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Clinical Trial

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Randomized controlled feasibility trial of an intervention to reduce infant bathing

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Abstract

Background **Bathing, even in tap water, alters skin physiology. Frequent infant bathing may increase the risk of eczema developing.**

Objectives **To undertake a randomized controlled feasibility trial of an intervention to reduce infant bathing frequency and intensity.**

Methods **In total, 105 pregnant women (aged ≥ 16 years) with a family history of atopy and carrying a healthy singleton fetus (54 male, 51 female) were randomized in a 1 : 1 ratio during pregnancy or postnatally prior to their infant's first bath. Caregivers in the intervention group were asked to reduce how often they bathed their infants (no more than once a week for the first 6 months of age) and to reduce the intensity of the bathing (keeping baths short, ensuring the water was not too hot and washing in 'plain' water being usually sufficient). The control group received the routine postnatal infant care advice offered by their maternity unit. The primary feasibility outcome was the proportion of eligible families willing to be randomized to the intervention. The secondary clinical outcome was a blinded assessment of infant eczema at 6 months of age, using an adaptation of the UK Working Party Diagnostic Criteria for Atopic Dermatitis. The trial was registered with the ISRCTN Registry on 24 July 2023 (ISRCTN51491794).**

Results **Altogether, 261 pregnant women were screened, of whom 21 were ineligible. Of the 240 women included, 105 (43.8%) were randomized to the intervention ($n = 52$) and control ($n = 53$) groups. Adherence to the intervention was high, with 80% ($n = 35/44$) of caregivers in the intervention arm bathing their infant once a week or less compared with 29% ($n = 14/49$) in the control group. In the intervention group, 95% ($n = 38/40$) of caregivers agreed or strongly agreed that the intervention was acceptable. There was minimal contamination of the control group as a result of awareness of the trial's purpose and accessing the intervention ($n = 1/46$). Follow-up was high, with 88.6% ($n = 93/105$) of families completing the final 6-month questionnaire and 81.9% ($n = 86/105$) attending the final visit. Eczema outcomes occurred less frequently in the intervention arm compared with the control arm, respectively: visible eczema 16% ($n = 6/38$) vs. 29% ($n = 14/48$); parent-reported eczema 9% ($n = 4/44$) vs. 12% ($n = 6/49$); and doctor-diagnosed parent-reported eczema 9% ($n = 3/44$) vs. 10% ($n = 5/49$). No noteworthy adverse effects of the intervention were reported.**

Conclusions **These findings support the feasibility of randomizing infants during pregnancy to a reduced frequency and intensity bathing intervention for eczema prevention.**

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Lay summary

Eczema is a common inflammatory skin condition. We know that bathing, even in normal tap water, can alter the skin's natural barrier. Previous research has suggested that frequently bathing infants may increase the risk of eczema. The risk may be particularly increased in children whose family has a history of allergies or related conditions. This is known as 'atopy'.

We carried out a test trial, known as a 'randomized controlled feasibility trial'. This involved 105 pregnant women who had a family history of atopy. We assigned the families at random to one of two groups either during pregnancy or shortly after their babies were born, before the baby's first bath. The groups were called the intervention group and the control group. Families in the intervention group were asked not to bathe their baby more than once a week during the first 6 months and to keep baths short and not too hot. Families in the control group received the standard infant care advice from their maternity units.

We wanted to know whether families would be willing to take part in our trial. Most families in the intervention group followed the advice. About 80% bathed their baby once a week or less, compared with 29% in the control group. After following-up with the families, we found that eczema occurred less often in babies who were in the intervention group than in the control group. We did not see any negative effects with reducing how often the infants were bathed.

The findings from our test trial suggest that we could conduct a larger trial to investigate whether reducing infant bathing can help prevent eczema.

What is already known about this topic?

- Bathing, even in tap water, affects skin physiology.
- Frequent immersive bathing is a modern practice, and frequent bathing during infancy has been associated with signs of impaired skin barrier integrity.
- Analyses of a previous clinical trial found that daily bathing was associated with increased eczema risk by 1 year of age.

What does this study add?

- Families adhered to an intervention to reduce bathing frequency and intensity with a significant reduction in infant bathing frequency.
- There was minimal contamination of the control group as a result of awareness of the trial purpose and accessing the intervention.
- All eczema outcomes occurred less frequently in the intervention arm compared with the control arm.

Eczema (also known as atopic eczema or atopic dermatitis) carries the highest global burden of all skin diseases. It usually begins in early life, affecting 15% of infants and 6% of older children.[1] Eczema prevalence varies internationally and, within countries, prevalence varies by ethnicity.[2] It is a chronic condition with no cure, substantially affecting people's quality of life through itch, emotional distress, sleep disturbance and increased susceptibility to skin infections.[3] Eczema reflects impaired skin barrier function, which precedes clinical disease.[4] While genetic risk factors for eczema, such as *FLG* mutations, have been well-characterized,[5] environmental risk factors are not fully understood. There has been recent interest in skincare practices during infancy, due to their potential to promote or disrupt skin barrier function.[6] While the application of moisturizers to infant skin does not seem to prevent or delay eczema development, it is possible that other skincare practices such as bathing may be relevant.[6]

Bathing, even in tap water, alters the skin's physiology by increasing pH, reducing lipid content and affecting enzymatic activity.[7,8] Frequent immersive bathing is a modern practice, and frequent bathing during infancy has been associated with signs of impaired skin barrier integrity.[9] A UK survey found highly variable infant bathing advice across antenatal services, with no standard National Health Service infant skincare guidelines, reflecting a lack of empirical evidence to guide practice.[10] UK Royal College of Midwives guidance previously recommended bathing infants 2–3 times weekly,[11] later shifting to industry-supported material recommending an everyday 'beneficial multisensory bath time routine' incorporating bathing with a liquid cleanser, followed by massage with oil or lotion, then some quiet time.[12]

In the Enquiring About Tolerance (EAT) Study, most infants at 3 months of age were bathed at least twice weekly, with 30% bathed daily.[13] A dose–response relationship was observed between bathing frequency and transepidermal water loss (TEWL),[14] with daily bathing associated with more than fourfold elevated TEWL compared with weekly bathing.[13]

Other than bathing frequency, factors such as water hardness,[15,16] temperature, duration and use of wash products, may contribute to skin barrier disruption. Hard water is associated with increased eczema and enhances the deposition of irritants such as sodium lauryl sulfate, especially in infants with *FLG* mutations.[17] Wash products, used by most families, are often alkaline and drying; washing with alkaline soap markedly increases infant skin pH and decreases lipid content.[8] Some analyses of a previous

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clinical trial found that daily bathing was associated with increased eczema risk by 1 year of age.[6,18]

Taken together, mechanistic, observational and clinical trial evidence suggests that reducing bathing frequency and intensity may be one potential approach to preventing infant skin damage and thereby lowering eczema risk. The BabyBathe study was designed to develop and test an intervention aimed at reducing infant bathing frequency and intensity. After qualitative work and co-design of intervention materials,[19] a randomized controlled feasibility trial was conducted (ISRCTN51491794). The protocol and study supporting materials are available on FigShare (https://doi.org/10.24376/rd.sgul.25126115).[20] This paper reports the feasibility trial findings.

In this study, we explored whether reducing the frequency and intensity of infant bathing could help prevent eczema, a common inflammatory skin condition. We know that bathing, even in normal tap water, can alter the skin's natural barrier. Previous research has suggested that frequent bathing in early life may increase the risk of eczema, particularly in children with a family history of allergies or related conditions (known as atopy).

We conducted a randomized controlled feasibility trial involving 105 pregnant women aged ≥ 16 years who had a family history of atopy and were expecting a healthy baby (54 boys and 51 girls). We randomly assigned participants to one of two groups either during pregnancy or shortly after birth, before the baby's first bath.

For families in the intervention group, we advised parents to bathe their baby no more than once a week during the first 6 months of life, while keeping baths short and not too hot. Families in the control group received the standard infant care advice routinely provided by maternity units.

Our main aim was to assess whether families would be willing to take part in such an intervention. Of 240 eligible women, 105 (43.8%) agreed to participate. Most families in the intervention group followed the advice: 80% ($n = 35/44$) bathed their baby once a week or less, compared with 29% ($n = 14/49$) in the control group. Parents generally found the intervention acceptable.

We achieved high follow-up rates, with most families completing questionnaires and attending the 6-month visit. Eczema occurred less frequently in the intervention group than in the control group across several measures. We did not identify any significant negative effects. Overall, our findings suggest that we could feasibly conduct a larger trial to investigate whether reducing infant bathing can help prevent eczema.

Participants and methods

The BabyBathe feasibility trial was a randomized controlled trial to test an intervention to reduce bathing frequency and intensity, with families randomly allocated in a 1 : 1 ratio to intervention or control groups. No significant changes were made to the study protocol after study commencement.

Inclusion criteria

The eligibility criteria for the trial were women aged ≥ 16 years with a healthy, singleton pregnancy; infant with a first-degree relative with parent-reported doctor-diagnosed eczema, hay fever or asthma; the consenting adult understood English; and women who gave birth before providing consent were eligible to give consent up to 2 weeks after giving birth or prior to their infant's first bath – whichever came first

Exclusion criteria

The exclusion criteria for the trial were an expected preterm birth (prior to 37 weeks' gestation); the infant had a sibling who was previously randomized into this trial; a known serious health issue in the developing infant; any antenatally diagnosed condition that would make the use of emollient inadvisable or not possible; and enrolment in another clinical study.

Participants

Participants were recruited from pregnant women attending their 36/40 antenatal scan at St George's Hospital, London, UK. Recruitment posters were also distributed in other South London antenatal services. All families were recruited from South London, an area where the water is either hard (200–300 mg L^{-1} $CaCO_3$) or very hard (> 300 mg L^{-1} $CaCO_3$). Women were approached by midwifery staff, and those interested in taking part provided consent for their details to be forwarded to the BabyBathe research team. Consent was taken by the midwifery staff face-to-face, by the BabyBathe research team face-to face or remotely using DocuSign.

