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Eczema monitoring online via questionnaires

Submission date
21/06/2021

Recruitment status
No longer recruiting

Registration date
29/06/2021

Overall study status
Completed

Last Edited
11/07/2024

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Other

Participant information sheet
See additional files

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

Secondary outcome measures
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

Overall study start date
07/01/2021

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

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
266

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
Afghanistan

Albania

Algeria

American Samoa

Andorra

Angola

Anguilla

Antarctica

Antigua and Barbuda

Argentina

Armenia

Aruba

Australia

Austria

Azerbaijan

Bahamas

Bahrain

Bangladesh

Barbados

Belarus

Belgium

Belize

Benin

Bermuda

Bhutan

Bolivia

Bonaire Saint Eustatius and Saba

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

Croatia

Cuba

Curaçao

Cyprus

Czech Republic

Côte d'Ivoire

Denmark

Djibouti

Dominica

Dominican Republic

Ecuador

Egypt

El Salvador

England

Equatorial Guinea

Eritrea

Estonia

Eswatini

Ethiopia

Falkland Islands

Faroe Islands

Fiji

Finland

France

French Guiana

French Polynesia

French Southern Territories

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

Morocco

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

Peru

Philippines

Pitcairn

Poland

Portugal

Puerto Rico

Qatar

Romania

Russian Federation

Rwanda

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

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 Kingdom

United States Minor Outlying Islands

United States of America

Uruguay

Uzbekistan

Vanuatu

Venezuela

Viet Nam

Virgin Islands, British

Virgin Islands, U.S.

Wallis and Futuna

Western Sahara

Yemen

Zambia

Zimbabwe

Åland Islands

Study participating centre

University of Nottingham
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Sponsor information

Organisation
University of Nottingham

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Sponsor type
University/education

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https://www.nottingham.ac.uk/dermatology

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
University/education

Funder Name
University of Nottingham

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype

Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/05/2023

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?
Participant information sheet	version v1.0	09/04/2021	08/07/2021	No	Yes
Protocol file	version 1.0	08/04/2021	18/08/2022	No	No
Other publications	Effect on recruitment of social media strategy	27/10/2022	31/10/2022	Yes	No
Results article	results	17/05/2023	17/05/2023	Yes	No