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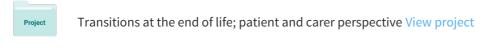


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Site initiation visit (SIV) training to improve practitioners' confidence in recruiting to a challenging critical care trial

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@eclipsestudy

Aim

To evaluate the effectiveness of site initiation visit (SIV) training on healthcare practitioners' (HCP) confidence in the recruitment of patients to EcLiPSE. The interactive SIV training included:

- protocol presentations from the trial team;
- screening and randomisation simulation (video and real-time);
- a video of the consent recruitment conversation informed by feasibility work with parents (CONNECT study), and
- a question and answer session.

EcLiPSE is an un-blinded pragmatic, randomised and controlled trial that compares the use of levetiracetam versus phenytoin in the treatment of status epilepticus in children.

Challenges to the success of EcLiPSE include: a vulnerable target population (children aged 6 months to <18 years); the need to administer the intervention without prior informed consent (termed, 'deferred consent'); and the use of levetiracetam, a relatively new anti-epileptic medication which is not traditionally usually used in this acute clinical setting.

Design

Mixed method study including a

14 item questionnaire
administered before and after
the site training and telephone
interviews with EcLiPSE
recruiters in the first 12 months
after site opening.

Setting: UK hospitals.

Participants: 26/30 (87%)
EcLiPSE sites including 170/333
(51%) practitioners, of which
125/333 (38%) were included in
analysis. We interviewed
Principal Investigators (n=5) or
lead research nurses (n=3)
between 6-12 (mean= 8.1)
months after training.



Site initiation visit training at Bristol Royal Hospital for Children



Simulation practice during site initiation training in The Children's Hospital, Cardiff



Recruitment conversation training video for staff taking consent, filmed at The University of Liverpool

Findings

- For most sites EcLiPSE was their first Emergency Department led paediatric clinical trial.
- Before training, over half (69/115, 60.2%) of practitioners anticipated that there would be practical or logistical difficulties issues in participating in EcLiPSE.
- Practitioners spoke of the importance of getting all staff "on board" and enthused.
- Following training there was a **significant positive change in practitioners' confidence** in explaining: the study (p=<0.001); randomisation (p=<0.001), research without prior consent (p=<0.001), and responding to parents who object to the study (p=<0.001).
- Valued aspects: videos, parent perspectives, and the number of EcLiPSE team members involved in training and attending the SIV.

"Good to see how nurse handled difficult questions" (P27, Research nurse)

"I think enough of you (EcLiPSE team) turned up"

(P4, Principal investigator)

Conclusions

training Interactive site effectively important assist in' practitioners 'buy challenging clinical trials. Our findings highlight how pre-trial feasibility work with parents can improve practitioners confidence recruitment and consent seeking in a paediatric critical care trial.



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