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Topical treatment use and under-use in childhood eczema: secondary analysis of RCTs and cohort data in the UK and the Netherlands

Halewijn, Karlijn van; Bohnen, Arthur; Macneill, Stephani; Ridd, Matthew; Stuart, Beth; Santer, Miriam; Bindels, Patrick; Elshout, Gijs

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Karlijn F. van Halewijn[1], MD

Arthur M. Bohnen[1], MD, PhD, general practitioner

Stephanie MacNeill[2], PhD

Matthew J Ridd[3], FRCGP, PhD, professor of primary health care

Beth Stuart[4], QMUL, professor of Medical Statistics

Miriam Santer[5], MRCGP, PhD, professor of Primary Care Research

Patrick J.E. Bindels[1], MD, PhD, professor of General Practice

Gijs Elshout[1], MD, PhD, general practitioner

[1]Department of General Practice, Erasmus MC, University Medical Center, Rotterdam, The Netherlands

[2] Bristol Trials Centre, University of Bristol, UK

[3] Centre for Applied Excellence in Skin and Allergy Research, University of Bristol, UK

[4] Queen Mary, University of London, Wolfson Institute of Population health, UK

[5] Primary Care Research Centre, University of Southampton, UK

Corresponding author: Karlijn F. van Halewijn, P.O. Box 2040, 3000CA Rotterdam

E-mail: k.vanhalewijn@erasmusmc.nl

Abstract

Background: Underuse of emollients and topical corticosteroids (TCS) contributes to uncontrolled atopic eczema, but variations between countries remain unclear.

Aim: To compare the actual use of emollient and TCS use in childhood eczema in the UK and The Netherlands (NL) and examine treatment adherence in relation to guidelines.

Design and setting: A secondary analysis of data from the Rotterdam Eczema cohort study (n=367) (NL), the BATHE trial (n=482) (UK) and BEE trial (n=520) (UK).

Methods: Frequency of emollient and TCS use were compared at baseline and after 12-16 weeks of follow-up by age, sex and disease severity. Treatment adherence was defined as: 1a) not using an emollient at all, 1b) not using an emollient when a TCS was used, 2) not using a TCS when eczema is mild or worse. Overall undertreatment was defined as category 1 and 2 combined.

Results: In total, questionnaire data from 1312 children (aged 3 months-17 years) with mostly mild (26%–37%) or moderate (45%–48%) eczema were analysed. Not using an emollient was significantly more prevalent in NL at baseline (14%) and follow-up (19%) than in the UK (4% and 7.6%, respectively). Not using a TCS when eczema is mild or worse differed significantly ($p<0.05$) between countries. The overall undertreatment rate was high and did not differ significantly between countries at baseline (UK 52.0%-NL 48.2%) and follow-up (UK 45.0%-NL 49.8%).

Conclusion: Undertreatment with emollients and TCS are common and a reminder for clinicians to explain treatment rationale and check treatment adherence. Differences in treatment practices between countries warrant further exploration.

Keywords:
primary health care, infant, child, eczema, emollients

How this fits in:

For the treatment of eczema flares, guidelines recommend daily emollients and topical corticosteroids depending on the severity of the eczema. Underuse of emollients and topical corticosteroids is a recognised reason for uncontrolled atopic eczema but if treatment adherence is in line with guideline recommendations is unknown. We found that undertreatment with emollients and TCS are common and a reminder for clinicians to explain treatment rationale and always check adherence to topical treatments.

Introduction

The main characteristics of the chronic inflammatory skin disease atopic eczema, also known as "atopic dermatitis" or "eczema", are itching and recurrent skin lesions. [1] With a frequency of up to 20% in children and 10% in adults, eczema is the skin disorder with the highest total disease burden.[2] In general practice, eczema is among the top 10 most frequent conditions in children under the age of 18.[3 4] The majority of eczema is treated in primary care, with fewer than 6% of all people with eczema referred to secondary care in most European countries.[5 6] To treat eczema flare-ups, the National Institute for Health and Care Excellence (NICE) and the Dutch College of General Practitioners guidelines recommend daily emollients, and topical corticosteroids (TCS) depending on severity of eczema. Both guidelines recommend that emollients should always be used, even when eczema is clear. [6 7]

It is known that patients, parents, and physicians have reservations about treating eczema using TCS. [8-10] A study from the UK revealed that TCS are under-prescribed in quantity and potency. [11] Furthermore, between 2009-2018, primary care TCS prescriptions for eczema in the UK decreased from 57.3% to 52.0%. [12] Underuse of emollients may also be a critical issue in children with eczema. In a comprehensive database study in 2014 in the Netherlands, in 61% of the children with eczema no relevant medication (emollients or TCS) was prescribed.[6 13] In the UK it has been found that, amongst children prescribed a topical steroid, half were not prescribed any emollient.[13] However, our understanding of how treatment use compares between different countries by disease severity is limited, particularly as most studies to date focus on prescribed medication rather than patients' (or carers') use of medication.

The UK and the Netherlands have similar healthcare and reimbursement systems, allowing comparisons to be made to provide greater insight into the prescribing and adherence to topical therapies and potential routes to better eczema management. The aim of this study is to compare the actual use of emollient and TCS use in children with eczema in the UK and The Netherlands, with a focus on examining whether treatment adherence is in line with guideline recommendations for continuous emollient use and TCS use during flare-ups.

Methods

Sources of data

Data from the Netherlands from the Rotterdam Eczema cohort study (n = 367) and UK data from the Bath Additives in the Treatment of cHildhood Eczema (BATHE) trial (n = 482) and Best emollients for eczema (BEE) trial (n= 520) are compared at baseline and after 12 -16 weeks follow-up. BATHE and BEE recruited children in primary care and collected age, sex, disease severity, frequency of emollient use, and frequency of TCS use. The Rotterdam Eczema study recruited children and adolescents mostly via general practice and in part via open recruitment, most of the participants were treated by their GP (81.7%).[14] For study details, see Table 1 and the protocol articles.[15-17]

Table 1. Sources of data

Study	Design	Aim	Recruitment	Age	Other key eligibility criteria	Duration of follow-up	Frequency of data collection on treatment	Participants
BATHE	Pragmatic, individually randomized, parallel group open-label superiority trial	To compare the clinical and cost-effectiveness of bath additives to standard eczema management	Primary care	1y-12y	UK diagnostic criteria and NESS >5	52 weeks	Weekly for 16 weeks, four weekly up to 52 weeks	482
Rotterdam Eczema Study	Prospective cohort	To determine the frequency and determinants of flare-ups of AD	Primary care & open recruitment	3m-17y	Diagnosed by GP	52 weeks	Weekly for 52 weeks	367
BEE	Pragmatic, individually randomized, parallel-group, open-label superiority trial	To compare the effectiveness and acceptability of lotion, cream, gel, and ointment types of emollients	Primary care	6m-11y	GP diagnosed eczema and POEM>2	52 weeks	Weekly for 16 weeks, four weekly up to 52 weeks	550

BATHE: Bath Additives in the Treatment of cHildhood Eczema; BEE: Best emollients for eczema; NESS: Nottingham Eczema Severity Score; POEM: Patient Orientated Eczema Measure; AD: Atopic dermatitis

Study variables

Age, frequency of emollient use, and TCS use were categorized to allow comparisons between the various trials. For age, we made 3 categories, 0-2 years, 3-7 years, and 8+ years, to make sure the groups were of comparable sizes. Frequency of topical medication use was captured differently in the studies: BEE and BATHE asked about number of days (0 to 7) used over the previous week, while

Rotterdam Eczema study registered in five categories of frequency of days per week (not used, 1-2 days, 3-4 days, 5-6 days, 7 days) (see Supplementary Box 1 for questionnaires of the studies). We dealt with this by categorizing emollient and TCS use per week in 4 categories: not used, 1-2 days, 3-4 days, 5-7 days. By doing this we created comparable categories.

In all three studies eczema severity was measured by the Patient Oriented Eczema Measure (POEM) score, the core outcome measurement for patient-reported symptoms in eczema trials.[18] POEM asks about the frequency of seven symptoms (itching, sleep disturbance, dryness, flaking, weeping or oozing, bleeding, and cracking) experienced within the last seven days. A POEM score can range from 0 to 28. We categorized POEM as stated by Charman et al.[19]; 0-2 as almost clear, 3-7 as mild, 8-16 as moderate and we combined severe (17-24) and very severe (25-28) in one category severe.

Definitions

We defined treatment adherence in three ways to compare the non-adherence of emollients and TCS in primary care in the UK and the Netherlands. Definitions 1 and 2 are based on the treatment approach of the NICE guideline and the Dutch GP guideline, in which it is recommended that emollients should always be used even when eczema is clear and a TCS should be added when eczema becomes mild or worse. [20 21]

- Definition 1 is divided into two groups: 1a, which identifies cases where emollients were not used at all and 1b, a subgroup of 1a, which identifies cases where emollients were not used in conjunction with TCS. Definition 1 is divided into two groups (1a and 1b) where 1b is a subgroup of 1a. Definition 1a) Not using emollients at all. 1b) not using an emollient when TCS was added or used by the participants. For 1b, we selected the participants from 1a (not using an emollient) and who were in the categories using TCS for 1-2 days, 3-4 days, and 5-7 days.
- Definition 2 was defined as not using TCS when eczema is mild or worse based on a POEM score of ≥3, equating to mild eczema or worse, where guidelines recommend to use of a TCS (unlike POEM 0-2, which equates to almost clear). We defined these types of undertreatment at baseline and at 12 weeks of follow-up to determine if treatment adherence changed over time.
- For definition 3 we combined definitions 1a and 2 to calculate overall non-adherence named 'undertreatment', for the Netherlands and the UK separately.

Data analysis

Participants were eligible for analysis if there was a POEM score at baseline. BEE started with reporting the frequency of medication use from week 1 onwards, so in the case of BEE, baseline data

is data from week 1. For the follow-up data, we only used the data of the first week between 12 to 16 weeks in which the POEM was reported, to create a comparable follow-up point for all three studies. When POEM was reported but the frequency of emollients or TCS was not reported, we recoded this as 'not used'. With this approach, the percentage of missing data was limited. Descriptive statistics were used to describe participant characteristics such as age, sex, and eczema severity (POEM score). For categorical data, the number of cases and percentages were presented. Differences between the Netherlands and the United Kingdom in undertreatment are compared with Pearson's Chi-square test. Differences between countries in emollient use (yes or no) were tested with logistic regression, controlling for confounders (age, sex, and POEM score). Differences between countries in TCS use (yes or no) were tested with logistic regression, controlling for confounders (age, sex, POEM score, and emollient use). All analyses are done at baseline and 12-16 weeks of follow-up.

Results

Participant characteristics

In total, we included 1312 children from the three studies. No relevant differences were seen in the number of boys and girls included in all studies (Table 2). The largest age category in BEE and BATHE were the 3–7 years old (43.3%–51.5%) and in The Rotterdam Eczema Study the 0-2 years old (39%). In all three studies, the children suffered most frequently from moderate (POEM 8-16; 44.6%-48.3%) or mild (POEM 3-7; 26.2%-36.9%) eczema, and at baseline most children used emollients 5-7 days a week (61.6-81.0%). Additionally, in all three studies, half or just more than half of the children did not use a TCS at baseline (49.7%-62.3%). At follow-up, the most frequent severity categories are still mild and moderate (30.9% and 37.3%, respectively). For all follow-up data on POEM severity and frequency of emollients and TCS use, see Supplementary Table 1.

Table 2. Participant characteristics at baseline

	Study = BEE	**Study = BATHE**	**UK total**	**Study = Rotterdam Eczema Study**	**TOTAL**
	N=496 (%)	N=480 (%)	N=976 (%)	N=336 (%)	N=1312 (%)
Sex					
Boys	265 (53.4)	236 (49.2)	501 (51.3)	160 (47.6)	661 (50.4)
Girls	231 (46.6)	244 (50.8)	475 (48.7)	176 (52.4)	651 (49.6)
Age					
0-2	149 (30.0)	127 (26.5)	276 (28.3)	131 (39.0)	407 (31.0)
3-7	215 (43.3)	247 (51.5)	462 (47.3)	96 (28.6)	558 (42.5)
8+	132 (26.6)	106 (22.1)	238 (24.4)	109 (32.4)	347 (26.4)
Mean POEM (SD)	9.3 (5.5)	9.5 (5.8)		10.8 (6.1)	
POEM score categorised					
0-2 (almost clear)	42 (8.5)	32 (6.7)	74 (7.6)	37 (11.0)	111 (8.5)
3-7 (mild)	183 (36.9)	154 (32.1)	337 (34.5)	88 (26.2)	425 (32.4)
8-16 (moderate)	221 (44.6)	232 (48.3)	453 (46.4)	153 (45.5)	606 (46.2)
17-28 (severe)	50 (10.1)	62 (12.1)	112 (11.5)	58 (17.3)	170 (13.0)
Frequency emollient use					
Not used	15 (3.0)	24 (5.0)	39 (4.0)	47 (14.0)	86 (6.6)
1-2 days	22 (4.4)	46 (9.6)	68 (7.0)	39 (11.6)	107 (8.2)
3-4 days	57 (11.5)	67 (14.0)	124 (12.7)	43 (12.8)	167 (12.7)
5-7 days	402 (81.0)	343 (71.5)	745 (76.3)	207 (61.6)	952 (72.6)
Frequency TCS use					
Not used	309 (62.3)	242 (50.4)	551 (56.5)	167 (49.7)	718 (54.7)
1-2 days	82 (16.5)	79 (16.5)	161 (16.5)	59 (17.6)	220 (16.8)
3-4 days	61 (12.3)	69 (14.4)	130 (13.3)	52 (15.5)	182 (13.9)
5-7 days	44 (8.9)	90 (18.8)	134 (13.7)	58 (17.3)	192 (14.6)

BEE: Best emollients for eczema; BATHE: Bath Additives in the Treatment of cHildhood Eczema; POEM: Patient Orientated Eczema Measure; TCS: topical corticosteroid.

Undertreatment 1a: not using emollients at all

Not using any emollients at all at baseline was 3.0% in the BEE study, 5.0% in the BATHE study, and highest in the Rotterdam study at 14.0% (table 2). At 12-16 weeks of follow-up (the rate of not using an emollient at all was 6.0% in the BEE study, 9.4% in the BATHE study, and 19.0% in the Rotterdam study. In the Netherlands, the overall percentage of participants who did not use an emollient at baseline (14%) and follow-up (19.0%) differed statistically significantly (baseline $p<0.01$, follow-up $p<0.01$) when compared to the UK (4.0% at baseline vs 7.6% at follow-up) (Table 3).

POEM severity categories were the categories that varied the most in undertreatment with emollients. In the category 'almost clear' the undertreatment was highest at baseline (8.1% in the UK and 48.6 % in the Netherlands, $p<0.01$). At follow-up, 'almost clear' was also the category with the highest emollient undertreatment rates in the UK 15.5%, and the Netherlands 47.5%, $p<0.01$. In the category 'severe' the undertreatment with emollients was lowest. At baseline this was 2.7% for the UK and 3.4% for the Netherlands ($p>0.05$), at follow-up, this was 3.8% for the UK and 8.3% for the Netherlands ($p>0.05$).

When differences between countries were adjusted for potential confounders (age, sex, POEM severity), emollients were significantly used less in the Netherlands compared to the UK at baseline (OR 0.26, 95%CI 0.16-0.40) and at follow-up (OR 0.35, 95%CI 0.24-0.51). For tables of logistic regression see appendix 3.

Table 3. Undertreatment 1a ("emollients not used" by sex, age category, and POEM severity category), undertreatment 1b, 2 and 3

Emollients not used	**UK Baseline**	**NL Baseline**	**P-value**	**UK follow-up week***	**NL follow-up week***	**p-Value**
	N=976 (%)	N=336 (%)		N=907 (%)	N=315 (%)	
Undertreatment 1a emollients not used by sex						
Boys	14 (2.8)	22 (13.8)	<0.01	39 (8.3)	26 (18.4)	<0.05
Girls	25 (5.3)	25 (14.2)	<0.01	30 (6.8)	34 (19.5)	<0.01
Undertreatment 1a emollients not used by age						
0-2 years	4 (1.4)	16 (12.2)	<0.01	23 (8.8)	18 (15.3)	0.06
3-7 years	18 (3.9)	14 (14.6)	<0.01	24 (5.7)	16 (17.6)	<0.01
8+ years	17 (7.1)	17 (15.6)	<0.05	22 (9.9)	26 (24.5)	<0.01
Undertreatment 1a emollients not used by POEM severity						
POEM 0-2 *Almost clear*	6 (8.1)	18 (48.6)	<0.01	30 (15.5)	38 (47.5)	<0.01
POEM 3-7 *Mild*	16 (4.7)	13 (14.8)	<0.05	20 (6.8)	13 (15.7)	<0.05
POEM 8-16 *Moderate*	14 (3.1)	14 (9.2)	<0.05	16 (4.7)	6 (5.2)	0.82
POEM 17-28 *Severe*	3 (2.7)	2 (3.4)	0.78	3 (3.8)	3 (8.3)	0.35
Undertreatment 1a emollients not used						
Overall	39 (4.0%)	47 (14.0%)	<0.01	69 (7.6%)	60 (19.0%)	<0.01
Under treatment 1b: No emollients used when TCS is used						
TCS used	N=425 (%)	N=169 (%)		N=393 (%)	N=130 (%)	
Undertreatment 1b	12 (2.8)	10 (5.9)	0.09	17 (4.3)	9 (6.9)	0.25
Under treatment 2: POEM ≥3 and TCS not used						
POEM ≥3	N=902 (%)	N=299 (%)		N=714 (%)	N=235 (%)	
Undertreatment 2 (all POEM categories)	492 (54.5)	134 (44.8)	<0.05	366 (51.3)	113 (48.1)	0.78
POEM 3-7 *Mild*	221 (65.5)	53 (60.2)	0.38	184 (62.4)	53 (63.9)	0.90
POEM 8-16 *Moderate*	232 (51.2)	64 (41.8)	0.05	156 (45.9)	45 (38.8)	0.20
POEM 17-28 *Severe*	39 (34.8)	17 (29.3)	0.50	26 (32.9)	15 (41.7)	0.41
Undertreatment 3: combined under treatment (=1a and/or 2)						
Total participants	N=976 (%)	N=336 (%)		N=907 (%)	N=315 (%)	
Total undertreated	508 (52.0%)	162 (48.2%)	0.23	408 (45.0%)	157 (49.8%)	0.14

** follow-up week were first POEM is available between 12-16 weeks.*

Undertreatment 1b: not using an emollient when TCS use reported

Not using an emollient when a TCS was used ranged from 2.8% in the UK and 5.9% in the Netherlands at baseline and from 4.3% in the UK and 6.9% in the Netherlands at follow-up (Table 3). There was no significant difference between the countries at either time point.

Undertreatment 2: not using TCS when eczema is mild or worse

When eczema was mild or worse, the percentage of children who did not use a TCS was high and around 50% at baseline and follow-up (Table 3). This percentage was significantly different ($p < 0.05$) between the UK (54.5%) and the Netherlands (44.8%) at baseline. At follow-up, there was no significant difference between the UK (51.3%) and the Netherlands (48.1%). When undertreatment 2 is broken down by POEM category, undertreatment is highest at baseline in the mild category for UK and the Netherlands (65.5% - 60.2%) and lowest in the severe category for UK and the Netherlands (34.8% – 29.3%).

In the UK, TCS was used less at baseline (OR 1.31, 95% CI 1.02-1.68), even when corrected for sex, age, POEM severity, and emollients use. TCS use did not differ between countries at follow-up after correction for confounders (OR 0.92, 95% CI 0.71-1.19). For tables of logistic regression see Supplementary Table 2 and 3.

Undertreatment 3: overall undertreatment

When categories 1a and 2 of undertreatment were combined, there was no significant difference between the UK (52.0%) and the Netherlands (48.2%) in the total percentage of undertreatment (Table 3), at baseline. Also, at follow-up, there was no difference between the UK (45.0%) and the Netherlands (49.8%). Overall undertreatment was high in both countries.

Discussion

Summary

Childhood eczema appeared to be undertreated with both emollients and TCS in the UK and the Netherlands. Overall, approximately half of the children with eczema non-adhered to treatment guideline with emollients at baseline (UK, 52.0% and NL 48.2%) and 12-16 weeks follow-up (UK 45.0% and NL 49.8%). Undertreatment with TCS when eczema was mild or worse, was prominent in both countries (UK 54.5% and NL 44.8%), even in the severe category undertreatment was high at baseline (UK: 34.8%; NL:29.3%) and at follow-up (UK: 32.9%; NL 41.7%). After correcting for sex, age, and the severity of the POEM score, emollients were used less in the Netherlands at baseline and follow-up. The only group where treatment adherence was high was the group of participants that reported using emollients during periods of TCS use (95%). These findings were remarkably consistent between countries and settings.

Strengths and limitations

This is the first study to compare actual emollient and TCS use, instead of prescribed or prescriptions collected from the pharmacy, in children with eczema in the UK and The Netherlands, using secondary analysis of three studies from the two countries.

A strength of the study is the use of prospective data resulting in less recall bias, comparable data as the POEM score and other data collection methods were similar across all three studies, and the detailed information on participant-reported treatment adherence in relation to eczema severity. Furthermore, because the healthcare and reimbursement systems in the UK and the Netherlands are comparable the results from both countries can be used to gain further insights into the underuse of topical treatments.

A limitation is the possibility of misclassification bias, whereby missing information regarding the frequency of TCS/emollient use is categorized as "not used." Although the POEM was known, indicating that the patient had completed the questionnaire, there may have been misclassification bias, which could have caused the underuse to be overclassified.

The variation in study design and data collection methods as described below, however minor, constituted a limitation of secondary analysis and data source integration.

A limitation is that taking part in a study may have led to higher rates of using an emollient, especially for participants in the BEE study where four types of emollients were compared. BEE participants

were told to use their emollient twice daily and when required. In the BATHE study participants in both groups were given standard advice regarding how to wash and signposted towards standard advice about emollient use. In contrast, the Rotterdam study was a cohort study and participants used their usual treatments. At baseline, in the BEE trial, there was a relatively high rate of daily emollients use (81.0%). Therefore, it is likely that the reported outcome of undertreatment is even higher in daily practice and differences observed between the UK and NL may, in part, be an artefact of the different study designs/interventions.

For the main outcome of the BATHE trial, there was no difference in emollient use and TCS use between the control group (usual care) and the intervention group (usual care + bath additive).[22] Also, for the BEE trial, there was no difference found between the four types of emollients.[23] So, the intervention itself probably had only a limited influence on the primary outcome in the follow-data and our treatment of the three studies as cohorts was justified.

The term 'under-treatment' in this paper relates to use of eczema treatments in terms of adherence to clinical guidelines. However, we acknowledge that parents may feel that their treatments decisions are appropriate and in line with their views and beliefs about eczema treatments. [10] Despite these limitations and the differences between the countries, studies and patient populations, our findings were remarkably consistent between countries and settings.

Comparison with existing literature

NICE recommends starting with a mild TCS when eczema is mild, contrary to the Dutch GP guideline, which suggests starting a mild TCS when eczema is moderate. However, the NICE guideline uses a "holistic" approach considering skin and physical severity and impact on quality of life and social wellbeing, while the Dutch GP guideline uses the Three Item Severity Score (TIS score, 0-9). A score of ≥3-5 is categorized as moderate eczema. So, this could be the case when erythema, edema/papules and scratch effects are scored mild. Therefore, a moderate TIS score corresponds with mild to moderate eczema when determined by the NICE guideline. However, we used the POEM score in all studies to determine severity and to prevent misclassifying mild eczema in the Netherlands.

In the Netherlands, emollients were used less. Even when corrected for sex, age, and POEM severity. On the other hand, when participants were using a TCS they did not substitute this for emollient as only a few participants did use a TCS without an emollient. Also, in both countries, emollients are free of charge for children <18 years of age. In the Netherlands, GPs report that they do emphasize the importance of using an emollient.[24] Qualitative data suggests that parents may feel reluctant to

use emollients in the long-term to prevent flare-ups and that it is possible that promoting the rationale for long-term use may address this.[25 26] Moreover, it is important to note that the NICE guideline recommends applying emollients "to the entire body, both during periods of clear eczema and while using all other treatments." However, our data does not take into account the area covered with emollients or the quantity of emollients used. It is possible that there is even greater undertreatment with emollients when considering the area covered or the amount used.

In a population-based study in Sweden in adolescents with mostly mild eczema (45% did not use a TCS in the last 12 months, which corresponds to our baseline data.[27] In data of Jacquet et al., which using data from the COMET study (a randomized controlled feasibility study of different emollient types, recruiting children with eczema aged 1 month to 5 years from in primary care in the UK), 54% had not used a TCS over the last week.[11] In our study, in total 54.7% were not using a TCS at baseline. Given these earlier results and our results the undertreatment regarding TCS is high and there are no major differences between studies and countries.

Additionally, the overall undertreatment was high for baseline and follow-up despite the differing recruitment strategies and to differences in inclusion criteria. To improve patient adherence to treatment, Teasdale et al recommend highlighting that eczema is a long-term episodic condition, providing clear information about routine emollient use, offering helpful suggestions like setting reminders to support co-management at home, and working with schools to ease topical treatment use, when necessary.[28] Additionally, signposting people to the online self-management intervention tool EczemaCareOnline.org.uk has been shown to improve eczema outcomes,[29] through improved understanding of, and confidence in, eczema management and reduced treatment concerns.[30]
In conclusion, information and recommendations spread by clinicians and interventions like an online tool could probably lower these high rates of undertreatment.

Implications for research and practice

The high rates of undertreatment with emollients and TCS, even when eczema is mild or moderate, are a strong reminder for clinicians to always check the treatment adherence of both emollients and TCS in children with eczema, and to explain treatment rationale. Clinicians should address the necessity of using emollients, not just in cases when eczema is mild or worse. Future studies may investigate more the reasons for not using emollients and or TCS in both countries. Furthermore, effective strategies to enhance treatment adherence should be implemented in daily practice.

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