AIM

To evaluate the effectiveness of presenting parents with a short video animation explaining the importance of routine data in clinical care and research, on the parental opt-out and withdrawal rates for the WHEAT trial.

OBJECTIVES

Primary Objective

To establish if parents are less likely to opt-out of their infant's participation in the WHEAT trial if they are given information on the use of routine data in clinical research, in addition to WHEAT trial specific parent information.

Secondary Objective(s)

To establish if parents are less likely to withdraw their infant from the WHEAT trial post randomisation if they are given information on the use of routine data in clinical research, in addition to WHEAT trial specific parent information.

DESIGN

A Study Within a Trial (SWAT): A cluster randomised trial nested within participating UK WHEAT trial sites.

Randomisation will be stratified on the level of unit (LNU/SCBU and NICU).

ELIGIBILITY

Inclusion criteria

- Parents of pre-term neonates eligible for inclusion in the WHEAT trial

Exclusion criteria

- Parents who do not speak one of the languages in which the patient information materials and video presentation are available (currently only in English).

INTERVENTION

WHEAT sites will be randomised 1:1 to either:

1. Intervention: A small card containing a link to a short, 3-minute animated video explaining the importance neonatal research and of routinely recorded clinical data for research. This will be delivered to parents at the same time as information about the WHEAT trial is provided to them.

2. Comparator: Information about the WHEAT trial only.

The intervention is a 3-minute animated video hosted on the WHEAT trial website (http://neoepoch.com/wheat-trial) which will be made available to parents by providing them with a small card with a QR code which links directly to the video clip. The video animation gives a plain English explanation of the importance of neonatal research and the use of routine clinical data in research and includes audio from interviews of parents who have had babies involved in research from the WHEAT trial Parent and Public Advisory Group.

Research staff at sites participating in the intervention arm of the SWAT sub-study will present parents of babies eligible for the WHEAT trial with a small card containing a QR code which links to the intervention video on the WHEAT trial website. Parents will be asked to scan the QR code using their own smartphone, from which they will watch the video animation.

Comparator arm sites will continue to approach parents/guardians of potentially eligible babies for the WHEAT trial in the usual way. The stratified block randomisation will be performed via two separate sequences of the arms for each stratum (NICU, LNU/SCBU) generated randomly by a statistical software code with the block size of 4. The randomisation sequence will be concealed from all researchers involving in the study.

OUTCOMES

Primary Outcome

- Parental opt-out rate for the WHEAT trial pre-randomisation

Secondary Outcomes

- Parental withdrawal rate from the WHEAT trial post-randomisation

SAMPLE SIZE

36 NHS Trusts are participating in the WHEAT trial and will be randomly allocated on a 1:1 basis (18 units in each arm) to intervention and comparator arms. Assuming an average cluster size of 50 babies, intraclass correlation of 0.05, and a baseline percentage for opt-out of 32% (based upon initial recruitment), 18 clusters in each arm will provide 80% power to detect a difference of 11.4% in opt-out rates between intervention and control at an alpha of 0.05. Additional participating sites will also be randomised into the SWAT as they open to recruitment to WHEAT.

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 modified Poisson model with a log link and robust variance of error, 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.