Engagement of children, families and health professionals in children's trials

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MRC Hubs for Trials Methodology Research
North West Hub

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Children's clinical trials: some issues

- Many treatments given to children not properly tested
- Recruitment/consent in children's trials often perceived as complicated
- More children's than adults' trials close prematurely (40 % v 29%)[1] – slow recruitment most common reason
- Distinct complexities in trials of emergency treatments for children

1 Schandelmaier et al, Journal of Pediatrics. 2017;184:209-14.

Feasibility of proposed trial of steroid delivery: juvenile arthritis

Sherratt, Roper, Stones; McErlane, Peak, Beresford, Foster, Ramanan, Rooney, Baildam, Young

- Qualitative interviews - children (N=9; 8-16 years) with JIA and parents (n=19) to inform design of proposed trial of different steroid induction delivery routes (SIRJIA study)
- Both parents and children pointed to challenges with the design
- Past experiences of steroids influenced willingness to participate
- But even those without direct experience of a particular steroid could have strong views on treatment suitability; clinician influence important here
- Preferences of children and parents often differed; children more willing to participate than parents

NHS
National Institute for Health Research

Optimising recruitment for future trial of non-operative treatment for simple acute appendicitis in children

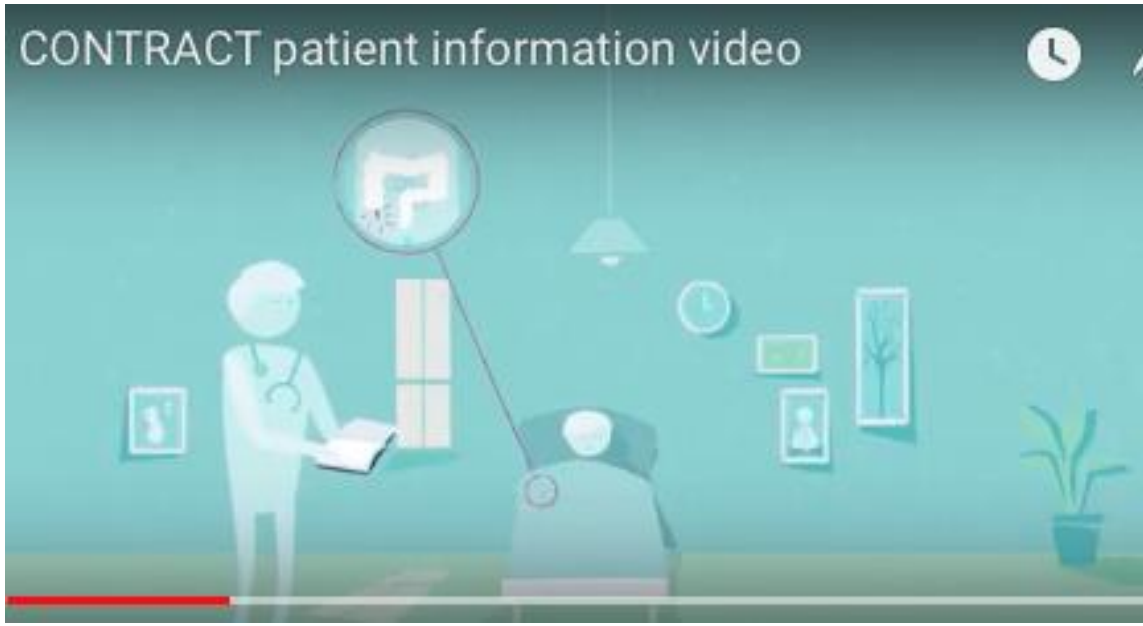
Frances Sherratt, Lucy Beasant, Esther Crawley, Nigel Hall & Bridget Young

- CONTRACT – pilot trial and feasibility study for future trial of non-operative treatment (antibiotics) v surgery for acute appendicitis
- Embedded qualitative study – to enhance communication and optimise recruitment

Methods:

- Recruitment consultations (N =58), practitioner interviews (N =36), and child/parent interviews (N =28 families)

CONTRACT: Lead Nigel Hall, University of Southampton



CONTRACT

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Initial findings

Families who declined concerned about treatment failure/recurrence with antibiotics

Parents tended to favour surgery - previous experience of perforated/complicated appendicitis

> [My appendix] was left when I was young and mine actually ruptured, so I was an emergency, rushed in… If we leave his and it doesn't work, I don't want him to be in that same boat

Children tended to prefer antibiotics/wanted to avoid surgery

> I wanted him to have the surgery… I briefly told him [son] what [the study] was and he just said, 'I want to do the study', because he didn't want the surgery

- Analysis of consultations and interviews informed clinician training
- Focus on giving balanced information about treatment arms and exploring treatment preferences

Initial findings

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Consent rate rose after clinician training; overall rate at end of trial was 50%

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information about treatment arms and exploring treatment preferences

TRECA study (Trials engagement with children and adolescents)

Lead: Peter Knapp, University of York

Develop multimedia websites for children/families when invited to a trial

- Phase 1: two rounds of qualitative interviews/focus groups with 62 children, parents and practitioners
- Phase 2: evaluation of websites via SWATs of recruitment in six trials

Qualitative findings – informed websites including: which information to make prominent, design, layout, animations, characters etc.,

Animations:

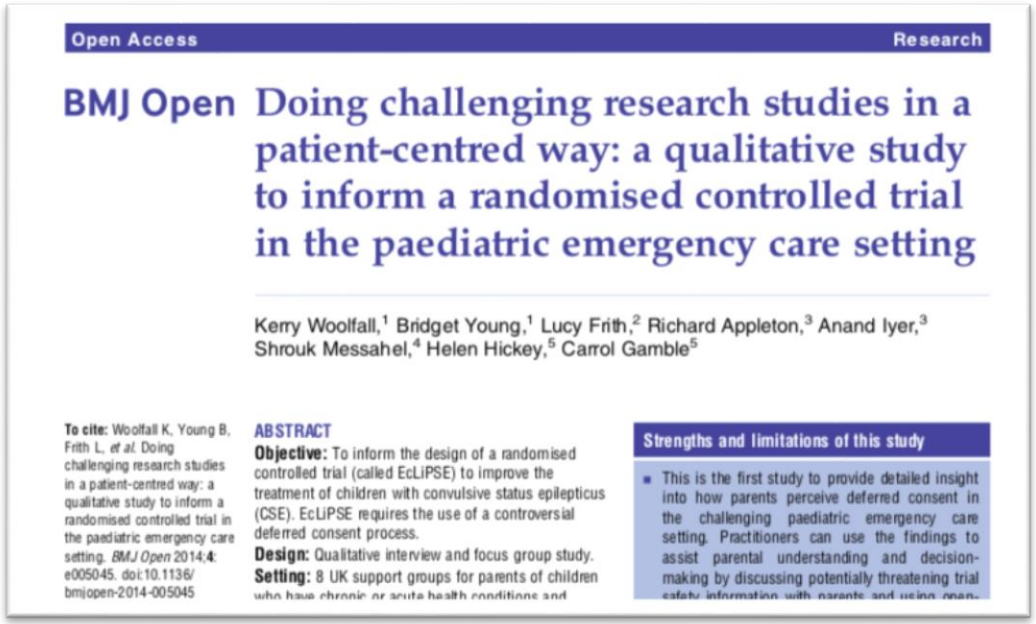
- Why do we do trials?
- What is a trial?
- Who is in a research team?
- Consent and assent
- Explainer animation – overview of each specific study

TRECA
TRials Engagement in Children and Adolescents

NHS
National Institute for Health Research

EcLiPSE trial: pre-trial qualitative feasibility study

Lead: Kerry Woolfall, University of Liverpool



Open Access Research

BMJ Open **Doing challenging research studies in a patient-centred way: a qualitative study to inform a randomised controlled trial in the paediatric emergency care setting**

Kerry Woolfall,[1] Bridget Young,[1] Lucy Frith,[2] Richard Appleton,[3] Anand Iyer,[3] Shrouk Messahel,[4] Helen Hickey,[5] Carrol Gamble[5]

To cite: Woolfall K, Young B, Frith L, *et al*. Doing challenging research studies in a patient-centred way: a qualitative study to inform a randomised controlled trial in the paediatric emergency care setting. *BMJ Open* 2014;**4**: e005045. doi:10.1136/bmjopen-2014-005045

ABSTRACT

Objective: To inform the design of a randomised controlled trial (called EcLiPSE) to improve the treatment of children with convulsive status epilepticus (CSE). EcLiPSE requires the use of a controversial deferred consent process.

Design: Qualitative interview and focus group study.

Setting: 8 UK support groups for parents of children

Strengths and limitations of this study

- This is the first study to provide detailed insight into how parents perceive deferred consent in the challenging paediatric emergency care setting. Practitioners can use the findings to assist parental understanding and decision-making by discussing potentially threatening trial

Treatment of status epilepticus in children not responding to first line treatment

'Research without prior consent' i.e. consent ***after*** giving the treatments being investigated

Interviewed parents (with experience of paediatric emergency care) supported the approach to consent, providing trial was safe

Method of consent acceptable ***in principle*** from parent perspective - main trial funded and ethics approval

Woolfall et al *BMJ Open* 2014 4.5: e005045

EcLiPSE

NHS National Institute for Health Research

CONNECT study: Consent methods in paediatric emergency and urgent care trials

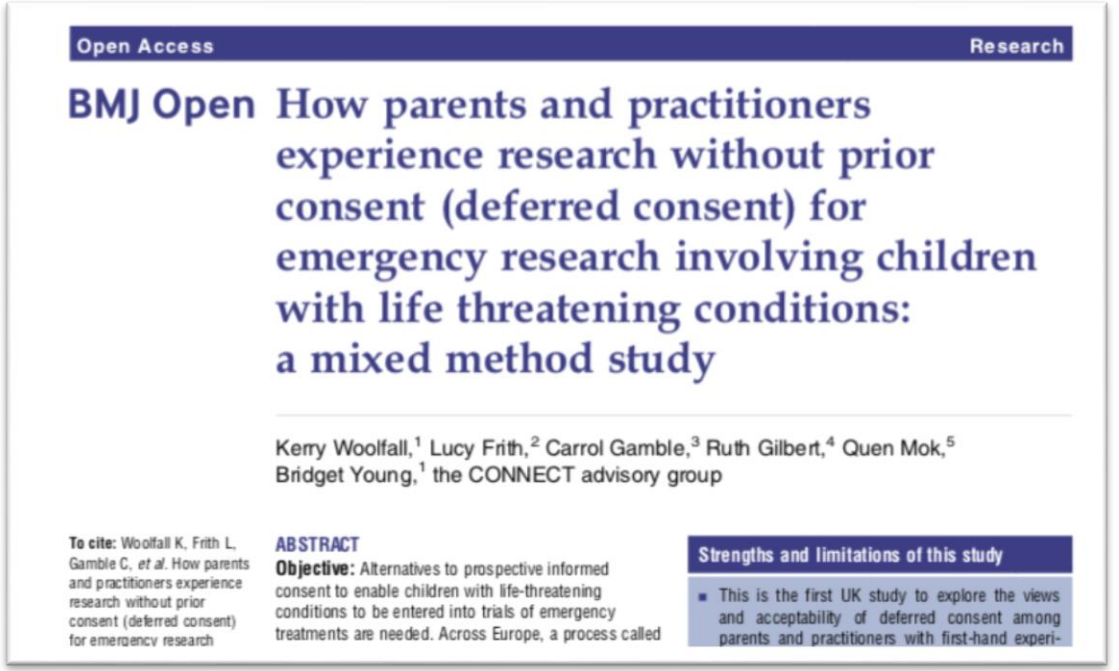
Mixed method study embedded in CATCH trial

275 parents surveyed; 20 parents interviewed; focus groups with 17 practitioners

Parents momentarily shocked that child had been entered into CATCH without their consent.

- Feelings resolved after practitioners explained reasons and that interventions were widely used in clinical care
- Parents felt decisions about participation had been voluntary but timing of discussions not always optimal

Practitioners initially apprehensive before seeking consent but this abated with experience



Open Access Research

BMJ Open

How parents and practitioners experience research without prior consent (deferred consent) for emergency research involving children with life threatening conditions: a mixed method study

Kerry Woolfall,[1] Lucy Frith,[2] Carrol Gamble,[3] Ruth Gilbert,[4] Quen Mok,[5] Bridget Young,[1] the CONNECT advisory group

To cite: Woolfall K, Frith L, Gamble C, *et al*. How parents and practitioners experience research without prior consent (deferred consent) for emergency research

ABSTRACT

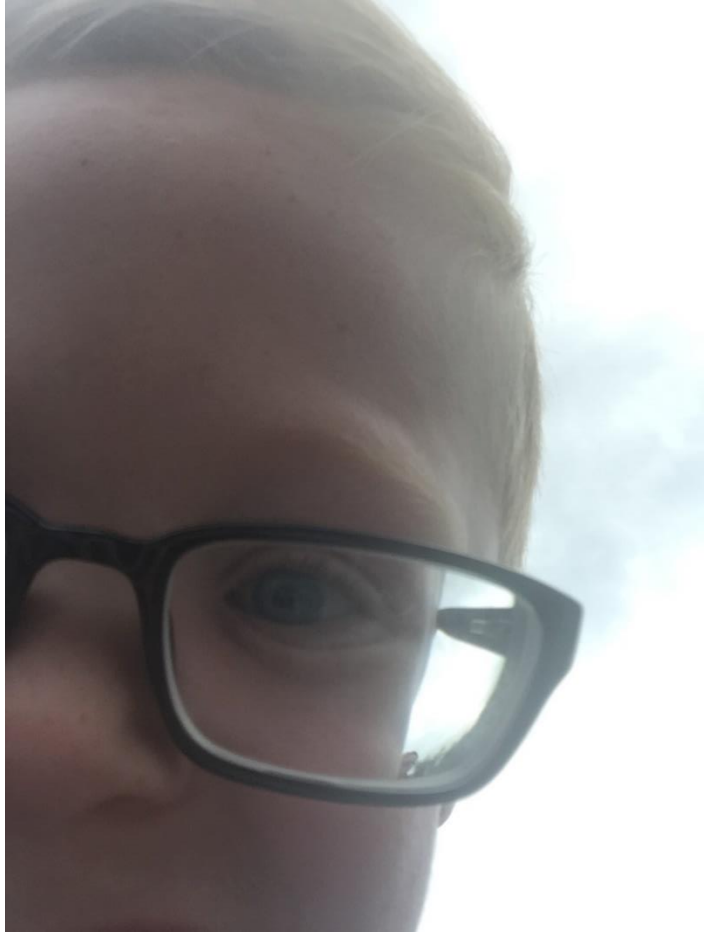
Objective: Alternatives to prospective informed consent to enable children with life-threatening conditions to be entered into trials of emergency treatments are needed. Across Europe, a process called

Strengths and limitations of this study

- This is the first UK study to explore the views and acceptability of deferred consent among parents and practitioners with first-hand experi-

The CONNECT Study

wellcome



What do children and young people think about research without prior consent (deferred consent) in critical care situations?

VOICES study - Woolfall et al

Paediatric critical care trials have high recruitment rates but children rarely participate in (deferred) consent discussions

VOICES study – interviewed children and young people (N= 16; 7-15 years) all had experience of critical care treatment in the previous 12 months

- Children felt research without prior consent was acceptable in emergency situations if trial interventions were safe
- Some held misconception that doctors would know which intervention was effective
- Felt children should be informed about the research on recovery and involved in discussions with clinicians/parents
- Suggested using an animation to help

Roper L, et al BMJ open. 2018 1;8(6):e022894.


THANK YOU