM and difference in means for all other outcomes. Note adjusted risk ratio for improvement in POEM 1.06 (95% CI 0.89 to 1.28).

3 - Itch intensity – Peak Pruritis Numerical Rating Scale (NRS) 24- hour peak itch [24] - a scale of 0 to 10, with 0 being 'no itch' and 10 being 'worst itch imaginable'

4 - RECAP – Recap of atopic eczema [25] - a total score ranging from 0 to 28, higher scores indicating less well controlled eczema

5 - Quality of life- a total score ranging from 0 to 30, higher scores indicating greater impairment on quality of life. IDQoL - Infants' Dermatitis Quality of Life Index [26], CDLQI - Children's Dermatology Life Quality Index [27] and DLQI - Dermatology Life Quality Index [28].

6 - Missing baseline data for 1 participant

Table 4: Secondary outcomes for frequency of use of usual eczema treatments assessed weekly over four weeks

	Daily bathing group (n = 218)	Weekly bathing group (n = 220)	Adjusted[1] difference[2] (95% CI)
Number of days moisturisers used in the previous week			
Baseline			
Median [25th, 75th centile]	7 [4, 7]	7 [4, 7]	
n	217	219	
Week 1			
Median [25th, 75th centile]	7 [4, 7]	7 [3, 7]	0 (-0.1 to 0.1)
n	182	183	
Week 2			
Median [25th, 75th centile]	7 [5, 7]	7 [3, 7]	0 (-0.2 to 0.2)
n	165	162	
Week 3			
Median [25th, 75th centile]	7 [5, 7]	7 [3, 7]	0 (-0.2 to 0.2)
n	141	155	
Week 4			
Median [25th, 75th centile]	7 [5, 7]	7 [3, 7]	0 (-0.2 to 0.2)
n	170	168	
Number of days flare control creams used in the previous week			
Baseline			
Mean [sd]	2.8 [2.5]	3.1 [2.6]	
n	217	217	
Week 1			
Mean [sd]	2.6 [2.5]	2.4 [2.5]	
n	182	184	
Week 2			
Mean [sd]	2.6 [2.5]	2.4 [2.5]	*Adjusted difference in means* -0.5 (-0.8 to -0.1)
n	164	160	
Week 3			
Mean [sd]	2.6 [2.5]	2.4 [2.6]	
n	143	155	
Week 4			
Mean [sd]	2.6 [2.5]	2.2 [2.4]	
n	170	169	

1 – Adjusted by minimisation variables and other baseline covariates as specified in Table 2

2- Strong evidence that assumptions for the multi-level linear model are violated for number of days in previous week that moisturisers used and so quantile regression at each time point used to estimate difference in medians.

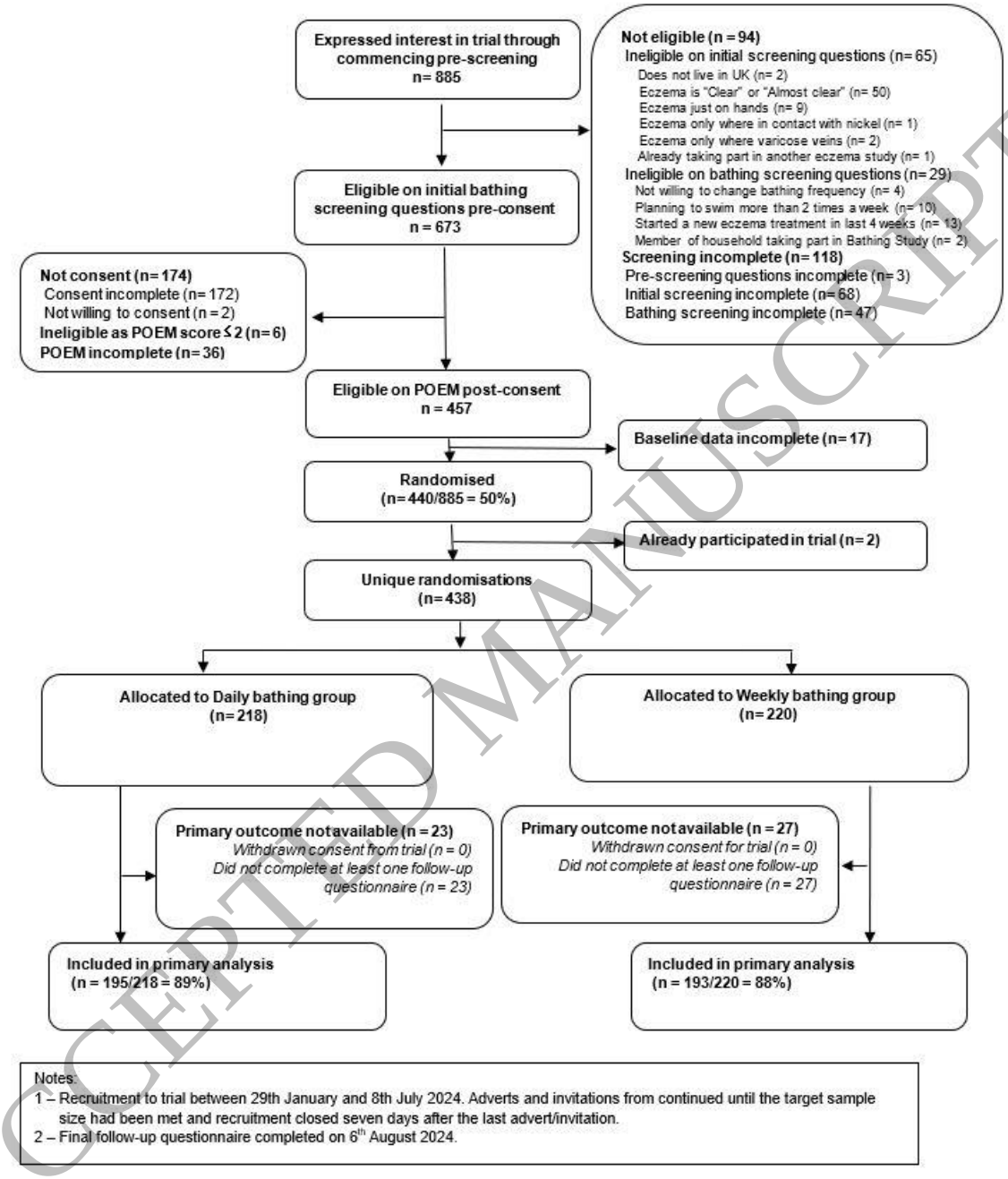
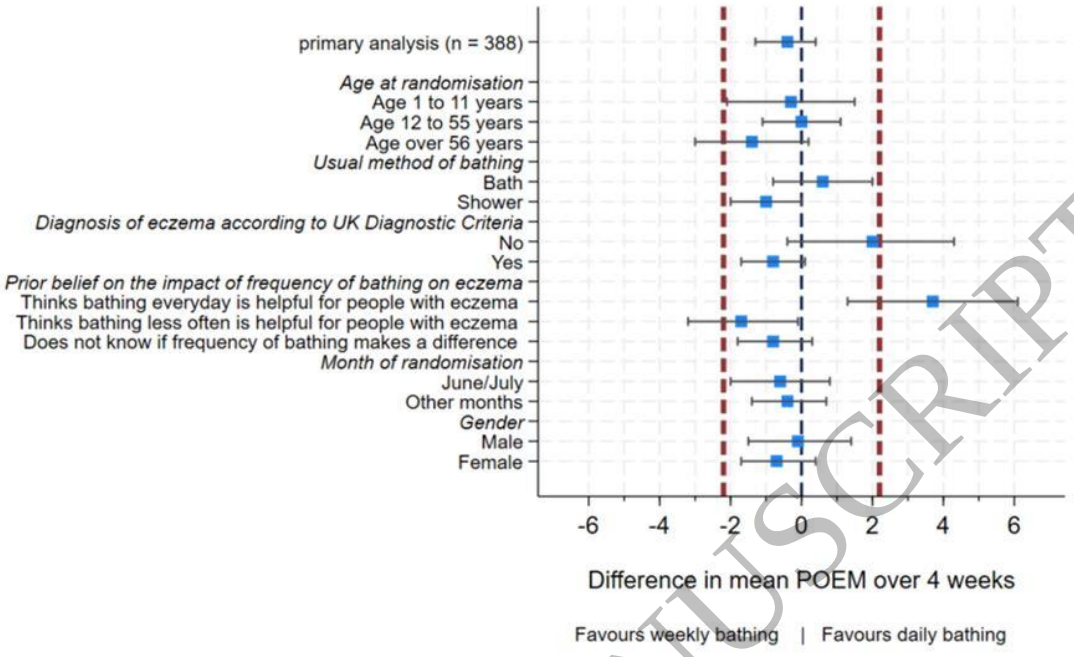


Figure 1
159x176 mm (x DPI)



Red lines show the target difference of 2.2 that the trial was designed to detect

Figure 2
159x102 mm (x DPI)