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Interventions to improve clinical trial recruitment with a focus on clinical staff from the recruiting site; a systematic review

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Abstract

Background Difficulties recruiting to clinical trials are well-documented. Strategies to engage staff from the clinical site where recruitment takes place may be helpful in increasing recruitment rates.

Aim To systematically review the literature to evaluate the effectiveness of interventions that aim to increase recruitment to clinical trials, focused on clinical site staff who support recruitment.

Methods A systematic search for randomised studies within a trial (SWATs) that aimed to improve recruitment to a randomised host trial in the field of health or social care aimed at clinical site staff was conducted. Studies were excluded if they aimed to increase retention, were targeted at participants, or the SWAT or host trial were non-randomised. Database and hand searches were conducted up to 25th July 2024. The primary outcome was the rate of recruitment. The Cochrane RoB2 tool was used to assess the risk of bias of included studies.

Results A total of seven studies were retrieved; all had a high risk or some concerns of bias. Studies evaluated heterogenous interventions and were synthesised narratively. A digital training for trainee principal investigators was the only intervention to demonstrate a statistically significant effect.

Conclusion Due to the small number of studies retrieved and the heterogeneity between them, it was not possible to make any conclusions of effectiveness of any strategy at helping clinical site staff to recruit at optimally. To prevent research waste, future SWATs need to

focus on replications of recruitment interventions in populations and settings of need, rather than further single-study replications.

Registration: PROSPERO CRD42022346585

Keywords Clinical trial, study within a trial, SWAT, nested study, embedded study, participant recruitment, participant selection, recruitment intervention, recruitment strategy

Abbreviations

EMBASE - Excerpta Medica database

Medline - Medical Literature Analysis and Retrieval System Online

NIHR - National Institute for Health and Care Research

ORRCA - Online Resource for Research in Clinical Trials

PROSPERO - International prospective register of systematic reviews

PRISMA - Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PROMETHEUS - Promoting The Use of SWATs

RCT - Randomised Controlled Trial

RoB - Risk of Bias

SIV - Site Initiation Visit

SWAT - Study Within A Trial

UK - United Kingdom

Introduction

Randomised controlled trials (RCTs) are considered the gold standard in assessing the effectiveness of interventions. [1] However, difficulties recruiting to RCTs are well documented. [2, 3] Suboptimal recruitment to clinical trials impacts on statistical power, increases costs and delays the production of evidence for patient benefit, leading to effective treatments not being implemented or ineffective treatments continuing to be used, thus contributing to research waste. [4-7]

Analysis of trials funded by UK healthcare funder, the National Institute of Health and Care Research (NIHR) between 1997 and 2020 showed that only 63% (n=245) reached their final recruitment target, illustrating the challenge of recruiting to time and target [8].

Although evidence-based healthcare decision-making originates from information produced by RCTs, this is not always the case for trial conduct decisions such as recruitment strategies.[9] Studies within a trial (SWATs) are a method to evaluate the effect of recruitment interventions. The availability of evidence regarding effective recruitment strategies, generated through SWATs, is growing, but recruiting to time and target continues to be hindered by the lack of robust evidence-based strategies. [9]

Previous research has identified the difficulty 'picking apart' factors influencing recruitment due to several strategies being used concurrently and not being evaluated using randomised methods, making it difficult to delineate the effects of each. [10] One of these factors is the role of clinical staff from recruiting sites. Bower et al.[11] identified a clear knowledge gap with regard to effective strategies aimed specifically at recruiters to RCTs. There are many different job roles within clinical teams, such as ward clerks, record keepers and nurses, who

can act as gatekeepers to potential participants, but their role in recruitment is not always as explicit as this. They can be key to successful recruitment to host trials by providing unofficial support, such as reminders about the trial to staff who can refer/recruit. It has been recognised that there is a need to credit and support this range of staff members whose involvement in recruitment is traditionally overlooked but is no less crucial to trial success.[12] In addition, gatekeeping by healthcare professionals has been identified as one of the most difficult recruitment barriers to overcome.[13]

Another factor suggested to contribute to low trial enrolment is the inaccurate assessment of challenges and risks associated with taking part in clinical trials, by both patients and staff. [14] Furthermore, a systematic review investigating the factors which affect recruitment to clinical trials found that both patients' and gatekeepers' decisions to participate are affected by their attitude towards the research and intervention under investigation, and a subsequent judgement between risk and reward of participation. [15] More recently, a qualitative evidence synthesis illuminated the influence of staff recruiters on participant screening and the complexities they navigate when recruiting to clinical trials. [16]

Despite this evidence, there has been relatively little investigation into interventions to aid this population to recruit participants effectively. [9, 17] Much of the investigation related to recruitment to clinical trials has focused on interventions targeted at prospective participants, with few focusing on effective interventions that could be used by staff recruiters. Of the 68 studies included in a Cochrane review by Treweek et al.[9], only 7% (n=5) were aimed at recruiters, which further highlights the dearth of high-certainty evidence in this area, and translates into a lack of evidence upon which trialists can use in the planning of clinical trials.

Given the growing body of evidence acknowledging the effect staff recruiters can have on recruitment, there have been attempts to develop interventions which target this population. For example, use of a designated person to recruit participants or the Qualitative Research Integrated in Trials (QuinteT) recruiter training intervention, which was developed to aid recruitment to surgical trials. [10, 18] Despite these interventions, there remains limited evidence of strategies aimed at clinical site staff who are involved in recruitment to clinical trials and, with the increasing prevalence of SWATs, it is likely that previous systematic review evidence on this topic is now outdated. [9, 17]

The aim of this review was to systematically review the literature to evaluate the effectiveness of interventions focused on clinical site staff (defined as: staff who are part of a clinical team at the recruitment site but separate to the core research team) who support recruitment to clinical trials.

The following objectives were set to achieve the aim:

1. Quantify the effect of identified interventions on recruitment rates to the host trial.

2. Explore the availability of cost and acceptability data of identified interventions

3. Evaluate the effect of interventions on participant screening rates.

Methods

The protocol for this review was prospectively registered on the International Prospective Register of Systematic Reviews (PROSPERO CRD42022346585).

This paper follows the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA). [19]

Eligibility

Participants: any member of staff from the clinical trial site (≥18 years), separate from the core research team, who was involved in any aspect of participant recruitment, either formally, such as taking informed consent, or informally, such as administrative staff reminding clinical staff to present a trial to eligible participants.

Interventions: any randomised SWAT aimed at improving recruitment to a randomised host trial in the fields of health or social care.

Outcome measures: recruitment rate to the host trial at the end of the SWAT period.

Types of studies: included studies were randomised studies within a trial (SWATs) embedded in a host RCT. Trials were excluded if they aimed to improve participant retention or were targeted at host trial participants. Interventions evaluated using non-randomised methods, or evaluating recruitment to non-randomised host trials were also excluded.

Information sources and search strategy

The electronic databases EMBASE, MEDLINE and PsycINFO were searched via the OVID platform from date of inception to 25th July 2024. Due to time and resources constraints, searches were limited to the English language, using a combination of terms related to SWATs and recruitment. Relevant terms were identified using the online resource PubMed PubReminer [20]. The search strategy was then piloted to ensure it retrieved a relevant, known paper. The full search strategy is given in Appendix 1.

The following resources were also hand-searched: the reference lists of included studies, F1000 Research SWAT collection[21], the Northern Ireland Hub for Trials Methodology

Research: SWAT Repository Store [22], the Trial Forge SWAT Network Group website [23] and the Online Resource for Research in Clinical triAls (ORRCA). [24]

To ensure ongoing or recently ended and unpublished research was included, the PROMoting the USE of SWATs (PROMETHEUS) Team at the University of York [25] were contacted to ask if they were aware of any relevant research.

Study selection and data collection

Retrieved records were managed using Endnote[26] for deduplication and exported into Covidence[27] for further deduplication and screening. Titles and abstracts were screened independently and in duplicate by two reviewers (L.H. and A.T.). Full texts of articles meeting the inclusion criteria were screened independently and in duplicate by L.H. and A.T. Disagreement between reviewers was resolved by discussion and by the inclusion of a third reviewer (L.C.). A data extraction template was developed and piloted for use in Microsoft Excel [28] (Appendix 2). Independent, double data extraction was performed by L.H., C.A. and L.C. The following data items were extracted:

SWAT

- Authorship
- Year of publication
- Title of publication
- Type of strategy / intervention used in the SWAT
- Length of intervention
- Randomisation type (e.g. - parallel / cluster)
- Allocation concealment
- Sample size (overall and by trial arm)

