SWAT 188: Stakeholder perceptions of recruitment to SafeBoosC III trial

Objective of this SWAT
To explore the experiences of recruitment to the SafeBoosC III trial (NCT03770741) and help to answer two methodological questions from the PRioRiTy study [1] that prioritised the top 10 questions for trial recruitment research:
PRioRiTy question 6: What are the key motivators influencing members of the public's decisions to take part in a randomised trial?
PRioRiTy question 7: What are the best approaches to ensure inclusion and participation of under-represented or vulnerable groups in randomised trials?

Study area: Recruitment, Retention
Sample type: Researchers, Trial Team, Participants
Estimated funding level needed: Medium

Background
We will conduct a qualitative descriptive study, based on the work of Sandelowski,[2,3] to explore the experiences of parents of recruitment to neonatal clinical trials. This will inform the understanding of health professionals and researchers working in neonatology and provide a greater insight into parents' perceptions and needs. The aim is to describe participants' perceptions, experiences and concerns and to comprehensively summarise these.[2,3] The researchers will stay close to the data and the final product will be a description of the participants' experiences in a language similar to the participants own language.[2]

Researchers using a qualitative descriptive (QD) methodology also stay close to the surface of words and events as described by participants.[2,4,5] A QD approach is appropriate when seeking to understand complex "phenomena" from the people who are directly experiencing it.[6] Using this approach will provide a description and facilitate understanding of participants' experiences of recruitment to neonatal clinical trials and the strategies they have used to navigate it. In this SWAT, this will involve purposive individual semi-structured interviews and qualitative content analysis.[7]

Interventions and comparators
Intervention 1: Sample Recruitment.
When ethical approval is granted, permission to access the sample of parents meeting the inclusion criteria will be sought from the Consultant and the Director of Midwifery of four level 4 hospitals with maternity/neonatal services. Following this approval, a participant information leaflet (PIL) will be sent to parents who meet the inclusion criteria. They will be provided with details about the study, including aims, objectives, focus, ethical considerations and their rights. They will be given a telephone number should they have any queries and asked to indicate whether they will be willing to participate in the study and to return their answers by email. Only those indicating an interest in participating will be followed up and they will be asked to sign a consent form if they agree to participate in the study.

Ethical considerations
Ethical principles demand that study participants' confidentiality and anonymity are guaranteed.[8] Any identifying personal information will be removed from audio and transcribed interview narratives [9] and pseudonym or code numbers will be used on tapes, notes and transcripts to help protect the confidentiality of participants.[10] Some participants may get upset recounting their stories. In this instance, the interviewer will stop the interview, the participant will be allowed time to regain their composure and the interview will only resume if the participant is happy to do so. The participants will be followed up on the day after an interview to determine if they wish to talk to a counsellor and access will be prearranged if required. All participants will be treated fairly and justly throughout the research process.[11]

Data Collection
Semi-structured individual interviews will be used to gather data, in order to gain deep and meaningful insight into the stories of participants' experiences.[12] The interviews will be organised around a set of predetermined open-ended questions, with other questions emerging as the conversation progresses. Interviews have several advantages as a data collection method. They are useful for the generation of rich detailed data.[13,14] The interviewer has the opportunity to

follow up on interesting responses and investigate underlying motives.[9] They allow the simultaneous observation of non-verbal cues that can add further meaning to verbal content.[15] They allow an estimation of the intensity of feelings [16] and can include the possibility of new and unexpected information.[8] However, there are also some limitations of interviews. Many authors have suggested that interviews are more time consuming and expensive than other methods of data collection and that data collected in interviews are not generalisable because sample sizes are small.[14] Some authors have suggested that there is no anonymity of responses and interviewees can be vulnerable or prone to over-disclosure.17] Others have suggested that interviewees may manipulate the interview for personal agenda.[18]. The pre-prepared questions in the semi-structured interviews will be used to encourage the participant to talk about aspects of their experience of their baby participating in a randomised trial. The researcher may modify the schedule as the interviews progress.[17] In the context of the COVID-19 pandemic and its associated measures, interviews may be conducted face to face, using video link (Zoom, Teams or WhatsApp) or telephone call in the event that the participant has poor internet quality at their home. All interviews will be carried out by the researcher on a one-on-one basis and will be audio recorded. Interviews will last 30 minutes approximately.

Pilot study
A pilot interview will be conducted to allow the researcher to test the interview schedule and the method of conducting the interview, either face to face or online. Any issue arising in the pilot study will be addressed and strategies put in place to minimise the issue in the main study.[9]

Index Type: Method of Recruitment

Method for allocating to intervention or comparator
No intervention or comparator group, this is a qualitative SWAT.

Outcome measures
Primary: Participants' experiences of being invited to consider including their baby in a neonatal randomised trial.
Secondary:

Analysis plans
Data analysis involves different stages of reduction, inference, conceptualization and categorising the data to provide new insights about the phenomenon under study.[15] In this SWAT, thematic data analysis using the 6-phase framework derived by Braun and Clarke [17] will be used to analyse the data: Phase 1: Familiarising with the data, Phase 2: Generating initial codes, Phase 3: Searching for themes, Phase 4: Reviewing Themes, Phase 5: Defining and naming themes, and Phase 6: Writing up the findings. Data will be transcribed verbatim. Analysis will begin by reading each transcript repeatedly to achieve immersion (Phase 1). Text that describes the phenomenon under study (participants' experiences and perceptions of recruitment of a neonate to a clinical trial) will be coded (Phase 2: open coding). Codes derived from participants' words (in-vivo codes) will initially be used to label these descriptions. When all data have been coded, each code will be examined and overlapping codes will be collapsed, to form larger more inclusive categories (Phase 3). This process will also make explicit the links between categories, enabling a hierarchical structure to emerge showing categories and their subcategories. The final categories will be organised into themes (Phase 4 and 5) [17] that "best fits the data".[2] Analysis will commence when the first interview is complete and be an iterative process throughout data collection.

Possible problems in implementing this SWAT
All research studies must demonstrate rigour and be open to critique in order to assess the worth of the study and the robustness with which it was carried out.[19] The criteria of credibility, dependability, transferability and confirmability identified by Guba and Lincoln [20] are viewed as appropriate measures of rigour in qualitative research. Credibility refers to the 'truth value' or believability of the findings.[17] Within this SWAT, credibility will be achieved by audio taping the interviews and transcribing them verbatim, keeping a field journal of reflective thoughts and by sharing findings with participants so they can judge whether these accurately reflect their experiences. Dependability relates to the degree to which the data change over time.[21] It is achieved through a process of auditing, and researchers must ensure that the process of research is logical, traceable and clearly documented.[22] Transferability refers to the extent to which the

findings of a study can be of use to other populations or settings similar to those in the study. Confirmability is concerned with demonstrating that the interpreted findings are clearly derived from the collected data and is dependent on participants and experts agreeing with the researcher's interpretation.[8,21]

References

1. Healy P, Galvin S, Williamson P, et al. Identifying trial recruitment uncertainties using a James Lind Alliance Priority Setting Partnership – the PrioRiTy (Prioritising Recruitment in Randomised Trials) study. Trials 2018;19:147.
2. Sandelowski 2000 Whatever happened to qualitative description. Res Nurs Health, 23: 334-340
3. Sandelowski 2010 What's in a name? Qualitative Description Revisited. Research in Nursing & Health. 33, 77-84.
4. M.A. Neergaard, MA, . Olesen, F., Jensen, AB, Sondergaard, J. 2008 Palliative care for cancer patients in a primary health care setting: Bereaved relatives' experience, a qualitative group interview study BMC Palliative Care, 7 p. 1
5. Neergaard MA, Olesen F, Andersen RS, Sondergaard J. Qualitative description - the poor cousin of health research? BMC Medical Research Methodology. 2009;9:52.
6. Bradshaw C, Atkinson S, Doody O. Employing a Qualitative Description Approach in Health Care Research. Global Qualitative Nursing Research 2017;4: 2333393617742282.
7. Hsieh and Shannon 2005 Three approaches to qualitative content analysis. Qualitative Health Research, 15(9), 1277-88 doi: 10.1177/1049732305276687
8. Parahoo K. Nursing research: principles, process and issues. United Kingdom: Macmillan Education 2014.
9. Lobiondo-Wood G, Haber J. Nursing research Methods and Critical Appraisal for Evidence-Based Practice, 9th edition 2018.
10. Burns N, Grove SK. Understanding nursing research, 5th edition, Philadelphia: Saunders 2010.
11. Beauchamp TL, Childress JF. Principles of biomedical ethics, 5th edition, New York: Oxford University Press 2001.
12. Silverman 2013 Doing qualitative research: A practical handbook. 4th Edition. Sage: London13. Creswell JW. Research Design. Qualitative, Quantitative and Mixed Methods Approaches, 3rd edition. Thousand Oaks, California: Sage 2009.
14. Polit and Beck 2012 Nursing Research: Generating and Assessing Evidence for Nursing Practice. 9th Edition, Lippincott, Williams & Wilkins, Philadelphia.
15. Creswell JW. Qualitative Inquiry and Research Design: Choosing among five approaches, 3rd edition. Thousand Oaks, Ca: Sage 2013.
16. Bazeley P. Qualitative Data Analysis: Practical Strategies. London: Sage 2013.
17. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology 2006;3(2):77-101.
18. Richards L. Handling Qualitative Data: A practical Guide, 3rd edition. London: Sage 2014.
19. Houghton C, Casey D, Shaw D, Murphy K. Rigour in qualitative case-study research. Nurse Researcher 2013;20(4):12-7.
20. Guba, E. G., & Lincoln, Y. S. (1994). Competing paradigms in qualitative research. In N. K. Denzin & Y. S. Lincoln (Eds.), Handbook of qualitative research (pp. 105–117). Sage Publications, Inc.
21. Lincoln Y.S. & Gubam E.G. 1985 Naturalistic Inquiry Sage Publications, Inc.
22. Streubert, H.J. and Carpenter, D.R. (2011) Qualitative Research in Nursing: Advancing the Humanistic Imperative. Wolters Kluwer, Philadelphia.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

1Delete2

People to show as the source of this idea: Dr Pauline Meskell
Contact email address: pauline.meskell@ul.ie

Date of idea: 1/JUN/2020
Revisions made by:
Date of revisions: