Appendix 2: STUDY WITHIN A TRIAL(SWAT) UK ONLY

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 (31). 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 (22). There is a need to explore potential alternative approaches to presenting trial information to parents (32) in the neonatal care setting, and in trials using opt-out consent, to facilitate recruitment, retention and informed decision making in neonatal trials.

SWAT Aim

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.

SWAT Objectives

1. To establish if parents are less likely to opt out of their infant's participation in the neoGASTRIC trial prior to randomisation if trial information is provided using hand-held multimedia, written and poster presentation compared to written and poster information alone
2. To establish if parents are less likely to opt out of their infant's participation in the neoGASTRIC trial post randomisation if trial information is provided using hand-held multimedia, written and poster presentation of information compared to written and poster information alone
3. To determine if the quality of parental decision making is affected by presentation mode.
4.

SWAT DESIGN

A cluster randomised trial within the neoGASTRIC trial, UK centres only. Sites will be randomised at a cluster level. The SWAT randomisation will be stratified on the level of unit (LNU/SCBU and NICU).

SWAT eligibility criteria

Inclusion criteria: Parents of children eligible for inclusion in the neoGASTRIC trial

Exclusion criteria: Parents who do not speak one of the languages in which the patient information materials and video presentation are available

SWAT recruitment and sampling

neoGASTRIC sites will be randomised to either:

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

The SWAT randomisation will be stratified on the level of unit (LNU/SCBU and NICU). Sites will be randomised via a secure randomisation website (developed by a Senior Trials Programmer) accessible to the Trial Manager.

SWAT objective 3 will be addressed through parents' participation in process evaluation interviews. Please see Section 11.5 for details of recruitment and sampling and 11.6 for data analysis. Interviews will include verbal questions and an administered questionnaire to assess quality of decision-making.

SWAT outcomes

Primary outcome:

parent did not opt out of infant's participation in the trial pre-randomisation

Secondary outcomes:

parent did not opt out of infant's participation in the trial post-randomisation

quality of parental decision making

SWAT sample size

In a cluster-randomised design, where 18 centres are randomised to the intervention and 18 centres to the comparator group, there would be 36 clusters of 277 parents (assuming a 30% incidence of multiple births). If an intra-cluster correlation coefficient of 0.05 is assumed, this would give a design effect of 15. Assuming equal-sized clusters, a background recruitment rate of 60% and two-sided 5% significance level, a cluster-randomised SWAT would have 90% power to detect a 12% absolute increase in uptake from 60% to 72% (i.e. reduction in opt-outs from 40% to 28%), and 80% power to detect a 10% absolute increase in uptake from 60% to 70% (i.e. reduction in opt-outs from 40% to 30%).

SWAT analysis

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 are 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.

For the analysis of the qualitative parental decision making data please refer to section 11.6 for detail. We will use descriptive statistics to summarise the parental decision making quantitative data.