TRAINING TRIAL RECRUITERS

An educational and training program for recruiters to neonatal trials

Final Report

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Acknowledgements

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List of Acronyms

MRC	Medical Research Council
HTA	Health Technology Assessment
PRIORITY	Prioritising Recruitment to Randomised Trials study
JLA-PSP	James Lind Alliance-Priority Setting Partnership
CTU	Clinical Trial Unit
TRAIN	Training Trial Recruiters; An Educational Intervention
ICMJE	International Committee of Medical Journal Editors
TCIDC	TRAIN Cooperative Intervention Development Committee
RCT	Randomised Controlled Trial
AASAP	Anticipate, Acknowledge, Standardize, Accept, Plan
NPEU	National Perinatal Epidemiology Unit
INFANT	Irish Centre for Maternal and Child Health Research
HRB-TMRN	Health Research Board, Trials Methodology Research Network
INHA	Irish Neonatal Health Alliance
PPI	Patient and Public Involvement

Introduction

Background

Clinical decision-makers and policy and guideline developers use the results of systematic reviews of randomised trials and other studies, to guide and inform healthcare practices. Randomised trials have long been considered the gold standard for testing the effectiveness of interventions, yet they are often wrought with challenges. One challenge is that of slow or suboptimal recruitment.

Reports cite that about half of all trials do not meet their recruitment target or do so only with an extension to the original trial duration.[1,2] For example, of 114 trials funded by the UK Medical Research Council (MRC) and the Health Technology Assessment (HTA) programme between 1994 and 2002, only 31% met their recruitment targets and over half (53%) required an extension.[3] More recently, of 73 trials funded by the UK MRC and the HTA programme between 2002 and 2008, 55% of trials recruited to their target sample size and nearly half (45%) received an extension.[4] Similar issues have been reported in the United States. A study investigating the prevalence and associated economic impact of low enrolling clinical studies at a single academic medical centre found that of the 837 clinical studies terminated during the study period, 31.1% were closed because of low recruitment at a cost of almost $1 million.[5]

Under recruiting or stopping a trial early due to poor recruitment has major implications for the study outcomes, not least, a reduction in the study's statistical power.[6,7] Underpowering a trial adds uncertainty; for example, an underpowered study may report no difference between groups on clinically important outcomes when, in fact, a difference may exist. Other implications of poor recruitment or stopping a trial early include increased burden and resource waste, ethical issues, and reduced impact on clinical care.[1,7]

To boost recruitment rates or address slow recruitment, trial coordinators often engage in responsive activities, for example, altered or increased communication strategies,[8] incentives[9] or formal site visits by the principal investigator,[6] yet sufficient, robust evidence on the effectiveness of many of these activities is lacking. Uncertainties further exist around elements of a trial design that might potentially impact recruitment. To explore and prioritise these uncertainties, the Health Research Board Trials Methodology Research Network (HRB-TMRN), in 2016, undertook the PRioRiTy study.[10] Using a James Lind Alliance-Priority Setting Partnership (JLA-PSP) approach, the PRioRiTy study identified and ranked the Top 10 priority questions for trial recruitment uncertainties. One thematic area that emerged in PRioRiTy was the education and training of trial recruiters; for example: What information should trialists communicate to members of the public who are being invited to take part in a randomised trial to improve recruitment to the trial? (PRioRiTy question 2); What are the best approaches for

designing and delivering information to members of the public who are invited to take part in a randomised trial? (PRioRiTy question 4). This finding also reflects a ranking exercise involving members of UK Clinical Trial Units (CTUs), where training site staff was identified as the number one priority for future evaluative research.[11]

Training recruiters has been found to improve enthusiasm for trials and build recruiter confidence in communicating about trials with patients.[12] Yet, evidence of the effectiveness of trial recruiter education and training interventions, and the types of training required, is largely lacking.[13] For this reason, the TRAIN (**T**raining t**R**ial recruiters; **A**n educational **IN**tervention) project developed and assessed the acceptability of an education and training intervention for recruiters to neonatal trials. Acknowledging that all trials can experience recruitment challenges, we specifically chose neonatal trials as the focus for TRAIN because recruitment challenges to these trials can be further compounded by having to approach parents at a challenging time (i.e., in the context of parental fear, worry and concern for a new baby who may be very unwell), and within a time scale that is often short for making a decision.[14]

Aim

The aim of TRAIN was to develop and assess the acceptability of an education and training intervention for recruiters to neonatal trials. To achieve this aim, TRAIN involved three sequential phases. These were 1) evidence synthesis, 2) intervention development and 3) intervention pilot and acceptability testing (Figure 1).

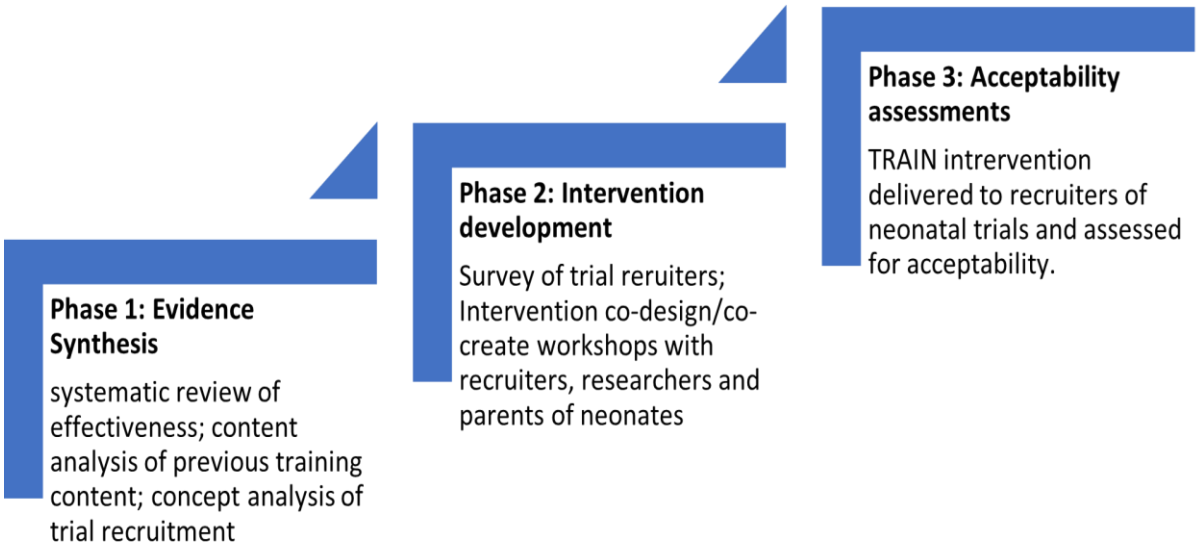

Figure 1: TRAIN Project Phases

Phase 1: Evidence synthesis

To synthesise the evidence on previous trial recruiter training interventions and to gain an in-depth understanding of the concept of trial recruitment, we undertook a systematic review of the effectiveness of existing training interventions, a content analysis of the content, format and delivery of existing training interventions, and a concept analysis of the concept '*trial recruitment*'. Collectively, these evidence syntheses provided preliminary information to develop the TRAIN intervention.

Systematic review

The systematic review of the effectiveness of previous education and training interventions for recruiters to trials is published[13] (Appendix I: source reference and link to Journal paper). In brief, the review included randomised and non-randomised controlled trials of any type of education and training intervention for recruiters to trials within any healthcare field. The primary outcome was recruitment rates, and the secondary outcomes were quality of informed consent, recruiter self-confidence, understanding and knowledge of trial information, numbers of potential trial participants approached, satisfaction with training, and retention rates.

Nineteen records were retrieved and reviewed in full text, of which six met the inclusion criteria for the review (Table 1). The studies were assessed as having a low or unclear overall risk of bias.

Table 1: Summary details of included studies

Healthcare setting(ref)	**Intervention**	**Control**	**Reported outcomes**
Oncology (older person)[15]	Standard information plus an educational symposium, educational materials, monthly mailings, and e-mails for 1 year, lists of available protocols on patient charts and a case discussion seminar	Standard information	Recruitment rates
Oncology (breast cancer)[16]	Communication skills course lasting one morning and one evening	No intervention	Quality of informed consent; Trial participants' understanding/knowledge of trial information
Mixed[17]	Communication training program aimed at teaching methods to improve informed consent	No intervention	Trial participants' understanding/knowledge of trial information
Oncology (breast cancer)[18]	Interactive face-to-face workshop with follow-up telephone call	No intervention	Recruiter self-confidence; Satisfaction with the intervention
Cardiovascular[19]	Clinical Trial Educator (CTE) program	No intervention	Recruitment rates
Cardiovascular[20]	Teleconference on ways to improve recruitment and software for each site with instructions on how to extract data lists of patients who were potentially eligible for the trial	No intervention	Recruitment rates

Due to heterogeneity of outcomes and methods across the included studies, meta-analysis was not possible for the primary outcome. Of the three studies that reported recruitment rates (Table 1), one favoured the education and training intervention for increased recruitment. The remaining two found no differences between the groups. Of the reported secondary outcomes, the quality of informed consent was improved, but no difference between the groups in understanding and knowledge of trial information was found (RR 1.03, 95% CI 0.97-1.10, 2 studies, 332 participants). The review concluded that there is limited evidence of effectiveness on the impact of education and training interventions on trial recruitment. Further work on developing an evidence base around the effectiveness of education and training interventions for recruiters to trials is required.

Content analysis

The aim of the content analysis was to extend our existing knowledge on trial recruiter training and education, including training content, format, and possible modes of delivery, to further inform the development of the TRAIN intervention. We used the directed analytical approach, guided by Bengtsson's framework for qualitative content analysis.[21]

We included published reports of any type of education and training intervention for recruiters to trials within any healthcare field. Participants were individuals involved in recruitment to trials, including research nurses, general practitioners, members of the trial team, or any other individual involved in recruiting trial participants. There were no restrictions regarding the origin of the study/report or location; however, inclusion was restricted to English language publications only. After implementing our search and selection strategy (Appendix II), we identified 24 studies that met our inclusion criteria (Appendix III: Summary characteristics of included studies). As we aimed to analyse the actual content of the education and training interventions (surface structure), rather than explore or interpret underlying meanings (deep structure), we chose the manifest analytical approach[22] for analysing the data. This involved:

- *Decontextualization:* Reading and re-reading the data to become familiar with the broader 'unit of analysis' (i.e., the text in its entirety), then coding the text into smaller 'meaning units' (i.e., related sentences/paragraphs of text). Coding was deductive based on a predefined categorisation matrix (Table 2, main category column)
- *Recontextualization:* Assessing whether any un-coded text should be included for analysis
- *Categorisation:* Aligning the codes with the matrix categories, which was iterative and involved moving, merging, re-labelling, and aligning or re-aligning the codes with the main, generic, or sub-categories
- *Compilation:* Compiling, organising, and presenting the results.

Table 2 presents the summary results of the content analysis. Appendix IV presents the details of the interventions in each of the included 24 studies.

Table 2: Summary results of content analysis

Main Category	Generic Category	Sub-category (n=no. of interventions)
Training Methods	Delivery method	Face-to-face (n=23) Online (n=4) Phone (n=5)
	Components	Didactic teaching (n=19) Individualised support (n=11) Roleplay (n=14) Follow-up (n=7)
	Learning materials	Copy of teaching materials (n=4) Reading material (n=6) Practical checklist/tips document (n=10) Recruitment materials (n=5)
Training Content	Contextual information	Information on RCTs (n=4) Background info on the study/trial (n=3) Information specific to trial group/field (n=6) The theoretical basis of the intervention (n=4)
	Trial management	Recruitment challenges (n=9) Recruitment pathways (n=5) Recruitment materials (n=4) Managing the trial team (n=3)
	Recruitment consultation	Equipoise (n=10) Patient treatment options/preferences (n=4) Patient needs when receiving trial info (n=12) Example patient cases/scenarios (n=7) Randomisation (n=6) Informed consent (n=2) Patient eligibility (n=1) Blinding (n=1)

The content analysis revealed that education and training interventions for recruiters to trials were most often delivered face-to-face using didactic teaching and role play. Online delivery of education and training was used in four studies only. Online platforms would allow for broader distribution of the intervention than in-person training, although the high frequency of role-play use, which requires face-to-face, might account for face-to-face being used more often. Focusing education and training on recruitment consultation only and/or content relating to broader trial management is an important consideration. The interventions analysed here included, for the most part, content pertaining to communicating about the trial during the recruitment consultation and contextual information about the trial/patient group/healthcare field. Few interventions addressed trial management topics, such as managing the trial team and recruitment challenges, pathways, and materials. The content analysis highlighted useful elements for consideration in developing the TRAIN intervention. These included the format for delivery and training components, the explicit content, the timing of intervention

delivery, and duration. These components provided a useful guide for designing the online survey questions for our intervention development activity in Phase 2.

Concept analysis

The International Committee of Medical Journal Editors (ICMJE) requires trials submitted for publication to be registered before enrolment of the first trial participant. However, there is ambiguity surrounding the definition of 'recruitment' and anchoring the trial start date, end date, recruitment, and enrolment, temporally to trial processes. As the potential for variation in how recruitment is reported and understood in trial protocols and trial reports, we undertook to conceptually analyse the concept of trial recruitment by i) developing a preliminary operational definition for trial recruitment and ii) finalising this operational definition in fieldwork; that is in discussion and consultation with recruiters involved in designing, implementing, and reporting trials and with parents of neonates who have taken part in neonatal trials. The report of the concept analysis is published[23] and is openly available at https://doi.org/10.12688/hrbopenres.13173.2.

In brief, the concept analysis was framed by Schwartz-Barcott and Kim's Hybrid Model for concept analysis.[24] Randomised and non-randomised trial reports published between Jan 2018 and Jun 2019 in the five top journals with the highest Impact Factor in medicine (Table 3) provided the source literature (n=1208 records). Considering the similar reporting format for each included journal, we then selected a 20% random sample of records from each of the five journals, providing 241 trial records to base the concept analysis. As extraction progressed, it became clear that similar data, and findings, were evident such that data saturation was achieved in advance of extracting data from all 241 included records. The concept analysis of trial recruitment was thus based on including 150 trial reports from across the five included journals.

Table 3: Journal accessed for concept analysis source literature

Journal Title	Impact factor (2019)
New England Journal of Medicine	55.873
Lancet	45.217
Journal of the American Medical Association	35.289
Annals of Internal Medicine	17.81
British Medical Journal	17.445

Extracted data included the study characteristics (data source, the aim of the study, location of study, and health condition); implicit or explicit temporal descriptions and definitions of the trial start date, end date, trial duration, gaining consent, recruitment, enrolment, and randomisation. Once data were

extracted, significant points of contrast and similarity were explored. When few explicit definitions of a concept are anticipated, Schwartz-Barcott and Kim recommend analysis of the author's writings to determine definitions of the concept under study, using the format of explicit description/definition, implicit description/definition, examples, and comments.[24]

We examined the extracted data for how recruitment was defined temporally to the four-time points of the enrolment and allocation sections of the CONSORT reporting guideline for randomised trials.[25] These were screening/assessing for eligibility, consent, randomisation, and allocation to the intervention or control. The results revealed that over half (51%, n=76) of the included studies did not identify a clear time point for when recruitment occurred in relation to screening, consent, randomisation, or group allocation. Most of the included trials (n=148) provided details of trial start and end dates, although the timeframe description differed between studies (Table 4). Twenty-five of the trial reports referred to recruitment as taking place *after consent and before randomisation* (explicit n=15, implicit n=10); 21 as the point *between screening and randomisation* (explicit n=10, implicit n=11) with the timing of consent unspecified; and nine referred to recruitment as the point *between screening and consent* (explicit n=3, implicit n=6). The remaining trials defined recruitment at the time-point *before screening* (explicit n=3, implicit n=2); *between randomisation and allocation* (n=1, explicit). There was also variation in the terminology to describe entry to the trial, with study reports using the terms enrolment, recruitment, and allocation. Often, multiple terms were used interchangeably.

Table 4: Reporting of trial start-end dates

Category	Descriptor	No. studies
Mixed	The time frame provided referred to more than one process, such as *enrolment* and *randomisation*	40
Trial duration	Providing a start and end date for the *trial* period	24
Randomisation	Reporting the start and end date for when *randomisation* took place	22
Enrolment	Reporting the start and end date for when *enrolment* took place	18
Recruitment	Reporting the start and end date for when *recruitment* took place	15
No start/end date reported	-	12
Screening	Reporting the start and end date for when *screening* took place	13
Other	Reporting a timeframe for trial processes not related to recruitment, such as *data collection* and *rounds of treatment*	6
Total		**150**

Based on the analysis of 150 trial reports, a preliminary temporal operational definition of trial recruitment was defined as 'the time point after screening and consent and before randomisation'.

An operational definition of the trial recruitment period was also defined as 'the time point after screening and consent of the first participant, and before randomisation of the last participant'. These preliminary definitions were then discussed with members of the TRAIN Cooperative Intervention Development Committee (TCIDC) during the workshop sessions facilitated as part of Phase 2 of the TRAIN project (see p.16 for further details). The TCIDC agreed that defining 'trial recruitment' is a challenging task, and while there may be exceptions to the preliminary definition, the definitions that emerged from the concept analysis offer acceptable definitions that provide a standardised approach of how trial recruitment may be temporally understood as part of overall trial processes.

Phase 2: Intervention development

Informed by the evidence generated in Phase 1, Phase 2 of TRAIN consisted of a survey of recruiters to neonatal trials and co-designed/co-produced intervention development workshops with recruiters, researchers and parents of neonates who had taken part previously in a neonatal trial. The TRAIN intervention, as developed in Phase 2, was then piloted for acceptability in Phase 3. Ethical approval for Phase 2 (and Phase 3) was granted by the lead author's University School Research Ethics Committee (Ref: 14th May 2019).

Online survey of recruiters

To ascertain the opinions of neonatal trial recruiters on the specific education and training requirements that they believed would enhance trial recruitment and to provide data from the perspectives of 'recruiter' stakeholders (e.g., front-line clinicians and researchers, principal investigators, trial managers, etc.) to further inform the development of TRAIN, an online survey of recruiters to neonatal trials was conducted. The survey (Appendix V) was designed using the findings from Phase 1, especially the findings of the content analysis (e.g., recruiters' preferences around training delivery format, training materials, duration of the training, and training content), and subjected to validity assessments by a panel of five experts, following which minor refinements were made. The survey included a mix of multiple-choice, Likert scale and open-ended questions with free text boxes for comments and was distributed online using the QuestionPro platform.

The target sample for the survey were all individuals involved in recruitment to neonatal trials, either directly or indirectly (i.e., in designing recruitment processes) across Ireland and the UK. The survey was distributed from November-December 2020 for four weeks, with a reminder sent at the end of week two. A purposive sampling approach was taken (supplemented by snowball sampling), whereby the survey was advertised by email and on social media via neonatal trials networks, clinical trial units, neonatal trial research facilities, and neonatal research symposiums, with a request to forward the survey to known others who were involved in recruitment to neonatal trials. Survey distribution was

supported by the National Perinatal Epidemiology Unit (NPEU) Clinical Trials Unit, the Irish Centre for Maternal and Child Health Research (INFANT), and the HRB-TMRN.

Ninety-three recruiters responded to the survey as follows: clinicians involved in front-line recruitment (37%), principal investigators (26%), trial managers (19%), researchers involved in frontline recruitment (11%), trial methodologists (4%) and other (3%). Respondent's experience in neonatal trial recruitment ranged from <two years' experience to >10 years' experience (Figure 2).

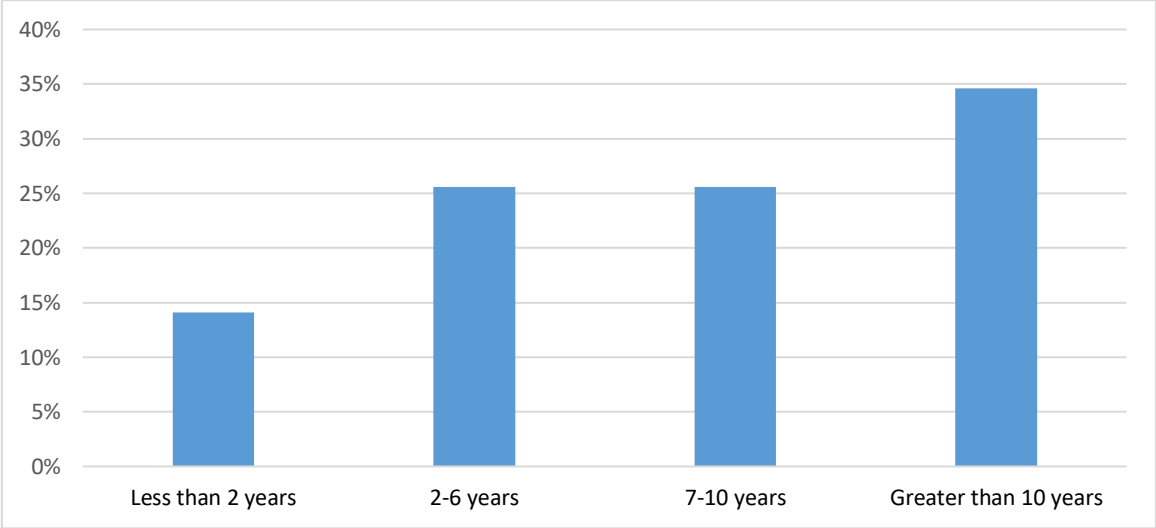

Figure 2: Experience in recruiting to neonatal trials

Not all respondents answered every item. Of 78 respondents who responded to item 12 *(the location of the most recent neonatal trial you were involved in recruiting to),* 74% indicated the UK, 26% the Republic of Ireland, and 9% elsewhere. A high proportion of respondents (87%) agreed that it would be helpful to receive training and education about neonatal trial recruitment, even though most had previously received training and education about trial recruitment (83%). Of these, 32% indicated that they had received training specific to neonatal trials, and 64% had received training about trials in general.

Respondents were asked to rank a list of eight training delivery methods in order of preference. The preferred method (ranked number 1 by participants) was 'face-to-face presentation or lecture format', followed by 'webinars', 'one-to-one support in practice', and 'through practice (such as roleplay)'. 'Post-training refresher sessions' were ranked low by participants (Figure 3) however one respondent commented that these sessions should be provided regardless of the delivery method originally received. Figure 4 presents respondents' preferences on the duration of the training.

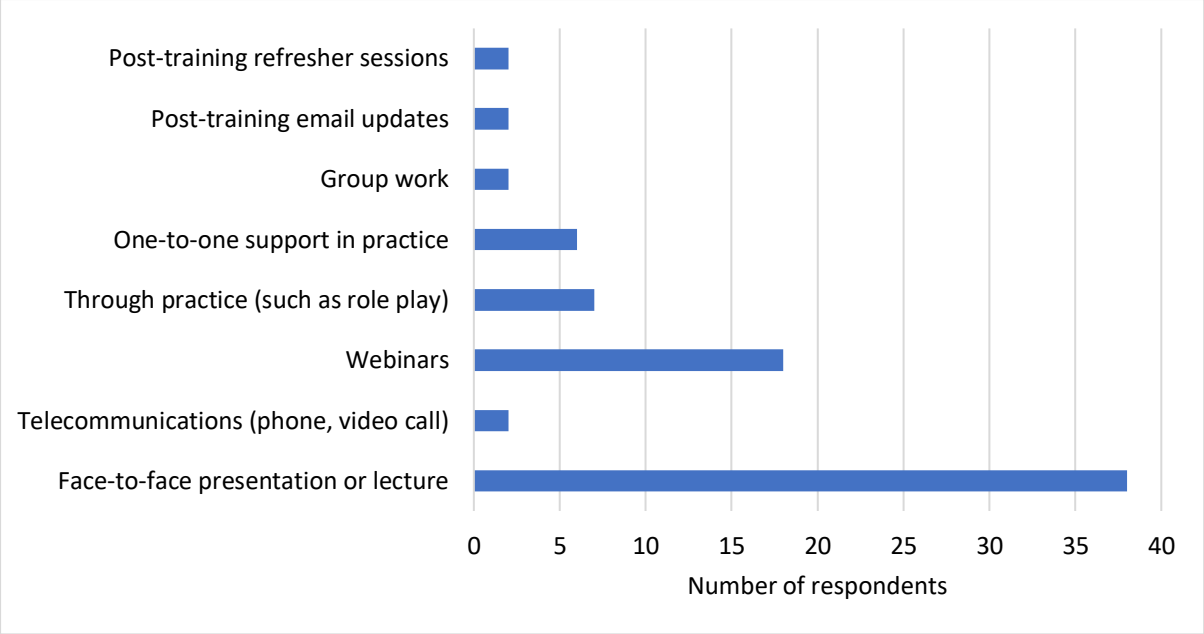

Figure 3: Preferred method of education and training delivery

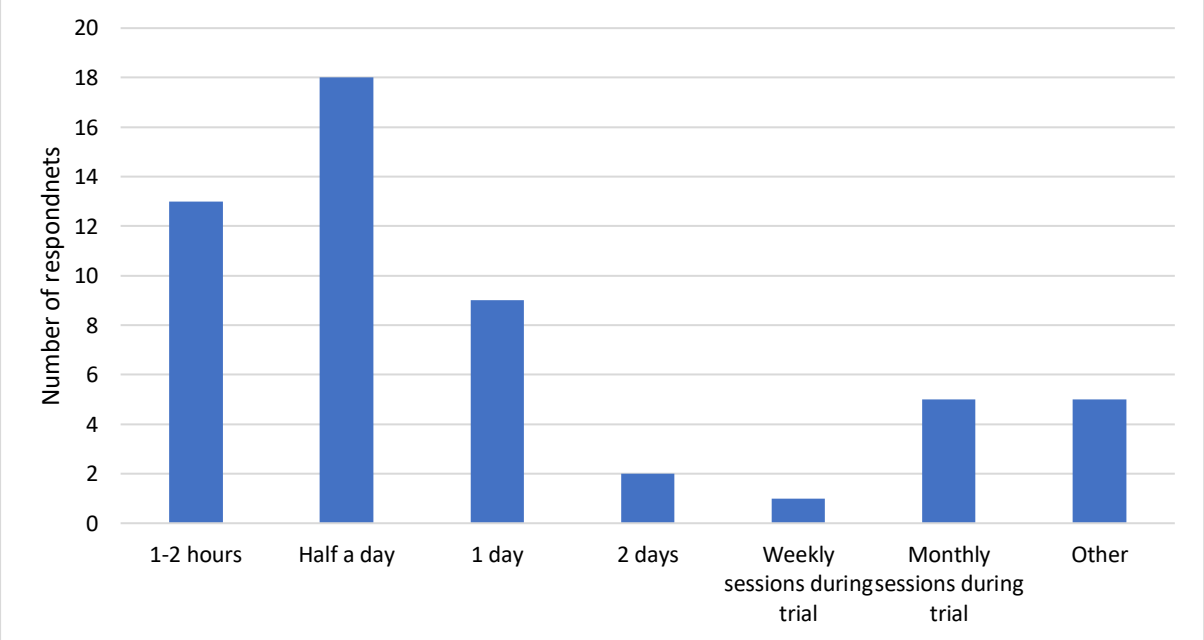

Figure 4: Duration of training sessions

Regarding supportive education and training materials, practical checklists and top tips documents were the most popular, followed by lecture notes/slides and template recruitment materials. Reading lists or reading material was the least preferred option. A list of sixteen trial recruitment topics was provided to respondents who were asked to rate these on a five-point scale from extremely beneficial

to not at all beneficial. The top three topics in the 'extremely beneficial' category included background information on the study (65%), informed consent (65%), and participant eligibility (56%) (Table 5).

Table 5: Aspects of trials that would be beneficial to have training on

Aspect*	1	2	3	4	5
Background information on the study	47 (65%)	24 (33%)	1 (1%)	0 (0%)	0 (0%)
Informed consent	47 (65%)	24 (33%)	0 (0%)	1 (1%)	0 (0%)
Participant eligibility	40 (56%)	27 (38%)	5 (7%)	0 (0%)	0 (0%)
Participants' needs receiving information	38 (53%)	29 (40%)	5 (7%)	0 (0%)	0 (0%)
Information specific to the trial topic area	37 (51%)	35 (49%)	0 (0%)	0 (0%)	0 (0%)
Recruitment challenges	35 (49%)	32 (45%)	4 (6%)	0 (0%)	0 (0%)
Recruitment pathways	34 (48%)	32 (45%)	5 (7%)	0 (0%)	0 (0%)
Recruitment materials	33 (46%)	35 (49%)	4 (6%)	0 (0%)	0 (0%)
Randomisation	32 (45%)	34 (48%)	3 (4%)	2 (3%)	0 (0%)
Completing trial documentation	32 (44%)	29 (40%)	10 (14%)	1 (1%)	0 (0%)
Participants' treatment options	31(44%)	32 (45%)	8 (11%)	0 (0%)	0 (0%)
Equipoise	31 (43%)	34 (47%)	5 (7%)	2 (3%)	0 (0%)
Blinding	26 (36%)	34 (47%)	9 (13%)	2 (3%)	1 (1%)
Bio samples	25 (35%)	30 (42%)	9 (13%)	6 (8%)	2 (3%)
General information on trials	22 (31%)	40 (57%)	3 (4%)	4 (6%)	1 (1%)
Management of the trial team	22 (31%)	32 (46%)	11 (16%)	5 (7%)	0 (0%)

* Not all respondents rated every aspect item
1: Extremely beneficial; 2: Beneficial; 3: Unsure; 4: Not beneficial; 5: Not at all beneficial

Respondents also had an option of adding any other aspects of trial recruitment that they thought would be beneficial for training. Fifteen participants completed this question with topic areas including communication skills (building rapport with parents, approaching distressed parents, building empathy), public and patient involvement in trial design and training design/delivery, trial monitoring, and embedding trials as a research culture in a unit. These responses also reflect free-text comments provided by respondents in relation to the barriers and facilitators to trial recruitment. The free-text comments were coded and organised into seven representative categories (Table 6).

Table 6: Perspectives on barriers and facilitators to recruitment

Category	Key perspectives and recommendations (n=number of respondents contributing to the recommendation)
Trial design	– Public and patient involvement in the trial design is important so that participants' and staff needs are considered (n=5) – Practically feasible trial processes and research questions are important (n=4)
Training	– Sufficient training, education, and written guidance for those responsible for recruitment is critical for trial recruitment (n=18)
Staff buy-in	– Improved awareness of trials (n=13) amongst staff and encouraging a research culture and 'buy in' of staff members through building motivation, enthusiasm (n=20) and providing clear information about the trial is needed (n=13)
Research culture and knowledge	– The benefit of approaching parents early (at antenatal stage if possible) was highlighted so that parents are made aware early of clinical trials and in providing time to consider the trial or be advised that they may be approached to take part in a trial (n=4) – Building participant trust in the research process is important for successful recruitment (n=10)
Staff communication skills and rapport with potential participants	– Appropriate communication skills of staff (including the timing of when to approach parents), considering the often sensitive and distressing context of neonatal trials, are necessary (n=13) – Due to the nature of many neonatal trials, the recruitment time is narrow and often in the immediate post-birth period, creating challenges for recruiters (n=14) – Parental fear and uncertainty amongst parents about the potential harmful effects to their baby during a time that is already distressing can present as a barrier to recruitment (n=11); being able to build a rapport is required (n=6)
Team support and dedicated time	– A dedicated research nurse and active engagement from the clinical team and PI, and ensuring multiple staff members are trained in recruitment and consent specific to the trial are important (n=35) – Limited staff availability, a lack of dedicated time, and competing with other trials are barriers that require consideration (n=3)
Participant documentation	– Clear documentation for potential trial participants is important (n=11)

TCIDC workshops: co-creating/co-producing the TRAIN intervention

The final stage of developing the TRAIN intervention adopted a Partnership approach using co-design/co-production methods. The TRAIN Cooperative Intervention Development Committee (TCIDC) was established (see p.2 for membership) and met with members of the core research team in two arranged workshops and liaised online to draft the TRAIN intervention. TCIDC members were purposively selected based on their expertise. Members were two neonatal clinicians, two neonatal research nurses, one neonatal trial manager and four PPI representatives (parents of neonates

previously involved in a neonatal trial) from the UK and Ireland. The intervention development workshops took place in March and April 2021 (online via Zoom due to COVID restrictions). The workshops were of 2-hrs duration and, with consent, were recorded and transcribed (for memory and recall purposes only).

The TRAIN research team initially proposed a draft TRAIN intervention based on the evidence syntheses and the online survey findings. This draft was shared with the TCIDC for review before the first workshop.

During Workshop 1, the TCIDC shared their feedback and experiences and new ideas and recommendations for TRAIN (summarised in Table 7; full details in Appendix 5). There was a clear message from the TCIDC that building a rapport and communicating empathetically with parents when inviting their infant to take part in a trial should be a significant component of the training intervention. During the workshop there was much discussion around developing tools to help recruiters see the recruitment scenario from a parent's perspective, which is often challenging given their busy caseloads.

Table 7: Summary recommendations from Workshop 1

TCIDC recommendation	Details
A set of slides summarising the protocol	Knowing the protocol well allows the recruiter space to focus on building trust and rapport with parents.
A graphic summarising the protocol	A resource for recruiters to easily refer to.
A session to consider challenging Qs	Questions that may arise from parents that are not included in the protocol.
'Pause and Think' message	To remind recruiters to take a moment before approaching parents, consider the parents' perspective and the wider context of the scenario for them.
A lanyard as a wearable reminder	With a summary of the trial protocol and a reminder to 'pause and think'.
A set of slides outlining the key points to consider when deciding if it's the right time to approach parents	Timing, the importance of the study, honesty, what else is going on in the ward, check-in with the parents.
A video message from parents	Sharing their experience of trial recruitment to help recruiters understand the parent's perspective.
A role play exercise	Inviting recruiters to role-play particular recruitment scenarios and take on the role of both the parent and the recruiter. And giving the recruiters permission to accept that it is a difficult task to recruit for neonatal trials.
An example script of a recruitment conversation	The steps and order of example recruitment conversations, as a means of building rapport.

The research team analysed the discussion transcripts from Workshop 1 and collated these in an overview table. This helped map the proposed changes and new ideas to the existing intervention and further refine and develop the intervention. The updated draft intervention was circulated to the TCIDC before Workshop 2. During the second workshop, the TCIDC provided their final feedback and recommendations. Recommendations from Workshop 2 included points mainly related to the intervention resources' order, structure, and format.

The TRAIN intervention

TRAIN aims to support neonatal trial recruiters with knowledge and skills to assist them when recruiting parent(s) of neonates (up to 28 days following birth) to a neonatal trial so that informed parental decision-making on the participation of their neonate in a trial, can be improved.

The learning outcomes (LO) of TRAIN are that by the end of the intervention, participants will

- ✓ Understand the trial protocol and be able to explain to parents what taking part will involve
- ✓ Understand and be able to explain the process of randomisation to parents
- ✓ Be aware of factors to consider when approaching parents for recruitment of their neonate to a trial
- ✓ Understand and be cognisant of parents' perspectives when recruiting their neonates to a trial
- ✓ Be prepared to engage in a recruitment conversation

TRAIN has been designed for online or face to face delivery. The intention is that TRAIN is offered to recruiters before trial recruitment begins, although Units 2 and 3 (Table 8) can be provided throughout trial recruitment as refresher sessions as necessary. A detailed training manual (Appendix VI), with reference to each resource and learning outcomes for each unit, describes specifically how TRAIN should be delivered. Once evaluated for effectiveness and finalised, a representative from any trial team can follow TRAIN's manual guidance in providing the education and training independently. TRAIN's three core learning units are:

- Unit 1: The trial protocol (50 minutes)
- Unit 2: Understanding randomisation (5 minutes)
- Unit 3: Approaching and engaging with parents (70 minutes)

Unit 1 is trial-specific and focuses on the trial protocol. Units 2 and 3 are generic with applicability to any neonatal trial. Table 8 presents an overview of each unit and the related resources with full details available in the intervention manual (Appendix VI).

Table 8: Overview of the TRAIN intervention and resources

Unit	Content	Resources
Unit 1: The trial protocol (50mins)		
1.1 Introduction (10 mins)	Welcome & Introduction	1.1 Introduction (presentation slides)
1.2 The trial protocol (15 mins)	– Aim/importance of the trial – Eligibility criteria – What taking part will involve including potential harms and benefits of the study	1.2 Trial Protocol (presentation)
1.3 Recruitment pathway (10 mins)	– An exercise asking participants to map out the host trial pathway to assess their understanding of the information from 1.2 Trial Protocol	1.3 Recruitment Pathway exercise 1.3 Infographic (diagram summarising the protocol)
1.4 Challenging questions (10 mins)	– Discussion on issues/challenging questions parents may have beyond the protocol information and how one might address these	1.4 Challenging Questions
1.5 Close of session & questions (5 mins)	– Questions/comments	
Unit 2: Understanding randomisation (5mins)		
2.1 Randomisation (5 mins)	– A video explaining the process of randomisation to assist recruiters in explaining the process to parents of neonates who are being invited to take part in a trial	2.1 Randomisation Video
Unit 3 Approaching and engaging with parents (70mins)		
3.1 Approaching parents (30 mins)	– Critical considerations for recruiters before approaching parents about the possibility of their neonate being involved in a trial	3.1 Approaching parents (+ Infographic) 3.1 Parent video vignettes 3.1 Lanyard
3.2 Engaging with parents* (15 mins)	– A template recruitment conversation and order of topics, with examples of opening sentences	3.2 Engaging with parents 3.2 Recruitment conversation guide
3.3 Practicing recruitment (20 mins)	– Roleplay session to work through challenging recruitment scenarios, with examples specific to neonatal trials. With feedback	3.3 Practicing recruitment
3.4 Close of session & questions (5 mins)	– Final questions/comments	

*The Qualitative Research Integrated within Trials (QuinteT) team of researchers at Bristol University, of whom co-author NM is a member, pioneer approaches to optimise recruitment and informed consent to randomised controlled trials (https://www.bristol.ac.uk/population-health-sciences/research/groups/social-sciences-health/quintet/). In unit 3.2 we adapted some of QuinteT's findings (see, for example, https://doi.org/10.1016/j.jclinepi.2008.02.010, https://doi.org/10.1186/1745-6215-15-5, https://doi.org/10.1016/j.jclinepi.2016.02.002, and https://doi.org/10.1186/s13063-017-2048-7) to the context of neonatal trials to consider how we engage with parents about their infants taking part in a trial.

Phase 3: Assessing the TRAIN Intervention for acceptability

In the final Phase of TRAIN, the TRAIN intervention was delivered to neonatal trial recruiters to assess for acceptability and to gain their feedback.

The target sample included all individuals who had ever been, or would be in the future, involved in recruiting to a neonatal trial. An invite to take part in TRAIN was advertised during October-November 2021. International neonatal trial recruiters were purposively invited to take part in the training and education sessions by email and via social media, neonatal trials networks, clinical trial units, neonatal trial research facilities, and neonatal trial teams, with a request to forward the invitation to other groups or individuals involved in recruiting to neonatal trials.

Invite distribution was supported by the NPEU Clinical Trials Unit, the INFANT Centre, and the HRB-TMRN. The invite included a link to register for one of four training dates in November 2021 which involved attending a 2-hour online TRAIN intervention workshop and completing a two-minute survey before and after taking part in TRAIN. Once participants registered for a training date, they were sent a confirmation email with a link to the online training and the baseline survey.

The training was delivered via Zoom, and each training session was facilitated by two members of the TRAIN core research team (AH, VS, HD). The training participants were involved in recruiting to different trials trial teams; therefore, in Unit 1, template content that outlined what would be presented for the specific trial was presented. Examples of the training resources were also shared with participants, allowing them to provide feedback on the content of this Unit 1. Units 2 and 3 were presented as they would be in a real training scenario. At the end of each Unit, participants had an opportunity to share comments or feedback on the Unit and reminded that further comments could be shared in the online follow-up survey.

The pre-and post-session surveys were designed to capture three outcome measures:

- Recruiters perceived preparedness and self-confidence as neonatal trial recruiters
- Recruiters perceived rating of their knowledge of the trial information
- Recruiters perceived satisfaction with the training intervention

The surveys (Appendix VII) included a mix of multiple-choice, Likert scale and open-ended questions with free text boxes for participants to include any other information.

A total of 11 recruiters registered to attend a training session; as the numbers were low, two training sessions were facilitated. Of the 11 who registered, seven did not attend or sent apologies closer to

the training date. Thus, four recruiters took part, two in each of the two training workshops. These recruiters were from Italy, Ireland, and the US.

The feedback on TRAIN was positive. All four participants could see the value of each of the training Units and resources, especially the 'recruiter lanyard' resource in Unit 1 and the parent video vignettes in Unit 3. Participants commented that if there was more flexibility in the training delivery (e.g., training divided across two workshops of shorter duration), this would make it more accessible for recruiters to attend. It was suggested that Units 2 and 3 would be beneficial to incorporate into Good Clinical Practice Training or as part of induction training for new staff joining neonatal units. Participants commented that two hours was too long for one session, and suggested that the Units should be delivered as two sessions:

- Session 1 (trial specific); Unit 1
- Session 2 (more general recruiting skills); Units 2 and 3

The participants felt that the role-play session in Unit 3 was only appropriate if all TRAIN participants were recruiting to the same trial. One also noted that facilitating this session would require a particular set of facilitation skills that could not be learned from guidance in the training manual alone. One other suggestion from the participants included translating the training and resources to multiple languages to improve its accessibility.

