Clinical Research Network
West of England

NHS
National Institute for Health Research

Research Information Sheet for Practices (RISP)

TEST – Trial of Eczema allergy Screening Tests

R&D assurances	Bristol / North Somerset / South Gloucestershire
CPMS ID	37831
IRAS ID	237046
Type of study	Interventional
Study design	Feasibility randomised controlled trial with economic scoping and nested qualitative study
Study aim and objectives	• To determine the feasibility of conducting a definitive randomised controlled trial to evaluate whether structured allergy history plus food allergy testing and advice can reduce the severity of eczema in children compared with usual care • To assess the feasibility of conducting an economic evaluation of the definitive RCT • To describe and explore GP and parent beliefs and practices regarding food allergy, food avoidance and allergy tests in children with eczema
Primary care organisation target	7 patients per practice
Duration of study recruitment	The study will run from 01/08/2018 to 31/01/2019
Service Support Costs (SSCs)	£144.94 per practice. Opportunistic invitation: £13.60 per patient, up to 5 patients per practice.
Research Costs (RC) (optional)	£451.92
Eligibility criteria	Inclusion: • Children aged 3 months or older and less than 5 years • Eczema diagnosed by an appropriately qualified healthcare professional (mild or worse) • Parent/carer able to give consent

	• Parent willing for their child to have allergy skin prick test (+/-) oral food challenge and complete outcome measures Exclusion: • medically-diagnosed food allergy or awaiting referral/investigations for possible food allergy • previous investigations for food allergy (does not include home testing)
	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) • Provide a consultation room for Research Nurse to conduct baseline and follow-up visits • GP available in unlikely event of severe adverse reaction to skin prick test at time of baseline visit • Practice manager attend meeting regarding electronic medical record review • Database search & export for electronic medical record review • Promote trial with poster and flyers
Patient involvement	**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 1:1 to the intervention or 'usual care' • Interventions include a structure allergy history; skin prick tests; followed by either reassurance and advice to ingest food(s); advice to avoid food(s) plus dietary advice; or referral for oral food challenge followed by reassurance or avoidance plus dietary advice

	• The research team will inform the GP of the treatment allocation and outcome of the tests **Follow up:** • Parents are asked to complete monthly questionnaires for 24 weeks following randomisation. • At 24 weeks, a member of the research team conducts a follow-up visit, usually in the participant's home. **End of study:** • At the 24 week visit, 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:** • Approximately 20 parents and 10 GPs will be interviewed at varying time points in the trial to capture any issues related to different stages of trial participation. • Beliefs about food allergies and experiences/ acceptability of skin prick tests and the conduct of the study will be explored
What are the likely benefits to the patient/primary care organisation?	There are potentially significant benefits for the NHS of improving long-term eczema management, avoiding serious allergic reactions, and improving childhood nutrition.
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RSI Contract	This is a recruiting study