

# A randomised controlled feasibility trial incorporating intervention development and process evaluation to determine whether families are willing to change baby bathing practice during the first months of life (BabyBathe study): study protocol

## Abstract

**Introduction:** Atopic eczema causes the highest global burden of all skin diseases and affects up to 15% of infants and 6% of older children. Environmental factors are believed to play an important role in the aetiology of skin barrier impairment and subsequent eczema in infancy. Bathing, even with tap water alone, adversely affects skin physiology and may be a key environmental risk factor for eczema in infancy.

**Methods and analysis:** We will work with pregnant women and their families to develop an acceptable intervention which aims to reduce infant bathing frequency and intensity. We will then undertake a randomised controlled feasibility trial recruiting 125 pregnant women from one hospital site in London, England. The sample size was rounded up and participants will be randomised at a ratio of 1:1 to the intervention advising reduced bathing frequency and intensity, with an associated reduction in use of wash products, versus standard care. The feasibility trial outcomes include: the proportion of eligible families willing to be randomised; reported adherence and acceptability of the intervention; contamination of the control group; unblinding of outcome assessments and loss to follow up. The clinical outcome will be the presence of eczema at six months of age assessed using a modified form of the UK Working Party Diagnostic Criteria for Atopic Dermatitis.

**Ethics and dissemination:** Ethical approval has been obtained from the North of Scotland Research Ethics Committee (22/NS/0120). Data analysis, interpretation and conclusions will be presented at national and international conferences, published in peer reviewed journals and disseminated via social media, patient charities and support groups.

**Trial Registration:** ISCTRN registration 10.1186/ISRCTN51491794

### **Strengths and limitations of this study**

- Substantial time and resources are allocated for intervention development - collaboratively applying theoretical frameworks and design criteria - to ensure the intervention is rooted in and draws upon behaviour change theory.
- The intervention will be co-designed with patients and draws on a wide range of patient and public contributions to ensure relevant design and applicability for the public.
- The feasibility study is randomised and controlled and designed to ascertain the feasibility of a large randomised controlled trial - data about acceptability, adherence and contamination will facilitate a thorough assessment of the feasibility of a large-scale definitive trial to estimate effectiveness of the intervention.
- This feasibility trial is set in the South-East of the UK, which may limit the generalisability to other locations. There may be potential barriers to recruitment and maintenance of the intervention including stigma around bathing babies infrequently. Participants not recording bathing frequency data constitutes a further potential barrier to assessing the effectiveness of whether the intervention has an effect on bathing frequency.
- This protocol adheres to the SPIRIT recommendations and the CONSORT extension for pilot and feasibility trials.

## Administrative Information

Title {1}	<b>A randomised controlled feasibility trial incorporating intervention development and process evaluation to determine whether families are willing to change baby bathing practice during the first months of life (BabyBathe study): study protocol</b>
Trial registration {2a and 2b}	ISCTRN registration: 10.1186/ISRCTN51491794
Protocol version {3}	V0.8, 1 <sup>st</sup> August 2022
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Role of sponsor {5c}	St George's, University of London is the study sponsor and has delegated all responsibility for the management of the trial and publication of the findings to the Chief Investigator and Co-Investigators. The sponsor plays no part in study design; collection, management, analysis and interpretation of data; writing of this or other reports or the decision to submit reports for publication.

Table 1: administrative Information

# Introduction

## Background and rationale {6a}

Eczema carries the highest global burden of all skin diseases and produces substantial disease-related morbidity worldwide – it is ranked as producing the 15<sup>th</sup> highest global burden of all non-fatal diseases.(1) Eczema affects up to 15% of infants and about 6% of older children and adolescents worldwide.(2,3) Eczema prevalence and time trends vary considerably between countries, but overall eczema appears to be increasing globally by an absolute rate of around 1% per decade in children and adolescents.(3) Eczema prevalence varies within countries. In the UK, eczema affects 16.5% of children aged two,(2) and rates of consultations to primary care and referrals to secondary care are increasing.(4) Eczema is more common in people who identify as being from Black and Ethnic Minority (BAME) groups than other ethnicities in England.(2) Eczema is not a new disease, but the significant variation in eczema prevalence and time-trends between and within populations suggests that the condition may be partly preventable.

Eczema is a chronic fluctuating condition which causes substantial impact on quality of life through itch, distress and loss of sleep and there is no cure.(5) Scratching due to the itching can damage the skin and result in bacterial infections. Eczema can be conceptualised as a visible manifestation of an impaired skin barrier and we have previously demonstrated that skin barrier impairment precedes the emergence of eczema.(6) Whilst there are genetic determinants of an impaired skin barrier such as inheritance of mutations in the filaggrin (FLG) gene,(7) environmental factors are believed to play an important role in the aetiology of skin barrier impairment and subsequent eczema in infancy. A key environmental risk factor for skin barrier impairment is bathing. Bathing in water alters skin physiology and often involves exposure to wash products such as soaps and detergents which can exacerbate any negative impact on the skin barrier.(8)

Frequent immersive bathing is a modern phenomenon. As Ashenburg records in *Clean – an unsanitised history of washing*, “Historically people cleaned themselves piecemeal, using a basin and pitcher for a stand-up wash, or a small, low tub in which they sat for a sponge bath. Ultimately, a full bath or shower became the gold standard of cleanliness, but this did not happen for the majority of Europeans until the twentieth century.”(9) UK Royal College of Midwives website until recently recommended infant bathing 2-3 times per week from birth to six months.(10) The Enquiring About Tolerance (EAT) Study(11) found 84% of infants were bathed  $\geq 2$  times per week and 30% at least daily at age 3 months.(12) At 3 months, almost 80% had at least one wash product used on them in a typical bath, and nearly a third had bubble bath added to their bath, in a population of 1303 infants from England and Wales. Conversely, only 16% of the infants were bathed once a week or less.(12)

Bathing, even with tap water alone, has a negative effect on skin physiology. Tap water (pH 7.9-8.2) increases naturally acidic skin pH by 0.19, decreases skin fat content by  $0.93 \mu\text{g}/\text{cm}^2$  and changes enzymatic activity in the upper epidermis.(8,13) In the EAT study(11) a dose response relationship was observed between bathing frequency at 3 months and an objective measure of skin barrier function, transepidermal water loss (TEWL).(12) Daily bathing was associated with an odds ratio of having an elevated TEWL ( $\geq 15 \text{ g}/\text{m}^2\text{h}$ ) of 4.62 (95% confidence interval (CI) 2.61-8.21) compared with bathing once a week or less. The PreventADALL study found that daily bathing led to a significantly increased risk of eczema by age 1 year (RR 1.57 95% CI 1.10-2.23).(14) The available evidence suggests that regular bathing with or without use of wash products may increase the risk of eczema, suggesting that advice to modify infant bathing practice by reducing bathing frequency or use of wash products may potentially prevent eczema development. Reducing the intensity of bathing may also impact on the risk of eczema developing. By ‘intensity’, we mean features of bathing which are likely to increase disruption of normal skin barrier function and skin physiology such as long duration of bathing, high water temperature and use of skincare products which adversely affect skin physiology and/or act as sensitising agents. Together, atopic conditions affect 1 in 3 children and young people and cost the

NHS over £1 billion per annum.<sup>(15)</sup> 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 to care for eczema and financial costs.<sup>(16)</sup> 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. The results of this feasibility trial will inform whether it is possible to undertake a large scale, multi-centre, RCT of the intervention.

## Aims and objectives {7}

The aims and objectives of the study are as follows:

- Work with pregnant women and their families to develop an acceptable intervention which aims to reduce infant bathing frequency and intensity.
- Undertake a randomised controlled feasibility trial to estimate the proportion of eligible families willing to be randomised to the intervention, their adherence to the intervention and its acceptability.

## Methods and Analysis

This protocol has been designed in accordance with the SPIRIT 2013 Guidelines.<sup>(17)</sup> The numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers.<sup>(18)</sup> The order of the items has been modified to group similar items. We aim to recruit to the feasibility trial between September 2023 and the end of June 2024. The study is expected to be completed by December 2024.

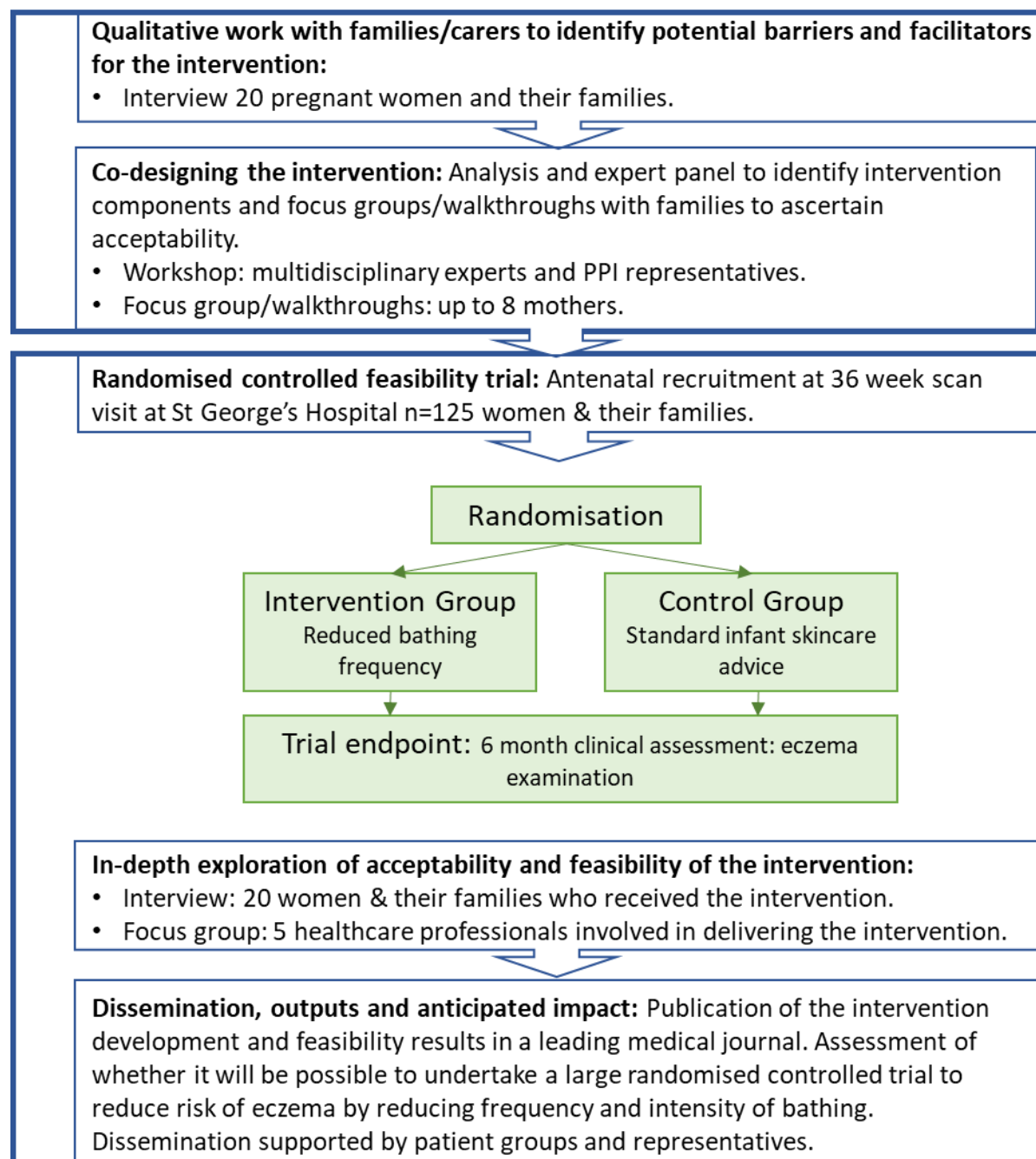
### Study Design

The BabyBathe study includes initial qualitative work to design the intervention to reduce bathing frequency and intensity (Phase 1). The intervention will then undergo feasibility testing in a feasibility randomised controlled trial (Phase 2). Administrative information is given in Table 1. Following the trial, a process evaluation using feedback and qualitative interviews will be undertaken (Figure 1).

Setting {9}

Recruitment for both phases will take place within the antenatal clinic at St George's Hospital, a hospital-based maternity service in London, UK, which serves one of the most one of the most multi-ethnic populations in the UK with 5000 deliveries per annum.

**Figure 1:** Overview of the BabyBathe study



## Phase 1: Identifying barriers and facilitators and co-designing the intervention

### Qualitative Research to identify barriers and facilitators

We will use a qualitative descriptive methodology to elicit in-depth accounts of family/carers views on and experiences of bathing infants, and on an intervention to reduce bathing frequency and intensity. This work will produce a specification of potential barriers and facilitators to uptake and maintain the intervention.

### **Sampling framework**

In the Enquiring About Tolerance study,(11) families with only one child were significantly more likely to bathe their infant daily or more, therefore we will purposively sample for family size. We will include families with and without atopy. We will seek maximum variation in ethnicity due to initial patient and public feedback about varied infant bathing culture and beliefs between different ethnic groups and will seek maximum variation in other family characteristics that might affect bathing behaviours, including age and socio-economic status. We will aim to recruit at least 20 families - using the 'ten plus three' rule for data saturation(19) - 10 families with children and 10 without children (both 5:5 with and without atopy).

### **Procedure**

Researchers will recruit pregnant women in the antenatal clinic waiting room during their intrauterine growth/foetal presentation scan appointment at 36 weeks gestation and invite the woman, her partner, and additional family members/child carers she thinks might be interested in participating (limited to six participants per family). Following informed consent, semi-structured interviews/focus groups using a topic guide (available as supplementary material S1) will allow participants to speak freely. Interviews will be digitally recorded and transcribed.



**Figure 2:** How the COM-B and TDF relate to each other

COM-B components as potential barriers and facilitators	Physical capability	Physical skills*	TDF Skills
	Psychological capability	Knowledge Cognitive and interpersonal skills* Memory, attention and decision processes Behavioural regulation	
	Physical opportunity	Environmental context and resources	
	Social opportunity	Social influences	
	Reflective motivation	Social/professional role and identity Beliefs about capabilities Optimism Beliefs about Consequences Intentions Goals	
	Automatic motivation	Reinforcement Emotion	

### Topic guide and theoretical frameworks

The topic guide will be informed by the ‘Template for Intervention Description and Replication’ (TIDieR) framework for reporting interventions,(20) Theoretical Domains Framework (TDF)(21) to ensure a broad coverage of potential barriers and facilitators influencing infant bathing. The TDF defines 14 domains of determinants of health behaviour (e.g., social influences, beliefs about consequences of behaviours, knowledge of behaviours - including information received about infant bathing and sources of information) and is commonly used in qualitative work to guide questioning around barriers and facilitators to behaviour change.(22) We will also use the Capability-Opportunity-Motivation-behaviours (COM-B) model(23) to prompt questions about barriers and facilitators – focussing on whether they are related to: (i) the capability to enact the required behaviours (e.g., having adequate knowledge about bathing practices and their likely consequences), (ii) the opportunity to engage in the behaviour (e.g., having appropriate family support and professional advice with regards to altering bathing practices), and (iii) motivation towards the behaviour (e.g., level of willingness to change bathing practices). Figure 2 illustrates how the COM-B and TDF relate to each other. Figure 3 shows key topic guide areas for each of the qualitative data collection rounds.

**Figure 3:** Topic guides

Phase 1; intervention design	Phase 2; end of trial qualitative work
<p><i>Topic guides informed by both the Theoretical Domains Framework (TDF)<sup>21</sup> to ensure broad coverage of factors influencing adherence and the capability-opportunity-motivation-behaviours (COM-B) model<sup>23</sup> to explore barriers and facilitators of adherence</i></p>	
<p><b>Family interviews</b></p>	<p><b>End of trial interviews with families</b></p>
<ul style="list-style-type: none"> <li>➤ Focus on identifying potential barriers and facilitators to uptake and maintenance of the intervention</li> <li>➤ General experience of and attitudes to infant bathing</li> <li>➤ Attitudes to bathing infant once a week or less</li> <li>➤ Social influences</li> <li>➤ Baby's skin health</li> <li>➤ Taking part in research trial</li> </ul>	<ul style="list-style-type: none"> <li>➤ Focus on exploring acceptability and feasibility</li> <li>➤ The bathing routine</li> <li>➤ Taking part in a research study</li> <li>➤ Social influences</li> <li>➤ Suggestions for improving the study</li> </ul>
<p><b>Workshop with multidisciplinary experts and PPI representatives</b></p>	<p><b>End of trial focus group with healthcare professionals</b></p>
<ul style="list-style-type: none"> <li>➤ Focus on questions posed in the MRC<sup>33</sup> and Behaviour Change Wheel<sup>23</sup> frameworks, including timing, and facilitators/barriers at practice level.</li> <li>➤ Re-examine the materials with reference to the APEASE criteria<sup>23</sup> and TIDieR framework<sup>20</sup> to ensure all important aspects of intervention design are considered.</li> <li>➤ Re-verifying with reference to the COM-B and TDF, do the study materials support the study's aim?</li> </ul>	<ul style="list-style-type: none"> <li>➤ Focus on exploring acceptability and feasibility</li> <li>➤ Delivery of the intervention</li> <li>➤ Study procedures</li> <li>➤ Suggestions for improving the study</li> <li>➤ Motivation for study participation</li> <li>➤ Experiences of and attitudes towards the intervention</li> <li>➤ Reasons for high or low adherence</li> <li>➤ Intentional non-adherence (e.g., deciding to bathe the infant more frequently than advised)</li> <li>➤ Unintentional non-adherence (e.g., forgetting to follow the bathing routine)</li> <li>➤ Acceptability issues identified in the theoretical framework of acceptability (TFA),<sup>26</sup> (affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy)</li> </ul>
<p><b>Focus group / walkthroughs with families</b></p>	
<ul style="list-style-type: none"> <li>➤ Refining the study procedure – using a walk through with draft materials</li> <li>➤ Refining the study materials</li> </ul>	

Topic guides

Qualitative data

## Co-designing the intervention

We will use a person-based approach to intervention development.<sup>(24)</sup> The information gathered will be used to co-design the intervention in three stages: (1) applying theoretical frameworks and design criteria to guide intervention development; (2) create draft intervention materials in a workshop with experts and PPI representatives; and (3) conducting focus group/walkthroughs with families expecting a baby, to consider the acceptability of the intervention materials and to refine them ready for testing in the feasibility trial.

### **(1) Applying theoretical frameworks and design criteria**

We will use the Behaviour Change Wheel<sup>(23)</sup> to determine which broad intervention types should be used to target the barriers and facilitators identified in the interviews (e.g., *education* about infant bathing, *persuasion* about changing bathing/bed-time routines). Using the standard taxonomy of 93 behavioural change techniques (BCTs),<sup>(25)</sup> we will list those BCTs typically used with our selected intervention types and identify potential modes of delivery for these BCTs, illustrated in Figure 4.

We will apply the APEASE (Affordability, Practicability, Effectiveness and cost-effectiveness, Acceptability, Side effects/safety and Equity) criteria, to aid decision-making regarding which intervention types, BCTs and modes of delivery are optimum,<sup>(23)</sup> before considering whether any aspects of the intervention should be tailored to different contexts or groups (e.g., related to cultural differences in bathing/bed-time routines).

**Figure 4:** Examples of mapping barriers to intervention types to BCTs to modes of delivery

Barrier identified in interviews	Intervention type	Potential behaviour change techniques	Potential modes of delivery
Limited knowledge of health consequences of infant bathing	Education	Information about health consequences of infant bathing (e.g. related to developing eczema)	Face-to-face Physical leaflet
Belief that they won't be able to manage the infant's bed-time routine without bathing	Persuasion	Verbal persuasions about their capability of changing their bathing/bed-time routines	Face-to-face
Night-time routine that focusses on infant bathing	Environmental restructuring	Restructuring the environment around a bed-time routine with less frequent bathing	Face-to-face Physical leaflet
Perceived social norm of frequent infant bathing among their peers and family	Modelling	Demonstration of the behaviour (e.g., how others manage their bedtime routine and infant bathing)	Video

## (2) Stakeholder workshop to create draft intervention materials

The stakeholder workshop will include up to two PPI representatives with experience of eczema and/or experience of caring for a child with eczema and 6-12 clinical/academic experts in areas such as dermatology, paediatrics, behavioural science, intervention design, health visiting and midwifery. The workshop participants will review the suitability of the BCTs and their modes of delivery, including giving feedback on draft intervention materials, drawing on their multiple perspectives and triangulating the findings for comprehensive insight into the challenges and the constraints imposed by “real world” contexts (see figure 3 for more details).

### **(3) Focus group/walk throughs to consider the acceptability of the intervention materials**

To examine acceptability we will conduct a focus group with up to eight mothers. The eligibility criteria and recruitment approach will be similar to the qualitative interviews already conducted. Up to six women will be newly recruited for a fresh perspective on the materials and two women who participated in the qualitative interviews and have a baby will also be included to use their experience of the prior qualitative interview and recent experience of baby bathing.

The focus group topics will be informed by the theoretical framework of acceptability (TFA),(26) which identifies the acceptability of healthcare interventions as being based on six key criteria: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy. Participants will review draft materials (e.g., information leaflets, self-monitoring wall charts) and consider how well these would help participants to follow the trial intervention in real-life scenarios.

#### **Analysis of focus group/walk throughs**

Data will be analysed both inductively from participant's accounts and deductively using the TFA,(26) to assess aspects related to acceptability and identify elements of the intervention to be refined. The results will be reported according to the COnsolidated criteria for REporting Qualitative research tool (COREQ).(27)

#### **Output of Phase 1**

At the end of stage 1, we will have specified the intervention materials in terms of behaviour change techniques and modes of delivery, and have developed final versions of the intervention materials.

## Phase 2: Testing the feasibility of BabyBathe in a randomised controlled trial

In phase 2, a feasibility study with an embedded process evaluation will be conducted to estimate the proportion of eligible families willing to be randomised to the intervention, their adherence to the intervention and its acceptability, with a view to conducting a subsequent definitive RCT to investigate whether reducing bathing frequency in early infancy can prevent eczema in high-risk babies.

### Trial design {8}

The feasibility study will use a single-centre, two-arm, parallel-group, individually-randomised, controlled design comparing the new intervention against usual care, with a 1:1 ratio.

### Intervention description {11a}

All women who give birth at the site are encouraged to watch a 20 minute YouTube video entitled “The ‘Going Home’ video” prior to their discharge from the postnatal ward. This does not include any information about infant skincare or bathing and defines usual care. The intervention group will be provided with the intervention regimen developed in phase 1 in addition to the ‘Going Home’ video. This intervention may include antenatal and/or postnatal components, depending on the findings of Phase 1.

### Explanation for the choice of comparators {6b}

The intention of the study design is that families in the control group receive the usual care advice that the recruitment hospital offers.

### Participants and recruitment {15}

We will recruit 125 pregnant women from antenatal clinics at St George’s Hospital over 12 months. Pregnant women will be invited to participate in the study at their intrauterine growth/foetal presentation scan appointment (at 36 weeks gestation). Randomisation will occur during the antenatal period so that expectant parents can become familiar with the intervention during this time or during

the immediate postpartum period; this decision will be made during the co-design process in Phase 1. If enrolled antenatally, research midwives will log enrolment, check delivery records and ensure that in the event of an unexpected outcome of delivery the mother in question would not be contacted further.

Interim analyses {21b}

After the first 50 participants have been randomised, we will review the baseline pre-randomisation questionnaire data. If approximately 40% of randomised participants stated in the baseline questionnaire that they were planning to bathe their baby only once a week or less, then we will modify further recruitment to families who are intending on bathing their babies more frequently than once per week.

Who will take informed consent? {26a}

Informed consent for study participation will be taken by researchers working on the study – either as part of the core study team or research midwifery team, with training in Good Clinical Practice.

Inclusion criteria {10}

- (1) Women aged 16 years or over with a healthy, singleton pregnancy
- (2) Child has a first-degree relative with a parentally reported, doctor diagnosis of eczema, hay fever or asthma.
- (3) Able to understand English and give informed consent

Exclusion criteria



- (1) Expected preterm birth (defined as birth prior to 37 weeks gestation)
- (2) Sibling previously randomised into this trial
- (3) Known serious health issue in the developing infant which, at parent or investigator discretion, would make it difficult for the family to participate
- (4) Antenatally diagnosed condition that would make the use of emollient inadvisable or not possible.

(5) Enrolled in another clinical study with requirements that conflict with those of the current study (e.g. changes to infants' skincare regimens).

Participant Timeline {13}

A timeline for the BabyBathe study is shown in Figure 5(a).

**Figure 5(a).** BabyBathe study timeline

		Study Period							
		Enrolment	Allocation	Post-allocation					Close-out
	TIMEPOINT**	$-t_1$	$t_0$	$t_1$	$t_2$	$t_3$	$t_4$	<i>etc.</i>	$t_x$
Enrolment	Eligibility screen	X							
	Informed consent	X							
	Randomisation	X							
	Allocation		X						
Interventions	Baby Bathe group								
	Control group								
Assessments	Baseline data collection	X							
	Diary of activities			X	X	X	X	<i>etc.</i>	
	Outcome data								X

Feasibility trial outcomes {12}

The feasibility trial study outcomes are shown in Figure 5(b).



**Figure 5(b).** BabyBathe feasibility trial outcomes

Trial Outcomes	<b>Primary outcome measure</b> The proportion of eligible families willing to be randomised.
	<b>Secondary outcome measures</b>
	<b><i>Clinical outcomes (measured at final 6 month assessment)</i></b>
	1. Presence of eczema, defined using an adaptation of the validated UK Working Party Diagnostic Criteria for Atopic Dermatitis to reflect the young age group included in the study (blind assessment).
	2. Trans-Epidermal Water Loss.
	<b><i>Feasibility outcomes</i></b>
	1. Reported adherence to the bathing frequency intervention.
	2. Acceptability of the intervention to participating families. Measured using questions on acceptability corresponding to the seven domains of the Theoretical Framework of Acceptability (TFA): Affective attitude, Burden, Intervention coherence, Perceived effectiveness, Self-efficacy, Opportunity costs, and Ethicality. Responses rated on a Likert scale to express the level of agreement with each statement, administered in the 6-month questionnaire.
	3. Proportion of the control group accessing the intervention.
	4. Ascertainment bias of the blinded investigator outcome assessments that become unblinded to treatment allocation.
	5. Loss to follow up.
	6. Completeness of eczema outcome (see clinical outcome) at age 6 months.
	7. Adverse events which might potentially be related to reducing the bathing frequency, including skin infections, omphalitis and nappy rashes.

Plans for assessment and collection of outcomes {18a}

Data will be collected via questionnaires at baseline and at close-out, 6 months postpartum. The assessment of eczema will be conducted by a clinician or research nurse blind to treatment allocation using an adaptation of the validated UK Working Party Diagnostic Criteria for Atopic Dermatitis to reflect the young age group in the study, as used successfully in the BEEP pilot study.(28,29) Study questionnaires are available as supplementary material S2.

Plans to promote participant retention and complete follow-up {18b}

Phase 1 will actively seek participant input to incorporate into the feasibility trial to encourage study retention and complete follow up. The study has a dedicated website (<https://www.sgul.ac.uk/about/our-institutes/population-health/projects/babybathe>) and study Twitter feed to facilitate engagement with the study. Response to the weekly adherence questionnaire will be monitored to allow rapid identification of families not completing these. These families will be contacted to help support their ongoing participation. Participants will be sent a summary of the study findings.

#### Sample Size {14}

As this is a feasibility study the sample size has been chosen with consideration to the precision with which we can estimate binary feasibility outcomes, including the proportion of eligible families willing to be randomised and the acceptability of the intervention. With 100 families we will be able to estimate feasibility proportions with 95% CI width of  $\pm 0.09$  assuming the most conservative scenarios for proportion with 0.5. In the intervention arm this will allow us to assess outcomes such as acceptability to  $\pm 0.125$ . 125 families will be recruited to allow for 20% lost to follow up.

#### Randomisation {16a}

Computer generated randomisation will be used, as implemented by the independent trial statistician (VC), stratified by number of family members affected by an allergic condition, or possibly by eczema specifically, depending on the outcomes of phase 1. Individual participants will be randomised, allocated in a ratio of 1:1 to intervention or control. The researcher will then be informed of the woman's treatment allocation and inform the participant.

#### Concealment mechanism {16b}

Randomisation will use an online computerised randomisation system, so that allocation is concealed from researchers until randomisation has taken place.

#### Implementation {16c}

Researchers at the study recruitment site will enrol participants and obtain group allocation via the online randomisation system.

#### Assignment of interventions: blinding

##### Who will be blinded {17a}

It is not possible for participating families to be blind to the study intervention. The clinical outcome, eczema at 6 months of age assessed using an adaptation of the validated UK Working Party Diagnostic Criteria for Atopic Dermatitis, will be assessed by a clinician blind to the infant's study group.

Procedure for unblinding if needed {17b}

Participants are not blinded.

Criteria for discontinuing or modifying allocated interventions for a given trial participant {11b}

There are no special criteria for discontinuing or modifying allocated interventions.

Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence {11c}

Strategies to improve adherence are developed in Phase 1 of the study. Adherence will be monitored using a self-report diary.

Relevant concomitant care and interventions that are permitted or prohibited during the trial {11d}

Trial participants are permitted to receive any concomitant care during the trial.

Provisions for post-trial care {30}

None, beyond infant skincare advice.

Adverse event reporting {22}

Adverse events which have been assessed as possibly related to reducing bathing frequency, intensity or use of wash products will be recorded. These include skin infections, omphalitis, nappy rashes and sepsis as well as the limited number of adverse events that could be related to using emollients.

Data management {19}

The participant ID code will be used on all case report forms (CRFs) for that participant. Researchers at St George's, University of London will enter data into an eCRFs on a secure server and review CRFs and the database for range errors and for missing data. To check for systematic errors, double data entry will be conducted for a random selection of 10% of CRFs.

Confidentiality {27}

All collected information will be kept strictly confidential and will be stored in accordance with the General Data Protection Regulation (GDPR) and the latest Directive on Good Clinical Practice (GCP).

Confidentiality of patient's personal data is ensured by not collecting patient names on CRFs and limiting access to personal information held on the databases. At trial enrolment, the participant will be issued a participant identification number and this will be the primary identifier for the participant. Any paper copies of personal trial data will be kept at the participating site in a secure location with restricted access and any paper copies of consent form, with patient name and signature, will be kept securely at the trial site separately to any additional patient data.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

No additional consent provisions are required.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

None

Data analysis plan {20a}

As this is a feasibility trial all analyses will be primarily descriptive. Withdrawals and loss to follow up will be reported including when they occurred. Baseline and outcome data will be summarised separately by arm. The feasibility trial is not powered to detect a clinically significant difference in the proportion of participants with the primary clinical outcome, so no between-arm hypothesis testing will be performed on binary variables. Effectiveness analyses will be reported as estimates of between-arm differences with 95% confidence intervals and will use the intention-to-treat principle to include participants in the arm they were randomised to regardless of adherence. We will report and explore predictors of missing data for the primary outcome and examine missing data patterns across variables.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

We will examine the impact of contamination by estimating the intervention effect in participants who only received standard care advice in the control arm. To do this we will conduct a Complier Average Causal Effect (CACE) analysis because it is less biased than intention-to-treat or per protocol analyses in

the presence of contamination.(30) We will also estimate the intervention effect by differing bathing frequency and intensity using the same principled approach to examine ‘adherence’ in the intervention arm.

Methods for additional analyses (e.g. subgroup analyses) {20b}

There will be no subgroup analyses.

Access to data {29}

All BabyBathe study team members will have access to the full dataset. To ensure confidentiality, data dispersed to project team members will be blinded of any identifying participant information.

Plans to give access to the full protocol, participant-level data and statistical code {31c}

The de-identified participant level dataset, full protocol and statistical code will be publicly available on Figshare, the St George’s online data repository.(31)

Composition of the coordinating centre and trial steering committee {5d}

The Chief Investigator (CI) will have overall responsibility for the study and its management. The Trial Management Group (TMG) at St George’s, University of London, including the CI (MP), lead for qualitative work (MU) and research fellow, will be responsible for the day-to-day running of the study. The TMG will meet as needed and will be supported by and report to the other co-investigators and an independent Trial Steering Committee (TSC). An independent Trial Steering Committee will monitor the progress of the trial, protocol compliance and safety of the study participants. We will adhere to the NIHR guidelines(32) for the role, constitution, composition, meeting requirements and primary reporting line for the Trial Steering Committees.

Composition of the data monitoring committee, its role and reporting structure {21a}

As this small trial is designed to assess the feasibility of running a subsequent RCT, rather than collect meaningful clinical outcomes, a Data Monitoring Committee (DMC) is not deemed necessary, and this function will be fulfilled by the independent TSC.

Frequency and plans for auditing trial conduct {23}

The Trial Steering Committee will meet at least every 6 months to audit trial conduct and progress. This will include independent monitoring of adherence to the study protocol; approving changes to the study protocol; monitoring study recruitment and the overall timetable; advising, as required, on specific scientific items that may arise; compliance with legislation; adherence to research governance; reporting to funders; and approving publication and dissemination strategies.

Plans for communicating important protocol amendments to relevant parties {25}

Amendments will be approved by the research ethics committee and Health Research Authority. Funders, sponsors and NHS Research and Development Offices will be routinely informed of amendments.

Post feasibility trial acceptability study

We will investigate acceptability and adherence in a focus group of 5 health professionals who helped deliver the intervention and by undertaking qualitative interviews with 20 families from the intervention group in the feasibility trial. We will purposively select for heterogeneity across adherence, family size, ethnicity, parental age, and socio-economic status. We will follow both the guidance for process evaluation of complex interventions(33) and maximising the impact of qualitative research in feasibility studies for RCTs.(34)

Patient and public involvement (PPI)

The initial proposal received input from the Centre of Evidence Based Dermatology (CEBD) Patient Panel (University of Nottingham). A PPI advisory group will play an integral role in monitoring and advising the study team. The PPI group will review interview questions, study materials and recruitment strategies and be closely involved in decision-making at all stages. PPI will be especially important in reviewing the acceptability of the proposed intervention and determining how best to monitor adherence.

## Ethics and dissemination

### Research ethics approval {24}

The North of Scotland Research Ethics Committee gave ethics approval for the study on 05/09/22 (22/NS/0120). Pregnant women aged 16-18 years will be able to consent to the study without the approval of their parent/guardian.

### Dissemination {31a}

Results will be published in a leading peer-reviewed medical journal and presented at national and international conferences. Our PPI co-investigator, AR, with another PPI representative, will lead public engagement and dissemination activities with the wider PPI group via social media and patient charities and support groups.

## Declarations

**Authors' contributions {31b}** MP, RB and CF conceived of the study. MP, RB, CF, MU, VC and AR were co-applicants for funding. MP, RB and MU are joint chief investigators. All authors contributed to the study design and to the development of the protocol. MP and RB led on the trial aspects of protocol development, MU led on qualitative/process evaluation aspects and VC (study statistician) led quantitative analysis aspects. MP, MU and RB wrote the study protocol, with comments and approval from CF, VC and AR. LG drafted the manuscript of the protocol paper. All authors have read and approved the final manuscript and have agreed to publication.

### Funding {4}

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**Informed consent materials {32}**

Informed consent forms and participant information sheets, are available in Supplementary Materials S3 and S4.

**Competing interests {28}**

The authors declare no completing interests.

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