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RESEARCH LETTER

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BabyBathe study protocol: A randomised controlled feasibility trial to change baby bathing practice during the first months of life

To the Editor,

Eczema carries the highest global burden of all skin diseases and produces substantial disease-related morbidity worldwide and affects up to 15% of infants and 6% of older children.[1] Eczema prevalence and time trends vary considerably between countries, but overall eczema appears to be increasing globally by an absolute rate of around 1% per decade in children and adolescents.[1] Eczema is not a new disease, but the significant variation in eczema prevalence and time trends between and within populations suggests that the condition may be partly preventable.

Eczema is a chronic fluctuating condition which causes substantial impact on quality of life through itch, distress and loss of sleep and there is no cure. Eczema can be conceptualised as a visible manifestation of an impaired skin barrier and we have previously demonstrated that skin barrier impairment precedes the emergence of eczema.[2] Whilst there are genetic determinants of an impaired skin barrier such as inheritance of mutations in the filaggrin (FLG) gene, environmental factors are believed to play an important role in the aetiology of skin barrier impairment and subsequent eczema in infancy. A key environmental risk factor for skin barrier impairment is bathing. Bathing in water alters skin physiology and often involves exposure to wash products such as soaps and detergents which can exacerbate any negative impact on the skin barrier.[3]

Frequent immersive bathing is a modern phenomenon. As Ashenburg records in *Clean – an unsanitised history of washing*, 'Historically people cleaned themselves piecemeal, using a basin and pitcher for a stand-up wash, or a small, low tub in which they sat for a sponge bath. Ultimately, a full bath or shower became the gold standard of cleanliness, but this did not happen for the majority of Europeans until the twentieth century.'[4] Routine infant skincare advice provided to women antenatally in the UK is very heterogeneous, often conflicting and not evidence-based.[5] The UK Royal College of Midwives website until recently recommended infant bathing 2–3 times per week from birth to 6 months. The Enquiring About Tolerance (EAT) Study[5] found 84% of infants were bathed ≥2 times per week and 30% at least daily at age 3 months.[6] At 3 months, almost 80% had at least one wash product used on them in a typical bath, and nearly a third had bubble bath added to their bath, in a population of 1303 infants from England and Wales. Conversely, only 16% of the infants were bathed once a week or less.[6]

Bathing, even with tap water alone, has a negative effect on skin physiology. Tap water (pH 7.9–8.2) increases naturally acidic skin pH by 0.19, decreases skin fat content by 0.93 μg/cm^2 and changes enzymatic activity in the upper epidermis.[3,7] In the EAT study[5] a dose–response relationship was observed between bathing frequency at 3 months and an objective measure of skin barrier function, transepidermal water loss (TEWL).[6] Daily bathing was associated with an odds ratio of having an elevated TEWL (≥15 g/m^{2}h) of 4.62 (95% confidence interval (CI) 2.61–8.21) compared with bathing once a week or less. The PreventADALL study found that daily bathing led to a significantly increased risk of eczema by age 1 year (RR 1.57 95% CI 1.10–2.23).[8] The available evidence suggests that regular bathing with or without use of wash products may increase the risk of eczema, suggesting that advice to modify infant bathing practice by reducing bathing frequency or use of wash products may potentially prevent eczema development. Reducing the intensity of bathing may also impact on the risk of eczema developing. By 'intensity', we mean features of bathing which are likely to increase disruption of normal skin barrier function and skin physiology such as long duration of bathing, high water temperature and use of skincare products which adversely affect skin physiology and/or act as sensitising agents.

We are undertaking the BabyBathe study (ISRCTN51491794) (Figure 1). The full protocol and study supporting materials are available from FigShare (https://sgul.figshare.com/). We will work with pregnant women and their families to develop an acceptable intervention which aims to reduce infant bathing frequency and intensity. We will then undertake a randomised controlled feasibility trial recruiting 125 pregnant women from one hospital site in London, England. The sample size was rounded up and participants will be randomised at a ratio of 1:1 to the intervention advising reduced bathing frequency and intensity, with an associated reduction in use of wash products, versus standard care. The feasibility trial outcomes include the proportion of eligible families willing to be randomised; reported adherence and acceptability of the intervention; contamination of the control group; unblinding of outcome assessments

and loss to follow-up. The clinical outcome will be the presence of eczema at 6 months of age assessed using a modified form of the UK Working Party Diagnostic Criteria for Atopic Dermatitis. Ethical approval has been obtained from the North of Scotland Research Ethics Committee (22/NS/0120). Data analysis, interpretation and conclusions will be presented at national and international conferences, published in peer-reviewed journals and disseminated via social media, patient charities and support groups.

A simple intervention that prevents infants developing eczema would be an important advance in population health and may result

Summary box

- To work with pregnant women to develop an acceptable intervention to reduce infant bathing frequency
- To undertake a randomised controlled feasibility trial to estimate the proportion of eligible families willing to be randomised to the intervention, their adherence to the intervention and its acceptability

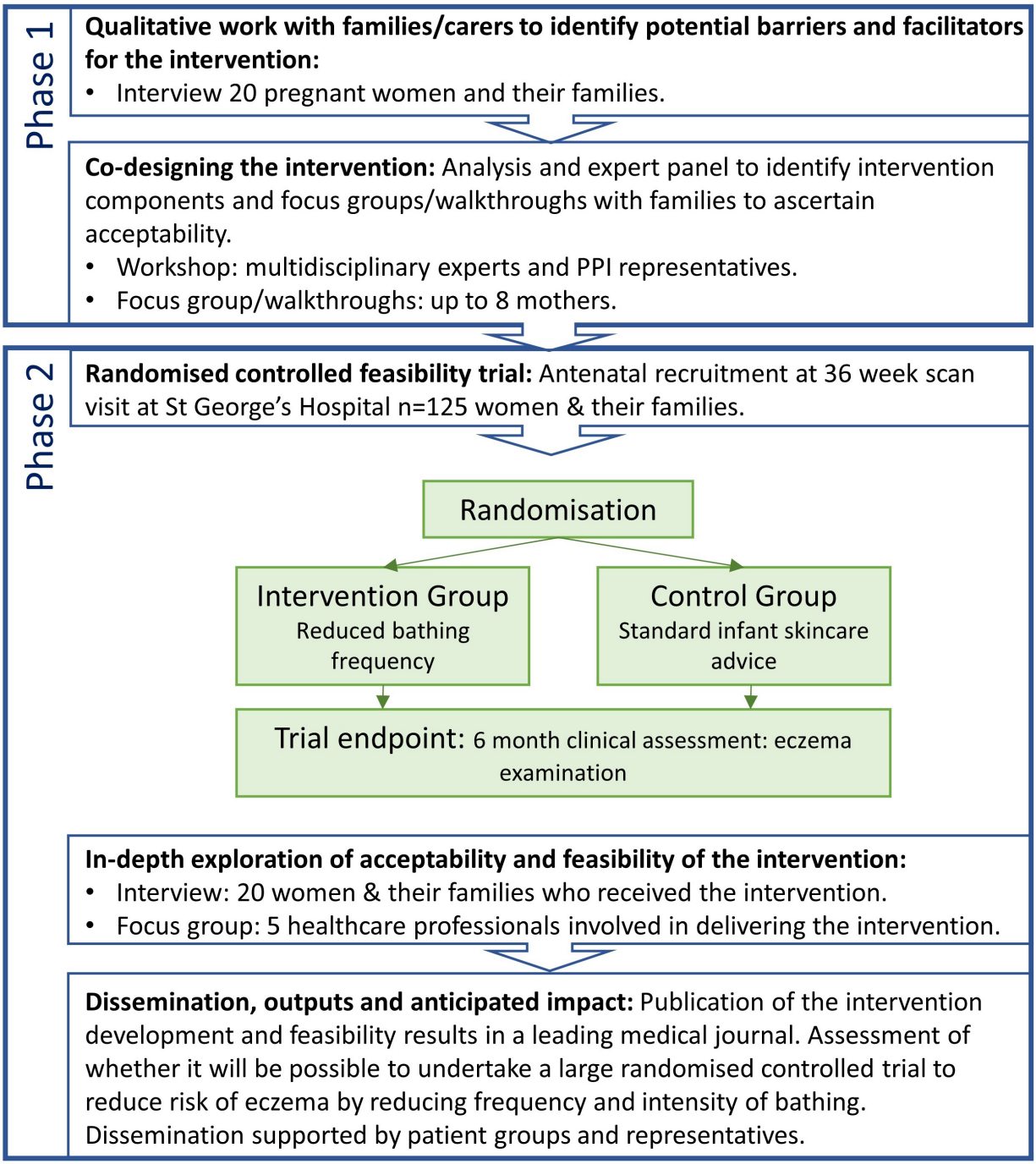

FIGURE 1 Overview of the BabyBathe study.

in direct savings to families and the environment through reducing the need to purchase bathing products and use hot water. The results of this feasibility trial will inform whether it is possible to undertake a large-scale, multicentre, randomised controlled trial of the intervention.

AUTHOR CONTRIBUTIONS

MP, RB and CF conceived of the study. MP, RB, CF, MU, VC and AR were co-applicants for funding. MP, RB and MU are joint chief investigators. All authors contributed to the study design and to the development of the protocol. MP and RB led on the trial aspects of protocol development, MU led on qualitative/process evaluation aspects and VC (study statistician) led quantitative analysis aspects. MP, MU and RB wrote the study protocol, with comments and approval from CF, VC and AR. MP drafted the research letter. All authors have read and approved the final manuscript and have agreed to publication.

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CONFLICT OF INTEREST STATEMENT

The authors declare no completing interests.

DATA AVAILABILITY STATEMENT

The study protocol and associated supporting materials are available open access at FigShare (https://doi.org/10.24376/rd.sgul.25126115.v1).

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