A total of 12 potential participants completed the baseline survey, of whom 72% reported that their clinical setting or trial site is active or extremely active in neonatal trial conduct. When asked about the level of support provided for recruiters to neonatal trials in their clinical setting/trial site, 64% reported setting/trial sites as supportive or extremely supportive, 27% indicated that they were not supportive/not at all supportive, and 9% were unsure. When asked about recruiting participants to a neonatal trial, 50% of respondents felt prepared or extremely prepared, 42% were unsure, and 8% felt not at all prepared. Regarding recruiter confidence and knowledge, 75% felt confident or extremely confident, 17% were unsure, 8% were not confident, 67% felt knowledgeable or extremely knowledgeable, and 25% were unsure.

All four recruiters who took part in TRAIN completed participants the follow-up survey. When asked about recruiting participants to a neonatal trial, all four responded that they felt prepared, confident or extremely confident, and knowledgeable or extremely knowledgeable. When asked to rate each of the elements of the TRAIN intervention on how useful to neonatal trial recruitment they perceived them to be, one was unsure about the duration of the training, and all four rated the remaining elements as extremely useful or valuable.

Securing recruiters for the TRAIN workshops was a significant challenge and a key consideration for a scale-up rollout of TRAIN. Greater flexibility in the format for delivering TRAIN is required and facilitating all three training Units as one session may not be feasible or acceptable. Dividing the units into two sessions may increase participation rates.

Conclusion

This report has provided an overview of the sequential development process and the TRAIN intervention acceptability assessment. The project has culminated in providing the TRAIN intervention that will need to be tested for effectiveness in a large Definitive Intervention trial with adjustments to how TRAIN is delivered. Reassuringly, TRAIN appears acceptable, although the numbers on which this testing was based were low. Securing funding to formally pilot test TRAIN, and test TRAIN for effectiveness in a randomised cluster trial is required.

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Appendix I: A systematic review of education and training interventions for trial recruitment

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REVIEW

Limited evidence exists on the effectiveness of education and training interventions on trial recruitment; a systematic review

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Abstract

Objective: The objective of this study was to examine the effectiveness of education and training interventions on recruitment to randomized and non-randomized trials.

Study Design and Setting: A systematic review of the effectiveness of education and training interventions for recruiters to trials. The review included randomized and non-randomized controlled trials of any type of education and training intervention for recruiters to trials, within any health care field. The primary outcome was recruitment rates, and secondary outcomes were quality of informed consent, recruiter self-confidence, understanding/knowledge of trial information, numbers of potential trial participants approached, satisfaction with training, and retention rates.

Results: Of the 19 records reviewed at full-text level, six met the inclusion criteria for our review. Owing to heterogeneity of outcomes and methods between the included studies, meta-analysis was not possible for the primary outcome. Of the three studies that reported recruitment rates, one favored the education and training intervention for increased recruitment; the remaining two found no differences between the groups. Of the reported secondary outcomes, quality of informed consent was improved, but no differences between groups in understanding/knowledge of trial information were found.

Conclusion: There is limited evidence of effectiveness on the impact of education and training interventions on trial recruitment. Further work on developing a substantial evidence base around the effectiveness of education and training interventions for recruiters to trials is required.

Keywords: Trial recruitment; Educational intervention; Training intervention; Systematic review; Effectiveness review; Trial methodology

1. Background

1.1. Introduction

Randomized control trials are considered the gold standard for testing the effectiveness of interventions. However, trialists face many challenges in trial processes. One major challenge is recruitment, with reports suggesting that fewer than half of trials reach their original recruitment targets or require an extension to the trial to do so [1].

In a survey of authors of published primary care trials, less than one-third reported that they recruited to target within the original timescale [2]. In addition, McDonald et al. [3] explored levels of recruitment in a cohort of 114 trials in the United Kingdom (from 1994 to 2002) and found that recruitment problems were identified in the early stages of 63% of the trials, only 31% achieved their original recruitment target and 53% were given an extension. More recently, Sully et al. [4] concluded that although recruitment has improved since McDonald's study, only half (55%) of the trials in their study recruited the original target sample size and 45% were extended.

Poor recruitment has many negative consequences, for instance, trial extensions are often required to reach

Conflict of interest: None.

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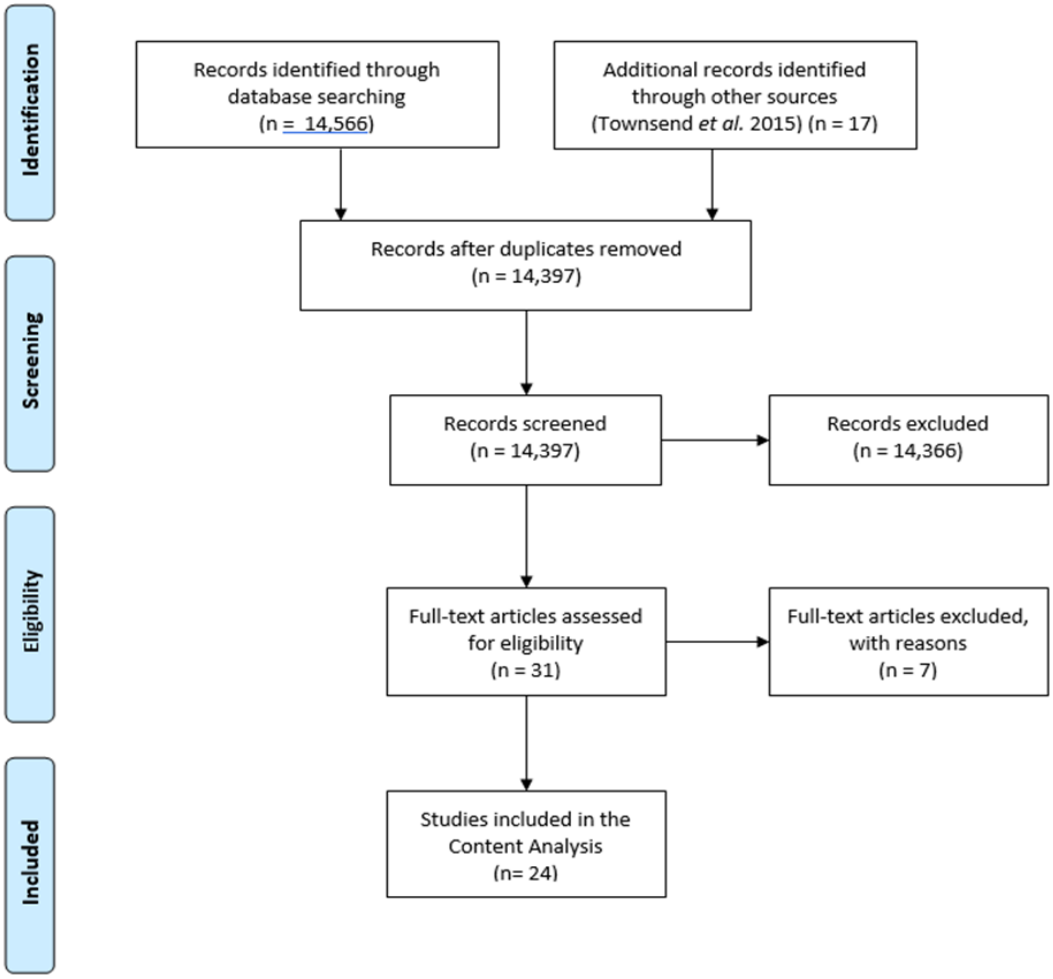
Appendix II: Search and selection strategy for content analysis

We identified a previous systematic review, published in 2015, of training programmes for recruiters to trials (Townsend D, Mills N, Savovic J, Donovan JL. A systematic review of training programmes for recruiters to randomized controlled trials. *Trials*. 2015; 16:432. doi:10.1186/s13063-015-0908-6) and included the studies from this review in our content analysis. We then searched the following electronic bibliographic databases: EMBASE, MEDLINE, and The Cochrane Library from publication of the systematic review (July 2015) to September 2018 (the date the searches were implemented). We used broad search terms such as recruitment, training, education, randomised control trials, and variations of these terms/synonyms, combined appropriately using the Boolean operands of 'OR' and 'AND', adapted across the databases. References were uploaded to Endnote, and duplicate citations were removed. The systematic review management software, Covidence, was used for the screening process. All titles and abstracts were screened for relevance and, following this process, potentially relevant reports were assessed on full-text review against the analysis inclusion criteria. The results are presented in the Flow Diagram below.



Appendix III: Summary characteristics of studies included in the content analysis

Author/Year	Aim of study	Location	Healthcare field	Study design	Target population	Timing of intervention implementation
Kimmick *et al*. 2005	To design and test a geriatric educational intervention to improve accrual of cancer patients aged 65 years+	USA	Oncology (Geriatric)	Randomised controlled	Members of the research team	Not specified: targeted at multiple trials
Kenyon e*t al*. 2005	To outline a strategy employed by a perinatal multi-centre randomised controlled trial that overcame poor recruitment rates	UK	Maternity	Uncontrolled pre-test post-test	Lead midwives	Ongoing trial: in response to slow recruitment
Hietanen *et al.* 2007	To explore whether communication skills training for trial recruiters improves quality of informed consent and patient satisfaction	Finland	Oncology (Breast Cancer)	Randomised controlled	Recruiting physicians and research nurses	No info on timing of intervention
Yap *et al.* 2009	To improve physician communication with parents using a physician-directed intervention, emphasizing a sequenced approach to informed consent	USA	Oncology (Paediatric)	Non-randomised controlled	Physicians	Not specified: targeted at multiple trials
Wuensch *et al.* 2011	To describe and evaluate the concept of a communication skills training intervention for trial recruitment	Germany	Oncology	Post-training survey	Physicians	Not specified: targeted at multiple trials
Kendall *et al.* 2012	To design and implement a Clinical Trial Educator program to accelerate trial recruitment	North/South America, Asia Pacific, Europe	Cardiovascular care	Non-randomised controlled	Investigators and trial site staff	Ongoing trial: in response to recruitment issues, targeted at low/non-recruiting sites
Fisher *et al.* 2012	To evaluate a theory-based, subject-centred, communication program -to address subject ambivalence and increase trial recruitment/retention	USA	Diabetes	Uncontrolled pre/post-test	Recruiting research assistants	Ongoing trial: in response to slow recruitment
Mann *et al.* 2014	A discussion and qualitative evaluation of the use of peer-review to train nurses and enhance recruitment in a trial	UK	Orthopaedic	Qualitative	Recruiting research nurses	From trial start: embedded in the pilot phase of the trial

