SWAT 97: TRECA (TRials Engagement in Children and Adolescents)

Objective of this SWAT
To evaluate multimedia information resources (MMIs) in a series of paediatric trials in the UK, testing their effects on recruitment and retention and decision-making by comparing the effect of providing standard written participant information with provision of the MMI either in addition to the standard written participant information or the provision of the MMI alone.

Study area: Recruitment, Retention, Quality of decision-making
Sample type: Participants
Estimated funding level needed:

Background
One important barrier to recruitment and retention is the quality of the information provided to potential trial participants [1]. Conventionally, participant information about a trial is provided in printed form, typically using a patient information sheets (PIS). These documents should be understandable to potential trial participants and assist their decision making [2]. However, the format of this information has received recurrent criticism, notably for being too long, difficult and technical [3,4]. Multimedia information resources (MMIs) offer a different method of providing information about clinical trials to children, young people and their families [5,6] and we will test them in this SWAT.

Interventions and comparators
Intervention 1: MMI only (participants receive information about the trial by viewing a multimedia website)
Intervention 2: PIS only (participants receive information about the trial by PIS)
Intervention 3: Both MMI and PIS (participants receive information about the trial by both MMI and PIS)

Index Type: Participant Information, Method of Recruitment

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Recruitment rate
Secondary: Retention rate; quality of decision making

Analysis plans
Planned meta-analysis. Details to be confirmed

Possible problems in implementing this SWAT
Difficulties with internet access at the sites for the host trials.

References
1. Ross S, Grant A, Counsell C, Gillespie W, Russell I, Prescott R. Barriers to participation in randomised controlled trials: a systematic review. Journal of Clinical Epidemiology 1999;52:1143–56.
2. Behrendt C, Golz T, Roesler C, Bertz H, Wunsch A. What do our patients understand about their trial participation? Assessing patients' understanding of their informed consent consultation about randomised clinical trials. Journal of Medical Ethics 2011;37:74–80.
3. Caldwell PH, Dans L, de Vries MC, Newman B, Hons J, Sammons H, et al. Standard 1: consent and recruitment. Pediatrics 2012;129(Suppl 3):S118–23.
4. Tarnowski KJ, Allen DM, Mayhall C, Kelly PA. Readability of pediatric biomedical research informed consent forms. Pediatrics 1990;85:58–62.
5. Tait AR, Voepel-Lewis T. Digital multimedia: a new approach for informed consent? JAMA. 2015;313:463–4.
6. Hutchison C, Cowan C, McMahon T, Paul J. A randomised controlled study of an audiovisual patient information intervention on informed consent and recruitment to cancer clinical trials. British Journal of Cancer. 2007;97:705–11.

Publications or presentations of this SWAT design

Developing and evaluating multimedia information resources to improve engagement of children, adolescents and their parents with trials (ISRCTN73136092)

Martin-Kerry J, Bower P, Young B, Graffy J, Sheridan R, Watt I, et al. Developing and evaluating multimedia information resources to improve engagement of children, adolescents, and their parents with trials (TRECA study): Study protocol for a series of linked randomised controlled trials. Trials. 2017;18:265

Examples of the implementation of this SWAT

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Date of idea: 1/APR/2015
Revisions made by:
Date of revisions: