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A pharmacist-led parent/carer education program to support the management of atopic eczema in children

Submission date
26/01/2021

Recruitment status
No longer recruiting

Registration date
01/02/2021

Overall study status
Completed

Last Edited
12/04/2024

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
Atopic eczema (atopic dermatitis) is the most common form of eczema, a condition that causes the skin to become itchy, dry and cracked. Atopic eczema is more common in children, often developing before their first birthday. But it may also develop for the first time in adults. It's usually a long-term (chronic) condition, although it can improve significantly, or even clear completely, in some children as they get older.
Patient education plays a key role in the successful management of atopic eczema. While Government policy supports the role of pharmacists in those with long-term conditions such as atopic eczema, there is only weak evidence that educational interventions by pharmacists can reduce the severity of eczema.
This study will investigate the impact on disease severity following an educational intervention provided by general medical practice-based, clinical pharmacists to parents/carers of children with atopic eczema. A modified Person-centred Dermatology Self-care Index (PEDESI) tool will be used by pharmacists to assess parents'/carers' knowledge and understanding of atopic eczema and its management, following which the pharmacists will provide educational advice where appropriate. Disease severity will be measured using the Patient-Oriented Eczema Measure (POEM) score at baseline.
The study has the potential to demonstrate the valuable contribution to care of patients with atopic eczema by practice-based pharmacists. If successful, the results would serve as an exemplar of best practice that can be more widely adopted within the NHS.

Who can participate?
Children aged between six months and six years of age with a diagnosis of atopic eczema, identified through searches of the general medical practice database, will be included.

What does the study involve?
Children and their parents will be invited to a consultation with the clinical practice-based pharmacist. During the consultation, pharmacists will assess parent/carer's knowledge and understanding of AE and ask participants to complete a specific eczema disease severity tool. At a follow-up appointment, the pharmacists will re-check participant knowledge and

understanding of eczema and repeat the eczema severity tool to assess for any changes.
In addition, telephone interviews will be conducted with a sample of parents, focusing on their views of the usefulness, acceptability, and impact of the intervention.

What are the possible benefits and risks of participating?
Benefits: We hope that after receiving the information and advice from the pharmacist that participants will be more confident at managing their child's eczema. Participants will also be helping to evaluate whether this type of service should become routine practice for pharmacists working within GP practices.
Risks: It is not anticipated that there will be any disadvantages or risks associated with the study. However, if participants experience any problems or are unclear about the study, they are encouraged to contact the pharmacist at the surgery who can hopefully answer any of their questions.

Where is the study run from?
Rotherham, Doncaster, and South Humber NHS Foundation Trust (RDaSH) (UK)

When is the study starting and how long is it expected to run for?
March 2020 to March 2022 (updated 19/08/2021, previously: August 2021)

Who is funding the study?
FONTUS HEALTH LTD (UK)

Who is the main contact?
1. Dr Rod Tucker (scientific), rodtucker.tucker@gmail.com
2. Miss Jeannie McKie (public), j.mckie@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Rod Tucker

Contact details
Yule Lodge
Cliff Road
Atwick
United Kingdom
YO25 8DF
+44 (0)7969155658
rodtucker.tucker@gmail.com

Type(s)
Public

Contact name
Miss Jeannie McKie

ORCID ID

https://orcid.org/0000-0003-4327-9681

Contact details
Grounded Research
Rotherham Doncaster & South Humber NHS Trust
Almond Tree Court
Woodfield Park
Doncaster
United Kingdom
DN4 8QP
+44 (0)7818 560176
j.mckie@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
270218

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 45309, IRAS 270218

Study information

Scientific Title
Evaluation of the impact on disease severity of treatment-related educational advice delivered by general practice-based clinical pharmacists to the parents/carers of children with atopic eczema: a randomised study

Study objectives
The hypothesis for the study is that as the experts in medicines, pharmacists play an important role in supporting patients (or parents in this case) to optimise the use of their medicines. Thus, the research question is “does education support on the management of atopic eczema delivered by practice-based pharmacists to the parents/carers of children with atopic eczema, lead to improvement in both knowledge and disease outcomes”.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/07/2020, East of England - Cambridgeshire and Hertfordshire REC (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8265; cambsandherts.rec@hra.nhs.uk), ref: 20/EE/0132

Study design

Interventional randomized controlled trial with qualitative follow up

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
See additional file ISRCTN17846245_PIS_v1.2_15June2020

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

Interventions
In the present study, eligible participants will be identified through a search of the GP practice database. Participants will be randomised at the practice level and for those assigned to the intervention group, a letter of invite, consent form and information sheet, will be sent to the parent/carer asking them to contact the practice pharmacist to arrange a mutually convenient time for an initial appointment. Participants assigned to the control groups will be sent the same information as the intervention group and a validated eczema severity tool, the patient orientated eczema measure (POEM) which they will be asked to complete on behalf of their child and return this to the practice pharmacist. They will be informed that the pharmacist will contact them in due course to arrange an appointment to provide advice and information on their child's eczema.

During the initial appointment for participants assigned to the intervention group, the clinical pharmacist will assess their knowledge and understanding of AE and its management using the Person-centred Dermatology self-care index (PeDeSI) which is a validated tool designed to explore patients' knowledge and understanding of a skin condition and its management. Participants will also be asked to complete the same POEM tool which was sent to those in the control arm. The verbal advice provided by the pharmacists will be supplemented with relevant written information.

The intervention group will be asked to return for a follow-up appointment 4 weeks later at which stage the pharmacists will re-assess participants' knowledge and understanding and ask them to complete a second POEM tool.

The participants in the control arm will be sent an invitation to an appointment with the clinical pharmacist approximately 4 weeks after returning the eczema severity score. At this appointment, the clinical pharmacist will assess participants understanding of the disease and its management using the PeDeSI tool and provide the same educational advice and information given to the intervention group during their initial consultation.

We will then compare changes in the POEM scores between both groups at the same time, i.e. at the follow-up appointment (intervention group) and initial appointment (control group) as this will provide a measure of the impact of the educational input from the pharmacists.

Patients/carers of the children will be contacted after completion of the study for a short telephone interview to gather their thoughts and experiences of the pharmacist consultation.

Intervention Type
Behavioural

Primary outcome measure
Eczema severity measured using Patient-Oriented Eczema Measure (POEM) score at baseline and 4 weeks

Secondary outcome measures
Eczema care knowledge and understanding among parents/carers measured using the Person-centred dermatology self care index (PeDesi) at baseline and 4 weeks

Overall study start date
06/03/2020

Completion date
31/03/2022

Eligibility

Key inclusion criteria
1. Parents of children aged 6 months - 6 years with a diagnosis of atopic eczema made by a GP or an appropriately qualified health care professional recorded in their medical notes
2. Children currently prescribed (prescriptions issued for the previous three months) one or more of the following treatments:
2.1. Any emollient products e.g. creams, ointments, bathing products, etc.
2.2. Topical steroids
2.3. Topical immunomodulators

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
Planned Sample Size: 118; UK Sample Size: 118

Total final enrolment
32

Key exclusion criteria
1. Parents (or carers) without adequate spoken and written English, as determined by the pharmacist, will be excluded as the study does not have sufficient funding to allow for the provision of an interpreter or for the education information to be translated into other languages
2. Children under the care of a dermatologist or other dermatology specialist
3. Children attending any specialist nurse-led eczema clinic
Children in the above categories are excluded because it is assumed that they will have received sufficient educational support and are therefore unlikely to benefit from additional advice

Date of first enrolment
01/02/2021

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
James Alexander Family Practice
Bransholme Health Centre
49 Goodhart Rd
Hull
United Kingdom
HU7 4DW

Study participating centre
Modality Partnership Hull Division
Bilton Grange Health Centre
2 Diadem Grove
Hull
United Kingdom
HU9 4AL

Study participating centre
Pocklington Group Practice
The Beckside Centre
1 Amos Dr
Pocklington
York

United Kingdom
YO42 2BS

Sponsor information

Organisation
Rotherham, Doncaster, and South Humber NHS Foundation Trust (RDaSH)

Sponsor details
St. Catherine's House
St. Catherine's Hospital
Tickhill Road
Doncaster
England
United Kingdom
DN4 8QN
+44 (0)1302 798456
Rdash.groundedresearch@nhs.net

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Industry

Funder Name
FONTUS HEALTH LTD

Results and Publications

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

Intention to publish date
01/09/2023

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 v1.2	15/06/2020	01/02/2021	No	Yes
Protocol file	version v1.2	02/06/2020	01/02/2021	No	No
Protocol file	version 1.4	22/10/2021	07/02/2022	No	No
HRA research summary			28/06/2023	No	No
Plain English results			12/04/2024	No	Yes
Results article		01/03/2024	12/04/2024	Yes	No