

Eczema care online

Submission date 25/11/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/11/2019	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/01/2024	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

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

Type(s)

Public

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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

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SO30 2UN

Study participating centre

NIHR CRN East Midlands

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Study participating centre

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Study participating centre**NIHR CRN Thames Valley and South Midlands**

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Sponsor information

Organisation

University of Southampton

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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