Randomization and blinding

Infants were randomized in a 1 : 1 ratio, stratified by maternal report of planned bathing frequency (once weekly or less vs. more than once weekly) and recruitment site. The randomization list was generated by the unblinded study statistician using the 'ralloc' function in Stata (StataCorp., College Station, TX, USA) and allocation was concealed online within REDCap (Research Electronic Data Capture),[21,22] using the REDCap randomization module. It was not possible for families to be blinded to the intervention; however, the final eczema assessment at 6 months was undertaken by an academic general practitioner (U.A.R.C., S.A.) blinded to the participant's treatment group. The academic general practitioners underwent training in assessing visible flexural dermatitis and undertaking Eczema Area and Severity Index (EASI) scoring with the study dermatologist (C.F.), as well as completing and passing the Marked Test for the recording of the signs of visible flexural dermatitis (https://xerte.nottingham.ac.uk/play_53210). Study data were collected and managed using REDCap and carer-reported outcomes using the REDCap mobile application (app), MyCap.[23] MyCap is a participant-facing mobile app for survey data collection. It is customizable for a specific study and is configured within, and syncs data to, a REDCap project.

Intervention

The intervention was advising reduced bathing frequency (i.e. once weekly or less) and intensity. For the purposes of BabyBathe, intensity was considered to include bath duration and temperature, as well as the use of wash products. To reduce bathing intensity, intervention families were advised to keep baths short and not too hot, and were provided with a thermometer to check the bath temperature. Specific bath durations and bath temperatures were not stipulated. No restriction on the use of wash products

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was made, but families were advised that washing in plain water would be sufficient in most instances.

Both study arms received the current discharge advice provided to women in their specific hospital. In St George's Hospital, all women who give birth are encouraged to watch a 20-min YouTube video entitled 'The "Going Home" video' (https://www.youtube.com/watch?v=14gBSXGJc5 M) before their discharge from the postnatal ward. This does not include any information about infant skincare or bathing.

Participants in both groups received the following material: a study group-specific booklet; a bookmark and fridge magnet as prompts or cues to enter study information; and links to study specific webpages. Additionally, the intervention group received the following: an online video on the intervention group-specific webpage to explain the rationale for the study, to encourage engagement, and to hear from a family who had bathed their infant infrequently in the first 6 months (https://youtu.be/koNfR-JDfpz8); a wallchart to aid self-monitoring of when bathing took place; a bath thermometer; and plastic day-of-the-week markers to help remember when baby was last bathed.

Study assessments

MyCap was used to complete a baseline demographic questionnaire, monthly questionnaires about bathing and eczema, and to report adverse events, and a longer questionnaire at 6 months, including feedback questions. The MyCap app facilitated monitoring adherence with the intervention by enabling dynamic recording each time the infant was bathed. Participants were invited when the infants were 6 months of age to attend the final assessment visit in the NIHR (National Institute for Health and Care Research) Clinical Research Facility at St George's Hospital.

Outcomes

Feasibility trial primary outcome

The feasibility trial primary outcome was the proportion of eligible families willing to be randomized. Based on our previous work, we estimated that 325 eligible families would need to be approached to enrol 125 (38.5%) in the trial.

Trial secondary outcomes: clinical outcomes

The secondary clinical outcomes were eczema defined using an adaptation of the UK Working Party Diagnostic Criteria for Atopic Dermatitis,[24,25] specifically the presence of visible eczema using the 'Observer's protocol for recording the sign of "visible flexural dermatitis"'.[26]

Trial secondary outcomes: feasibility outcomes

The secondary feasibility outcomes were reported adherence to the intervention: bathing frequency recorded on the MyCap app and in the 6-month questionnaire; acceptability of the intervention to participating families; contamination of the control group due to awareness of the trial's purpose; ascertainment bias (if the blinded investigator eczema assessments become unblinded); loss to follow-up; completeness of eczema outcome collection at 6 months of age; and adverse events such as skin infections, omphalitis, nappy rashes and sepsis.

A series of criteria were also determined a priori for use at the end of the trial to judge the success of the feasibility study and to make a recommendation for the suitability to progress to a definitive trial (Table S1; see Supporting Information). These included achieving a minimum of 80% of the recruitment target (100 participants).

Patient and Public Involvement statement

Patient and Public Involvement (PPI) was integral to the BabyBathe study from inception. Early input from the University of Nottingham dermatology patient panel shaped the study design, highlighting cultural practices, particularly in Black and Asian communities, and the need to involve healthcare professionals in the intervention development. This led to broader participant representation and the inclusion of midwives and health visitors. Ongoing PPI feedback informed trial timing, adherence measurement and design decisions. A dedicated PPI representative contributed throughout trial management. A study website supported participants and the public.

Statistical considerations

Sample size

As this was a feasibility study the analysis was primarily descriptive. Baseline characteristics and outcome measures were summarized separately for each arm. Frequencies and proportions were calculated by arm to summarize categorical data, and continuous outcome measures were summarized using mean (SD) or median [range or interquartile range (IQR)] as appropriate. Participants were analysed as allocated to follow an intention-to-treat approach regardless of subsequence adherence. Missing outcome data were reported and no imputation for outcome data was performed. The change in bathing frequency was reported with a 95% confidence interval (CI).

Results

Altogether, 261 pregnant women interacted with recruiters between December 2023 and December 2024. Twenty-one were ineligible (1 infant was born preterm, 2 had no family history of atopy and 18 did not complete consent within the postpartum time window – prior to 2 weeks of age or first infant bath, whichever came first) and 135 were not interested in participating. Therefore, 105 of 240 (43.8%) eligible women enrolled (Figure 1). Baseline demographic and clinical characteristics were similar between the control and intervention groups (Table 1).

Adherence to the intervention

In the 6-month questionnaire, families in the intervention group were significantly more likely to report infrequent bathing: 80% ($n=35/44$) of infants were bathed once a week or less in the intervention group vs. 29% ($n=14/49$) in the control group (risk ratio 2.78, 95% CI 1.74–4.44). A change in bathing behaviour was observed in infants of all enthnicities (Figure S1; see Supporting Information).

Acceptability of the study and study materials

Families reported study participation to be acceptable: 97% ($n=84/87$) agreed or strongly agreed that they were satisfied with

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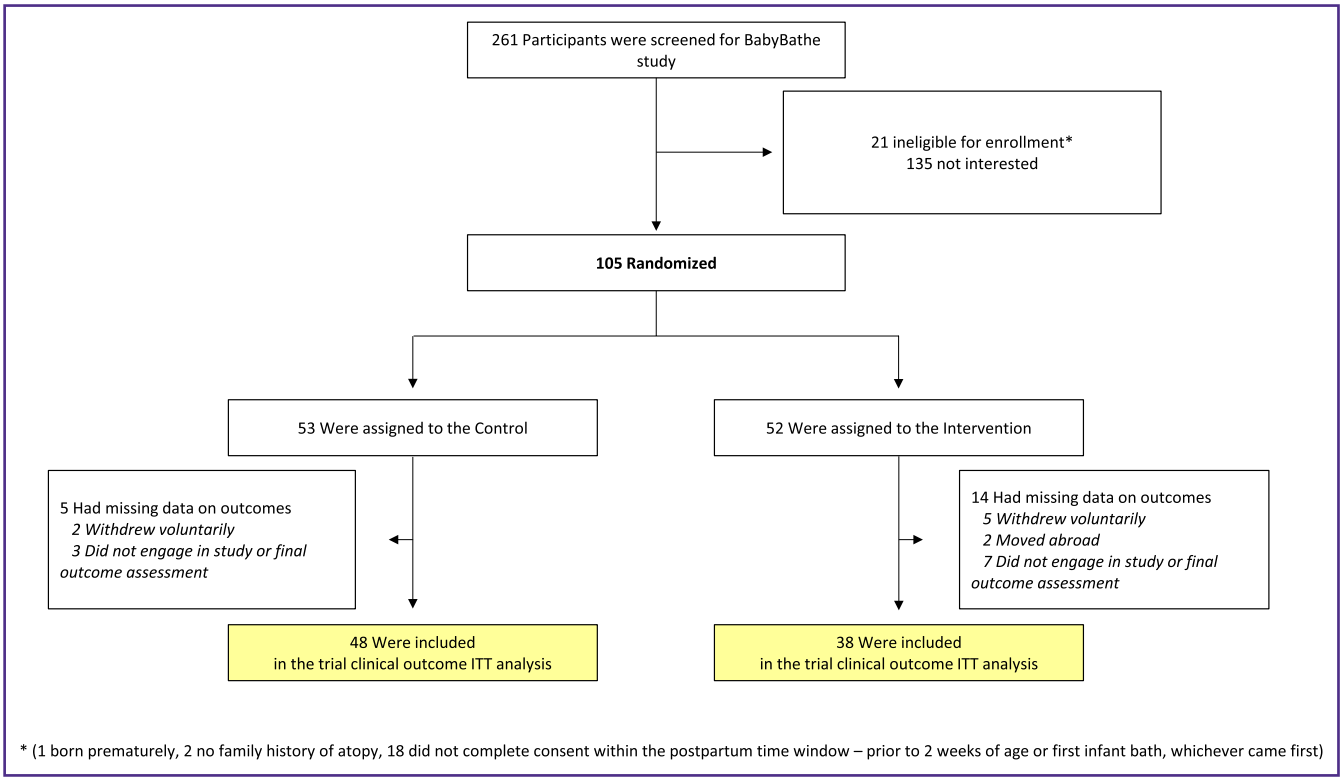


