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Infant bathing frequency feasibility trial

Submission date
17/03/2023

Recruitment status
No longer recruiting

Registration date
24/07/2023

Overall study status
Completed

Last Edited
17/06/2024

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Eczema is a dry, itchy skin condition affecting 15% of infants and young children, with a disproportionately high burden on children from ethnic minorities. Eczema has a significant impact on quality of life and is not currently preventable or curable. Whilst genetic factors which damage the skin barrier play a part in eczema emerging, the increase in eczema during the twentieth century means environmental factors must also be important. Because most eczema genes cause a damaged skin barrier, and it is known that bathing babies can damage the skin barrier too, the research team want to find out whether advising families to bathe their babies less often might stop babies from getting eczema. Currently, about one in three babies in England is bathed at least once daily, often using soaps, which is much more often than people used to bathe babies before they had ready access to hot water. Water and soaps can both damage baby skin and recent research findings suggest that reducing bathing frequency might be an effective way to prevent babies from developing eczema. Before it can be proven whether or not changing bathing practices might prevent eczema, the team first needed to work out how to persuade families to change their baby's bathing routine. Through interviews and focus groups with diverse groups of expectant mothers and their families, including those with and without other children, the team have developed an intervention to encourage families to bathe their infants once a week or less. In this study, the team will see whether pregnant women are willing to be randomised to the intervention. The study will establish whether they were able to follow the intervention advice and reduce the frequency they bathe their baby.

Who can participate?
Pregnant women aged 16 years or more with a family history of a first-degree relative (the pregnant woman, her partner or a sibling) with a parent-reported doctor diagnosis of eczema, hay fever or asthma.

What does the study involve?
Pregnant women are invited to join this study while they are at their 36-week ultrasound scan. Participants are randomly allocated to one of two groups. Those in the intervention group are asked to bathe their infant no more frequently than once a week through to six months of age. Those in the control group can bathe their infant as frequently as they choose. Participants use the MyCap study app to record when they bathe their infant and to complete monthly questionnaires. When the infant is 6 months old they attend St George’s Hospital to undertake an assessment to see if they have eczema.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. This study will determine whether the intervention to reduce bathing frequency is feasible. If it is, then the research team propose undertaking a larger study to see if the intervention can reduce the development of eczema.

Where is the study run from?
The BabyBATHE study is being run by St George's, University of London (UK)

When is the study starting and how long is it expected to run for?
July 2022 to June 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Michael Perkin, m.perkin@sgul.ac.uk (UK)

Study website
https://www.sgul.ac.uk/about/our-institutes/population-health/projects/babybathe

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number
311086

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
V0.8 (01/08/22), IRAS 311086. CPMS 53844

Study information

Scientific Title
Feasibility testing of an intervention to prevent potentially harmful skincare practices during infancy

Acronym
BabyBathe

Study objectives
Is it feasible for families of infants to undertake an intervention to reduce infant bathing frequency?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/08/2022, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 22/NS/0120

Study design
Feasibility randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Prevention of eczema

Interventions

This study is part of a feasibility study program consisting of four work packages:
• Work package 1: Identifying what can be changed: Qualitative work with families/carers to identify potential barriers and facilitators to the intervention
• Work package 2: Co-designing the intervention: Analysis and expert panel to identify intervention components and focus group/walkthroughs with families to assess acceptability and refine intervention materials
• Work package 3 (This Study): Randomised controlled feasibility trial. Pregnant women will be recruited at their 36-week antenatal scan.
• Work package 4: In-depth exploration of acceptability of and adherence to the intervention: interviews/focus groups with families receiving the intervention and with health professionals delivering the intervention

If the feasibility trial is successful then a proposal to undertake a full-scale randomised controlled trial will follow.

This study is work package 3: Intervention group: Reducing infant bathing frequency to no more than 1/week through to six months of age
Control group: Infant bathing frequency as per family's preference
Randomisation:
Participants will be randomised using the REDCap Randomization Module set up by the study statistician with all other study members blinded to allocation.

Modes of delivery:
Intervention Group:
• Intervention group-specific booklet
• Wallchart (for recording when the infant is bathed)
• Plastic "day of the week" bookmarks to remind the family when the last bath took place
• Study reminders (fridge magnet and a bookmark) to remind families of the key aims of the intervention group.
• Intervention Group specific study webpage
• Intervention Group study video

Control Group:
• Control group-specific booklet
• Study reminders (fridge magnet and a bookmark) to remind families of the key aims of the control group.
• Control Group specific study webpage

Duration of intervention and follow-up:
Through to six months of age

Intervention Type

Behavioural

Primary outcome measure

The proportion of eligible families willing to be randomised: a ratio of the number of families who are randomised to the number of eligible families who review the trial information sheet, to be measured at the end of trial recruitment

Secondary outcome measures

Clinical outcomes
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, clinically examined by a blinded investigator (clinician) and recorded in the trial CRF at the final 6-month assessment
2. Trans-Epidermal Water Loss, measured at 6 months

Feasibility outcomes
1. Reported adherence to the intervention. Each infant bath will be recorded by participating dynamically on the Study MyCap app which links to the REDCap study database. Bathing frequency over the 6 months follow-up period will be determined from the REDCap database.
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. Questions are administered in the 6-month questionnaire.
3. Proportion of the control group accessing the intervention. Control group participants will be asked if they discussed the intervention advice with anyone in the active arm or watched the intervention group's video. Questions are administered in the 6-month questionnaire.
4. Ascertainment bias of the blinded investigator outcome assessments that become unblinded to treatment allocation. Questions are completed by clinical undertaking the outcome assessments in the 6-month questionnaire.
5. Loss to follow up. The proportion of enrolled participants who do not undergo the 6-month visit.
6. Completeness of eczema outcome (see clinical outcome) at age 6 months. The proportion of enrolled participants who have the clinical outcome undertaken.
7. Adverse events which might potentially be related to reducing the bathing frequency, including skin infections, omphalitis and nappy rashes assessed monthly on the Study MyCap app.

Overall study start date
01/07/2022

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Healthy, singleton pregnancy
2. Child has a first-degree relative with a parentally reported, doctor diagnosis of eczema, hay fever or asthma.
3. Mother aged ≥16 years old
4. Consenting adult has the ability to understand English

Participant type(s)
Patient

Age group
Mixed

Lower age limit

16 Years

Sex
Female

Target number of participants
125 infants and their families for feasibility trial

Key exclusion criteria
1. Expected preterm birth (defined as birth prior to 37 weeks gestation)
2. Sibling previously randomised into this trial
3. Severe known health issues in the developing infant which, at parent or investigator discretion, would make it difficult for the family to take part in the trial
4. Any antenatally diagnosed condition that would make the use of emollient inadvisable or not possible
5. Enrolled in another clinical study which requirements that are likely to conflict with the provisions of this feasibility randomised trial directly

Date of first enrolment
01/09/2023

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St George's University Hospitals NHS Foundation Trust
Blackshaw Road
London
United Kingdom
SW17 0RE

Sponsor information

Organisation
St George's, University of London

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Sponsor type
University/education

Website
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ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Anticipated outputs of this project are:
1. To establish whether the intervention is feasible
2. Publication of the feasibility trial results in a leading medical journal
3. To determine whether it will be possible to subsequently undertake a large randomised trial

to investigate the effect of advice to reduce harmful skincare practices on eczema development.
4. Dissemination plan will ensure engagement with patient groups and representatives

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository: Figshare, https://sgul.figshare.com/. Anonymised full study data will be made available from the SGUL secure repository within three months of the study completion date. Consent from participants was not required or obtained for an anonymised dataset.

IPD sharing plan summary
Stored in publicly available repository