Goff *et al.* 2016	To describe the recruitment and retention techniques used in a randomised controlled trial to reduce barriers to using publicly reported data	USA	Maternity (racial/ethnic minority pregnant women)	Observation	Study staff responsible for recruitment	From trial start: training 6 months prior to beginning recruitment
Wells *et al.* 2017	To develop and test a Cultural Competency and Recruitment Training Program	USA	Oncology (Radiation Therapy)	Quasi-experimental single-group pre-test post-test	Clinical research associates and physician investigators	Not specified: targeted at multiple trials
Maxwell *et al.* 2017	To investigate if a complex intervention involving a recruitment review, increases recruitment rates to a randomised controlled trial	UK	Stroke	Randomised controlled	Principal investigator and trial team	Ongoing trial: in response to slow recruitment
Tilley *et al.* 2017	To examine the effectiveness of a trust-based continuous quality improvement intervention to increase minority recruitment into clinical trials	USA	Speciality clinics/care	Randomised controlled	Principal investigator and trial coordinator	Not specified: targeted at multiple trials
Brown *et al*. 2007	To develop and explore the impact of a set of strategies based on ethical principles, for gaining consent to Phase II and III clinical trials.	Australia	Oncology	Uncontrolled pre/post-test	Medical oncologists	Not specified: targeted at multiple trials
Butow *et al.* 2015	To train doctors in collaborative and ethical communication about informed consent and evaluate the impact on doctor behaviour/stress/satisfaction	Australia, New Zealand, Switzerland, Austria, Germany	Oncology (Breast Cancer)	Randomised controlled	Medical oncologists	Not specified: targeted at multiple trials
Jenkins *et al*. 2005	To evaluate a training intervention to improving healthcare professionals' communication with cancer patients about Phase III trials	UK	Oncology	Uncontrolled pre/post-test	Recruiting healthcare professionals	Not specified: targeted at multiple trials
Fallowfield *et al.* 2012	To evaluate a training intervention to improving healthcare professionals' communication with cancer patients about Phase III trials	UK	Oncology (Phase I trials)	Uncontrolled pre/post-test	Any healthcare professional regularly attending team meetings	Not specified: targeted at multiple trials

Jenkins *et al.* 2013	To outline a multidisciplinary team training workshop aimed at improving: awareness, communication, and recruitment to cancer trials	UK	Oncology	Uncontrolled pre/post test	Any healthcare professional regularly attending team meetings	Not specified: targeted at multiple trials
Fallowfield *et al*. 2014	To assess the effect of a modified multidisciplinary team training workshop on awareness and clarity about breast cancer trials	UK	Oncology (Breast Cancer)	Uncontrolled pre/post-test	Any healthcare professional regularly attending team meetings	Not specified: targeted at multiple trials
Donovan *et al.* 2009	To developed and evaluate a complex intervention to increase randomization and informed consent in a multi-centre trial	UK	Oncology (Prostate Cancer)	Uncontrolled pre/post-test	Trial management group and trial recruiters	From trial start: embedded in feasibility study, and main trial sites with slow recruitment
Paramasivan *et al.* 2011	To explore reasons for low recruitment and improve recruitment rates by implementing changes suggested by a qualitative recruitment investigation	UK	Oncology (Bladder Cancer)	Qualitative	Trial management group and trial recruiters	Ongoing trial: in response to slow recruitment during feasibility study
Blazeby *et al.* 2014	To determine the feasibility of an RCT by integrating qualitative research to establish whether recruitment was possible	UK	Oncology (Oesophageal SCC)	Uncontrolled pre-test post-test	Surgeon and oncologist recruiters	From trial start: embedded in feasibility study
Realpe *et al.* 2016	To develop and implement a simple six-step model to inform patients and to support them in deciding about trial participation	UK	Surgery (Arthroscopic)	Qualitative	Trial recruiters	From trial start: embedded in feasibility study
Mills *et al.* 2018	To describe the QuinteT RCT Recruitment Training and evaluate its impact on surgeons and research nurses	UK	Surgery	Uncontrolled pre-test post-test	Surgeons/nurses actively recruiting or planning to recruit	Not specified: targeted at multiple trials
Elliott *et al.* 2018	To describe how clinicians conceptualise equipoise and how this affects recruitment	UK	Oncology (Prostate Cancer)	Qualitative	Trial management group and trial recruiters	From trial start: embedded in feasibility study, difficult recruitment anticipated

Appendix IV: Details of the training interventions for each study included in the content analysis

Author/year	Intervention	Delivery	Training components	Learning materials	Duration/Frequency
Kimmick *et al.* 2005	A multifaceted educational intervention to improve recruitment	Face-to-face: symposium and case discussion seminar; Email	Didactic teaching	Bibliography; Lecture/teaching slides Video recording of teaching	Monthly emails for the year after the educational symposium
Kenyon *et al.* 2005	An intervention to employ and train lead midwives to promote and aid trial recruitment	Face-to-face: induction program and study days	Didactic teaching Individualised support Follow-up training	Trial promotional materials	2-day induction; 6 monthly study days
Hietanen *et al*. 2007	A short course in communication skills to improve the quality of informed consent	Face-to-face: training	Didactic teaching Roleplay	Reading material; Practical checklist/tips document	1 evening + 1 morning
Yap *et al.* 2009	A physician-directed intervention emphasizing a sequenced approach to informed consent	Face-to-face: seminar	Didactic teaching Role Play Follow-up sessions	Lecture/teaching slides; Practical checklist/tips document; Reading material	1 day seminar
Wuensch *et al*. 2011	Communication skills training addressing disclosing information about clinical trials	Face-to-face: 4 modules	Didactic teaching; Roleplay; Individualised support; Follow-up coaching	Practical checklist/tips document	17 hours in total
Kendall *et al.* 2012	Clinical Trial Educator Program to accelerate recruitment	Face-to-face: training	Didactic teaching; Individualised support	Not stated	Regular site visits
Fisher *et al.* 2012	AASAP Program - a practical communication strategy to address patient ambivalence	Face-to-face: meetings and workshops	Teamwork; Roleplay; Follow-up review	Not stated	Weekly team meetings; 2 x 2-hour workshops
Mann *et al.* 2014	Internal Peer-review for Recruitment Training in Trials (InterPReTiT)	Face-to-face: meetings	Roleplay	Reading material	5 meetings over 12 weeks

Goff *et al.* 2016	Navigator Training to address recruitment and retention barriers	Face-to-face: training and discussions	Didactic teaching; Roleplay; Individualised support	Not stated	During the 6 months before the start of trial recruitment
Wells *et al.* 2017	Cultural Competency and Recruitment Training Program (CCRTP)	Face-to-face or online: training	Didactic teaching	Not stated	4hour training
Maxwell *et al.* 2017	Promoting Recruitment using Information Management Efficiently (PRIME Intervention)	Teleconference	Individualised support; Follow-up review	Software to access eligible patients	Follow-up review 6 months after 1st review
Tilley *et al.* 2017	Trust-based Continuous Quality Improvement (CQI) intervention	Face-to-face: kick-off session; Webinars: 5 core modules; Phone call; Teleconference	Didactic teaching; Teamwork; Individualised support; Follow-up call	Recruitment reports; Recruitment maps	6-hour kick-off session; 5 x 1-hour modules; Follow-up call 2 weeks after each module; Monthly calls post-training until end of recruitment
Brown *et al.* 2007	Communication skills training program	Face-to-face: workshop	Didactic teaching; Roleplay	Practical checklist/tips document	1 intensive day
Butow *et al.* 2015	Communication skills training program	Face-to-face: workshop Phone calls	Didactic teaching; Roleplay; Follow-up call	Practical checklist/tips document	7-hour workshop; 1-2 follow-up calls over 2mths
Jenkins *et al*. 2005	Educational program for health professionals communicating about randomised trials	Face-to-face: 4 modules	Didactic teaching; Roleplay	Facilitator handbook; Bibliography; Example recruitment materials	8 hours: over 2 days: 4 modules
Fallowfield *et al.* 2012	Educational program for health professionals communicating about randomised trials	Face-to-face: 5 modules	Didactic teaching; Roleplay	Facilitator handbook; Bibliography; Example recruitment materials	8 hours over 2 days; 5 modules
Jenkins *et al*. 2013	Teams Talking Trials workshop (TTT) for teams to enhance communication and recruitment	Face-to-face: workshop	Didactic teaching; Teamwork; Roleplay	Not stated	1.5-day workshop
Fallowfield *et al.* 2014	Teams Talking Trials workshop (TTT) for teams to enhance communication and recruitment	Face-to-face: workshop	Didactic teaching; Teamwork; Roleplay	Not stated	1 day workshop

Donovan *et al.* 2009	QuinteT Recruitment Intervention (QRI)	Face-to-face: review and training	Individualised support; Didactic teaching; Role play	Practical checklist/tips document	Training occurred annually and biennially depending on the year
Paramasivan *et al*. 2011	QuinteT Recruitment Intervention (QRI)	Face-to-face; Teleconference	Individualised support; Didactic teaching; Roleplay	Practical checklist/tips document	Not stated
Blazeby *et al.* 2014	QuinteT Recruitment Intervention (QRI)	Face-to-face	Individualised support Didactic teaching	Practical checklist/tips document	Not stated
Realpe *et al.* 2016	A six-step model for good recruitment practice - modified QRI intervention	Face-to-face: training	Individualised support	Practical checklist/tips document	Not stated
Mills *et al.* 2018	QuinteT Recruitment Intervention (QRI)	Face-to-face: workshop	Didactic teaching	Practical checklist/tips document	3 x 5-hour workshops
Elliott *et al*. 2018	QuinteT Recruitment Intervention (QRI)	Face-to-face: training; Email Newsletter	Individualised support	Practical checklist/tips document	Feedback/training began 11-months after trial start and continued for 16-months until end of recruitment

Appendix V: Online survey of recruiters to neonatal

Part 1

1. Which one of the following best describes your main role in recruitment to neonatal trials?

While you may identify with more than one role, please tick the most appropriate current/most recent role.

- Researcher involved in frontline recruitment to trials (e.g. research assistant, research associate, research nurse/midwife, etc.)
- Clinician involved in frontline recruitment to trials (e.g. doctor, nurse, midwife, other allied health care professional)
- Principal investigator
- Trial manager and co-ordinator/clinical research co-ordinator
- Trial methodologist (someone who specializes in methods of how trials are designed, including recruitment processes)
- Other (please specify)

2. What do you think is the main facilitator, if any, for optimising recruitment in neonatal trials? (Please use text box below)

Text box

3. What do you think is the main barrier, if any, to optimising recruitment in neonatal trials? (Please use text box below)

Text box

4. Have you ever received structured, formal training and education about trial recruitment? (E.g. a training course/workshop of any duration, in any format; this could include, for example, standardised training in taking consent, structured training on recruiting to a trial during a site initiation visit or Good Clinical Practice training)

Yes

No [route to Q6]

5a. Was the training you received specific to… (Please select all that apply)

Neonatal trials

Trials in general

Trials in another specific healthcare field/condition (please specify) _____

5b. Please describe what was involved in the training and education in the text box below (this might include the duration, format (online/face-to-face), whether it was specific to aspects of recruitment to trials/a trial, etc.)

Text box

6. Irrespective of whether you ever received training and education about trial recruitment, do you think it would be helpful for you to receive training and education about recruitment to neonatal trials?

Yes

No [route to Part 2]

7a. Please indicate from the list below which trial aspects you think it would be beneficial to have training and education on, to help recruitment to neonatal trials…(please select one option on the scale from extremely beneficial to not at all beneficial)

	Extremely beneficial	Beneficial	Unsure	Not beneficial	Not at all beneficial
General information on randomised control trials					
Background information on the study					
Information specific to the trial topic area					
Recruitment challenges					
Recruitment pathways					
Recruitment materials (e.g. invitation letters and patient information leaflets)					
Management of the trial team					
Equipoise					
Potential trial participants' treatment options and preferences					
Potential trial participants' needs when receiving information about the trial					
Randomisation					
Informed consent					
Completing trial documentation (e.g. case report forms/e-case report forms/serious adverse event forms/data collection forms)					
Bio samples in trials (e.g. blood or tissue)					
Participant eligibility					
Blinding					

7b. If there are any other aspects of the recruitment process that would benefit from training and education, please describe in the text box below…

Text box

Part 2. Some questions about your recruitment training and education preferences

If you were to take part in training and education for trial recruitment…

8. What would be your preferred method of delivery?

Please list the options in order of preference from most preferred as 1 to least preferred as 8

Face-to-face presentation or lecture	
Telecommunications (phone, video call)	
Webinars	
Through practice (such as role play)	
One-to-one support in practice	
Group work	
Post-training email updates	
Post-training refresher sessions	

If you have any other preferred methods of delivery please specify below

Text box

9. What type of supportive education and training materials would you prefer to receive?

Please list the options in order of preference from most preferred as 1 to least preferred as 5

Reading list and/or specific documents to read in advance of training	
Practical checklist	
Top tips document	
Lecture notes (including a copy of the teaching slides/presentation)	
Template recruitment materials (such as invitation letters and patient information leaflets)	

If there are any other supportive education and training materials you would prefer to receive please specify below

Text box

10. How long do you think the training should be? (please select one option)

1-2 hours

Half a day

1 day

1.5 days

2 days

Weekly sessions for duration of trial

Monthly sessions for duration of trial

A mix of the above

Other (please specify)

Part 3. Some questions about you

To make sure we gather responses from a wide range of people, it would be helpful to know a little more about you. Your answers will be treated in confidence and no individual will be identified when the results are presented.

11. How many years have you been involved in recruitment to neonatal trials? (Please select one option)

Less than 2 years

2-6 years

7-10 years

Greater than 10 years

12. What was the main location of the most recent neonatal trial you were involved in recruiting to? (Please select one option)

England

Scotland

Wales

Northern Ireland

Republic of Ireland

Other (please specify)

13. Gender? (Please use text box below or click *Next* if you would prefer not to answer)

_____

14. What was the subject area of the most recent neonatal trial you were involved in recruiting to? (E.g. pre term birth, neonatal feeding etc.)

Text box

15. Next steps after this survey

Once this survey has closed, we will be asking some people to take part in an online focus group or one-to-one discussion about how an education and training intervention might enhance neonatal trial recruitment processes. Would you consider taking part in an online focus group or one-to-one discussion?

Yes

No [route to Thank You page]

16. Thank you for considering taking part further in this study. Please provide details for your preferred method of contact to arrange potentially taking part in an online focus group or one-to-one discussion. This will be kept confidential and secure, in accordance with the Data Protection Act (Amended) 2008 and General Data Protection Regulation (2016)

Name:

Email:

Thank you

Thank you for taking part in our survey, your answers are important to us and we really appreciate your time.

Your answers have now been submitted.

Appendix VI. Recommendations from Workshop 1

Format
A combination of face to face and online. Face to face needs to be interactive and with small group work. Online pre-recorded or live elements embedded.
Written materials with theory to back up the interactive/face to face/pre-recorded elements
A multi-modal format to make it as accessible as possible - to include separate stand-alone units that can be accessed depending on need and time
It needs to be multi-disciplinary, and the wider team should attend at least some elements of the training
Mandatory vs Optional - potential to have particular modules that are mandatory
Pre-recorded elements should be short, and the face to face (online or in-person) can be longer but should be interactive
Background Info
A simplified summary of the protocol outlining the who, how and why of the study and potential questions/issues from parents that may not be covered in the protocol
Highlight the negative impact on trust if a recruiter is seen to be guessing/not clear on trial information - it's better to admit you don't know and find out/look it up later.
Outlining to parents the other trials you've been involved in and the positive impact of those trials to build trust and interest
Building trust and outlining the benefits/potential harms are most important in the initial meeting- if you can initially generate trust and portray that it is an important study that is key (details on potential harms does need to be presented in detail to parent early on)
Info specific to the trial area
Combine this section with the Background Information section
Highlighting the importance of the study and the relevance of the research question (often recruiters will arrive at training already with their mind made up on whether or not it's an important research question). Present the study to recruiters in a way that will bring people along that wouldn't have necessarily bought into it.
Present the benefits and harms maybe as a graphic. Also highlighting that if the study is not done, that is considered as a potential harm
Eligibility criteria
Presented as a checklist but needs to be available and visible in practice (e.g., on a lanyard or poster)
A lanyard with eligibility criteria would be helpful but this should also include a reminder to 'pause and think' about the parents' context and to question is this a good time to approach
Timing/approaching parents
Build awareness amongst recruiters on how to prepare before approaching a parent: look at your environment, look at the people, their faces, what's going on around, what have the parents already/just been told, their new environment, the enormity of the situation and the trauma, put yourself in their position, what's going on in the unit in general, is there another baby who is particularly unwell at the moment, that may be influencing that

particular family if they have become friendly with them, being aware of everything that's going on in the environment within the unit, not just the baby they're focusing on.
Do some engaging activities to help the recruiters think from the parent's perspective (e.g., think of a traumatic time they experienced), facilitating the recruiters to accept that it is a difficult task to recruit for neonatal trials
Identifying when to bow out and when the timing is not right and when the parent needs someone or something else at that moment (e.g., lactation specialist etc.)
Communication skills/rapport
Roleplay with actual parents if possible or actors and multiple scenarios (and time for reflection on this)
The recruiter being in a better headspace to pause before approaching and less stressed so better able to build rapport – this could be helped by them feeling confident in the background info about the trial
Provide an example of how a conversation might go – the steps; don't launch into a discussion about the trial, ask the parent how they are first, build a rapport, be aware of the balance and the recruiter-participant dynamic vs person-person dynamic (again a video from a parent or a video of good/bad examples)
Explain the importance of the order of information – info and updates on the baby's health must always come before a discussion about the trial '*You have to be careful about what you come across as wanting from them*'
Shadowing or a buddy/mentor system for inexperienced recruiters to learn in practice
To consider that it is not just about mothers, both parents should be considered and be clear of who needs to give consent from the outset so not to undermine the fathers when they give consent
Provide information from parents on what they need, what would make them feel comfortable in giving consent
Parents' needs
A reminder to consider that the parents will be struggling both emotionally *and* physically
A video recording of mother and father and their experience, maybe record an interview/conversation with them to hear and understand their stories.

Appendix VII: The TRAIN intervention training manual

Manual for the TRAIN Intervention

November 2021

Introduction

The **T**raining t**R**ial recruiters: **A**n educational **IN**tervention (TRAIN) study is being carried out by the Health Research Board-Trials Methodology Research Network (HRB-TMRN) in collaboration with the TRAIN Steering Group Committee (Appendix 1). TRAIN aims to design, pilot, and acceptability test an education and training intervention for recruiters to neonatal trials. This document provides the TRAIN intervention's manual (description and implementation).

Intervention development

The TRAIN educational and training program was developed by the TRAIN research team in collaboration with the TRAIN Cooperative Intervention Development Committee (TCIDC) (a stakeholder group including parents of neonates previously recruited to a neonatal trial and clinicians and researchers as recruiters to neonatal trials). Intervention development was informed by a systematic review of the effectiveness of education and training interventions for trials, a content analysis of previous recruitment education and training interventions, and an online survey of the education and training needs of those involved in recruitment to neonatal trials in Ireland and the UK. The TRAIN research team developed a proposed outline of the TRAIN education program based on the systematic review, content analysis and survey findings. This outline was then presented to the TCIDC in two workshop sessions. The committee members contributed to the design of the intervention plan through discussions and by providing perspectives, thoughts, and ideas on how the intervention might be further refined and developed; based on the committees' experience and expertise in neonatal trials.

- Workshop 1 (March 2021): A research team member presented an initial outline of the intervention plan for discussion and to gain the TCIDC's thoughts and ideas as to how the intervention could be further developed and enhanced.
- Workshop 2 (April 2021): a revised draft TRAIN intervention was presented to the TCIDC based on suggestions from Workshop 1 for further discussion. The TRAIN draft intervention was developed for piloting and acceptability testing with recruiters to neonatal trials based on input and consensus during this meeting.

Following development, TRAIN was piloted and acceptability tested with recruiters to neonatal trials**.**

Aim of the TRAIN intervention

To support neonatal research/clinical team members with knowledge and skills to assist them when recruiting parent(s)[1] of neonates (up to 28 days following birth) to a neonatal trial; so that informed parental decision-making on the participation of their neonate in a randomised trial, can be improved.

TRAIN Learning Outcomes

At the end of the TRAIN intervention, participants will:

- Understand the trial protocol and be able to explain to parents what taking part will involve
- Understand and be able to explain the process of randomisation to parents
- Be aware of factors to consider when approaching parents for recruitment of their neonate to a trial
- Understand and be cognisant of parents' perspectives when recruiting their neonates to a trial
- Be prepared to engage in a recruitment conversation

The TRAIN Manual

This manual was designed to describe the TRAIN intervention's content and guide the TRAIN facilitator through the program's three core learning units, including their delivery. The three core learning units that comprise the intervention are:

1. Unit 1: The trial protocol (50 minutes)
2. Unit 2: Understanding randomisation (5 minutes)
3. Unit 3: Approaching and engaging with parents (70 minutes).

In delivering the TRAIN intervention, please follow the guidance below and refer to the documents and resources in the TRAIN folder (provided with this manual). There is detailed guidance for each presentation in the notes section on each slide.

[1] Parent(s) is used in this manual to mean one or both parents of a neonate, or other legal guardian as the decision maker for the neonate participating in a research trial.

Unit 1 – The trial protocol (50 minutes)

Unit 1. Learning outcomes

At the end of Unit 1 participants will:

- ✓ Understand why the trial is being conducted
- ✓ Be aware of the eligibility criteria
- ✓ Understand and be able to explain to parents of neonates as potential trial participants what taking part in the trial will involve, including potential benefits and harms of the study, follow-up measures and timeframes
- ✓ Be aware of potential challenging questions that parents may have about their neonate taking part in the trial

Unit 1. Session overview

Session	Content	Resources
1.1 Introduction (10 minutes)	Welcome	1.1 Introduction
1.2 The trial protocol (15 minutes)	– Aim/importance of the trial – Eligibility criteria – What taking part will involve inc. potential benefits and harms of the study	1.2 Trial Protocol
1.3 Recruitment pathway (10 minutes)	– An exercise asking participants to map out the trial pathway for participating neonates to assess their understanding of the information from 1.2 Trial Protocol	1.3 Recruitment Pathway exercise 1.3 Infographic (diagram summarising the protocol)
1.4 Challenging questions (10 minutes)	– Discussion on issues/challenging Qs the parents may have beyond protocol information and how one might address these	1.4 Challenging Questions
1.5 Close of session and Q's (5 minutes)	– Questions/comments	

Unit 1. Facilitation guidance

1.1 Introduction (10 minutes)

- Open the TRAIN workshop with the Introduction presentation (there is detailed guidance in the notes section of each slide)
- Deliver [1.1 Introduction]

1.2 The trial protocol (10 minutes)

- Deliver [1.2 Trial Protocol]

1.3 Recruitment pathway exercise (5 minutes)

- Deliver [1.3 Recruitment Pathway exercise] (see notes in powerpoint slides for detailed guidance)
- Provide [1.3 Infographic resource]

1.4 Challenging questions exercise (10 minutes)

- Deliver [1.4 Challenging Questions]

1.5 Close and questions (5mins)

- End the session and invite participants to ask any questions

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Unit 2 – Randomisation (5 minutes)

Unit 2. Learning outcomes

At the end of Unit 2, participants will:

- ✓ Understand the process of randomisation to neonatal trials
- ✓ Be able to explain the process of randomisation to parents of neonates being invited to take part in a trial

Unit 2. Session overview

Session	Content	Resources
2.1 Randomisation (5 minutes)	A video explaining the process of randomisation to assist recruiters in explaining the process to parents of neonates who are being invited to take part in a trial	2.1 Randomisation Video

Unit 2. Facilitation guidance

2.1 Randomisation (5 minutes)

- Inform participants that you will play a short video explaining the process of randomisation
- Play [2.1 Randomisation Video]

Unit 3 – Approaching and engaging with parents (70 minutes)

Unit 3. Learning outcomes

At the end of Unit 3, participants will:

- ✓ Understand the factors to consider before approaching parents to invite their neonate to take part in the trial
- ✓ Understand the parents' perspective on the recruitment process
- ✓ Be prepared to engage in a recruitment conversation

Unit 3. Session overview

Session	Content	Resources
3.1 Approaching parents (30 minutes)	– Key considerations for recruiters before approaching parents about the possibility of their neonate being involved in a trial	– 3.1 Approaching parents – 3.1 Infographic summarising approaching parents – 3.1 Parent video vignettes – 3.1 Lanyard
3.2 Engaging with parents (15 minutes)	– A template recruitment conversation and order of topics, with example opening sentences	– 3.2 Engaging with parents – 3.2 Recruitment conversation guide
3.3 Practicing recruitment (20 minutes)	– Role-play session to work through challenging recruitment scenarios, with examples specific to neonatal trials. With feedback.	– 3.3 Practicing recruitment
3.4 Close of training and Q's (5 minutes)	– Final questions/comments	

Unit 3. Facilitation guidance

3.1 Approaching parents (30 minutes)

- Inform participants that you will present a short presentation explaining the key points to consider before approaching parents about a trial.
- Deliver [3.1 Approaching parents]
- Provide [3.1 Lanyard resource]

3.2 Engaging with parents (15 minutes)

- Inform participants that you will deliver a short presentation about engaging with parents.
- Deliver [3.2 Engaging with parents]

3.3 Practicing recruitment (20 minutes)

- Inform participants that this session involves role-play to practice the information that we have covered in each session; in particular, it will allow participants to practice the 'pause and think' technique from session 3.1 and the conversation guide from session 3.2.
- Deliver [3.3 Practicing recruitment]

3.4 Close and final questions (5 minutes)

- End the session and invite participants to ask final questions
- Thank participants for their time.

Appendix 1:

TRAIN Steering Group Committee

Name	**Affiliation**	**Role in SG**
Prof David Torgerson	York Trials Unit, University of York	Independent Chair
Prof Shaun Treweek	Trial Forge, University of Aberdeen	Member
Prof Carrol Gamble	ORRCA database, University of Liverpool	Member
Dr Nicola Mills	QuinteT, University of Bristol	Member
Ms Mandy Daly	INFANT entre, University College Cork	Member (Neonatal patient advocate)
Prof Eugene Dempsey	NPEU CTU, University of Oxford	Member (Neonatal rep. Ireland)
Ms Kayleigh Stanbury	Director of Advocacy & Policy Making, Irish Neonatal Health Alliance	Member (Neonatal rep. UK)

Appendix VIII: Phase 2 baseline and follow-up surveys

BASELINE SURVEY:

Welcome to the TRAIN survey

Please complete the following 2 minute survey before attending the TRAIN pilot training

1. How prepared do you feel for recruiting participants to a neonatal trial?

- Not at all prepared
- Not prepared
- Unsure
- Prepared
- Extremely prepared

2. How confident do you feel in recruiting participants to a neonatal trial?

- Not at all confident
- Not confident
- Unsure
- Confident
- Extremely confident

3. How knowledgeable did you feel about recruiting to a neonatal trial previously? (Please choose not applicable if you have never recruited previously)

- Not at all knowledgeable
- Not knowledgeable
- Unsure
- Knowledgeable
- Extremely knowledgeable
- Not applicable

4. In your opinion, how research active is your clinical setting/trial site?

- Not at all active
- Not active
- Unsure
- Active
- Extremely active

5. What level of support do you think is provided for recruiters to neonatal trials in your clinical setting/trial site?

- Not at all supportive
- Not supportive
- Unsure
- Supportive
- Extremely supportive

6. Please indicate the type of clinical setting where you recruit to a neonatal trial:

- Maternity
- General hospital
- Community
- Other (please, specify)

7. If you are currently recruiting, what stage in recruitment is the trial currently at?

- Not applicable (not recruiting)
- Month 1 of recruitment
- Months 2-4 of recruitment
- Months 5-8 of recruitment
- 8 months or more of recruitment

***END: Thank you for taking the time to complete this survey – please click 'Done' to submit your answers**:*

FOLLOW-UP SURVEY

Welcome to the TRAIN survey

Thank you for taking part in our online training, we really appreciate your time.

As a follow-up to the training please complete the 5 minute survey below:

1. After taking part in the TRAIN intervention, how prepared do you feel for recruiting participants to a neonatal trial?

- Not at all prepared
- Not prepared
- Unsure
- Prepared
- Extremely prepared

2. After taking part in the TRAIN intervention, how confident do you feel in recruiting participants to a neonatal trial?

- Not at all confident
- Not confident
- Unsure
- Confident
- Extremely confident

3. After taking part in the TRAIN intervention, how knowledgeable do you feel about recruiting to a neonatal trial?

- Not at all knowledgeable
- Not knowledgeable
- Unsure
- Knowledgeable
- Extremely knowledgeable

4i. Please rate the following elements of the TRAIN intervention on how useful, to neonatal trial recruitment, you perceive them to be:

	Extremely useful	Useful	Unsure	Not useful	Not at all useful
The TRAIN training overall					
Unit 1 Overall (The Trial Protocol)					
Unit 1 Resource (Protocol summary graphic)					
Unit 1 Activity A (trial pathway)					
Unit 1 Activity B (challenging Qs)					
Unit 2 Randomisation animation					
Unit 3 Overall (Approaching parents)					
Unit 3 Resource (Pause+Think graphic)					
Unit 3 Parent videos					

Unit 3 Lanyard					
Unit 3 Recruitment conversation script					
Unit 3 Role play practicing recruitment					
Overall duration of the training					
Overall delivery format of the training					

4ii. Any additional comments?

Text box

5. Are there any topic areas that you think had too little information?

Yes/No

Please specify … Text box

6. Are there any topic areas that you think had too much information?

Yes/No

Please specify … Text box

7. Are there any elements of the training that you found particularly helpful?

Yes/No

Please specify … Text box

8. Are there any elements of the training that you found were not particularly helpful?

Yes/No

Please specify … Text box

9. What would be your preferred method of delivery for the training?

- Online
- In person (once Covid restrictions are eased)
- Other (please specify)

10. Please provide any further feedback, or suggestions on how we could improve the <u>delivery</u> or <u>content</u> of the TRAIN intervention…

Text box

11. Please indicate the type of clinical setting where you recruit to a neonatal trial:

- Maternity
- General hospital
- Community
- Other (please, specify)

END: Thank you for taking the time to complete this survey – please click 'Done' to submit your answers: