

# Confidential Contact Information (Paper)

Mother First Name	
Mother Last Name	
Mobile Number (Mother)	
Email (Mother)	
Address Line 1	
Address Line 2	
Town	
Post Code	
Mobile Number (Grandparent)	(Back up mobile of a grandparent)
Mobile Number (Friend)	(Back up mobile number of a friend)
GP Name	
GP Practice Name	
GP Practice Address (if known)	(Researcher to look up if family uncertain)

# Confirmation of Consent

Study ID	<div></div>
Study informed consent obtained?	<div><div></div> Yes</div> <div><div></div> No</div>
Type of consent	<div><div></div> Written</div> <div><div></div> Electronic (DocuSign)</div>
Date of informed consent	<div></div>

# Randomisation

Family agree to be randomised onto the BabyBathe study?	<div><input type="radio"/> Yes</div> <div><input type="radio"/> No</div>
Randomisation group	<div><input type="radio"/> Control</div> <div><input type="radio"/> Intervention</div>
Date of randomisation	<div></div>

# Baseline Demography

## Family Size

Do you have any other children?

- ☐ Yes  
☐ No

Number of sons

\_\_\_\_\_

Number of daughters

\_\_\_\_\_

## Paternal Ethnicity

Father's demographic details

- ☐ Not known  
☐ Known  
(If father's details are unknown, check box and leave other ethnicity questions blank.)

Father DOB

\_\_\_\_\_

Father Ethnicity

- ☐ Asian or Asian British  
☐ Black, Black British, Caribbean or African  
☐ Mixed or multiple ethnic groups  
☐ White  
☐ Other ethnic group

Father Ethnicity - Asian or Asian British

- ☐ Indian  
☐ Pakistani  
☐ Bangladeshi  
☐ Chinese  
☐ Any other Asian background

Father Ethnicity - Black, Black British, Caribbean or African

- ☐ Caribbean  
☐ African  
☐ Any other Black, Black British, or Caribbean background

Father Ethnicity - Mixed or multiple ethnic groups

- ☐ White and Black Caribbean  
☐ White and Black African  
☐ White and Asian  
☐ Any other Mixed or multiple ethnic background

Father Ethnicity - White

- ☐ English, Welsh, Scottish, Northern Irish or British  
☐ Irish  
☐ Gypsy or Irish Traveller  
☐ Roma  
☐ Any other White background

Father Ethnicity - Other ethnic group

- ☐ Arab  
☐ Any other ethnic group

**Baseline demographic information**

Age at leaving full time education

- ☐ 16 or less  
☐ 18  
☐ 19 or more

Does anyone in the infant's household smoke?

- ☐ Mother  
☐ Father  
☐ Other household member

Any pets in the household?

- ☐ Dogs  
☐ Cats  
☐ Other

If other, what pets are in the household?

---

Does the infant's home have a water softener fitted?

- ☐ Yes  
☐ No

Water softener install date

---

**MyCap App Fields - Do Not Modify**

UUID

---

Start Date

---

End Date

---

Schedule Date

---

Status

- ☐ Deleted  
☐ Completed  
☐ Incomplete

Supplemental Data (JSON)

---

Serialized Result

# Birth Details

---

Infant Date of Birth

---

---

Infant Gender

- ☐ Male  
☐ Female

---

Mode of delivery

- ☐ Vaginal  
☐ Caesarian

---

Gestation

---

(Enter as weeks+days e.g. 41+6)

---

Birthweight (in kg)

---

---

Mother well post-partum?

- ☐ Yes  
☐ No

---

Baby well post-partum?

- ☐ Yes  
☐ No

# Baby Bathed

Date of bath

Interval (days) since last bath

(Hidden from respondent)

Less than fourteen days since last bath

(Hidden from respondent)

Time of bath

☐ Morning

☐ Afternoon

☐ Evening

MyCap App Fields - Do Not Modify

UUID

Start Date

End Date

Schedule Date

Status

☐ Deleted

☐ Completed

☐ Incomplete

Supplemental Data (JSON)

Serialized Result

# Monthly Questionnaire

---

## Eczema Questions

---

Eczema questions: In the last month has your baby been diagnosed with eczema by a doctor or nurse?

- ☐ Yes  
☐ No

How long would you say your baby's bath lasts on average (in minutes)?

How often do you use a wash product when you bathe your baby?  
e.g. soap, gel, cleanser, body wash, bubble bath, moisturiser

- ☐ Never  
☐ Rarely  
☐ Sometimes  
☐ Often  
☐ Always

Have you applied nappy cream to your baby's bottom in the last month?

- ☐ Never  
☐ Rarely  
☐ Sometimes  
☐ Often

Other than nappy cream, in the past month, have you put any oil, moisturising cream or protective ointment on your baby's skin'?

- ☐ Yes  
☐ No

How often have you applied this oil, cream or ointment to your baby's skin?

- ☐ Once a week or less  
☐ 2-4 times a week  
☐ 5-6 times a week  
☐ Daily  
☐ More than daily

In the last month has your baby had any skin infections?

- ☐ Yes  
☐ No

How many skin infections has your baby had in the last month?

Did you see your doctor for the skin infection/s?

- ☐ Yes  
☐ No

What did your doctor call it?  
(tick all that apply)

- ☐ Impetigo  
☐ Folliculitis  
☐ Boils  
☐ Other bacterial infection  
☐ Other viral infection  
☐ Other infection  
☐ Doctor didn't know  
☐ Can't remember

In the last month has your baby experienced any of the following other issues with their skin:

- ☐ Nappy rash  
☐ Sore tummy button  
☐ Other concern about your baby's skin  
☐ No other skin issues



Please tell us about your concern about your baby's skin?

Did you change anything to do with your baby's skincare as a result of this issue?

- ☐ Yes
- ☐ No

What did you change about your infant's skincare?

MyCap App Fields - Do Not Modify

UUID

Start Date

End Date

Schedule Date

Status

- ☐ Deleted
- ☐ Completed
- ☐ Incomplete

Supplemental Data (JSON)

Serialized Result

# 6m Questionnaire MyCAP

Which group have you been in for the BabyBathe study?

- ☐ Control group  
☐ Intervention group

Has your baby had an ITCHY skin condition?  
(By 'itchy' we mean scratching or rubbing the skin)

- ☐ Yes  
☐ No

Has your baby had this ITCHY skin condition in the last week?

- ☐ Yes  
☐ No

Has this itchy skin condition affected the skin creases?  
By skin creases we mean the fronts of the elbows, behind the knees, the front of the ankles, under the buttocks, around the neck, around the eyes or the ears?

- ☐ Yes  
☐ No

Has this skin condition affected the skin away from the skin creases?  
For example, the cheeks, the forearms or the lower legs?

- ☐ Yes  
☐ No

Does your baby suffer from generally dry skin?

- ☐ Yes  
☐ No

Does your child have eczema?

- ☐ Yes  
☐ No

Was this confirmed by a doctor?

- ☐ Yes  
☐ No

Have you taken your infant swimming?

- ☐ Never  
☐ Once a month or less frequently  
☐ More than once a month

What milk does your baby have currently?

- ☐ Breast milk only  
☐ Formula milk only  
☐ Mixed breast and formula milk

Has your infant started solid (non-milk) food?

- ☐ Yes  
☐ No

The information given to me before I joined the study was everything I wanted to know (for example: what was expected, time commitment, who to contact with questions)

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

I found being enrolled to the study OK

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

I found being randomised OK

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

I understood what was being asked of me and my family regarding bathing my baby

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

I felt comfortable that I could ask questions during the trial

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

I changed the skin care/bathing routine of my baby as a result of being in the study

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

The time and effort taken to record my study-related activities was OK

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

I found taking part in the study difficult

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

Overall, I was satisfied with my experience of taking part in the study

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

I enjoyed talking part in the study

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

I would recommend others to take part in a similar study

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

Did you discuss with anyone in the intervention group, the advice that they were given about reducing bathing frequency?

- ☐ Yes  
☐ No

---

Did you watch the intervention group's video at any point?

- ☐ Yes  
☐ No

---

Study Aids: Did you read the BabyBathe study booklet?

- ☐ Yes  
☐ No

---

Did you find the BabyBathe study booklet helpful?

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

Did you use the fridge magnet?

- ☐ Yes  
☐ No

---

Did you find the fridge magnet helpful?

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

Did you use the bookmark?

- ☐ Yes  
☐ No

---

Did you find the bookmark helpful?

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

Did you use the wallchart (for recording when baby was bathed)?

- ☐ Yes  
☐ No

---

Did you find the wallchart helpful?

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

Did you use the the plastic "Day of the week" bookmarks?

- ☐ Yes  
☐ No

---

Did you find the the plastic "Day of the week" bookmarks helpful?

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

Did you visit the Intervention Group website?

- ☐ Yes  
☐ No

---

Did you find the Intervention Group website helpful?

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

Did you watch the Intervention Group study video?

- ☐ Yes  
☐ No

---

Did you find the Intervention Group study video helpful?

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

Did you visit the Control Group website?

- ☐ Yes  
☐ No

---

Did you find the Control Group website helpful?

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

I enjoyed following the Babybathe intervention

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

It took a great deal of effort to follow BabyBathe

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

It was clear how Babybathe might help with my baby's skin health

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

I felt confident about being able to follow the Babybathe intervention

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

Babybathe helped me to bathe my baby less frequently

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

I found the support materials as a whole useful

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

I felt that Babybathe was consistent with my personal values

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

I felt that Babybathe was consistent with my cultural values

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

I would recommend the Babybathe intervention to other families with new babies

- ☐ Strongly Disagree  
☐ Disagree  
☐ Don't Know  
☐ Agree  
☐ Strongly Agree

---

If you didn't reduce the frequency of bathing your baby to once a week or less, why was that?

---

---

Do you have any suggestions for improving the study?

---

---

### **MyCap App Fields - Do Not Modify**

UUID

---

---

Start Date

---

---

End Date

---

---

Schedule Date

---

---

Status

- ☐ Deleted  
☐ Completed  
☐ Incomplete

---

Supplemental Data (JSON)

---

---

Serialized Result

# 6m Eczema Assessment

Date of 6m visit

## Skin Examination Protocol

(as per Nottingham photographic protocol)

**Has the baby got signs of visible eczema (poorly demarcated erythema (redness) with surface change, ie fine scaling, vesicles, oozing, crusting or lichenification) in any of the following places?**

**Individual patches have to be larger than 1cm to be scored positive for skin creases and greater than 2cm to be scored positive for non-flexural skin)**

	No	Yes
Around the eyes (skin crease)	<input type="radio"/>	<input type="radio"/>
Around the ears (skin crease)	<input type="radio"/>	<input type="radio"/>
Around the sides or front of the neck (skin crease)	<input type="radio"/>	<input type="radio"/>
Fronts of the elbows (skin crease)	<input type="radio"/>	<input type="radio"/>
Under the buttocks (skin crease)	<input type="radio"/>	<input type="radio"/>
Behind the knees (skin crease)	<input type="radio"/>	<input type="radio"/>
Fronts of the ankles (skin crease)	<input type="radio"/>	<input type="radio"/>
Cheeks (any patch involving one or both cheeks, non flexural)	<input type="radio"/>	<input type="radio"/>
Forearms (elbow to wrist), at least one patch on EACH forearm (non flexural)	<input type="radio"/>	<input type="radio"/>
Lower legs (knee to ankle), at least one patch on EACH leg (non flexural)	<input type="radio"/>	<input type="radio"/>

Does the child have clinically dry skin?

☐ Yes  
☐ No

Is there palmar hyperlinearity?

☐ Yes  
☐ No

## SCORAD

**If eczema is present**

SCORAD - Area

Percentage of Body Surface Area (BSA) affected

**Objective SCORAD Intensity**

**A representative area of eczema is selected. In this area, the intensity of each of the following signs is assessed as none (0), mild (1), moderate (2) or severe (3).**

	None	Mild	Moderate	Severe
Redness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Swelling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Oozing/Crusting	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Scratch marks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Skin thickening (lichenification)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dryness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Patient-Orientated Eczema Measure (POEM)**

**For proxy completion (by parent)**

	No days	1-2 days	3-4 days	5-6 days	Every day
Over the last week, on how many days has your child's skin been itchy because of their eczema?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Over the last week, on how many nights has your child's sleep been disturbed because of their eczema?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Over the last week, on how many days has your child's skin been bleeding because of their eczema?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Over the last week, on how many days has your child's skin been weeping or oozing clear fluid because of their eczema?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Over the last week, on how many days has your child's skin been cracked because of their eczema?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Over the last week, on how many days has your child's skin been flaking off because of their eczema?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Over the last week, on how many days has your child's skin felt dry or rough because of their eczema?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



**Unblinding**

Have you (the person completing the skin examination) become aware of which group the infant was randomised to?

- ☐ Yes  
☐ No  
☐ Unknown

When did you become aware?

- ☐ Before the skin examination  
☐ During the skin examination  
☐ After the skin examination

Please briefly describe the circumstances leading to the unblinding?

---

# Adverse Event Recording

---

Were any adverse events experienced?

- ☐ No  
☐ Yes  
(Indicate if the subject experienced any adverse events.)

---

AE Identifier

(Record unique identifier for each adverse event for this subject. Number sequence for all following forms should not duplicate existing numbers for the subject.)

---

What is the adverse event term?

(Record only one diagnosis, sign or symptom per form (e.g., nausea and vomiting should not be recorded in the same entry, but as two separate entries).)

---

What is the date the adverse event started?

(Record the start date of the adverse event using the MM-DD-YYYY format.)

---

At what time did the adverse event start?

(If appropriate, record the time the AE started using the HH:MM (24-hour clock) format.)

---

Is the adverse event still ongoing?

- ☐ No  
☐ Yes  
(Select one.)

---

What date did the adverse event end?

(Record the end date of the adverse event using the MM-DD-YYYY format.)

---

At what time did the adverse event end?

(If appropriate, record the time the AE ended using the HH:MM (24-hour clock) format.)

---

What was the severity of the adverse event?

- ☐ Mild  
☐ Moderate  
☐ Severe  
(The reporting physician/healthcare professional will assess the severity of the event using the sponsor-defined categories. This assessment is subjective and the reporting physician/ healthcare professional should use medical judgment to compare the reported Adverse Event to similar type events observed in clinical practice. Severity is not equivalent to seriousness.)

What is the CTCAE severity grade of the adverse event?	<p><input type="radio"/> Grade 1 (Mild)</p> <p><input type="radio"/> Grade 2 (Moderate)</p> <p><input type="radio"/> Grade 3 (Severe)</p> <p><input type="radio"/> Grade 4 (Life-threatening)</p> <p><input type="radio"/> Grade 5 (Death related to AE)</p> <p>(Common Terminology Criteria for Adverse Events (CTCAE) v5.0The reporting physician/healthcare professional will assess the severity of the adverse event using the CTCAE severity grades.)</p>
Is the adverse event serious?	<p><input type="radio"/> No</p> <p><input type="radio"/> Yes</p> <p>(Assess if an adverse event should be classified as serious based on the serious criteria defined in the protocol.)</p>
Is the adverse event associated with a congenital anomaly or birth defect?	<p><input type="radio"/> No</p> <p><input type="radio"/> Yes</p> <p>(Record whether the serious adverse event was associated with congenital anomaly or birth defect.)</p>
Did the adverse event result in persistent or significant disability or incapacity?	<p><input type="radio"/> No</p> <p><input type="radio"/> Yes</p> <p>(Record whether the serious adverse event resulted in a persistent or significant disability or incapacity.)</p>
Did the adverse event result in death?	<p><input type="radio"/> No</p> <p><input type="radio"/> Yes</p> <p>(Record whether the serious adverse event resulted in death.)</p>
Did the adverse event result in initial or prolonged hospitalisation for the subject?	<p><input type="radio"/> No</p> <p><input type="radio"/> Yes</p> <p>(Record whether the serious adverse event resulted in an initial or prolonged hospitalisation.)</p>
Is the adverse event life threatening?	<p><input type="radio"/> No</p> <p><input type="radio"/> Yes</p> <p>(Record whether the serious adverse event is life threatening.)</p>
Is the adverse event a medically important event not covered by other ?serious? criteria?	<p><input type="radio"/> No</p> <p><input type="radio"/> Yes</p> <p>(Record whether the serious adverse event is an important medical event)</p>
Is this event related to the study intervention?	<p><input type="radio"/> Definitely</p> <p><input type="radio"/> Probably</p> <p><input type="radio"/> Possibly</p> <p><input type="radio"/> Not Related</p> <p>(Indicate if the cause of the adverse event is related to the study treatment and cannot be reasonably explained by other factors (e.g., subject's clinical state, concomitant therapy, and/or other interventions).)</p>

---

What action was taken in relation to the study intervention?

- ☐ Intervention continued  
☐ Intervention ceased  
☐ Unknown  
(Record changes made to the study treatment resulting from the adverse event.)

---

What other action was taken in response to this adverse event?

---

(Record all action(s) taken resulting from the adverse event.)

---

What was the outcome of this adverse event?

- ☐ Fatal  
☐ Not recovered / Not resolved  
☐ Recovered / Resolved  
☐ Recovered / Resolved with sequelae  
☐ Recovering / Resolving  
☐ Unknown  
(Record the appropriate outcome of the event in relation to the subject's status.)

---

Did the adverse event cause the subject to be discontinued from the study?

- ☐ No  
☐ Yes  
(Record if the AE caused the subject to discontinue from the study.)

# End of Trial

---

Date 6 m visit due on:

---

---

Date 6 m visit took place on:

---

---

If no 6m visit has taken place by due date, date of last contact:

NB check Baby Bathed Instrument for most recent bath date recorded

---

---

If no 6m visit, specify reason for discontinuation:

- ☐ Moved away
- ☐ Infant death
- ☐ Withdrawal of consent
- ☐ No response
- ☐ Trial terminated
- ☐ Other

---

Reason for withdrawal of consent?

---

---

Other reason for study discontinuation?

---