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

Summary

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.

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. The primary outcome measure will be the change in POEM score at four weeks (compared to baseline), with changes in PEDESI scores as a secondary outcome.

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.

Background

The enhanced clinical and health-management role of pharmacists is largely Government-driven in developed countries. The White Paper, *Pharmacy in England*[1] has augmented the Government's aspirations for pharmacists, underlining hat pharmacists can impact positively the health outcomes of patients with long-term

conditions. Furthermore, in the General Pharmaceutical Council's recently published discussion paper on the subject of 'tomorrow's pharmacy team', emphasises the need for pharmacists to relieve the current pressures in primary care, for example in general medical practices.[2] Recently, NHS England has announced additional funding to extend clinical pharmacists based within general medical practices, providing greater opportunity to care for those with long-term conditions.[3]

One area in which such clinical pharmacists could make a valuable contribution is the care of patients with long-term skin conditions such as atopic eczema. Atopic eczema (AE) affects approximately 20% of children, with half developing symptoms within the first year of life and 95% experiencing onset before five years of age.[4] The cost of managing atopic eczema is considerable. One study in children aged between one and five year estimated mean annual costs to the NHS of £80 per child (at 1996 prices), representing an annual cost of £47m in England.[5]

The cornerstone of treatment for atopic eczema is the regular and appropriate use of emollients and it is essential that patients (or carers) have a good understanding of the condition and its management. However, research suggests that a major cause of treatment failure is poor adherence, arising from a number of factors such as lack of understanding of topical treatments or that use of such products is too time-consuming.[6] This point was reiterated in the NICE guideline on the management of AE in children, concluding that lack of education about therapy leads to poor adherence and therefore treatment failure.[7]

An addition barrier to effective management, is seen from qualitative research with the parents of children with AE, identifying how parents are frustration with both medical care and prescribed treatments, believing that their child's suffering was not taken seriously and the suggestion that the child would "grow out of it" were perceived as being "fobbed off".[8] Other studies illustrate how carers feel exasperated that they have not received sufficient information to manage their child's condition effectively.[9,10]

Indeed, one longitudinal cohort study found that practical demonstration by dermatology nurses resulted in an 89% decrease in severity of eczema, primarily due to increased use of emollients.[11]

Several studies have demonstrated the positive impact of educational programmes on the severity of atopic eczema.[12-14] In a recent Cochrane systematic review of randomised controlled trials of educational interventions provided to parents of children with atopic eczema, out of nine studies nine studies, reported statistically significant improvements in disease severity.[15]

There is a dearth of evidence of the impact of pharmacist support to those with atopic eczema, with only two small studies in the public domain. In the first, which is available only as an abstract, Tinkler et al,[16] reported that pharmacists identified 1597 issues in 225 patients, the most common (20%) of which were related to concerns about topical steroids and lifestyle (15%). Pharmacists made 1747 interventions, of which verbal advice (76%) was the most common. The authors concluded that many of the concerns or issues experienced could be addressed by pharmacists. Carr et al[17] reported data from a pilot study in which advice on the appropriate use of emollients, led to a small, but statistically significant reduction in itch and irritability but no change in either sleep disturbance or appearance of the skin.

Evaluating the response to treatment requires tools which have been shown to be both valid and reliable. In a review of outcome measures of disease severity in eczema, Charman and Williams found that the majority of 13 such tools had not been properly validated.[18] Furthermore, a systematic review of the best outcome measures for atopic eczema found that out of 20 identified measures, only three (SCORAD, EASI and POEM) perform adequately.[19]

The Patient-Oriented Eczema Measure (POEM) is based on patients' perception of what constitutes disease severity as opposed to physician assessment and has been developed using patients from both primary and secondary care settings.[20]

Potential implications

The present study provides an opportunity to demonstrate the potential value from the input of general practice-based clinical pharmacists, in supporting the parents/carers of children with atopic eczema with an overarching aim of optimisation of treatment use to improve patient-related disease outcomes.

If successful, this study would provide much needed evidence for the development of pharmacist-led dermatology services within primary care which could ultimately result in more effective self-management of patients with a range of common skin conditions with the potential to reduce the burden on secondary care services.

Aim and objectives

Aim

To determine the impact of an educational intervention delivered by practice-based clinical pharmacists to the parents/carers of children with atopic eczema on disease severity and parental knowledge.

Objectives

1. To determine the effects of the educational intervention on disease severity

2. To examine the effect of the intervention on parental knowledge of AE and its management

3. To evaluate any changes in use of treatments after the intervention

METHODS

Design

A randomised controlled trial, employing a standard care wait-list control group and practice level randomisation.

Setting

General practices

Inclusion criteria

Given the estimate that half of children experience the onset of eczema symptoms within the first year of life and that by the age of five years, 95% will be symptomatic, eligible patients will therefore be aged between six months and six years.[21]

These children will have a diagnosis of atopic eczema made by a GP or an appropriately qualified health care professional recorded in their medical notes.

They will be currently prescribed (prescriptions issued for the previous three months) one or more of the following treatments:

- Any emollient products e.g. creams, ointments, bathing products, etc.
- Topical steroids
- Topical immunomodulators

Exclusion criteria

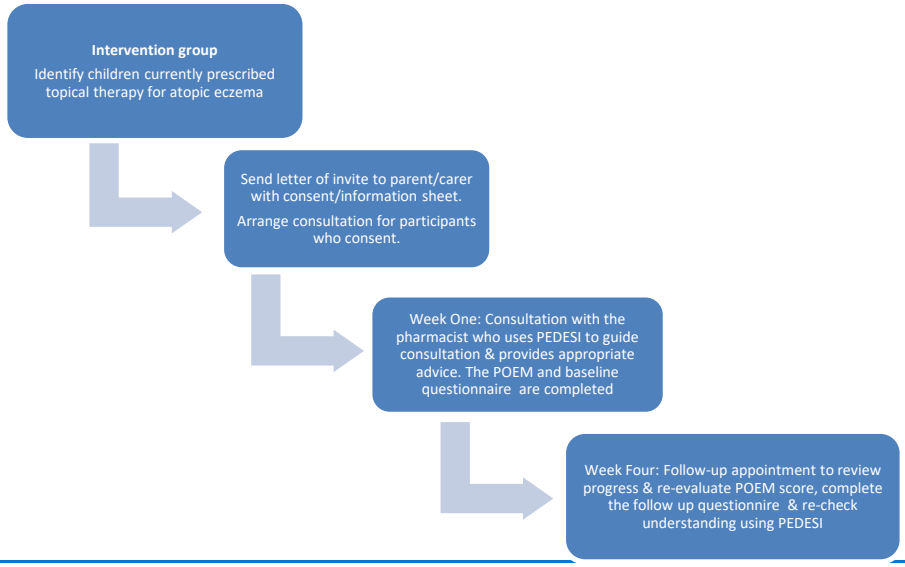
Parents (or carers) without adequate spoken and written English, as determined by the pharmacist, will be excluded. The following children will be excluded:

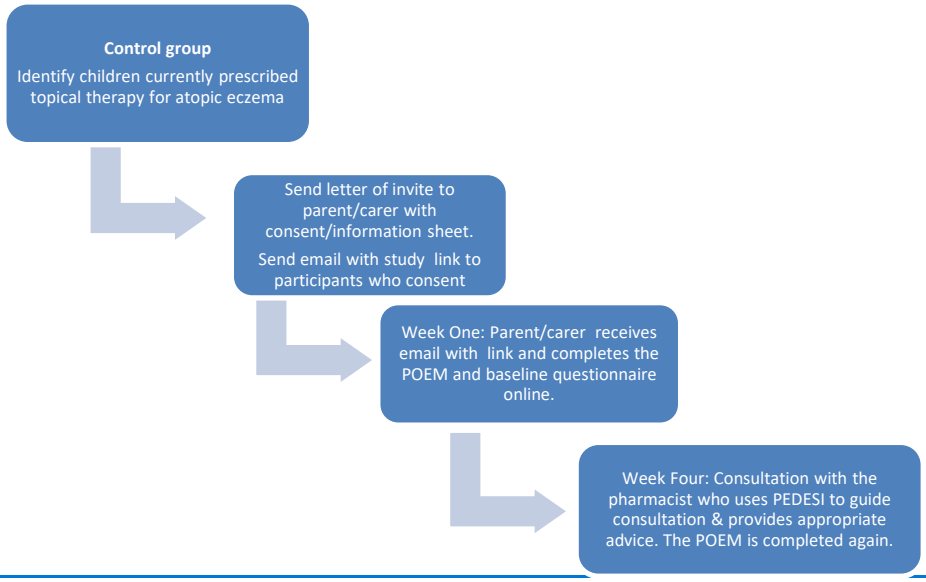
- Those under the care of a dermatologist or other dermatology specialist
- Attending a nurse-led eczema clinic
- Currently being treated for infected eczema, using wet wraps or in receipt of phototherapy
- Prescribed any oral therapies for atopic eczema

Identification

A search of the practice database will be performed by practice staff to identify children with a diagnosis of atopic eczema/dermatitis, and fulfilling the inclusion/ exclusion criteria as shown below.

Flow-charts representing process of recruitment and consultation for Intervention and Control groups





Recruitment

The parents/carers of those children meeting the above criteria will be sent a "letter of invite" with a participant information sheet and consent form.
Parent/carers agreeing to take-part in the study will be asked to return the completed consent form to the practice.

- For the Practices randomised to the intervention group, the pharmacist will then contact the parent/carer to arrange a mutually convenient time for the initial consultation during which the pharmacist will use the participant consent form to re-confirm informed, written consent.
- For Practices randomised to the control group, the Pharmacist will email the parent/carer a link to confirm consent and complete the POEM and baseline questionnaire online.

Intervention group

At the outset of the consultation, pharmacists will ask parents/carers to complete a baseline POEM Tool and the baseline questionnaire. This data will be collected electronically in the eCRF. The PeDeSI tool[22] will be used to guide the consultation, i.e., so that all the pharmacists adopt the same approach. The PEDESI tool allows the pharmacist to assess the individual parent/carer's current level of knowledge and understanding of their child's condition and its management. This tool comprised ten questions assessing parents/carers understanding of atopic eczema, triggers, use of treatments and scores each of these items separately from 0 (no understanding) to 3 (full understanding). The scores for each question are summed to provide an overall score that reflects parental/carers' level of understanding of eczema and its

management. Using the answers provided by the parent/carer, the pharmacist is then able to individualise the educational advice provided to parents/carers. Parents/carers will also be asked to complete a short questionnaire at the outset which explores how they are currently using any prescribed eczema treatments for their child. It is anticipated that the consultation will last up to 20 minutes

Follow-up consultation (intervention group only)

For participants assigned to the intervention group, the pharmacists will arrange for a second consultations approximately four weeks after the initial consultation. The purpose of this visit is for the pharmacists to re-assess the POEM and PEDESI scores. The visit will also provide an opportunity for parents/carers to ask pharmacists any further questions and a summary of responses will be recorded in the patients' medical notes. At this follow-up appointment, the pharmacist will also ask parents to complete a short questionnaire to determine if there have been any changes to their use of current treatments.

Control group

Parents/carers in the control group will be sent an email with a link to complete a baselinePOEM tool and the baseline questionnaire online. The central research team will notifiy the Pharmacist when the they have been completed. The pharmacist will then arrange an appointment with the parent/carer, approximately 4 weeks later. At this appointment, the parent/carer will be asked to complete a second POEM tool and the pharmacist will follow the same PeDeSi guided approach used for the intervention group.

Note the Control group do not complete the follow up questionnaire.

Recruitment of Practices

We will aim to recruit 10 clinical pharmacists based in different GP practices giving variation across socio-demographic areas. We will make use of the clinical research networks to help with practice recruitment. This approach has been successfully employed in several other pharmacy-based studies.

Randomisation of Practices

This will occur at the level of the practice, not at the individual patient level and MS Excel will be used to generate a randomised assignment so that every practice is either designated as a control or intervention site.

Pharmacist training

All participating pharmacists will be provided with a bespoke training pack on the management of atopic eczema which in addition to the provision of information on the data collection methods will include:

1. A brief outline of atopic eczema and its cause
2. A description of the treatments for atopic eczema with an emphasis on how to use those treatments with children
3. Any relevant advice to help facilitate effective self-care of atopic eczema.

The training material will be developed and provided in the form of an online resource.

Outcome measures

Primary outcome measure

- *Change in POEM score at four weeks compared to baseline*

Secondary outcome measures

- *Change in modified PEDESI score at four weeks compared to baseline*
- *Parent/carer self-reported changes in use of treatments*

Sample size

The minimal clinically significant difference for the POEM score has been estimated as 3.0.[23] In that study, the mean baseline POEM score was 8.80 (SD = 5.72) in a sample of children with a mean age of 21.7 months. Using Gpower with power set at 0.9, a two-tailed test and independent means, gives a total sample size of 92 (46 per group). Allowing for a 10% attrition rate, this gives a total sample size of 100 patients. Thus, we anticipate that each practice would recruit 10 patients.

Data collection

All participants will be allocated a unique code that will be anonymous to all but the practice team.

For the intervention group, the pharmacist will complete the POEM and baseline questionnaire with the participant during the consultation and their responses

entered directly into the eCRF (an online version of the questions). A similar approach will be adopted at the subsequent follow-up appointment.

For the Control Group, once the consent form has been received back from participants, they will be sent an email with a link to an online version of the POEM tool and baseline questionnaire. Once these have been submitted, the research team will alert the participant's practice that a participant has responded so that an appointment for the consultation can be arranged 4 weeks later. As per the intervention group the consultation data will be entered directly into the online eCRF.

All anonymised data submitted from the practices will be collated by the research team for subsequent analysis.

Analysis

The intention is to determine the effect of the intervention by comparing observed outcomes for both groups at four weeks. Where data are normally distributed independent t-tests will be used to determine the impact on the intervention primary outcome measure. In the case of skewed data, equivalent non-parametric statistical tests shall be used. Statistical significance shall be determined as $p < 0.05$ and analysis of quantitative data shall be performed using the latest version of SPSS (SPSS Inc., Cary).

Dissemination

The findings of this study will be presented at appropriate regional and national conferences and we will seek to have the findings published in international Pharmaceutical and Dermatological journals. In addition, we will seek to have information on the study and outcomes published in the most popular pharmacy and GP magazines to ensure dissemination of the results to practicing healthcare professions.

STUDY TIMETABLE

Months	Activity
Pre-study (1- 3 months)	Obtain Ethics and governance approval
4 – 8 months	Recruitment of patients
9 – 12 months	Undertaking of patient and pharmacist interviews Data analysis/report writing

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