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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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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
University of Southampton

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

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?
Results article		08/12/2022	13/12/2022	Yes	No
Results article	within-trial economic evaluation results	09/01/2024	10/01/2024	Yes	No

Protocol article	protocol	05/02/2021	09/02/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other files	Health economic analysis plan version 1.0		07/11/2022	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 4	08/10/2020	12/10/2022	No	No
Statistical Analysis Plan			12/10/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes