







Eczema Bathing Study – how often should we bathe?

Submission date 15/11/2023	Recruitment status Not yet recruiting	 Prospectively registered
Registration date 22/11/2023	Overall study status Ongoing	 Protocol not yet added
Last Edited 01/12/2023	Condition category Skin and Connective Tissue Diseases	 SAP not yet added
		 Results not yet expected
		 Raw data not yet expected
		 Record updated in last year

Plain English Summary

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 March 2025

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

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

Study website
<https://rapideczematrials.org/>

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

329123

ClinicalTrials.gov number

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 hypothesis

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)

Submitted 14/11/2023, London - Surrey Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 1048088; 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

Secondary study design

Randomised controlled trial

Study setting(s)

Home, Internet/virtual

Study type(s)

Quality of life, Treatment

Participant information sheet

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

Condition

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 measure

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

Secondary outcome measures

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 adherence to 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.

Overall study start date

01/09/2022

Overall study end date

31/03/2025

Eligibility

Participant 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

Age group

Other

Lower age limit

1 Years

Sex

Both

Target number of participants

Participant 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

Recruitment start date

01/01/2024

Recruitment end date

31/12/2024

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

All recruitment will take place online via the Rapid Eczema Trials website

<https://rapideczematrials.org/>

United Kingdom

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Sponsor information

Organisation

Nottingham University Hospitals NHS Trust

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Researchsponsor@nuh.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<https://www.nuh.nhs.uk/>

ROR

<https://ror.org/05y3qh794>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

NIHR Research, NIHRresearch, National Institute for Health Research, NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Results of the study will be submitted for publication in peer-reviewed journals and presented at conferences, but it is anticipated that results will be released back to the Eczema Research Community as quickly as possible on completion of the study, using lay-friendly formats.

Members of the "Eczema Science Community" will help to publicly share the findings as rapidly as possible, and will help drive the dissemination strategy to encourage new knowledge to be shared amongst patients and health practitioners.

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 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