Figure 1 Participant flowchart. [a]One infant born prematurely, 2 had no family history of atopy, 18 did not provide consent within the postpartum time window (prior to 2 weeks of age or the infant's first bath, whichever came first). [b]One cultural concerns, 1 was not keen to participate in a study, 8 were unhappy to be randomized, 8 did not want to change their planned bathing regimen, 2 had concerns about maternal mental health, 11 exceeded the window to provide consent, 46 were no longer interested, 17 gave no reason, 20 were not contactable, 4 had partners who were not keen on participating, 5 had pregnancy complications, 7 were too busy, 1 wanted payment and 4 deemed it too burdensome. ITT, intention-to-treat.

their experience of taking part in the study (Figure S2; see Supporting Information). In the intervention group, 95% ($n = 38/40$) agreed or strongly agreed that the intervention was acceptable (Figure S3; see Supporting Information). The intervention was not felt to have clashed with personal or cultural values (see Figure S3).

Trial contamination

One participant in the control group independently chose to follow the infrequent bathing intervention.

Ascertainment bias

One of the blinded 6-month assessments was accidentally unblinded.

Loss to follow-up and completeness of eczema assessment at 6 months

Of the enrolled families ($n = 93/105$; 88.6%) who completed the final 6-month study questionnaire, 55 questionnaires were completed on the MyCap app and 38 on a paper version. Eighty-two per cent ($n = 86/105$) of enrolled infants underwent the 6-month skin assessment. Seventy-one assessments took place in person and 15 were undertaken remotely by video link.

Five infants in the control group did not undergo the final skin assessment (two were withdrawn and three families did not engage with the study and/or did not attend the final assessment). Fourteen infants in the intervention group did not have data available for the final skin assessment (five were withdrawn, two families had moved abroad and seven families did not engage and/or did not attend the final assessment).

For the six infants in the intervention group who did not attend the 6-month final assessment (one Asian, one Black and four White infants), but had completed 6-month questionnaires, their bathing frequency was not significantly different to those intervention families who did attend the 6-month visit [infrequent bathing 50% ($n = 3/6$) vs. 84% ($n = 32/38$)].

Adverse events

Eighty-two families (41 in the control group and 41 in the intervention group) completed between 1 and 6 monthly questionnaires [control group median 5 (IQR 3–5); intervention group median 4 (IQR 3–5)] and hence provided adverse event data. With regard to adverse events, no statistically significant difference between the intervention and control groups was reported (Table S2; see Supporting Information). There were no hospitalizations for skin-related issues. Six families in each group reported their infant had experienced one or more skin infections. Four of the six families in the control group saw their general practitioner for a skin infection in their infant [three reported the infection as an 'other infection' (i.e. not bacterial or viral) and one stated the doctor did not know the cause], compared with none of the six families in the intervention group.

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Table 1 Baseline participant demographic and clinical characteristics

Demographic/characteristic	Treatment		Total ($n=105$)
	Control ($n=53$)	Intervention ($n=52$)	
Infant sex, male	28 (53)	26 (50)	54 (51.4)
Maternal age (years), mean (SD)	35.0 (4.7)	34.3 (3.9)	34.7 (4.4)
Maternal ethnicity[a]			
Asian or Asian British	3 (6)	8 (15)	11 (10.5)
Black, Black British, Caribbean or African	3 (6)	6 (11)	9 (8.6)
Mixed or multiple ethnic groups	6 (11)	1 (2)	7 (6.7)
White	40 (75)	36 (69)	76 (72.4)
Other ethnic group	1 (2)	1 (2)	2 (1.9)
Maternal age leaving full-time education (years)[a]			
≤ 16	4 (8)	2 (4)	6 (6.1)
18	2 (4)	6 (12)	8 (8.2)
≥ 19	44 (88)	40 (83)	84 (85.7)
Planned baby bathing frequency			
Less than once weekly	0 (0)	3 (6)	3 (2.9)
Once weekly	8 (15)	3 (6)	11 (10.5)
2–4 times weekly	11 (21)	15 (29)	26 (24.8)
5–6 times weekly	1 (2)	1 (2)	2 (1.9)
Daily	11 (21)	5 (10)	16 (15.2)
More than daily	0 (0)	1 (2)	1 (1.0)
Undecided	22 (42)	24 (46)	46 (43.8)
Maternal asthma	15 (28)	11 (21)	26 (24.8)
Maternal eczema	19 (36)	22 (42)	41 (39.0)
Maternal hay fever	25 (47)	22 (42)	47 (44.8)
Paternal asthma	9 (17)	9 (17)	18 (17.1)
Paternal eczema	8 (15)	11 (21)	19 (18.1)
Paternal hay fever	18 (34)	11 (21)	29 (27.6)
Any sibling asthma	1 (2)	0 (0)	1 (1.0)
Any sibling eczema	6 (11)	9 (17)	15 (14.3)
Any sibling hay fever	0 (0)	0 (0)	0 (0)
Mode of delivery			
Vaginal	30 (57)	31(60)	61 (58.1)
Caesarean	23 (43)	21 (40)	44 (41.9)
Parents have other children[b]	25 (50)	21 (43.8)	46 (46.9)
Mother smokes[b]	0 (0)	0 (0)	0 (0)
Father smokes[b]	2 (4)	2 (4)	4 (4.1)
Dogs in household[b]	15 (30)	9 (19)	24 (24.5)
Cats in household[b]	5 (10)	10 (21)	15 (15.3)
Other pets in the household	2 (4)	5 (10)	7 (7.1)
Maternal age ≥ 16 years	53 (100)	52 (100)	105 (100)

Data are presented as *n* (%) unless otherwise stated. [a]Presented as the UK Census 2021 categories and were the options presented to the families for completion. [b]$n=98$.

Feasibility trial: clinical outcomes

All eczema outcomes occurred less frequently in the intervention arm compared with the control arm: visible eczema 16% ($n=6/38$) vs. 29% ($n=14/48$); parent-reported eczema 9% ($n=4/44$) vs. 12% ($n=6/49$); and doctor-diagnosed parent-reported eczema 7% ($n=3/44$) vs. 10% ($n=5/49$) (Table 2). Visible eczema, when present, was mild in severity: mean (SD) EASI score 4.0 (4.9); mean (SD) Patient-Oriented Eczema Measure score 5.6 (5.4).

Bathing monitoring: MyCap and 6-month questionnaire

Ninety per cent ($n=95/105$) of families installed the MyCap app and 85.7% ($n=90/105$) recorded one or more baths on the app (Figure 2). The (SD) mean infant age at which the first bath was recorded in the app was similar for the two groups: control group 17.2 (13.5) days, intervention group 17.7 (9.4) days. However, this

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cannot be confirmed to be the age at first bath, as it was also influenced by when a family first started using the app to record baths.

The mean (SD) infant age at recording the last bath was 154 (57) days. Forty-two per cent ($n = 38/90$) of families were still recording baths when their infant was 180 days old (Figure S4; see Supporting Information). There was a good correlation between the average bathing frequency over the first 6 months of life reported in the 6-month questionnaire and the corresponding recording of bathing frequency in the MyCap app (Figure S5; see Supporting Information).

Table 2 Eczema outcomes

Eczema outcomes	Control	Intervention
Six-month visit ($n = 86$)		
Eczema at 6-month visit (principal clinical outcome)	14/48 (29)	6/38 (16)
Six-month questionnaire ($n = 93$)		
Itchy skin condition	10/49 (20)	5/44 (11)
Parent-reported eczema	6/49 (12)	4/44 (9)
Doctor diagnosed parent-reported eczema	5/49 (10)	3/44 (7)

Data are presented as *n*/*N* (%).

Bathing intensity

Seventy-eight per cent ($n = 82/105$) of families completed one or more of the monthly questionnaires on the MyCap app. Although intervention families were encouraged to keep baths short, the mean (SD) bath duration was similar in both groups: 7.61 (3.46) min in the control group compared with 7.78 (3.49) min in the intervention group. Families in the intervention group used wash products with bathing less frequently than those in the control group: 46% (19/41) of families in the intervention group rarely or never used wash products, compared with 20% ($n = 8/41$) in the control group.

Skincare

Most participants reported applying moisturizer (85% of all participants; $n = 70/82$), but more infants in the intervention group were never moisturized (20%; $n = 8/41$) compared with infants in the control group (10%; $n = 4/41$). There was a possible relationship between bathing frequency and moisturizer use, with the lowest moisturization rate being in the bathing less than once weekly

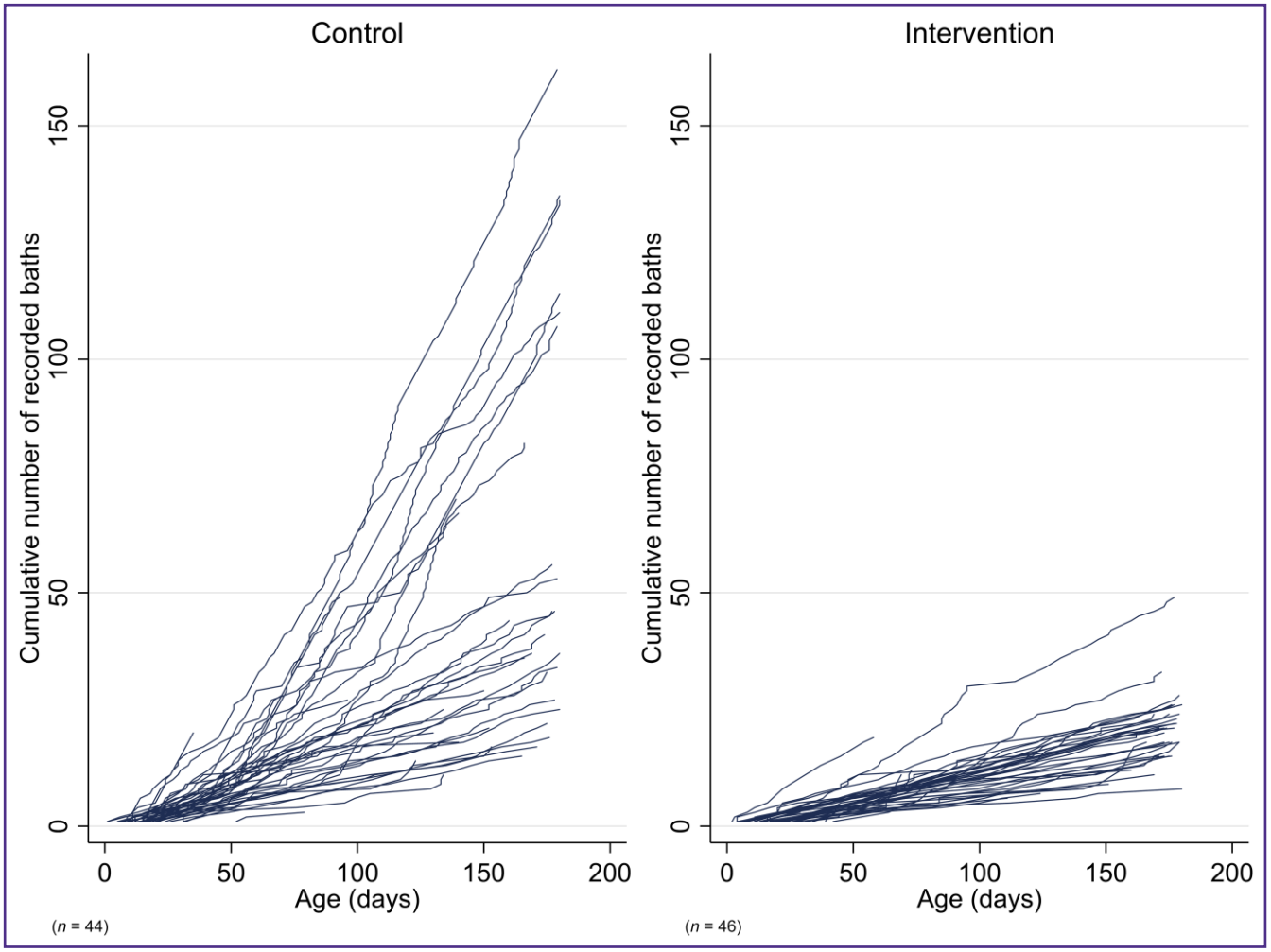


Figure 2 Cumulative number of recorded baths on the MyCap mobile application over time, by study group.

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group ($n = 11/15$; 73%), whereas 100% of infants bathed 5–6 times weekly ($n = 5/5$) or daily ($n = 10/10$) were being moisturized.

Intervention duration

When families in the intervention group were asked if they would have been willing to continue the infrequent bathing intervention through to 1 year of age the responses were: 23% 'extremely likely' ($n = 9/40$), 25% 'likely' ($n = 10/40$), 15% 'neutral' ($n = 6/40$), 20% 'unlikely' ($n = 8/40$) and 18% 'extremely unlikely' ($n = 7/40$).

Use of study material

The intervention video had 19 viewings of a mean duration of 1 min 47 sec (47% of the overall video duration of 3 min 49 s). Hence only a minority of intervention families watched the video and, those that did, watched less than half of it, on average.

Feasibility criteria for main trial

All the a priori determined feasibility criteria to proceed with a full trial were met (Table 3).

Discussion

In this feasibility trial, we found that an intervention encouraging reduced bathing frequency and intensity during the first 6 months of an infant's life was acceptable and changed bathing behaviour in all ethnic groups. The primary outcome, that 44% of eligible families were willing to be randomized, exceeded our a priori estimate of 38%. All study secondary feasibility outcomes were met, as well as the additional specific criteria set a priori with regard to the decision to proceed with a definitive trial. All the eczema outcomes, including the primary clinical outcome of eczema diagnosed in a blinded assessment at age 6 months, were lower in the intervention group, supporting the possibility of a beneficial health effect of reduced bathing intensity and frequency.

The intervention had an impact on bathing intensity, as well as bathing frequency, with intervention families reporting using washing products with bathing significantly less frequently. Infrequently bathed infants were also moisturized less.

The international variation in eczema prevalence has been linked to affluence. Access to running water inside homes is a modern phenomenon – and to hot water even more so – and immersive bathing has only became more widespread in more recent human history.[9] The potential vulnerability of the neonatal and early infant skin barrier has led to intervention studies seeking to enhance the skin barrier through the application of moisturizers. However, findings from such studies suggest that moisturizer application on its own is unlikely to delay or prevent eczema.[27] Thus, interventions are needed that better protect infant skin during infancy, and reducing potentially harmful infant skincare practices such as frequent bathing is one potential approach.

Recruitment was compromised by significant research midwife staffing issues in the recruitment centre resulting in periods when women who were pregnant could only be approached regarding participation on 2 days in the week. The principal limitation is that this was a feasibility study with a small number of participants. It was not powered to find a statistically significant reduction in eczema and the eczema that occurred was mild in severity. Caution should therefore be exercised in interpreting these findings. A strength of the study is that, despite the small numbers, participants reflected a variety of ethnic backgrounds.

UK Working Party Criteria for defining eczema, including the 'observer's protocol for recording the sign of "visible flexural dermatitis"', were developed for older children and have not been validated in the first 6 months of life. Indeed, eczema diagnosis at this age can be difficult and there is a previous history of pilot or feasibility trials suggesting successful eczema prevention in the first 6 months,[28] which has not been confirmed in a larger definitive trial. [29]

Table 3 Full trial a priori defined criteria: outcomes

Criterion	Metric	Result
Acceptable recruitment	Enrolling at least 100 eligible participants within the planned time frame for enrolment	105 participants recruited
Acceptability of the enrolment and randomization procedures, including the participant information sheet	Assessed by Likert feedback questions incorporated in the final 6-month outcome assessment, and through qualitative interviews with up to 20 representative families	Proportion agreeing or strongly agreeing: • Enrolment OK: 99% ($n = 88/89$) • Randomization OK: 100% ($n = 89/89$) • Information OK: 98% ($n = 85/87$)
Acceptable questionnaire completion	Follow-up and final visit questionnaires completed for at least 70% of participants	Follow-up questionnaires: 78%; final visit questionnaire: 88%
Acceptable adherence to the intervention	≥70% of infants in the intervention group bathed once a week or less during the intervention period	80% of infants in the intervention group bathed once a week or less, on average
Intervention is safe	No serious safety concerns related to the intervention are identified	None identified
Intervention does not appear ineffective	95% confidence interval for development of eczema by age 6 months excludes the possibility of a ≥ 10% risk reduction	46% risk reduction in visible eczema was found
No evidence of significant uptake of the intervention in the control group	Infants in the control group bathed once a week or less during the intervention period ≤ 30%	28% of infants in the control group were bathed once a week or less

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The emergence of eczema in an infant is strongly associated with the development of other allergic conditions such as food allergy, asthma and allergic rhinitis. Together, atopic conditions affect one in three children and young people in the UK and many other countries, and cost the UK public health system over £1 billion per annum.[30] The family impact of caring for a child with moderate or severe eczema is greater than that of caring for children with type 1 diabetes mellitus, mainly due to sleep deprivation, employment loss, time needed to care for eczema and financial costs.[31] A simple intervention that prevents infants developing eczema would be an important advance in population health, and may result in direct savings to families and the environment through reducing the need to purchase bathing products and use hot water. In light of these findings, it seems appropriate to proceed with a larger, multicentre trial.

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Author contributions

Michael R. Perkin (Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology [equal], Resources [equal], Software [equal], Validation [equal], Visualization [equal], Writing—original draft, Writing—review & editing [equal]), Michael Ussher (Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Supervision [equal], Writing—original draft, Writing—review & editing [supporting]), Lucy P. Goldsmith (Conceptualization, Data curation, Investigation, Methodology, Project administration, Writing—review & editing [equal], Formal analysis [supporting]), Charlotte Wahlich (Investigation, Methodology [equal], Project administration, Writing—review & editing [supporting]), Kathryn Willis (Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Validation, Visualization, Writing—review & editing [equal]), Umar A. R. Chaudhry (Data curation, Investigation, Writing—review & editing [equal]), Selma Audi (Data curation, Investigation [equal], Writing—review & editing [supporting]), Carsten Flohr (Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Writing—review & editing [equal], Project administration [supporting]), Amanda Roberts (Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology [equal], Writing—review & editing [supporting]), V. Cornelius (Data curation, Formal analysis, Methodology [equal], Writing—review & editing [supporting]), and Robert J. Boyle (Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Validation, Visualization, Writing—review & editing [equal])

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Conflicts of interest

M.R.P. declares travel/accommodation reimbursement from the British Society of Allergy and Clinical Immunology for conference presentation. C.F. is Evidence-Based Dermatology Section Editor for the BJD (receives an honorarium). R.J.B. declares payment for editorial work from Cochrane Skin, Wiley and the British Society for Allergy and Clinical Immunology; payment for expert witness work in legal cases relating to anaphylaxis and to infant formula health claims; travel/accommodation reimbursement from the European Academy of Allergy and Clinical Immunology and the British Society for Allergy and Clinical Immunology for conference presentations. M.U., L.P.G., A.R., V.C., C.W., K.W., U.A.R.C. and S.A. declare no conflicts of interest.

Data availability

Data underlying the results, the protocol and the study intervention material are available from the City St George's, University of London Data Repository (https://doi.org/10.24376/rd.sgul.25126115). Any data shared will be pseudonymized, which may impact on the reproducibility of published analyses.

Ethics statement

Ethical approval was obtained from the North of Scotland Research Ethics Committee (22/NS/0120).

Patient consent

Written consent for participation in the feasibility study was obtained from all participants. The Patient Information Sheet included informing participants of the intention to publish the trial results in scientific journals.

Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's website.

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