SWAT 194: The neoGASTRIC SWAT: to evaluate the effectiveness of presenting parents with different modes of trial information

Objective of this SWAT
To evaluate the effectiveness of presenting parents with trial information using hand-held digital multimedia and written information leaflet, compared to a standard written information leaflet, on recruitment, retention and informed decision making in the neoGASTRIC trial (ISRCTN16710849).

Study area: Recruitment, Retention, Informed Decision Making
Sample type: Carer/Parent
Estimated funding level needed: Very Low

Background
Parents in neonatal units can experience high levels of stress and fear related to their infants' condition and the unfamiliar environment can exacerbate parental stress.[1] Parents may be approached about participation in a research study when their newborn is critically ill, and may therefore struggle to comprehend written information, or have the capacity to make an informed consent decision.[2] There is a need to explore potential alternative approaches to presenting trial information to parents [3] in the neonatal care setting, and in trials using opt-out consent, to facilitate recruitment, retention and informed decision making in neonatal trials.

Interventions and comparators
Intervention 1: Information leaflet, neoGASTRIC study posters and a video presentation of trial information
Intervention 2: Information leaflet and neoGASTRIC study posters

Index Type: Participant Information

Method for allocating to intervention or comparator
Various

Outcome measures
Primary: Parent did not opt out of infants participation in the trial pre-randomisation.
Secondary: Parent did not opt out of infant's participation in the trial post-randomisation and the quality of parental decision making.

Analysis plans
The primary analysis will be based on an intention-to-treat approach. Participants with outcome data will be analysed in the SWAT groups to which they were assigned, regardless of deviation from the protocol or procedure received.
The comparator group will be used as the reference group in all analyses.
For the primary and secondary binary outcomes, risk ratios and confidence intervals will be calculated using a mixed binomial or Poisson model with a log link, with cluster as a random effect, and adjusting for level of unit as a fixed effect. Risk differences will also be calculated using a mixed binomial model with an identity link.
Descriptive statistics will be used to summarise the quantitative data on parental decision making.

Possible problems in implementing this SWAT

References
1. Dudek-Shriber L. Parent Stress in the Neonatal Intensive Care Unit and the Influence of Parent and Infant Characteristics. American Journal of Occupational Therapy 2004;58(5):509-20.
2. Deja E, Roper L, Tume LN, Dorling J, Gale C, Arch B, et al. Can they stomach it? Parent and practitioner acceptability of a trial comparing gastric residual volume measurement versus no gastric residual volume in UK NNU and PICUs: a feasibility study. Pilot and Feasibility Studies 2021;7(1):49.

3. Duane S, Vellinga A, Smith V, Tierney M, Beecher C, Burke M, et al. The effectiveness of digital multimedia presentation of trial information on recruitment and retention of patients: Protocol for a study within a trial (SWAT). [version 1; peer review: 2 approved]. HRB Open Research 2020;3(10).

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: National Perinatal Epidemiology Unit (NPEU) Clinical Trials Unit, University of Oxford
Contact email address: neoGASTRIC@npeu.ox.ac.uk
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Revisions made by:
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