SWAT 225: Impact on recruitment of using an infographic in addition to the participant information sheet

Objective of this SWAT
1. To assess the impact on recruitment of using a simple specially developed information graphic (infographic) in addition to the standard participant information sheet (PIS) to explain the two treatment arms of the EASY Study [NIHR152733] to parents/guardians of eligible children.
2. To explore satisfaction with and understanding of the EASY study consent process.

Study area: Recruitment, Retention
Sample type:
Estimated funding level needed: Very Low

Background
Recruitment and retention to trials in a paediatric emergency setting is challenging because there is very little or no time for parents/guardians to consider research information and decide about their baby's involvement in a study. Parents can be distressed and understandably focused on their baby, often prioritising verbal information provided by clinicians over written study information. However, brief verbal information provision by practitioners in the emergency setting has been associated with poor parental understanding and poor recall of any aspect of the study presented [1]. Furthermore, practitioner views and preferences may influence how they present the study or lead to misunderstanding by parents/guardians, which may impact upon trial recruitment and retention [2, 3].

We will explore ways to improve this in this cluster randomised Study Within a Trial (SWAT), including assessing the effect of an infographic and collecting information on the consent process. Guidance on how to use the infographic will be provided to those sites allocated to use it during the site initiation visit. The infographic is a simple, brief representation of the information provided in the standard PIS about the two treatments and was developed with input from the Patient and Public Involvement and Engagement (PPIE) group for the EASY study. The intention is to prompt a more structured conversation between the consenting clinician and the parent/guardian of the eligible child and how the randomisation will influence their child's care pathway.

After being provided with the EASY study participant information sheet and infographic (if in the SWAT intervention arm), staff will ask each parent/guardian to complete a brief questionnaire within 48 hours post-screening. This will include those who were approached but declined their child's involvement in the trial. The questionnaire will aim to explore satisfaction with and understanding of the EASY study consent process, factors that may have informed decisions to decline participation in the EASY study and quality of decision making, which will be measured using the validated SURE scale [4]. The questionnaire will be placed in a stamped self-addressed envelope and returned by post to the Northern Ireland Clinical Trials Unit (NICTU), who are managing the trial. To avoid identifiable data being sent to the NICTU, written consent from the parent/guardian will not be sought for the questionnaire and, instead, consent will be implied by its completion and return.

Interventions and comparators
Intervention 1: EASY study sites allocated to the SWAT intervention arm will provide parents/guardians with an infographic in addition to the standard PIS during the consent process.
Intervention 2: Sites allocated to the control arm will use the standard PIS.

Index Type: Participant Information

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Recruitment rates

Secondary: Immediate post-randomisation withdrawal rate; retention rate at 28 days post-randomisation; cost per participant recruited and participant retained; satisfaction with and understanding of the consent process; and quality of parental decision making.

Analysis plans
Descriptive statistics will be used to summarise the outcomes by SWAT arm (where appropriate) including number (%) and means (95% confidence intervals). A separate SWAT analysis plan will be written before final analysis of the data.

Possible problems in implementing this SWAT
No problems are envisaged for the first objective. However, for the second objective, because the questionnaire will be given to all parents/guardians approached for consent, including those who decline their child's involvement in the trial, it is difficult to predict how many questionnaires will be returned.

References
[1] Roper L, Lyttle MD, Gamble C, et al. Seven-step framework to enhance practitioner explanations and parental understandings of research without prior consent in paediatric emergency and critical care trials. Emergency Medical Journal 2021;38(3):198-204.
[2] Deja E, Peters MJ, Khan I, et al. Establishing and augmenting views on the acceptability of a paediatric critical care randomised controlled trial (the FEVER trial): a mixed methods study. BMJ Open 2021;11(3):e041952.
[3] Pant S, Elias MA, Woolfall K, et al. Parental and professional perceptions of informed consent and participation in a time-critical neonatal trial: a mixed-methods study in India, Sri Lanka and Bangladesh. BMJ Global Health 2021;6(5):e005757.
[4] Ferron Parayre A, Labrecque M, Rousseau M, et al. Validation of SURE, a four-item clinical checklist for detecting decisional conflict in patients. Medical Decision Making 2014;34(1):54-62.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Revisions made by:
Date of revisions: