Eczema monitoring online via questionnaires

Submission date	Recruitment status	[X] Prospectively registered			
21/06/2021	No longer recruiting	[X] Protocol			
Registration date	Overall study status	Statistical analysis plan			
29/06/2021	Completed	[X] Results			
Last Edited	Condition category	[] Individual participant data			
11/07/2024	Skin and Connective Tissue Diseases				

Plain English summary of protocol

Background and study aims

Eczema is a chronic inflammatory skin condition that affects children and adults. It is characterised by periods of remission and relapse, indicating the fluctuating nature of the disease. Online questionnaires completed by participants are often used in eczema clinical trials to capture participant's views about their eczema. This allows researchers to measure the effectiveness of different treatments. It is possible that completing questionnaires regularly (known as monitoring) can change the way that people manage their eczema and so result in improved eczema severity. This might be due to the completion of the questionnaires triggering participants to think about their eczema more or to apply treatments more often. This is a concern within clinical trials because completing regular questionnaires may make it harder to identify changes in eczema resulting from the treatments being tested. This study will assess whether completing questionnaires regularly changes participants' behaviour and affects eczema severity. The overall aim of this study is to inform the design of future eczema clinical trials about the effect of monitoring.

Who can participate?

Patients aged 1 year or older with eczema

What does the study involve?

Participants will be split into two groups: the intervention group will be asked to complete questionnaires weekly for 8 weeks, and the control group will be asked to complete questionnaires at the beginning and end of the study only. The online questionnaire takes about 10 minutes to complete. This will allow the researchers to evaluate the effect of regular monitoring on eczema severity.

What are the possible benefits and risks of participating?

There will be no direct benefit to participants, but their participation will help to improve future eczema research. Participating in this study will allow participants to track their eczema symptoms at home, which they may find useful and interesting. There are no anticipated risks to participants from taking part. Participants will be able to use their normal eczema treatment throughout this research study.

Where is the study run from?

Centre of Evidence-Based Dermatology at the University of Nottingham (UK)

When is the study starting and how long is it expected to run for? January 2021 to April 2022

Who is funding the study? University of Nottingham (UK)

Who is the main contact?
Arabella Baker
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Contact information

Type(s)

Scientific

Contact name

Miss Arabella Baker

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

EMO 120421

Study information

Scientific Title

Evaluation of the effect of symptom monitoring with patient-reported outcome measures on clinical outcomes in eczema: an online, parallel-group randomised controlled trial (EMO trial)

Acronym

EMO

Study objectives

Weekly symptom monitoring will enhance self-management of eczema, which in turn will improve adherence to standard treatment use, which will lead to improved eczema severity at 8 weeks.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 23/04/2021, Faculty of Medicine & Health Science Research Ethics Committee, University of Nottingham (Faculty Hub, Room E41, E Floor, Medical School, Queen's Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH, UK; +44 (0) 115 74 85060; FMHS-ResearchEthics@nottingham.ac.uk), ref: 239-0421

Study design

Online parallel-group randomized controlled clinical trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Eczema

Interventions

This is a methodological trial and there will be no treatment intervention involved. The intervention will be the online Patient Oriented Eczema Measure (POEM) questionnaire. Eligible participants will be randomised online and assigned to either the intervention group or to the control group using the REDCap software. The randomisation schedule will be based on computer-generated codes using random permuted blocks of varying size, stratified by age and baseline disease severity. The PhD student will deal with participant queries, thus she will have access to group allocation, but the other trial team members and the trial statistician will remain blinded. Participants in the intervention group (weekly group) will be asked to complete the POEM questionnaire weekly for 8 weeks. The control group will not receive the intervention.

Intervention Type

Other

Primary outcome(s)

Eczema severity measured by the self-reported or proxy (parent/carer reported) POEM questionnaire score at baseline and 8 weeks

Key secondary outcome(s))

- 1. Adherence to eczema treatment use, assessed in two ways:
- 1.1. Eczema treatment use assessed by the emollient and topical corticosteroid use questionnaire over the last week from baseline to 8 weeks

- 1.2. Eczema treatment use assessed by the overall eczema treatment use questionnaire 2 months prior to joining the study and at the end of the study at 8 weeks
- 2. Missing data: the proportion of fully completed questionnaires at 8 weeks

Completion date

03/04/2022

Eligibility

Key inclusion criteria

- 1. Self-report or parent/carer report of eczema diagnosis by a healthcare professional
- 2. Person aged 1 year or older
- 3. Able and willing to provide informed consent
- 4. If under 16 years old, a parent/carer needs to provide informed consent on behalf of the child
- 5. Able to read and understand written English
- 6. Have access to the internet and to an internet-enabled device
- 7. POEM score of 3 or above at eligibility screening

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Total final enrolment

296

Key exclusion criteria

- 1. Unable/unwilling to provide informed consent
- 2. Currently taking part in another eczema clinical trial

Date of first enrolment

14/09/2021

Date of final enrolment

16/01/2022

Locations

Countries of recruitment

United Kingdom

England

Afghanistan

Åland Islands



Bosnia and Herzegovina
Botswana
Bouvet Island
Brazil
British Indian Ocean Territory
Brunei Darussalam
Bulgaria
Burkina Faso
Burundi
Cabo Verde
Cambodia
Cameroon
Canada
Cayman Islands
Central African Republic
Chad
Chile
China
Christmas Island
Cocos (Keeling) Islands
Colombia
Comoros
Congo
Congo, Democratic Republic
Cook Islands
Costa Rica

Gabon
Gambia
Georgia
Germany
Ghana
Gibraltar
Greece
Greenland
Grenada
Guadeloupe
Guam
Guatemala
Guernsey
Guinea
Guinea-Bissau
Guyana
Haiti
Heard Island and McDonald Islands
Holy See (Vatican City State)
Honduras
Hong Kong
Hungary
Iceland
India
Indonesia
Iran

Iraq
Ireland
Isle of Man
Israel
Italy
Jamaica
Japan
Jersey
Jordan
Kazakhstan
Kenya
Kiribati
Korea, North
Korea, South
Kosovo
Kuwait
Kyrgyzstan
Lao People's Democratic Republic
Latvia
Lebanon
Lesotho
Liberia
Libya
Liechtenstein
Lithuania
Luxembourg

Macao
Madagascar
Malawi
Malaysia
Maldives
Mali
Malta
Marshall Islands
Martinique
Mauritania
Mauritius
Mayotte
Mexico
Micronesia, Federated States of
Moldova
Monaco
Mongolia
Montenegro
Montserrat
Могоссо
Mozambique
Myanmar
Namibia
Nauru
Nepal
Netherlands

New Caledonia
New Zealand
Nicaragua
Niger
Nigeria
Niue
Norfolk Island
North Macedonia
Northern Mariana Islands
Norway
Oman
Pakistan
Palau
Palestine, State of
Panama
Papua New Guinea
Paraguay
Реги
Philippines
Pitcairn
Poland
Portugal
Puerto Rico
Qatar
Romania
Russian Federation

Réunion
Saint Barthélemy
Saint Helena, Ascension and Tristan da Cunha
Saint Kitts and Nevis
Saint Lucia
Saint Martin (French part)
Saint Pierre and Miquelon
Saint Vincent and the Grenadines
Samoa
San Marino
Sao Tome and Principe
Saudi Arabia
Senegal
Serbia
Seychelles
Sierra Leone
Singapore
Sint Maarten (Dutch part)
Slovakia
Slovenia
Solomon Islands
Somalia
South Africa
South Georgia and the South Sandwich Islands
South Sudan

Rwanda

Spain
Sri Lanka
Sudan
Suriname
Svalbard and Jan Mayen
Sweden
Switzerland
Syria
Taiwan
Tajikistan
Tanzania
Thailand
Timor-Leste
Togo
Tokelau
Tonga
Trinidad and Tobago
Tunisia
Turkmenistan
Turks and Caicos Islands
Tuvalu
Türkiye
Uganda
Ukraine
United Arab Emirates
United States Minor Outlying Islands

Vanuatu
Venezuela
Viet Nam
Virgin Islands, British
Virgin Islands, U.S.
Wallis and Futuna
Western Sahara
Yemen
Zambia

Study participating centre
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Zimbabwe

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Uruguay

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Sponsor information

Organisation

University of Nottingham

ROR

https://ror.org/01ee9ar58

Funder(s)

Funder type

University/education

Funder Name

University of Nottingham

Alternative Name(s)

The University of Nottingham

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Results article	results	17/05/2023	17/05 /2023	Yes	No
Other publications	Effect on recruitment of social media strategy	27/10/2022	31/10 /2022	Yes	No
Participant information sheet	version v1.0	09/04/2021	08/07 /2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11 /2025	No	Yes
Protocol file	version 1.0	08/04/2021	18/08 /2022	No	No