Establishing and augmenting acceptability of the Fever trial: a mixed methods feasibility study

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Introduction: Optimal fever management in critically ill children is unknown. We explored parent and practitioner views on the feasibility of a trial investigating temperature thresholds (37.5°C v 39.5°C) for the administration of paracetamol in children with fever and suspected infection.

Methods: 1) Pre-trial focus groups with practitioners and interviews with parents to inform the pilot trial design. 2) Embedded study within the pilot trial involving focus groups and surveys with parents and practitioners and interviews and questionnaires with parents of randomised children. Data analysis drew on Sekhon et al’s (2017) theoretical framework of acceptability.

Results: 1) Parents (n=25) were interviewed and practitioners (n=56) took part focus groups. Overall parents found the proposed trial acceptable. However, parents and practitioners raised concerns regarding proposed thresholds and not using paracetamol for pain or discomfort. Findings informed changes to the pilot trial protocol, participant information and site training. 2) Sixty parents of 57 randomised children took part in interviews and/or questionnaire; and practitioners (n=98) took part in either a focus group or survey. Both groups found the pilot RCT acceptable, with pre-trial research assisting practitioner ‘buy-in’. However, concerns about children being in pain or discomfort when weaned from ventilation led to cases of withdrawal and protocol non-adherence. Nevertheless, n=87/100 parents provided consent and supported the trial. Practitioners had polarised views on the acceptability of the higher temperature threshold; those trained by the Fever team found it more acceptable than those trained by site colleagues.

Discussion: Challenges to delivering proposed trial included concerns about the acceptability of the protocol. Pre-trial research and experience of pilot trial conduct augmented views, providing insight into how challenges may be overcome; such as changing the inclusion criteria and delivery of site training. All seven constructs of the framework of acceptability would then be met. The Fever trial was deemed feasible.