

Which emollients for children with atopic eczema/dermatitis?

Findings from the Best Emollients for Eczema trial

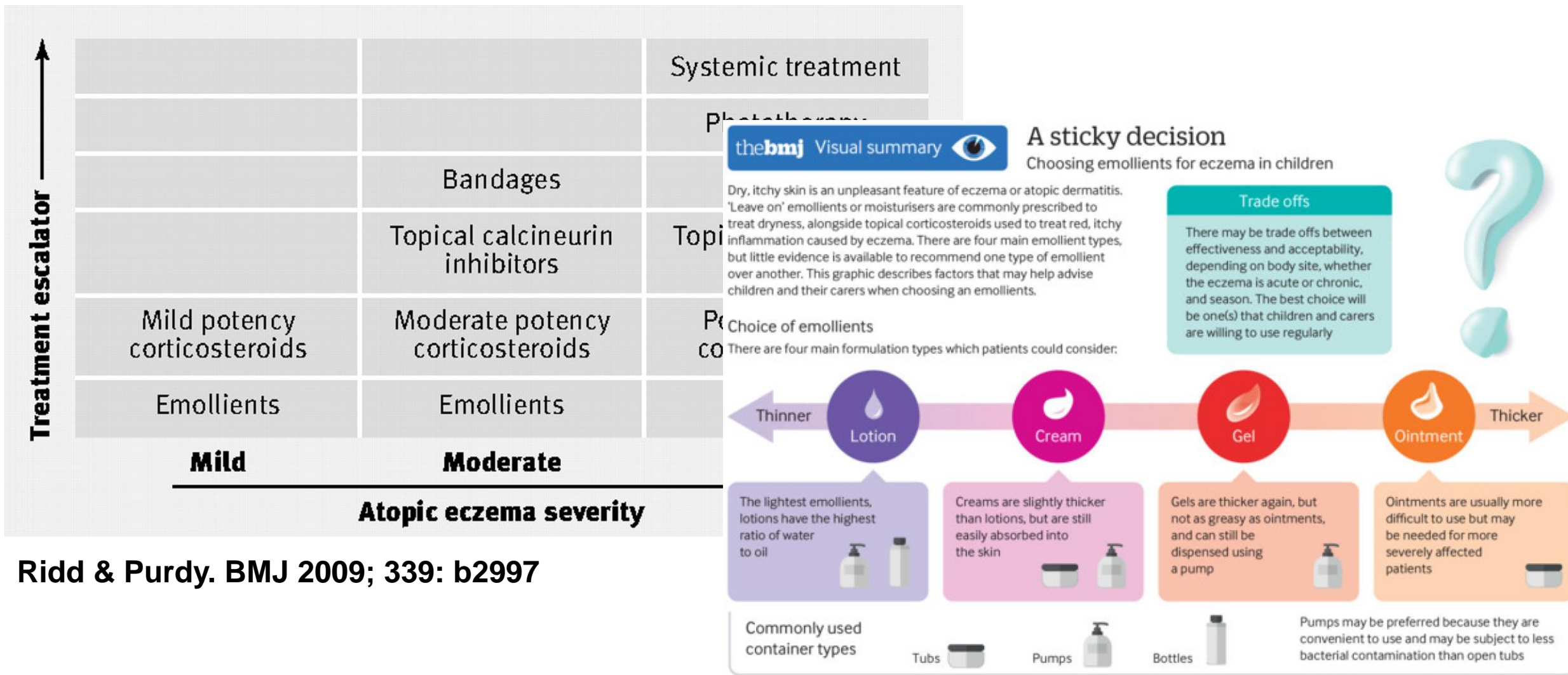
Matthew Ridd, Miriam Santer, Stephanie J MacNeill, Emily Sanderson, Sian Wells, Jonathan Banks, Alison Shaw, Eileen Sutton, Amanda Roberts, Julie Clayton, Kirsty Garfield, Lyn Liddiard, Tiffany Barrett, Athene Lane, Laura Howells, Helen Baxter, Alastair Hay, Hywel Williams, Kim Thomas

EudraCT: 2017-000688-34

ISRCTN: ISRCTN84540529

www.bristol.ac.uk/bee-study

Childhood atopic eczema/dermatitis



Ridd & Purdy. BMJ 2009; 339: b2997

Emollient formularies

| | Chan 2018 | Amakye 2022 |
|----------------------------------|-----------------|-------------|
| Year | 2017 | 2021 |
| Setting | England & Wales | England |
| No CCGs ↓ | 209 | 105 |
| No formularies ↓ | 102 | 72 |
| No named emollients ↑ | 109 | 126 |
| Emollient types recommended (1+) | | |
| Lotion | 85% | 83% |
| Cream | 99% | 100% |
| Gel | 85% | 94% |
| Ointment | 98% | 100% |

Chan et al. BMJ Open 2018;8:e022009. doi: 10.1136/bmjopen-2018-022009

Amakye et al. Clin Exp Dermatol 2022; DOI : 10.1111/ced.15197

Design [1]

- **Research question:** “Which are the best emollients to prescribe for treating the symptoms of childhood eczema – lotion, cream, gel or ointment?”
- **Setting:** Primary care (GP practices) in England
- **Participants:** Children with eczema
 - 6 months to <12 years
 - Mild or worse (POEM>2)
 - No known sensitivity to study emollients or their constituents
- **Intervention:**
 - Only leave-on emollient for 16 weeks
 - All paraffin based
 - None contained antimicrobials or urea
 - Directions to apply twice daily and when required



Lotions
with glycerol



Creams
no humectant
or lanolin



Gel
no povidine



Ointment
no additives

Design [2]

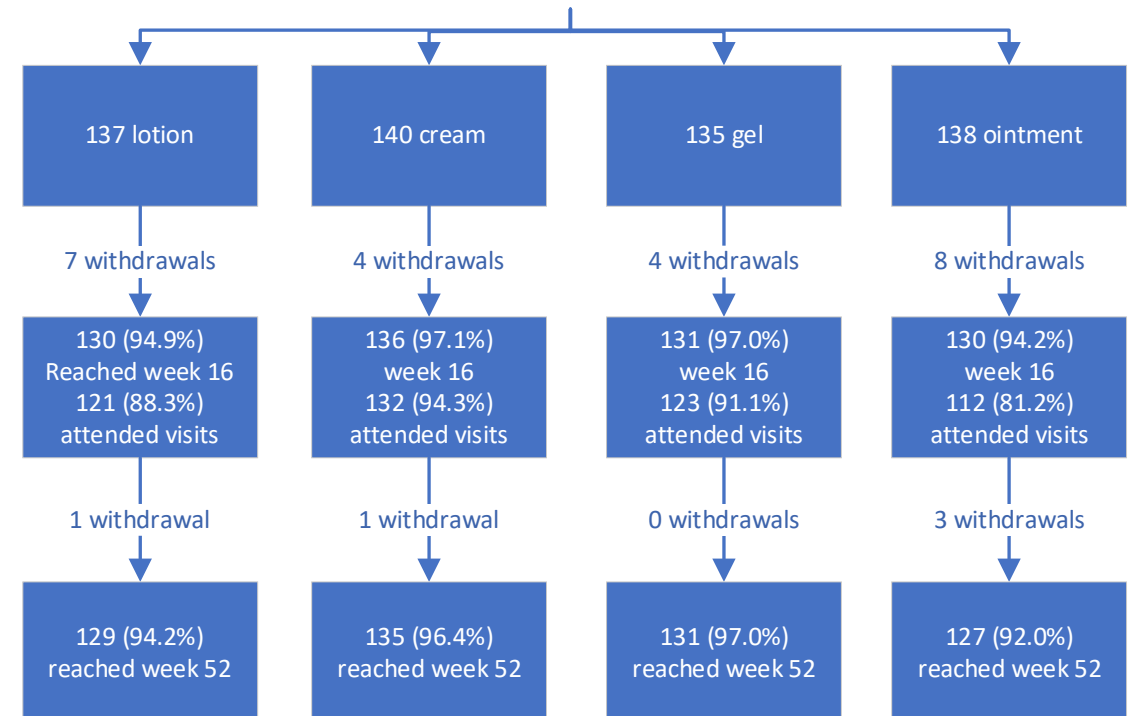
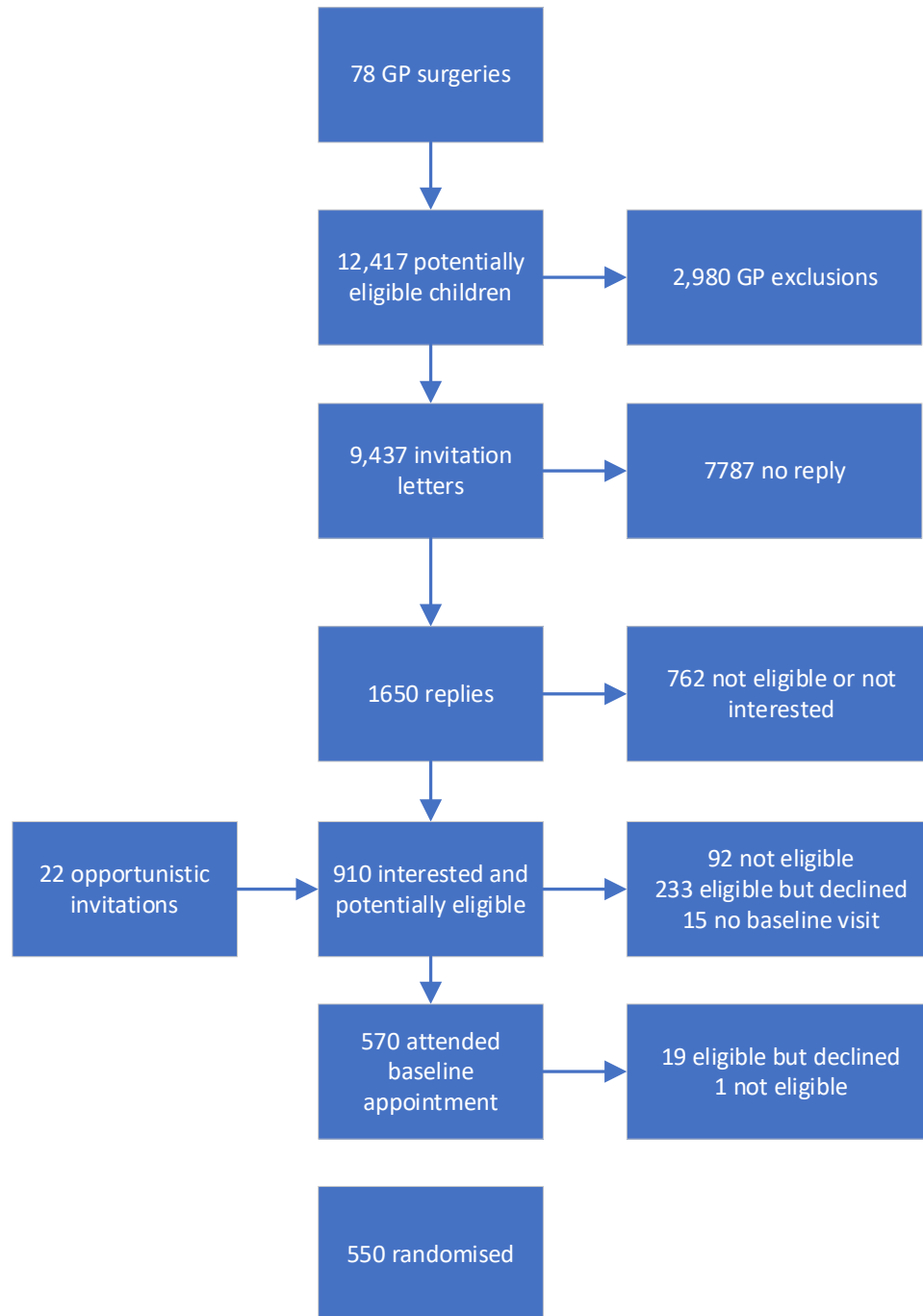
- **Primary outcome:** Patient Orientated Eczema Measure (POEM), measured weekly for 16 weeks
- **Sample size:** 520 (130 per group to detect difference of 3.0 (MCID) in POEM scores between any two groups with 90% power)
- **Nested qualitative study**
- [Health economic analysis]
- Public & Patient Involvement



Quick
poll
question



Participant recruitment and follow-up



| | Lotion (n=137) | Cream (n=140) | Gel (n=135) | Ointment (n=138) | All (n=550) |
|--|-------------------|------------------|----------------|---------------------|----------------|
| Mean (IQR) age in years | 4 (2, 7) | 5 (2, 8) | 4 (2, 8) | 4 (2, 7) | 4 (2, 8) |
| Female | 46.7% | <u>55.0%</u> | <u>40.0%</u> | 43.5% | 46.4% |
| White ethnicity | 86.9% | 90.0% | 83.0% | 84.1% | 86.0% |
| Meet UK diagnostic criteria for atopic dermatitis | 82.5% | 77.1% | 80.7% | 84.8% | 81.2% |
| Mean (SD) POEM | 8.7 (5.2) | 9.3 (5.3) | 9.8 (5.4) | 9.5 (6.0) | 9.3 (5.5) |
| Median (IQR) EASI | 3.3 (2.0, 7.2) | 3.2 (2.0, 6.3) | 4.0 (2.5, 8.0) | 3.3 (1.6, 6.5) | 3.5 (1.9, 6.9) |

Participant characteristics at baseline

Study-approved emollients prescribed

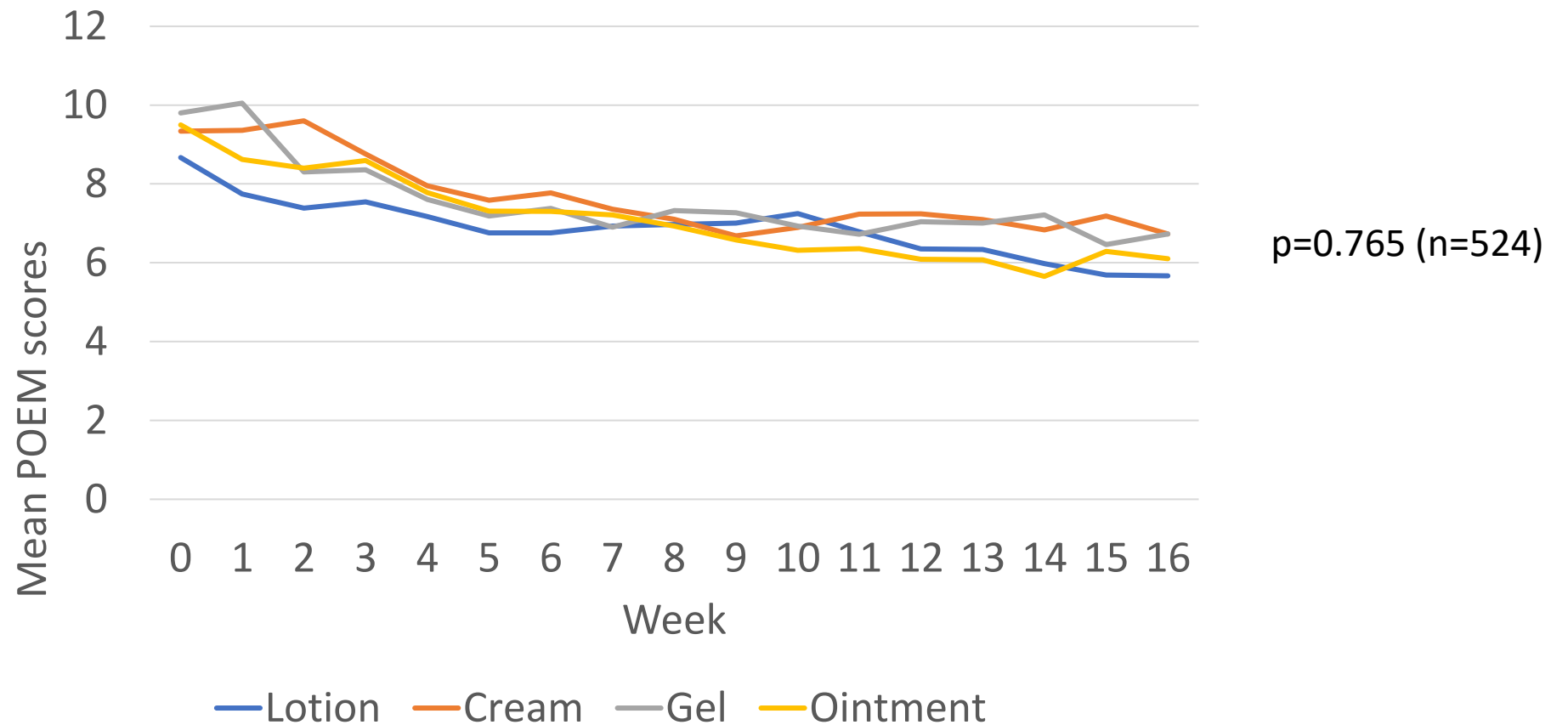
| Lotions | n | % | Creams | n | % | Gels | n | % | Ointments | n | % |
|------------------|-----|-------|-----------------|-----|-------|-------------------|-----|-------|-------------------------|-----|-------|
| QV lotion | 77 | 56.2 | Epimax cream | 72 | 51.4 | Epimax Isomol gel | 96 | 71.1 | 50/50 ointment | 88 | 63.8 |
| Cetraben lotion | 37 | 27.0 | Zerobase cream | 40 | 28.6 | Zerodouble gel | 21 | 15.6 | Emulsifying ointment BP | 29 | 21.0 |
| Diprobace lotion | 15 | 10.9 | Diprobace cream | 10 | 7.1 | Doublebase gel | 9 | 6.7 | Diprobace ointment | 9 | 6.5 |
| | | | Aquamax cream | 8 | 5.7 | AproDerm gel | 1 | 0.7 | | | |
| Non-lotion | 2 | 1.5 | Non-study cream | 2 | 1.4 | Non-gel | 2 | 1.5 | Non-ointment | 3 | 2.2 |
| Unknown | 6 | 4.4 | Unknown | 8 | 5.7 | Unknown | 6 | 4.4 | Unknown | 9 | 6.5 |
| | 137 | 100.0 | | 140 | 100.0 | | 135 | 100.0 | | 138 | 100.0 |

Results



Primary outcome

No difference between treatment groups in eczema severity (POEM) over the first 16 weeks



Mean POEM scores over the first 16 weeks by treatment group

POEM and EASI over/at 16 weeks

| | Allocated emollient | | | | |
|--------------------------|---------------------|----------------|------------------|-----------------|---------|
| | Lotion | Cream | Gel | Ointment | p-value |
| | | | | | |
| Mean POEM (SD) | (n=131/137) | (n=137/140) | (n=130/135) | (n=126/138) | |
| Baseline | 8.7 (5.2) | 9.3 (5.3) | 9.8 (5.4) | 9.5 (6.0) | |
| Over 16 weeks | 6.79 (5.14) | 7.62 (5.37) | 7.45 (5.81) | 7.04 (6.13) | 0.765 |
| | | | | | |
| Median EASI (IQR) | (n=121/137) | (n=132/140) | (n=123/135) | (n=112/138) | |
| Baseline | 3.3 (2, 7.2) | 3.15 (2, 6.3) | 4 (2.35, 8) | 3.3 (1.58, 6.5) | |
| 16 weeks | 2.15 (0.6, 3.6) | 2.3 (0.9, 4.7) | 2.25 (0.9, 5.15) | 2.2 (0.8, 4.8) | 0.420 |

No evidence of any difference between groups on the following secondary outcomes/analyses:

Other secondary outcomes

- Health related **quality of life** at 6 weeks, 16 weeks and 52 weeks (ADQol and CHU9D)
- Dermatitis **Family Impact** at 16 weeks and 52 weeks
- The proportion of weeks with **well controlled symptoms** (a POEM score of ≤ 2 in weeks 1 – 16)

Other analyses

- POEM sub-group analyses:
 - Parent expectation
 - Age
 - Eczema severity
 - UK atopic dermatitis diagnostic criteria
- COVID-19
 - Before/after COVID guidance (hand washing, etc.) was imposed.

Parent report use of study emollients (“adherence”), other emollients (“contamination”) and TCS

Median (IQR) number of days of use per participant-week

| | Lotion (n=115/137) | Cream (n=116/140) | Gel (n=110/135) | Ointment (n=114/138) | Overall | P-value ^a |
|-----------------------------------|-----------------------|----------------------|--------------------|-------------------------|----------|----------------------|
| Study emollient use: | 5 (0, 7) | 6 (0, 7) | 4 (0, 7) | 3 (0, 7) | 4 (0, 7) | 0.481 |
| Non-study emollient use | 0 (0, 1) | 0 (0, 0) | 0 (0, 1) | 0 (0, 2) | 0 (0, 7) | 0.112 |
| Topical corticosteroid use | 0 (0, 2) | 0 (0, 2) | 0 (0, 2) | 0 (0, 2) | 0 (0, 2) | 0.819 |

Adverse reactions by emollient type

| Proportion (%) of participants reporting at least one adverse reaction in weeks 1-16 | | | | | |
|---|--------|-------|-----|----------|---------|
| Adverse event | Lotion | Cream | Gel | Ointment | Overall |
| Worsening of eczema | 20 | 25 | 27 | 23 | 24 |
| Itching | 18 | 24 | 28 | 21 | 23 |
| Redness/inflammation | 18 | 20 | 24 | 20 | 20 |
| Dryness | 14 | 16 | 20 | 15 | 16 |
| Stinging | 20 | 17 | 19 | 9 | 16 |
| ... | | | | | |
| Skin infection | 2 | 1 | 3 | 3 | 2 |
| Slip or fall | 1 | 3 | 0 | 3 | 2 |
| Total | 36 | 39 | 40 | 35 | 37 |

Nested qualitative study

44 parents (25 children)

Themes

- Balancing effectiveness and acceptability
- Effectiveness as the primary driver of preference
- Acceptability influences choice when effectiveness is satisfactory
- Emollients evaluated through ideas of 'thickness' and 'absorption'

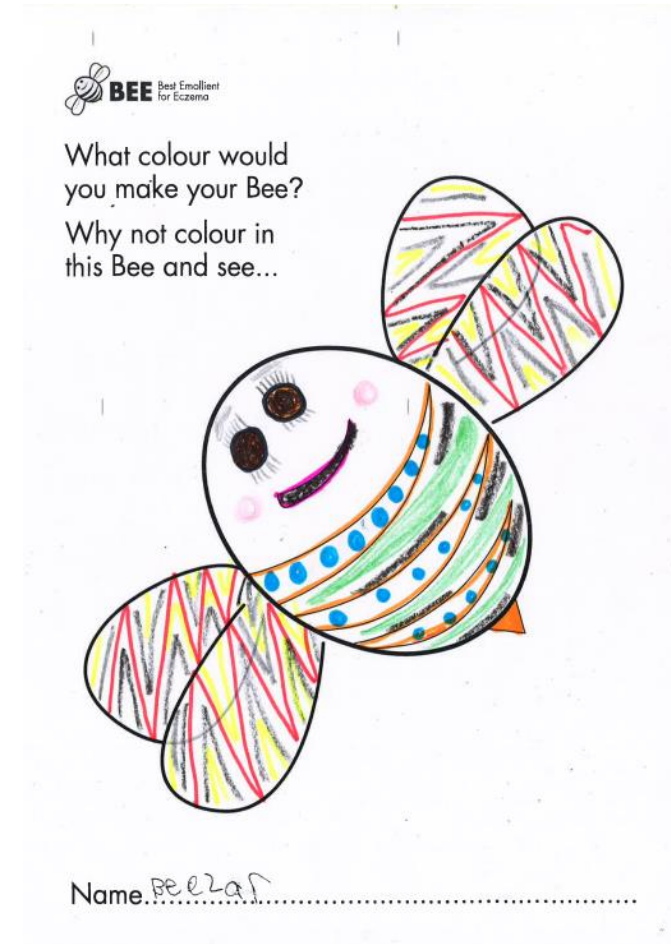
No “one size fits all”

Strengths

- Pragmatic, randomised, parallel group trial
- Commonly used types of emollients in primary care population
- Repeated measures analysis
- Objective, secondary outcome
- Nested qualitative study
- PPI

Weaknesses

- Patient completed outcome by unmasked parent
- Challenging to capture use of topical treatments
- “Study-approved” lotions, creams, gels and ointments
- No control group



Quick
poll
question



Summary

- First trial to directly compare emollients commonly used in UK
- No one type of emollient more effective than another
 - Symptoms (POEM, inc by expectation, age, severity and UK diagnostic criteria)
 - Signs (EASI)
 - Quality of life, impact on family or disease control
- Weekly use similar across different types
- Localised skin reactions common (~1:3)
 - Less stinging with ointments
- Educate and offer choice
 - Awareness of different types
 - Share decision making
 - How to use



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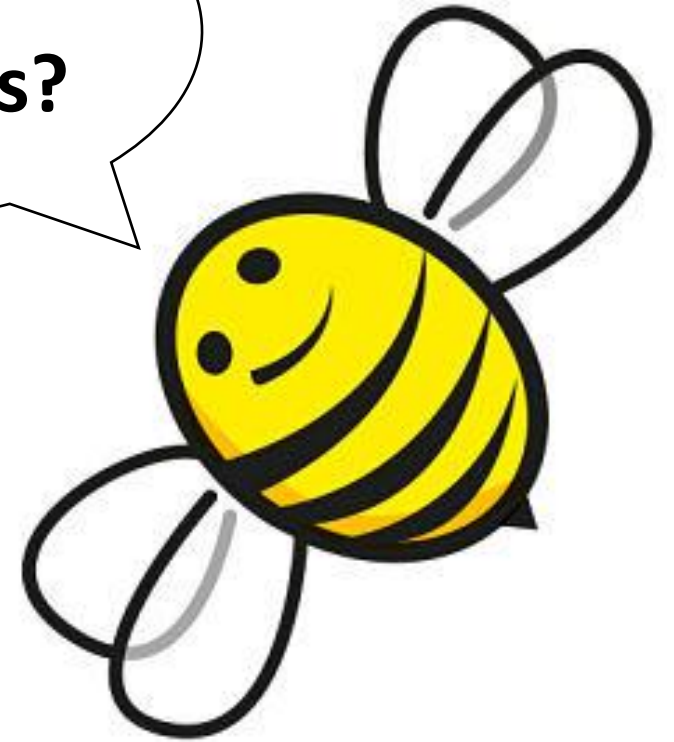
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**Any
questions?**



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