- Proportion of participants recruited to each of the SWAT arms
- Participant screening rate for each of the arms of the SWAT
- Intervention cost-effectiveness data
- Data on acceptability of the intervention
- Timing of SWAT in relation to host trial (at the start, or part way through)
- Participant characteristics (age, gender, ethnicity, role in host trial, job role, experience)

Host study:

- Country
- Sample size (target / actual)
- Health condition area
- Randomisation type
- Setting (e.g. – primary / secondary care)
- Time / funding extension needed to recruitment period (Y/N)

Outcome measures

Primary: proportion of participants recruited to the intervention arm and the control arm (as a percentage for each arm). The final report of recruitment was accepted. Data was extracted per publication and could not be converted due to heterogeneity in outcome reporting.

Secondary: Costs and acceptability of interventions.

Participant screening rates: the number of participants screened over the screening period (in months).

Data synthesis

The heterogeneity of interventions and outcome measures meant that statistical pooling of study results was inappropriate and pooled recruitment rates could not be calculated. Therefore, studies were grouped by intervention type and synthesised narratively.

To capture all studies meeting the inclusion criteria and allowing for replication recommendations, those at high-risk of bias were included in the narrative synthesis.

Planned subgroup analysis to explore the impact of interventions in different clinical settings, such as surgical and mental health settings, could not be performed due to the level of clinical heterogeneity and small number of records retrieved.

There were no planned sensitivity analyses.

Risk of bias

Two reviewers independently and in duplicate assessed risk of bias for each of the included records (L.H. and M.T.) using the Cochrane Risk of Bias 2 for cluster-randomised trials tool [29], resolving discrepancies by discussion between them.

Missing data was not sought from authors due to time constraints.

Results

Study selection

As detailed in the PRISMA flow diagram[19] (Figure 1), after deduplication, 1611 records were screened. Twenty-eight studies were assessed for eligibility, of which 21 were excluded due to ineligible study design (n=14) and ineligible study population (n=7).

A total of seven studies published between 2006 and 2022 were eligible for inclusion in this systematic review.

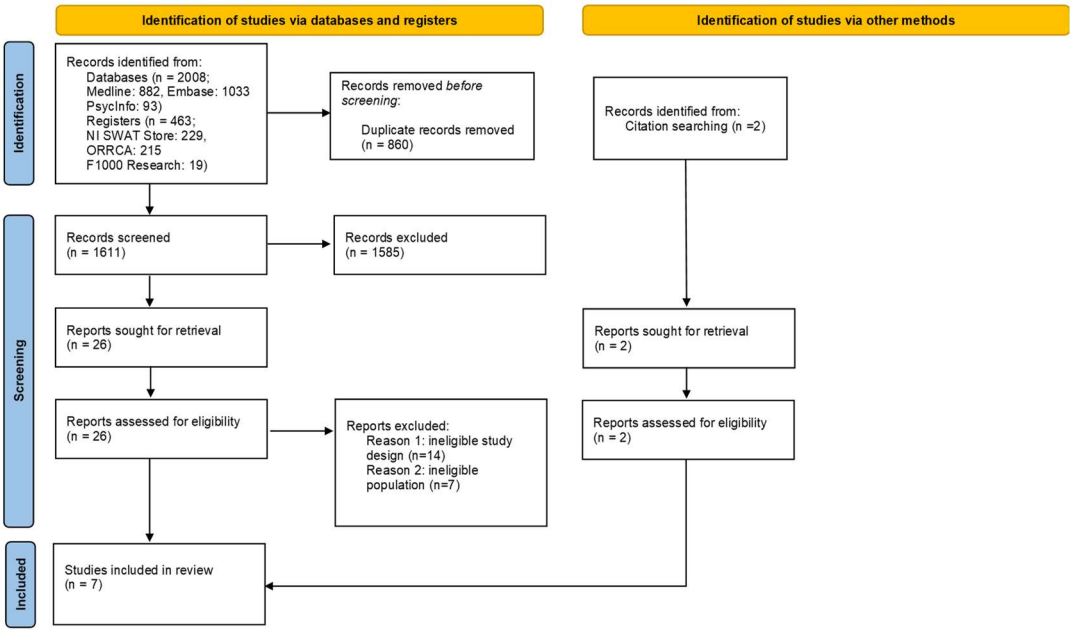

Figure 1. PRISMA flow diagram of identified records.

Characteristics of included studies

All seven studies were randomised using cluster randomisation. Three out of seven retrieved records were SWATs embedded in a host trial in a surgical setting [30, 31 32] two in oncology[33, 34], one in stroke[35] and one in diabetes.[36]

Study settings varied, with most studies based in UK countries (n= 4). [30-32, 35] The remaining studies were based in Australia (n=1) [33], France (n=1) [34] and multiple continents incorporating Asia, Australasia, Europe and North America (n=1). [36]

Information on the individual job roles comprising the participant population were not well-described in any included study. Four studies reported some information on the roles of people targeted by the interventions: healthcare professionals, research nurses, principal investigators, radiology contacts, research physiotherapists and surgeons. [30-32, 35]

Study characteristics are presented in tables one, two and three.

Risk of Bias

Risk of bias was assessed using the Cochrane Risk of Bias 2 tool for cluster-randomised trials. [29] Results of the assessment are shown in Figure 2.

[Insert Figure 2.]

Figure 2. Risk of bias of included studies.

Overall, three studies were assessed as having a high risk of bias [33, 34, 36] and four as having some concerns. [30-32] The main domains driving high risk of bias were missing outcome data (n=2) [33, 36] and bias due to deviations from intended intervention (n=1) [34]. The bias in the studies assessed as having some concerns was largely driven by bias due to deviations from intended intervention and bias in the selection of the reported result.

Analysis

Due to the lack of consistency in the interventions evaluated in the included studies, it was inappropriate to undertake a meta-analysis and hence a narrative synthesis is presented below.

Interventions and outcomes

Site initiation visits (SIV)

Two studies investigated the impact of onsite visits. [31, 34]

Table 1. Characteristics of studies investigating site initiation visits.

Author & year of publication	Setting of SWAT	Location of SWAT	Summary of SWAT intervention		Unit of allocation	Outcome data
			Intervention	Comparator		
Jefferson et al. (2018)	Secondary care - surgical	England and Wales	On-site site initiation visit (SIV)	Remote SIV	Site level	Mean number of host trial participants recruited per site: Remote SIV: N=17 mean (SD) = 10.9 (11.0) On-site SIV: N=20 mean (SD) = 9.7 (8.1)
Lienard et al. (2006)	Secondary care – oncology	France	On-site SIV and on-site ongoing monitoring.	Non-visited sites	Site level	Number of host trial participants recruited: 302 in the visited (intervention) group versus 271 in the non-visited group. 11% increase in recruitment in the visited group. No statistical difference.

Table 1 shows a small benefit of onsite versus remote initiation visits to a surgical trial ("The mean number of participants recruited was 10 for the on-site group and 11 for the remote

group" pp. 16, Jefferson et al.[31]). No statistical analysis was performed to determine significance of the difference.

Liénard et al.[34] found site initiation and ongoing monitoring visits resulted in 11% higher recruitment in sites that had onsite initiation visits and ongoing monitoring visits versus sites that did not. The authors state this difference was not significant but did not report statistical values (302 participants versus 271 respectively).

Training

Two studies examined the effectiveness of interventions with a staff training element at increasing recruitment rates.[30, 32]

Table 2. Characteristics of studies investigating staff training interventions.

Author & year of publication	**Setting of SWAT**	**Location of SWAT**	**Summary of SWAT intervention**		**Unit of allocation**	**Outcome data**
			Intervention	Comparator		
Parker et al. (2022)	Secondary care - surgical	UK	Additional training – QuinteT recruitment intervention: addressing obstacles and challenges of recruitment.	Normal recruitment practices	Sites were cluster randomised. The intervention was aimed at an individual level.	At six months post-training the rate of eligible host trial participants being recruited was 55% (number of staff n=13) in the intervention group and 63% (number of staff n=22) in the control group. No significant difference in recruitment rate (coefficient 0.07, 95% CI, 0.43 to 0.29, p=0.66).
Agni et al. (2022)	Secondary care - surgical	UK	4-armed SWAT comparing: 1. Enhanced trainee principal		Sites were cluster randomised. The intervention was aimed at	Number of host trial participants recruited: Enhance Trainee Principal Investigator Package (TPI) = 279

		investigator training (TPI) 2. Personalised digital nudge 3. Combination of arm 1 and 2. 4. Usual practice.		an individual level: trainee principal investigators.	Digital nudge = 147 TPI plus nudge = 410 Usual practice = 379 TPI in isolation effective at increasing recruitment in first six months of the trial; IRR 1.23 (95% CI, 1.09-1.40) P=0.001

Two studies examined the effectiveness of interventions with a staff training element at increasing recruitment rates.[30, 32]

The QuinTeT recruitment intervention, which was tested in one study (Parker et al.[32] Table 2) comprises a one-day training course for all staff involved in recruitment (surgeons, research nurses and allied health professionals) on the challenges of trial recruitment and strategies to overcome them.[10] The one-day training was supplemented by online e-learning materials, designed to equip recruiters with the skills to discuss RCT recruitment with patients. The intervention yielded no difference in the recruitment rate between intervention and control group,- which continued with normal recruitment practices (coefficient -0.07, 95% CI, -0.43 to 0.29, p=0.66).[32]

An enhanced digital training for trainee principal investigators (TPI) was the only intervention to demonstrate a statistically significant effect.[30] Over a six-month recruitment period, there was statistically significant benefit to recruitment in TPI arm (Incidence risk ratio (IRR) 1.23, 95% confidence interval (CI, 1.09 to 1.40, p=0.001). When a digital nudge, involving a personal email expressing appreciation and encouragement for recruitment was coupled with TPI, a significant interaction was observed, enhancing recruitment (IRR 2.09, 95% CI, 1.64 to 2.68. p<0.001). However, in the nudge only arm, recruitment was reduced at

a significant level (IRR 0.62, 95% CI, 0.51 to 0.75, P<0.001) indicating the digital nudge only had a beneficial effect on recruitment when combined with TPI and was harmful to recruitment when used in isolation.

Additional communication, funding, and recruitment plus software to aid patient identification

Three studies reported a range of heterogenous strategies. One study investigated the effect of additional communication, including frequent email contact and report of recruitment performance [36]; one examined the provision of additional funding to the sites[33]; and one investigated whether the provision of software package aimed at helping recruiters identify eligible patients was effective[35].

Table 3. Characteristics of studies investigating additional communication, funding, and recruitment plus software to aid patient identification.

Author & year of publication	Setting of SWAT	Location of SWAT	Summary of SWAT intervention		Unit of allocation	Outcome data
			Intervention	Comparator		
Monaghan et al. (2007)	No information - Diabetes	Asia, Australasia, Europe and North America	Additional communication strategies between central trial coordinators and clinical sites, including frequent email contact, personalised mail-outs of recruitment performance, certificates, and study-branded items.	Usual communication strategies.	Site level	No significant difference in the median number of host trial participants randomised per centre between the additional (intervention) and usual communication groups (37.5 vs. 37.0, p= 0.68). The median time to half randomisation target was lower in the additional

						communication group compared to the usual group, (4.4 months vs. 5.8 months, p= 0.08).
Parker et al. (2017)	Secondary care - Oncology	Australia	Additional funding to clinical trial sites. Funds could be spent as per site preferences and were most commonly used to increase staffing and to cover a pre-existing funding shortfall versus.	Sites that received usual funding plus a one-off incentive payment of 700 AUD.	Site level	No significant difference between sites with additional funding and those without. Change in yearly new recruited participants per site: Funding intervention arm, N= 16 Median (IQR) -2.0 (-5.0, 3.5) Control arm, N=18 Median (IQR) -2.5 (-10.0, 3.0). (ratio, 0.99; 95% CI, 0.69-1.43).
Maxwell et al. (2017)	Secondary care - stroke	England, Wales, Scotland	Complex intervention: recruitment advice focusing on the use of software aimed at identifying eligible patients and 6-month review of recruitment progress.	The same site prior to receiving the intervention. (stepped wedge design)	Sites were randomised and intervention aimed at individual members of the clinical team.	No significant difference in the recruitment rate of host trial participants between the intervention state and control state. Adjusted rate ratio for the number of host trial participants randomised per month after allocation to the intervention was 1.06 (95% CI 0.55 to 2.03) p=0.87).

As shown in Table 3., frequent email contact, regular personalised mail-outs, league tables and graphs comparing their site recruitment relative to other centres showed no significant difference in median number of participants randomised between intervention and control groups (37.5 vs. 37.0, p= 0.68). [36]

In one study, additional funding was provided to some recruitment sites. This could be used as sites wished, with most using the funds to increase staff hours or staffing levels, followed by being added to general funds to cover budget deficits. The additional funds provided to these sites did not result in a significant difference to recruitment when compared to site with no additional funding (ratio, 0.99; 95% CI, 0.69 to 1.43, p= 0.96).[33]

Recruitment advice focusing on the use of software aimed at identifying eligible patients and a 6-month review of recruitment progress did not significantly improve recruitment when compared to sites that did not receive the intervention (rate ratio: 1.06; 95% CI 0.55 to 2.03, p=0.87). [35]

Cost-effectiveness of interventions

An exploration of cost data found that costs of interventions were not reported well in any included records.

Three studies provided a descriptive commentary of costs but only Jefferson et al.[31] reported costs of the intervention; the average cost to set up a site in the intervention arm was £1,016.93 versus £727.10 in the control arm.

Acceptability of interventions

Four studies provided data on the acceptability of interventions, which were assessed using survey methods. [30-32, 35]

Jefferson et al.[31] found a preference for remote SIVs (16/28 respondents) and an on-site meeting for the final site visit (17/28).

Support using software to identify eligible participants from audit data was found to be useful by clinical site staff (93%, n=28), but time and resource pressures constrained its use.[35]

All of the participants who received an enhanced trainee PI training package were extremely satisfied with the induction and ongoing support. 90% of participants engaged with the induction activity and 86.7% with follow-up communication during the 6-month SWAT. [30]

Parker et al.[32] found that participants felt positive about the training intervention, they learned a lot from it, and that it would influence their future recruitment practices. Average ratings from 0-10 (10=highest rating): how positive participants felt about the training intervention 9.3 (SD 1.0), how much they learned during the intervention 9.2 (SD 0.9), and how much difference the intervention made to future recruitment practices 8.7 (SD 0.9).

Screening rate

None of the included studies provided information on the effect of the intervention on screening rates.

Discussion

Main findings

This review identified seven studies investigating the effect of randomised interventions aimed toward clinical site staff at improving recruitment rates to trials in the field of healthcare. The level of clinical and statistical heterogeneity between populations and interventions prevented the calculation of a pooled effect estimate for any single intervention. Only one intervention showed a statistically significant improvement in recruitment to the host trial, an enhanced trainee principal investigator training package. [30]

Similar to previous reviews on clinical trial recruitment, [9, 17] these results highlight the lack of high-quality evidence regarding strategies targeted at staff at the clinical recruitment site upon which trialists can make recruitment decisions. Little appears to have changed since previous reviews on this topic with studies still characterised by incomplete reporting and evaluations of single-study, heterogeneous interventions. [9, 17]

Strengths and Limitations

Previous research identified a wide range of clinical site staff roles as having the potential to affect participant recruitment [12] This review built on this by including a wide population, including any member of staff from the clinical recruitment site, unrestricted in terms of profession. This meant that any studies aimed at a broad range of job roles, such as ward clerks and administration staff could be included and summarised, although none of the included studies described inclusion of this often-overlooked population. The nature of cluster randomisation means it is difficult to understand the nuanced effect the intervention may have on individuals and how this could differ across job roles. Including this information in detail would highlight areas of need and prevent research waste.

Due to time and resource constraints, included studies were restricted to the English Language only, introducing the possibility of selection bias, although it is likely this would have a limited impact on the number of studies retrieved, as the majority of SWAT results are published in English Language journals.

This review is only concerned with interventions evaluated by randomised methods and therefore does not take account of non-randomised interventions, identified as potentially providing value to recruitment. [37]

Recommendations for future research

- SWATs aimed at clinical site staff are needed in all fields of health and social care.
- Future studies should provide information regarding the job roles and level of experience in research of staff targeted by interventions, which will aid understanding for who and how the interventions are effective or ineffective and so inform future replications.
- To prevent research waste, it is recommended that cost and acceptability data is included in all future planning and reporting of SWATs.
- The authors advocate for much wider promotion of the need for evidence-based trial methodology.
- Future SWATs should report standardised outcome data, such as recruitment rates, to allow for comparison between studies and meta-analysis of data to produce pooled effect estimates.

Conclusion

This paper highlights the dearth of good-quality evidence of effective interventions aimed at clinical site staff recruiters to enable them to recruit participants at optimal levels. The few records that were identified were too dissimilar to draw any useful conclusions regarding their effectiveness. To prevent research waste, future SWATs need to focus on replications of recruitment interventions in populations and settings of need, rather than further single-study replications.

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Appendix 1. Full search strategy

MEDLINE

1	study within a trial.mp
2	swat.tw
3	(embed* adj3 stud*).tw.
4	(nest* adj3 stud*).tw.
5	(embed* adj3 trial*).tw.
6	(nest* adj3 trial*).tw.
7	exp *Clinical Trials as Topic/
8	(embed* or nest*).ti,kw.
9	7 and 8
10	1 or 2 or 3 or 4 or 5 or 6 or 9
11	(patient* adj3 (select* or participat* or recruit*)).tw.
12	exp Patient Selection/
13	((participat* or recruit* or incentiv* or motivat*) adj4 trial*).tw.
14	(motivat* adj3 (participat* or select*)).tw.
15	(consent* adj3 (trial* or participat* or select*)).tw.
16	exp Patient Participation/
17	Informed Consent/
18	11 or 12 or 13 or 14 or 15 or 16 or 17
19	10 and 18

PSYCINFO

1	(patient* adj3 (select* or participat* or recruit*)).tw.
2	exp Patient Selection/
3	((participat* or recruit* or incentiv* or motivat*) adj4 trial*).tw.
4	(motivat* adj3 (participat* or select*)).tw.
5	(consent* adj3 (trial* or participat* or select*)).tw.
6	exp Client Participation/
7	exp Informed Consent/
8	1 or 2 or 3 or 4 or 5 or 6 or 7
9	study within a trial.mp
10	swat.tw
11	(embed* adj3 stud*).tw.
12	(nest* adj3 stud*).tw.
13	(embed* adj3 trial*).tw.
14	(nest* adj3 trial*).tw.
15	[(embed* or nest*).ti,kw.]

16	exp Clinical Trials/ or exp Intervention/
17	15 and 16
18	9 or 10 or 11 or 12 or 13 or 14 or 17
19	8 and 18

EMBASE

1	(patient* adj3 (select* or participat* or recruit*)).tw.
2	exp Patient Selection/
3	((participat* or recruit* or incentiv* or motivat*) adj4 trial*).tw.
4	(motivat* adj3 (participat* or select*)).tw.
5	(consent* adj3 (trial* or participat* or select*)).tw.
6	exp Patient Participation/
7	Informed Consent/
8	1 or 2 or 3 or 4 or 5 or 6 or 7
9	study within a trial.mp
10	swat.tw
11	(embed* adj3 stud*).tw.
12	(nest* adj3 stud*).tw.
13	(embed* adj3 trial*).tw.
14	(nest* adj3 trial*).tw.
15	(embed* or nest*).ti,kw.
16	exp *"clinical trial (topic)"/
17	15 and 16
18	9 or 10 or 11 or 12 or 13 or 14 or 17
19	8 and 18
20	limit 19 to conference abstracts
21	19 not 20

Appendix 2. Data extraction form

Author	
Year of publication	

Title of publication	
Target Sample size	
Disease area (can use ICD-10 criteria)	
Type of study (Randomised / non-randomised)	
Design - factorial, individual, cluster	
Setting	
Type of SWAT intervention	
Time / funding Extension needed to recruitment period	
length of recruitment period	
Country	
SWAT DATA	
Randomisation type	
Allocation concealment	
Target Sample size: Overall Intervention Control Group 3 Group 4	
Actual sample size: Overall Intervention Control Group 3 Group 4	
Proportion of participants recruited to intervention arm (n)	
Proportion of participants recruited to intervention arm (%)	
Proportion of participants recruited to control arm (n)	
Proportion of participants recruited to control arm (%)	
Proportion of participants recruited group 3 (n)	
Proportion of participants recruited to group 3(%)	
Proportion of participants recruited to group 4 (n)	
Proportion of participants recruited to group 4(%)	

Participant screening rate: intervention arm	
Participant screening rate: control arm	
cost effectiveness: cost of intervention Cost per participant recruited	
Data on acceptability of the intervention	
When did SWAT begin (e.g. start/part way through recruitment)	
Type of SWAT intervention	
Length of SWAT intervention	
Participant characteristics: Age (n (%)) Overall Intervention Control Group 3 Group 4 Gender Overall Intervention Control Group 3 Group 4	
Ethnicity	
Role in host trial	
Job role	
Length of experience in job role	