RISP

Research Information Sheet for GP surgeries

BEE - The Best Emollient for Eczema trial

CPMS ID	34197
IRAS ID	214900
Study design	Phase IV pragmatic, multi-centre, individually randomised, parallel group superiority trial of four types of emollients in children with eczema, with internal pilot and nested qualitative study.
Study procedures	**Baseline visit**: • a member of the research team will confirm eligibility • explain the study, receive consent and • undertake baseline assessments • Participants will be then randomised by the research team in a 1:1:1:1 ratio to a lotion, a cream, a gel or an ointment (with directions to apply twice daily and as required) as the only leave-on emollient for 16 weeks. Other treatments, such as topical corticosteroids, can be used in line with standard care. • The research team will then inform the GP of the treatment allocation and the GP will be asked to issue the prescription for the emollient. **Follow up:** • Parents are asked to complete weekly questionnaires for 16 weeks following initiation of treatment. • At 16 weeks, a member of the blinded research team conducts a follow up visit. • Parent/child are then 'free' to use the emollient of their choice • Parents are asked to continue to complete monthly study questionnaires for 36 weeks. **End of study:** • At 52 weeks, parents are asked to complete a final questionnaire, including study experiences. • Relevant data will then be extracted from the participant's GP electronic medical record data from 4 weeks before and the duration of their time in the study. **Nested qualitative study:** • Initial recording of ~10-40 recruitment interviews with rapid analysis and feedback to recruiters to optimise recruitment process; in particular, identifying carer preferences and

	readiness to use allocated emollient as the only leave-on treatment for the first 16 weeks.
	• Two rounds of interviews with carers +/- children participants, including those who withdraw (actively or passively) and those who change emollients.
	  ○ First round with ~20 participants within first four weeks, with focus on emollient acceptability and perceived effectiveness.
	  ○ Second round with ~40 participants after 16 weeks will focus on experiences of emollient use and decision making around future use. Thematic analysis using constant comparative method.
	
	The primary end point of the study is at 16 weeks. Participants will be followed-up for 52 weeks.

Study aim and objectives	<u>Primary objective</u> To compare the medium-term (16 weeks) effectiveness of the four types of study emollient in children with eczema with respect to patient-reported eczema symptom. <u>Secondary objectives</u> To compare study emollients, medium- (16 weeks) and long-term (52 weeks), in respect to: • Patient-reported eczema symptoms • Objective assessment of eczema signs • Quality of life for the child • Impact of eczema on the family • Adverse events • Acceptability of and parent/carer satisfaction with study emollient • Frequency and quantity of study emollient and other emollient use • Use of other eczema treatments (including topical corticosteroids and topical calcineurin inhibitors) • Number of well-controlled weeks Qualitative study: • To understand and optimise recruitment processes • To explore facilitators or barriers to study emollient use • To explore carers' and children's experiences of study emollient use and their views about perceived effectiveness and/or acceptability of study emollients • To contextualise the trial findings, as an aid to interpreting the results and their potential impact on clinical practice
Primary care organisation target	7 (it is expected that practices with a patient list size ~20,000 will recruit double this).

Eligibility criteria	• Children aged 6 months or older and less than 12 years • Mild, moderate or severe eczema (Patient-Oriented Eczema Measure, POEM, greater than 2) diagnosed by an appropriately qualified healthcare professional • No known sensitivity to study emollient • Willing to be randomised to and use allocated emollient as sole leave-on emollient for 16 weeks • Not participating in another study currently or in the last 4 months Carer able to give consent and complete outcome measures.
Study activities	
Primary care organisation activities	Practices will be asked to: • Attend a site set up meeting (GP & practice manager time) • Conduct database search • Check list for exclusions • Send study team anonymised complete database search which includes reason for exclusion • Send invite letters (via Docmail) • Prescribe allocated study emollient (initial and any repeat prescriptions) • Practice manager attend meeting regarding electronic medical record review • Database search & export for electronic medical record review • Promote trial with poster and flyers • Practices with a list size of >10,000 will be offered to undertake a second database search, check lists for exclusions and mail out.
Research team contact details	Sian Wells, Trial Manager bee-study@bristol.ac.uk