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Eczema Bathing Study – how often should we bathe?

Submission date
15/11/2023

Recruitment status
No longer recruiting

Registration date
22/11/2023

Overall study status
Completed

Last Edited
02/07/2025

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The Eczema Bathing Study is part of the Rapid Eczema Trials project. The researchers hope to answer many questions about how to manage eczema through this project.People with eczema are helping to prioritise, design and run these studies. This means that the project will answer important questions for people with eczema. In the Eczema Bathing Study, the researchers will test how often people with eczema should have a bath or a shower to best manage their eczema.

Who can participate?
People aged 1 year or older who have eczema can join the study. The researchers are encouraging people from all different backgrounds to take part.

What does the study involve?
People will join the study by signing up on the study's website. They will give information about their eczema and how they usually bathe. For this study, bathing means taking a bath or a shower.They will then be put into one of two groups by a computer. One group will be asked to have a bath or shower no more than 1 or 2 times a week. The other group will be asked to have a bath or shower 6 or more times a week. People will be asked to follow this advice for 4 weeks. They will be asked to complete some questions, sent to them by email/text message each week. People can take part from home and do not need to travel.

What are the possible benefits and risks of participating?
By taking part people may help the researchers to understand more about managing eczema in the future. Some people like to feel they are helping others by taking part, and some people like to try new things out for themselves.
Some people may find their eczema gets better but some might find that it gets worse. They can still use their regular creams and treatments to help relieve the symptoms.
As soon as the study results are known, they will be shared as quickly as possible on the study's website (https://www.RapidEczemaTrials.org).

Where is the study run from?
The study is being organised by Nottingham University Hospitals NHS Trust (the Sponsor) and is coordinated by the University of Nottingham. Participants join the study online and take part from home so can live anywhere within the UK.

When is the study starting and how long is it expected to run for?
September 2022 to October 2024

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

Who is the main contact?
RapidEczemaTrials@nottingham.ac.uk

Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
329123

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Sponsor ref: 22DE002, IRAS 329123, CPMS 58276

Study information

Scientific Title
Impact of weekly bathing or daily bathing on eczema symptoms, quality of life and disease control in children and adults with eczema: an online, superiority randomised controlled trial

Acronym
Eczema Bathing Study

Study objectives
Is weekly bathing better than daily bathing for people with eczema in terms of participant-reported symptoms over 4 weeks?

This study is part of the Rapid Eczema Trials project which aims to answer many questions about how to manage eczema through the delivery of multiple, online clinical trials. An "Eczema Science Community" of people with eczema is helping to prioritise, design and run these studies. This means that the project will answer important questions for people with eczema.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/10/2023, London - Surrey Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 104 8088, +44 (0)207 104 8131; surrey.rec@hra.nhs.uk), ref: 23/PR/0899

Study design
Two-arm parallel-group superiority randomized controlled trial with internal pilot

Primary study design
Interventional

Study type(s)

Quality of life, Treatment

Health condition(s) or problem(s) studied
Eczema

Interventions
Randomisation will be carried out by the participant using a secure, online randomisation system. Participants will be randomised 1:1 to either weekly bathing or daily bathing using a minimisation algorithm with a probabilistic element balancing on the following factors:
1. Eczema severity POEM score (3-7 mild, 8-16 moderate, 17-28 severe)
2. Age (<4 years, 4-11 years, 12-15 years, 16-25 years, 26-55 years, >55 years)
3. Usual method of bathing (bath or not bath)

Weekly bathing group: no more than 1 or 2 times per week
Daily bathing group: 6 or more times per week

Participants will be randomised to either the weekly bathing group or the daily bathing group. Following randomisation, participants will be provided with intervention guidance detailing how often they should bathe according to their allocation, and will be asked to follow this bathing pattern for 4 weeks. Participants will be asked not to change any of their other bathing practices e.g. method of bathing, use of wash products etc.

Intervention Type
Behavioural

Primary outcome(s)
Eczema symptoms measured using the Patient-Oriented Eczema Measure (POEM) at baseline and weekly over 4 weeks

Key secondary outcome(s))
The study will include the Harmonising Outcome Measures for Eczema (HOME) core outcome set (https://www.homeforeczema.org).

1. Itch intensity measured using the Peak Pruritis Numerical Rating Scale (NRS) 22 24-hour peak itch - one item, scored 0 to 10. Assessed at baseline and 4 weeks.
2. Eczema control measured using the Recap of atopic eczema (RECAP) – 7 items, scored 0 to 28. Assessed at baseline and 4 weeks.
3. Skin-specific quality of life measured using the Infants' Dermatitis Quality of Life Index (IDQoL) (under 4 years), Children's Dermatology Life Quality Index (CDLQI) (from 4 years to 15 years) or Dermatology Life Quality Index (DLQI) (16 years and over), depending on age – 10 items, scored 0 to 30. Assessed at baseline and 4 weeks.
4. Use of usual eczema treatments assessed weekly over 4 weeks by questionnaire:
4.1. Number of days in the last week flare control creams (topical corticosteroids or calcineurin inhibitors) used – this outcome will be used as an indication of days with eczema flares
4.2. Number of days in the last week moisturisers (emollients) used
5. Proportion of participants who achieve an improvement in POEM at week 4 of ≥3 points compared to baseline
6. Global change in eczema compared to baseline. Assessed by questionnaire at week 4.
7. Adverse events: the researchers do not anticipate adverse events related to changing bathing

practices but will collect whether participants changed their eczema treatments or sought advice from a health care provider as a result of a worsening of the eczema. Assessed by questionnaire at week 4.

Additional variables will be collected to inform analysis and interpretation of the trial. These include:
1. Minimisation variables, prior belief on the frequency of bathing and eczema symptoms, demographics, UK Diagnostic Criteria for Eczema and usual bathing practices (e.g. usual temperature of the water, use of shampoo, use of emollient wash products, and application of emollients/flare control creams after bathing). Assessed by questionnaire at baseline only.
2. Number of times had bath or shower in the previous week, assessed by questionnaire weekly over 4 weeks to evaluate adherenceto the allocated frequency of bathing routine.
3. Ease of bathing as allocated, willingness to continue, things that helped or made it difficult to bathe as allocated, and experience of being in the trial (for process evaluation). Assessed by questionnaire at 4 weeks.

Completion date
11/10/2024

Eligibility

Key inclusion criteria
1. Aged ≥1 year with self-report of eczema(syn. atopic dermatitis, atopic eczema)
2. Usual residence in the UK
3. Able and willing to give informed consent (or parent/legal guardian able and willing to give informed consent for children under 16 years)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Lower age limit
1 years

Sex
All

Total final enrolment
440

Key exclusion criteria
1. None or very mild eczema symptoms (POEM score ≤2)
2. Eczema only present on hands (likely to be hand eczema or contact dermatitis); limited to locations where skin exposed to nickel e.g. jewellery (likely to be contact dermatitis); or eczema only around varicose veins (likely to be varicose eczema)

3. Started a new eczema treatment (including antibiotics for eczema) other than emollients in the last 4 weeks
4. Taking part in another eczema intervention trial
5. Unable or unwilling to change bathing practices for 4 weeks
6. Planning to swim more than twice a week in the next 4 weeks (including surfing, scuba diving etc)
7. Member of household already participating in this trial

Date of first enrolment
29/01/2024

Date of final enrolment
08/07/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
All recruitment will take place online via the Rapid Eczema Trials website
https://rapideczematrials.org/
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Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Nottingham Clinical Trials Unit (NCTU) (ctu@nottingham.ac.uk) in accordance with NCTU's data sharing procedure. Access to the data will be subject to review of a data sharing and use request by a committee including the CI and sponsor and will only be granted upon receipt of a data sharing and use agreement. Any data shared will be de-identified. Consent from participants to share data was obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		14/10/2024	10/02/2025	Yes	No
Basic results		18/06/2025	02/07/2025	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.0	31/10/2023	05/01/2024	No	No
Statistical Analysis Plan	version 1	29/08/2024	29/08/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes