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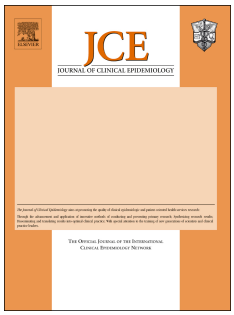

Limited evidence exists on the effectiveness of education and training interventions on trial recruitment; a systematic review

Hannah Delaney, Declan Devane, Andrew Hunter, Marita Hennessy, Adwoa Parker, Louise Murphy, Patricia Cronin, Valerie Smith

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

Authors:

Hannah Delaney[a,b,c*], Declan Devane[a,b,d], Andrew Hunter[b,d], Marita Hennessy[d,e], Adwoa Parker[f], Louise Murphy[d,g], Patricia Cronin[c], Valerie Smith[c]

[a] Health Research Board-Trials Methodology Research Network (HRB-TMRN), NUI Galway, Ireland

[b] School of Nursing and Midwifery, National University of Ireland Galway, Ireland

[c] School of Nursing and Midwifery, University of Dublin Trinity College Dublin, Ireland

[d] Qualitative Research in Trials Centre (QUESTS), School of Nursing and Midwifery, National University of Ireland Galway, Ireland

[e] Health Behaviour Change Research Group, School of Psychology, National University of Ireland Galway, Ireland

[f] York Trials Unit, Department of Health Sciences, University of York, UK

[g] Department of Nursing and Midwifery, University of Limerick, Ireland

*Corresponding Author:

Hannah Delaney

Tel: 00353 (0)91 495415

Email: hannah.delaney@nuigalway.ie

Address: School of Nursing and Midwifery, National University of Ireland Galway, Ireland

Abstract

Objective: To examine the effectiveness of education and training interventions on recruitment to randomised and non-randomised trials.

Study Design and Setting: A systematic review of the effectiveness of education and training interventions for recruiters to trials. 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 secondary outcomes were: quality of informed consent, recruiter self-confidence, understanding/knowledge of trial information, numbers of potential trial participants approached, satisfaction with training, retention rates.

Results: Of the 19 records reviewed at full text level, six met the inclusion criteria for our review. Due 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 favoured 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

Running title: Effectiveness of education and training interventions on recruitment to trials

Word count: 3115

1.0 Background

1.1 Introduction

Randomised 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 in order 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]. Additionally, McDonald *et al.* [3] explored levels of recruitment in a cohort of 114 trials in the United Kingdom (UK) (from 1994-2002) 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 recruitment targets, these are costly [5,6]. If recruitment targets are not met the research question often remains unanswered, wasting money, much research effort and participants' time. Strategies are often implemented to improve recruitment rates such as offering incentives to potential participants or tailored recruitment materials. However, as highlighted by Treweek *et al*. [1] there is limited high-quality evidence on whether or not particular recruitment strategies are effective. They found high-certainty evidence for three recruitment strategy comparisons (out of 72), and concluded that further evaluation and replication of evaluations are required to strengthen the evidence base.

1.2 Rationale

This review is part of a wider study (**T**raining **R**ecruiters-**A**n educational **In**tervention (TRAIN)) which aims to develop and evaluate an education and training intervention for recruiters to trials. A previous review of training programmes for recruiters to trials, by Townsend *et al*. [7], reviewed all study types (e.g. qualitative, pre-test/post-test, randomised and non-randomised), assessed their quality using the Effective Public Health Practice Project (EPHPP) tool, and summarised the results narratively. They found that some training interventions increased recruiter self-confidence when communicating trial information, but found little evidence that interventions increased recruitment rates, informed consent, patient understanding and satisfaction. They concluded that further development of training interventions for trial recruiters, with a focus on improving recruitment and informed consent, is required.

The current review was carried out to provide contemporary, up-to-date evidence on the effectiveness of education and training interventions for recruiters to trials, so as to inform the design of the TRAIN intervention. Although some studies included in the Townsend *et al*. [7] review were likely eligible for inclusion in our review, our review, in addition to searching for new trials, includes randomised and non-randomised control trials only which evaluated education and training interventions within the context of a planned or an ongoing trial ('host trial') and reported outcomes of effectiveness.

1.3 Aims and objectives

To determine the effectiveness of education and training interventions on recruitment to randomised and non-randomised control trials (here after referred to as trials). Our primary objective is to explore whether or not training and educational interventions for recruitment to trials positively affects recruitment rates.

2.0 Methods

2.1 Protocol and registration

The review protocol is registered on PROSPERO (ID=CRD42018108019) and can be accessed here: http://www.crd.york.ac.uk/PROSPERO/display_record.php?

2.2 Eligibility criteria

We included studies that reported on any type of education and training intervention for recruiters to trials within any healthcare field, compared to no education and training, or an alternative education or training intervention. For the purpose of this review, education and training interventions are defined as structured training delivered in any format, of any duration and using any approach, such as: face to face, online, seminars, lectures, workshops. Participants were individuals involved in recruitment to trials. This could include research nurses, general practitioners, members of the trial team, or any other individual involved in recruiting trial participants. We included only randomised trials (including cluster trials) and non-randomised (i.e. quasi-) controlled trials. We defined non-randomised controlled trials as trials where participants were allocated to the different groups using a method that was not random [8].

2.3 Outcome measures

Primary outcome

- Recruitment rates: proportions of eligible participants or centres recruited to the host trial. The host trial refers to any trial in which the participants of the education and training intervention were involved in recruiting individuals to.

Secondary outcomes

- Quality of informed consent reported by participants of either the host trial or participants of the education and training trial
- Recruiter self-confidence
- Host trial participants' understanding/knowledge of trial information
- Numbers of potential trial participants approached in the host trial

- Participants' satisfaction with training in the education/training trial
- Retention rates to the host trial

2.4 Search strategy and selection:

We searched the following electronic bibliographic databases: EMBASE, MEDLINE, and The Cochrane Library from July 2015 (end search date of Townsend *et al*. [7] review) to September 2018 (date the searches were implemented). We used broad search terms such as recruitment, training, education, randomised control trials, and variations of these terms/synonyms with Boolean operands, adapted across databases (see Appendix A). No language restrictions were applied to the search strategy; however, the inclusion of studies was restricted to English language publications.

References were initially uploaded to Endnote, and duplicate citations removed. The systematic review management software, Covidence, was used for the screening process. All titles and abstracts were screened for relevance independently by at least two from a team of seven reviewers (PC, HD, AH, MH, LM, AP, VS). Reports of studies were assessed for full text review against the review's inclusion and exclusion criteria. Potentially relevant full texts were uploaded to Covidence and assessed independently for inclusion by two reviewers (VS and HD). Any conflicts in decisions were discussed until agreement was achieved.

2.5 Data collection and data items:

A pre-piloted data extraction form was used to extract details including: study setting and aim, details of the training interventions and control conditions, numbers participating, recruitment strategies, study methodology, outcomes measured and results. Missing data were requested from study authors as necessary. Two reviewers (HD and VS) extracted data independently, with any discrepancies resolved through discussion and consensus.

2.6 Risk of bias:

Included trials were assessed independently by a pair of reviewers (HD and VS) for methodological quality using the Cochrane 'Risk of Bias' tool [9]. Studies were judged to be of low, unclear or high risk of bias, on selection bias, performance bias, detection bias, attrition bias, reporting bias and any other biases. Any differences between reviewers were resolved by discussion and consensus.

The unit of analysis was trial participants, for both the education/training embedded trial and the host trial. For dichotomous outcomes such as numbers recruited to the host trial, we analysed the data based on the number of events and the number of people assessed in the intervention and comparison groups. We used these data to calculate the risk ratio (RR) and 95% confidence interval (CI). For continuous measures, we analysed the data based on the mean, standard deviation (SD) and number of people in the intervention and control groups to calculate mean difference (MD) and 95% CI. If more than one study measured the same outcome using different tools, we calculated the standardised mean difference (SMD) and 95% CI using the inverse variance method in RevMan [10].

3.0 Results

3.1 Results of the search:

The search yielded 14,566 records, largely due to the broad nature of the search terms. An additional five studies were sourced for inclusion from the Townsend *et al*. [7] review. Of the total records, 186 were duplicates and were removed. Of the 14,385 titles and abstracts screened, 14,366 were excluded as they did not report on a trial of an education and training intervention for recruiters to trials. This resulted in 19 records assessed at full text level. Of these 19, eight met the inclusion criteria for our review [11-18]. On further assessment, two of the eight were subsequently excluded as one was an ongoing study [18], and the second did not report on any of our pre-specified outcome measures [17]. This resulted in the inclusion of six trials in our review [11-16]. 11 other studies assessed at full text level were excluded [19-29] with reasons provided in Figure 1. (see Figure 1 for the search and selection flow diagram [30]).

Figure 1: Search and Selection Flow Diagram

3.2 Characteristics of included studies:

Appendix B presents the summary characteristics of the included studies. Of the six included studies, two were multi-national studies [14,15], two were conducted in the United States (U.S.) [11,13], one was conducted in the UK [16] and one in Finland [12]. Of the six included studies, four [11,12,14,16] were randomised trials (of which three were cluster-randomised [11,12,16]) and two were non-randomised trials [13,15]. The education and training interventions for the included studies were implemented in the healthcare fields of oncology (n=3), cardiovascular care (n=2) and paediatrics (n=1). In two of the studies, the education and training interventions were targeted at recruitment to a specific host trial, while three focused more generally on institutions/centres that were running trials (the remaining study did not report on the timing of the intervention). Two studies focused on the recruitment of specific groups (children and the elderly). All of the trials compared the education and training intervention with no education and training (for one study, the control group received standard information relating to recruitment, but no extra training or education [11]).

The education and training interventions in three of the studies focused mainly on communication skills [12,13,14]. One involved a communication skills course, lasting one evening and one morning, to improve quality of informed consent, with role play and feedback [12]. A second involved 'Informed Consent Seminars' [13], and the third involved a workshop on patient information delivery and strategies to improve shared decision making with potential trial participants [14].

Kimmick *et al*. [11] assessed an educational symposium along with the provision of educational materials such as monthly mailings and lists of available protocols for use on patient charts. Kendall *et al.* [15] evaluated a targeted educational approach; with regular visits to the host trial sites to educate investigators and site personnel, and to help overcome any recruitment challenges. The remaining included study focused on practical ways to improve recruitment to the host trial with the provision of software for each site, and educational instructions on how to extract from data lists of patients who were potentially eligible for trial recruitment [16].

One study did not report on the number of sites included in their trial [14]. The other five trials included a total of 1,201 trial sites/institutions/centres. Three studies reported specifically on the number of individual participants enrolled to the study (both intervention and control); 132 physicians/oncologists in total (another study reported on the number of physicians attending each element of the training). Two studies reported on the number of patients involved in the host trials, which was 347 in total.

3.3 Risk of bias

The majority of studies were assessed overall as low or unclear risk of bias (see Figures 2 and 3 and Appendix C). One study had low risk for allocation concealment and sequence generation, as a programmer independent of the trial created the computer-generated random allocation sequence [16]. Kendall *et al*. [15] and Yap *et al*. [13] were assessed as high risk due to non-randomisation, and the remaining three studies were judged unclear due to insufficient information in the trial report to adequately assess. Due to the nature of the interventions it was impossible to blind participants and personnel. However, trials reporting objective measures only were assessed as low risk of bias [11,15,16]; and trials reporting subjective measures only were assessed as high risk of bias [12, 13].

When insufficient information was provided to assess risk of bias, we judged these to be unclear [14]. Detection bias was unclear for all studies, except Maxwell *et al*. [16] which had low risk. All studies had low attrition and reporting bias, except Yap *et al*. [13], which was judged unclear on attrition bias. One study was judged high risk for other bias due to differences in characteristics between the control and intervention groups [12].

Figure 2: Risk of Bias Graph

Figure 3: Risk of Bias Summary

3.4 Effectiveness of the interventions

None of the included studies reported on the outcomes: retention rates, numbers of potential trial participants approached.

3.4.1 Recruitment rates

Three studies reported on recruitment rates. Maxwell *et al.* [16] reported no significant change in the cumulative randomisation total over time between the training intervention and the control sites (adjusted RR 1.06, 95% CI 0.55 to 2.03, p = 0.87, after adjusting for site, site location, and time since the start of the intervention). Kimmick *et al*. [11] reported no differences in recruitment rates between training intervention and control institutions. Before the intervention, 40% of patients in intervention institutions compared with 36% in controls were recruited. During the first and second years post-intervention, 36% and 31% were registered for trials in the intervention group and 32% and 31% in the control group. Kendall *et al.* [15] also reported on recruitment rates, and categorised sites as low and high recruiting sites (1–5, 6–10, 11–15, 16–20, and >20 patients) and reported that the intervention institutions had a higher proportion of high-recruiting sites; the control institutions had a higher proportion of low-recruiting sites.

3.4.2 Quality of informed consent

Quality of informed consent was reported in one study [12], using the Quality of Informed Consent Questionnaire. Significantly more patients with doctors in the training intervention group reported that *'the physician offered other therapeutic options'* compared with the control group (97% versus 91%; RR 1.10, 95% CI 1.04 to 1.17) and reported a greater awareness of the study aim (89% versus 71%; RR 1.15, 95% CI 1.03 to 1.28).

Two studies reported on the host trial participants' understanding/knowledge of trial information, including all aspects of the trial [12] or randomisation only [13]. The results demonstrated no differences between the groups in understanding/knowledge of trial information (RR 1.03, 95% CI 0.97 to 1.10, 2 studies, 332 participants) (Figure 4). Furthermore, no difference between groups was

found in participants' ability to understand their voluntary choice about trial participation (RR 1.38, 95% CI 0.98 to 1.93, 1 trial, 59 participants).

Figure 4: Host trial participant's knowledge/understanding of trial information

3.4.3 Recruiter self-confidence

Butow *et al*. [14] reported narratively on recruiter self-confidence in their information provision, describing no difference from pre to post randomisation between the training intervention and control groups.

3.4.4 Participants' satisfaction with the training intervention

Butow *et al.* [14] also reported on participants' satisfaction with the training intervention, describing median satisfaction scores of 57.5 (range=41-57) and 56.0 (range=38-73) for SGA centres (Swiss, German, Austrian) and ANZ centres (Australian/New Zealand) respectively.

4.0 Discussion

4.1 Summary of principal findings

This review examined the effectiveness of education and training interventions for recruiters to trials. Six trials evaluating education and training interventions were identified and included. Due to limited evidence and differences between the included studies, in terms of outcomes and approaches, it is difficult to draw definite conclusions.

Meta-analysis was possible for one outcome, that is, host trial participant's understanding/knowledge of trial information; no differences between the groups were found. The results of the remaining reported outcomes, due to heterogeneity across the included studies, were summarised narratively. For our primary outcome of recruitment rates, reported in three of the six included studies, the evidence of effect of education and training interventions remains conflicting.

An education and training intervention, however, was found to yield greater quality in informed consent.

4.2 Strengths and limitations

This review provides contemporary, up-to-date evidence of effect underpinned by rigorous systematic review methods. Although language restrictions were not applied to the search strategy, inclusion of studies was restricted to English language publications only. This has the potential to introduce language bias and limit the scope of a review; however, none of the retrieved studies that were screened at full-text level were excluded on the basis of language, thus minimising the potential for any language bias. We also acknowledge that identifying trials for inclusion pre-2015 was based on the Townsend et al. [7] search strategy. While we are confident that all pre-2015 trials were captured with this search, we recognise this also as a potential limitation.

4.3 Comparison with existing literature

Similar to Townsend *et al*. [7], we found minimal evidence of effect of training interventions on recruitment rates to trials. Since 2015, the publication date of the Townsend review, only one further study (and one ongoing study) were identified on the effectiveness of education and training interventions. Our review thus further emphasises Townsend's suggestion that, not only are further training interventions for trial recruiters required, but that these interventions should be evaluated using more robust methods to better asses impact on recruitment rates. Additionally, Treweek *et al*. [1] highlight that further high-certainty and in-depth evidence is required around strategies to improve recruitment to trials; in particular, replication of evaluations are required to strengthen the evidence base. To add to this, we found that there has been very little evaluation, by means of controlled trials, carried out on education and training interventions for recruiters to trials specifically.

4.4 Implications for research and recruitment practice

Due to limited evidence it is difficult to recommend any meaningful suggestions for improving recruitment practices. To address recruitment issues relating to trials, further work on developing a substantial evidence base around the effectiveness of education and training interventions for recruiters to trials is required. Furthermore, due to the differences in outcomes and evaluation methods used in the included studies, it was difficult to undertake higher level syntheses such as meta-analysis on all reported outcomes, except host trial participant's knowledge/understanding of trial information. For this reason, there is a need for a standardised or core set of outcome measures for use in future trials of recruitment training interventions. The use of a core outcome set would strengthen the evidence base as it would enable enhanced comparisons between studies, and ensure that outcomes that are assessed are of relevance to key stakeholders.

5.0 Conclusion

There is limited evidence of effect on the impact of education and training interventions for recruiters to trials, on trial recruitment rates, so it is difficult to draw definite conclusions. To address recruitment issues relating to trials, further work on developing a substantial evidence base around the effectiveness of education and training interventions for recruiters to trials is required. Additionally, there is a need for a standardised set of outcome measures, for use in future trials and systematic reviews of recruitment education and training interventions.

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Declarations of interest: none

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Figure 1: Search and Selection Flow Diagram

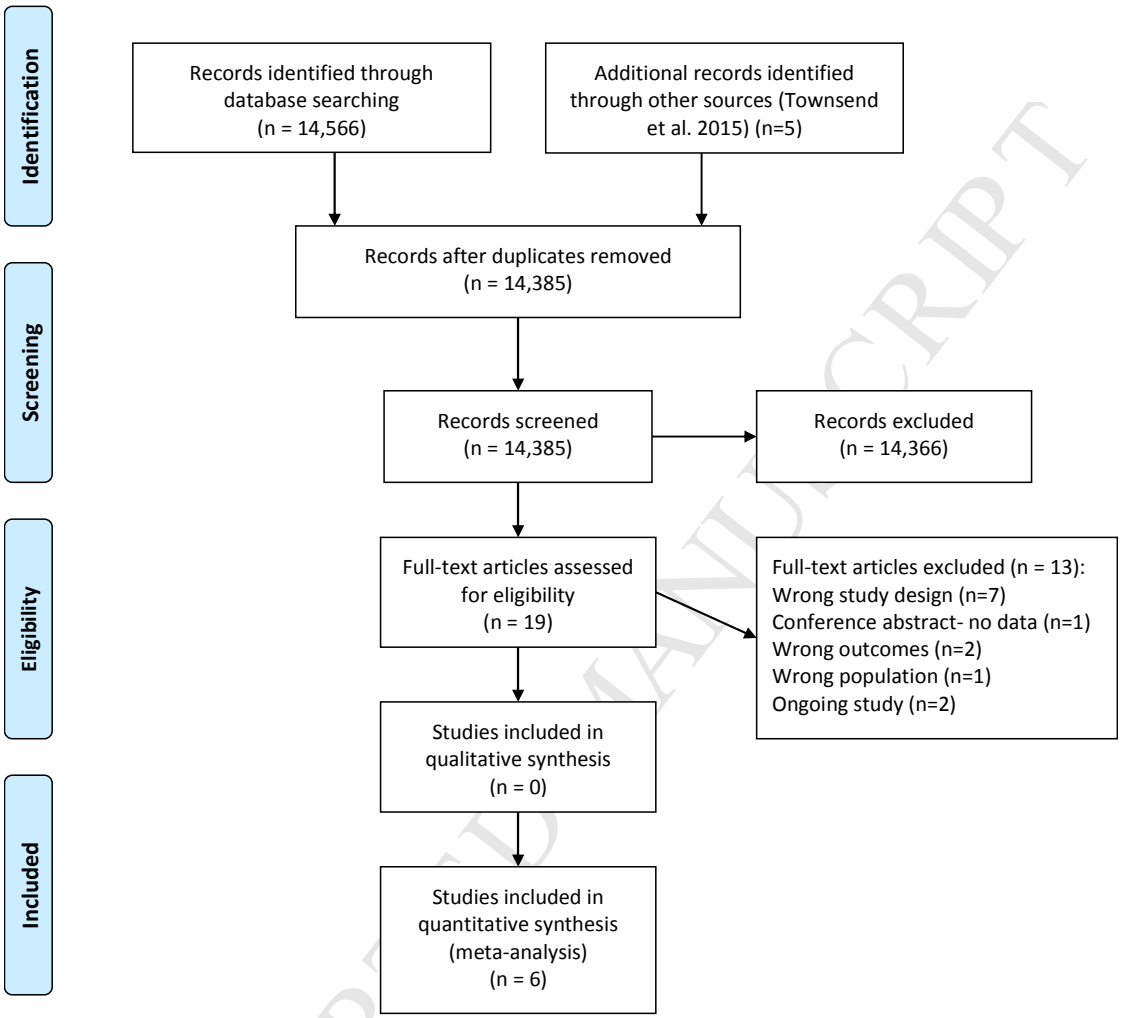


Figure 2: Risk of Bias Graph

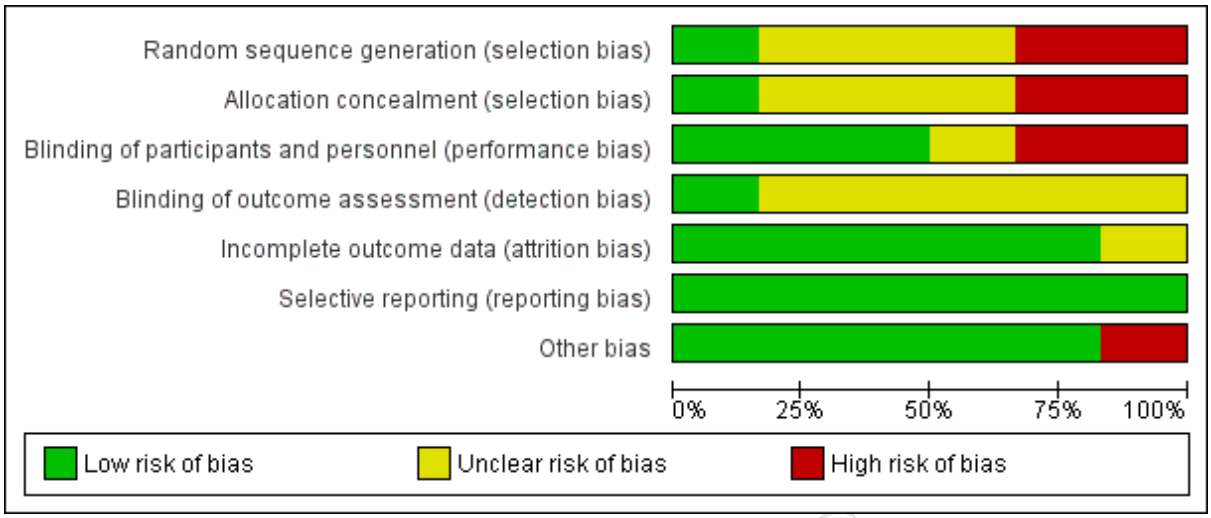


Figure 3: Risk of Bias Summary

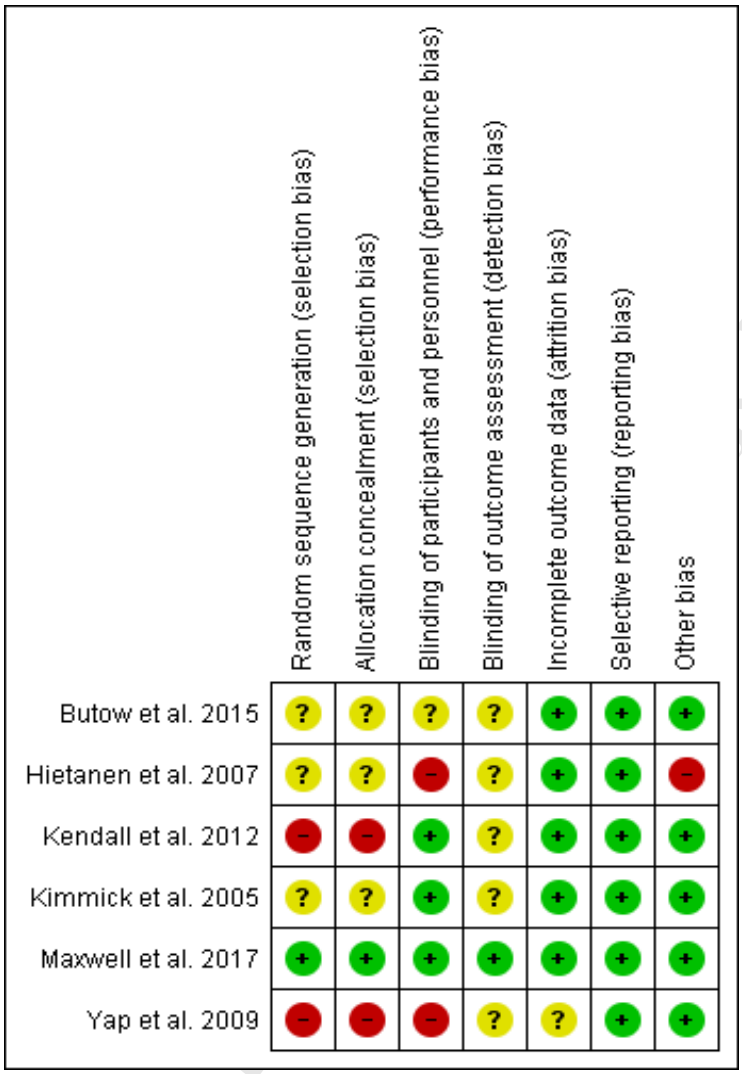
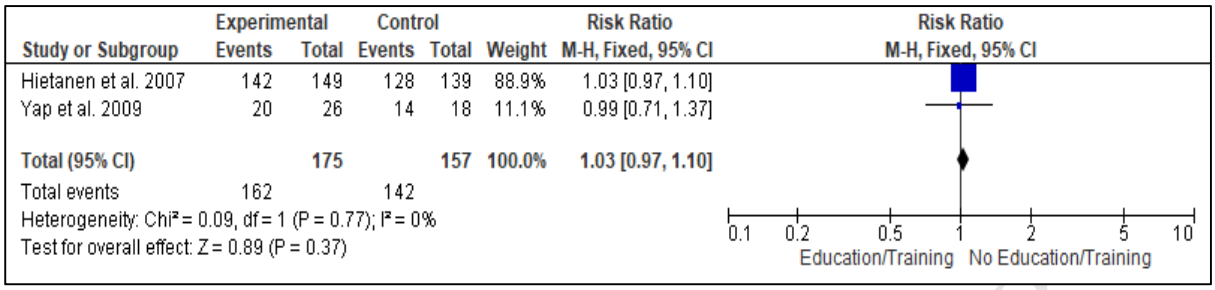


Figure 4: Host trial participant's knowledge/understanding of trial information



What is new?

Key findings

- There is limited evidence overall, on the effectiveness of education and training interventions on recruitment to trials, and the evidence that exists is conflicting.
- Education and training interventions, however, have demonstrated improved quality of informed consent.

What this adds to what is known?

- Further work on developing a substantial evidence base around the effectiveness of education and training interventions for recruiters to trials is required.
- Outcome measures and methods of measuring outcomes across studies is varied, making it difficult to synthesise, and compare and contrast study's findings.

What is the implication and what should change now?

- A standardised set of outcome measures is required for use in future evaluations of trial recruitment education and training interventions.