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# Eczema care online

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 25/11/2019 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [X] Statistical analysis plan |
| 28/11/2019 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 10/01/2024 | Skin and Connective Tissue Diseases | |

## Plain English summary of protocol

Background and study aims
Eczema is a common skin disorder causing itchy skin and dryness. Eczema leads to poor quality of life (sore or bleeding skin, itching and poor sleep). Most people with eczema benefit from two treatments: (1) moisturisers (emollients) for dry skin, which need to be applied daily; and (2) topical corticosteroids for inflamed skin and eczema flares. Commonly, if eczema is not well-controlled it is because treatments are not used appropriately. There are many reasons why people may find it difficult to use eczema treatments: they can be time-consuming to apply; treatments may sting when first applied to inflamed skin; there are concerns about the safety of some treatments; and because people often receive conflicting or insufficient advice about how and when to use treatments.

The trialists have developed online toolkits to help parents/carers of children with eczema (aged 0-12 years) and young people with eczema (aged 13-25 years) manage eczema more effectively. Toolkits cover a range of topics relevant to people with eczema. The aim of this study is to test the effectiveness and cost-effectiveness of these online toolkits in two studies: one for parents /carers of children with eczema and one for young people with eczema.

Who can participate?
Participants will be invited to take part if they are either: (1) a young person aged 13-25 years with eczema; or (2) a parent/carer of a child aged 0-12 years with eczema. The participant must be able to access the internet and the eczema must be mild, moderate or severe but not very mild.

What does the study involve?
Parents/carers and young people with eczema will be invited to take part in the studies through their GP surgeries. Participants will be asked to register online and complete an online consent form and baseline questionnaire before being allocated by chance (randomly) to either the group who will use the online toolkit, or to the group who will receive their usual care. All participants will continue with their normal eczema treatments during the study. All participants will be asked to fill in a very short 4-weekly questionnaire about their eczema and a longer questionnaire after 24 weeks and 52 weeks. Participants in the group receiving usual care will get access to the online toolkit after 52 week follow-up.

What are the possible benefits and risks of participating?
The research participants benefit from access to the ECO website which provides support for self-management of eczema. Participants in the treatment group will access the website immediately while participants in the control group will have access to this 12 months after they sign up. It is not anticipated there are any risks for the participants.
If the study websites are effective, health professionals will be encouraged to prescribe them as part of standard care.

Where is the study run from?
The University of Southampton, UK

When is the study starting and how long is it expected to run for?
December 2019 to January 2022

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

Who is the main contact?
1. Julie Hooper (public)
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2. Dr Miriam Santer (scientific)
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### Study website
https://www.nottingham.ac.uk/eco/

# Contact information

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Public

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Scientific

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# Additional identifiers

**EudraCT/CTIS number**
Nil known

**IRAS number**

**ClinicalTrials.gov number**
Nil known

**Secondary identifying numbers**
42660

# Study information

**Scientific Title**
Eczema Care Online (ECO): two randomised controlled trials of online interventions to support self care for eczema for young people with eczema and for parents of children with eczema

**Acronym**
ECO

**Study objectives**
Online interventions supporting eczema self-care can lead to improved outcomes for people with eczema.

**Ethics approval required**
Old ethics approval format

**Ethics approval(s)**
Approved 25/10/2019, (South Central – Oxford A Research Ethics Committee, Whitefriars, Level 3 Block B, Lewins Mead, Bristol, BS1 2NT, UK; nrescommittee.southcentral-oxforda@nhs.net; +44 (0)207 104 8048), ref: 19/SC/0351

## Study design
Randomized; Both; Design type: Screening, Psychological & Behavioural, Management of Care, Active Monitoring, Qualitative

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Internet/virtual

## Study type(s)
Treatment

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

## Health condition(s) or problem(s) studied
Dermatitis and eczema

## Interventions
Two trials (trial-YP and trial-PC) of two online behavioural interventions will be carried out. Intervention-YP is for young people aged 13-25 with eczema and intervention-PC is for parents /carers of children with eczema aged 0-12. The interventions were developed using the Person-Based Approach, are evidence based, and draw on theoretical frameworks. They cover a wide range of topics and are designed to support self-management of eczema.

The majority of study procedures will be carried out online through the intervention websites (developed using LifeGuide software). Participants wishing to take part in the study will provide consent or assent (where required) and complete an online baseline questionnaire as indicated in the schedule of observations before being randomised to either the intervention group or the control group.

Intervention arm: Participants in the intervention group will then have access to the intervention website (either intervention-YP or intervention-PC, depending on which trial they are in).

Control arm: Participants in the control group will be given access to the intervention website after 52 week follow-up.

All participants will be asked to complete a 4-weekly POEM measure online for a period of 52 weeks. Participants will also be asked to complete a 24 week and 52 week follow-up questionnaire online. Automated emails and text messages will be sent to notify participants when their follow-up questionnaires are available for completion. Reminder emails and texts will be sent to non-responders after 3 days followed by reminder telephone calls approximately 3 days later from the research team, at which point participants will be invited to complete follow-

up questions over the phone. Using purposive sampling, we will select a number of participants from both groups to be invited to take part in a qualitative interview 3 months after randomisation.

Randomisation: Randomisation will be automated by the Lifeguide software. It will be carried out in blocks and stratified by age e.g. 13-17; 18-25 (trial-YP), and 0-5; 6-12 (trial-PC), baseline eczema severity (POEM scores 6-7; 8-16; 17-28) and recruitment site as these may influence how participants engage with the interventions.

## Intervention Type
Behavioural

## Primary outcome measure
The primary outcome measures for both trials will be eczema severity over 24 weeks measured by 4-weekly POEM (Patient-Oriented Eczema Measure)

## Secondary outcome measures
1. Eczema severity will be measured using the POEM (Patient-Oriented Eczema Measure) 4-weekly from week 0 to 52-week follow-up (corrected/moved from the primary outcome measures 23/09/2020)
2. Quality of Life will be measured in both trials:
2.1. In trial-YP, Quality of Life will be measured using the EQ-5D-5L self-completed by the young person, at baseline, 24-week and 52-week follow-up
2.2. In trial-PC, Quality of Life will be measured by proxy using the Child Health Utility - Nine Dimensions (CHU-9D) for those children aged 2 to 12 years, at baseline, 24-week and 52-week follow-up
3. Long-term control will be measured by RECAP (Recap for atopic eczema patients), at baseline, 24-week and 52-week follow-up
4. Itch intensity measure (worst itch in last 24 hours) measured using Itch intensity single item (only validated for adults). In Trial-YP but not for Trial-PC., at baseline, 24-week and 52-week follow-up
5. Enablement, the self-perceived ability to understand and cope with health issues, will be measured using the Patient Enablement Instrument (PEI), at baseline, 24-week and 52-week follow-up
6. Health service use and medication use will be measured by medical notes review, during the 3 month period prior to baseline and the whole 52 week trial period
7. Cost-effectiveness combining quality of life and health service use and medication use, during the 3 month period prior to baseline and the whole 52 week trial period
8. Prior belief about the effectiveness of the intervention measured using self-report at baseline
9. Online resource use (websites or apps) for eczema measured using self-report at baseline
10. Self-reported barriers to adherence will be measured using the Problematic Experiences of Therapy Scale (PETS), at baseline, 24-week and 52-week follow-up
11. Frequency of treatment use (emollients, topical steroids, and topical calcineurin inhibitors) over the past week will be measured by self-report, at baseline, 24-week and 52-week follow-up
12. Intervention usage (e.g. number of visits, time spent on the website, pages visited) will automatically be recorded by LifeGuide software for each participant over the whole 52 week trial period

## Overall study start date
01/03/2019

### Completion date
31/01/2022

# Eligibility

### Key inclusion criteria
Trial-YP:
1. Young person aged 13-25 years with eczema
2. Identified from GP records as having eczema and have obtained a prescription for eczema treatment in the past 12 months
3. POEM score greater than 5 to include mild to severe eczema, but exclude those with very mild eczema to avoid floor effects
4. Internet access

Trial-PC:
1. Parent / carer of a child aged 0-12 years with eczema
2. Child was identified from GP records as having eczema and has obtained a relevant prescription in the past 12 months
3. Child has a POEM score greater than 5 to include mild to severe eczema, but exclude those with very mild eczema
4. Have internet access

Only 1 person per household will be able to take part in each trial. If a parent / carer in trial-PC has more than one child who meets the inclusion criteria they will be asked to specify one child to participate in the trial.

### Participant type(s)
Mixed

### Age group
Mixed

### Sex
Both

### Target number of participants
Planned sample size: minimum of 200 for trial-PC and minimum of 200 for trial-YP; UK sample size: minimum of 200 for trial-PC and minimum of 200 for trial-YP

### Total final enrolment
677

### Key exclusion criteria
1. Unable to give informed consent
2. Unable to read and write English as the intervention content and outcome measures are in English
3. Taken part in another eczema intervention in the past 3 months.
4. Took part in think-aloud interviews as part of ECO intervention development. (Qualitative interviewees who did not view intervention materials will NOT be excluded)

**Date of first enrolment**
02/12/2019

**Date of final enrolment**
29/11/2020

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Southern Health NHS Foundation Trust**
Southampton
United Kingdom
SO40 2RZ

**Study participating centre**
**Solent NHS Trust**
Southampton
United Kingdom
SO19 8BR

**Study participating centre**
**NIHR Wessex CRN**
Southampton
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SO30 2UN

**Study participating centre**
**NIHR CRN East Midlands**
Leicester
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LE1 5WW

**Study participating centre**

**NIHR CRN West of England**
Bristol
United Kingdom
BS1 2NT

**Study participating centre**
**NIHR CRN Thames Valley and South Midlands**
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OX3 9DU

# Sponsor information

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**Sponsor type**
University/education

**ROR**
https://ror.org/01ryk1543

# Funder(s)

**Funder type**
Government

**Funder Name**
NIHR Central Commissioning Facility (CCF); Grant Codes: RP0PG-0216-20007

### 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
Current publication and dissemination plan as of 24/01/2022:
Planned publication in a high-impact peer-reviewed journal
Intervention development paper: young people - 31 May 2022
Intervention development paper: parents/carers – 31 May 2022
Trial protocol – 2020
Trial paper – 2023
Health economic paper – 2023
Process evaluation paper – 2023

Previous publication and dissemination plan:
Planned publication in a high-impact peer-reviewed journal
Intervention development paper: young people - 2020
Intervention development paper: parents/carers – 2020
Trial protocol – 2020
Trial paper – 2023
Health economic paper – 2023
Process evaluation paper – 2023

### Intention to publish date
31/12/2022

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the difficulty in anonymising it. We shall make quantitative data available with as few restrictions as feasible, while retaining exclusive use until the publication of major outputs. Anonymised data may be deposited in a data repository at a later date.

### IPD sharing plan summary
Not expected to be made available

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 05/02/2021 | 09/02/2021 | Yes | No |
| Protocol file | version 4 | 08/10/2020 | 12/10/2022 | No | No |
| Statistical Analysis Plan | | | 12/10/2022 | No | No |
| Other files | Health economic analysis plan version 1.0 | | 07/11/2022 | No | No |
| Results article | | 08/12/2022 | 13/12/2022 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Results article | within-trial economic evaluation results | 09/01/2024 | 10/01/2024 | Yes | No |