Trials

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# Theory and behaviour change techniques informing strategies to improve recruitment to clinical trials: a systematic review of randomised evaluations

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## Abstract

**Introduction** Efficiently meeting recruitment targets is foundational to clinical trial success. Past reviews on improving recruitment efficiency have highlighted only a few evidence-supported strategies; some of which may be context-specific, infeasible, or unsustainable. Re-framing research participation as a behaviour subject to the same forces as other human behaviours allows us to consider whether knowledge about behaviour change in other contexts can be applied to trial recruitment, potentially leading to more efficient theory-informed strategies. This study assessed randomised evaluations of recruitment interventions regarding (1) whether and how they reported using theory and (2) the extent behaviour change techniques (BCTs) were identifiable within recruitment methods and interventions.

**Methods** We examined reports of randomised evaluations of recruitment interventions from a Cochrane review of trials evaluating strategies to improve recruitment, and the online resource for research in clinical trials database. To be eligible, studies had to include recruitment or willingness-to-participate outcomes. First, we assessed how and to what extent authors reported using theories, models, or frameworks in any part of their trial. Second, we extracted use of BCTs from study recruitment methods guided by the BCT taxonomy.

**Results** We included 122 recruitment intervention studies. Few ($n=23$, 19%) explicitly reported theory, model, or framework use; most often, theory was used to inform the intervention design ($n=15$, 12%) or justification ($n=14$, 11%). The most frequently cited theories included the theory of planned behaviour ($n=7$, 6%) and prospect theory ($n=3$, 3%). Studies contained anywhere from one identifiable BCT ($n=43$, 35%) up to seven ($n=2$, 2%); these typically included providing information about health consequences (e.g. side effects; $n=25$, 21%), information about social and environmental consequences (e.g. helping society; $n=30$, 25%), and prompts/cues (e.g. reminders; $n=25$, 21%). Many studies did not report any codable BCTs ($n=35$, 29%).

**Conclusions** Studies evaluating recruitment interventions often fail to report any consideration of theories, models, or frameworks, and many well-understood behaviour change techniques are generally not reported. Future research that frames clinical trial participation as one or more behaviours may broaden the range of empirically based

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strategies available to support participation and lead to more productive evaluations of theory-guided, elemental, and empirically supported recruitment strategies.

**Keywords** Behaviour change, Recruitment interventions, Systematic review, Theory

## Introduction

Clinical trial recruitment remains an enduring challenge, one central to the efficient conduct of health care research and the advancement of health care. Multiple studies have described how a large proportion of clinical trials (40% or more) are discontinued or fail to meet recruitment targets [1–5], despite the median funding for such studies amounting to millions or tens of millions of dollars [6, 7]. The consequences of poor recruitment and the resulting delayed or failed trials can be varied and substantial, and include wasted resources, opportunity costs, delayed innovation, potentially biased results, and ethical problems associated with exposing participants to risk without any scientific gain [8]. It is therefore not surprising that an active literature has developed around approaches to improve clinical trial recruitment.

Trialists seeking guidance on how to maximise the chances of trial success have been faced with limited high-quality evidence to support specific practices. Systematic reviews of the literature identify many strategies that are context-specific, not always feasible, sustainable, or ethical, and many studies display a high risk of bias [9–12]. The most recent Cochrane review on the topic (68 randomised trials with over 74,000 participants) identifies only two interventions that are supported with high quality evidence that they increase recruitment (telephone reminders to people not responding to postal requests and open rather than blinded trials) [12]. International initiatives have sought to build on this evidence, including efforts to systematise the registration, conduct, and reporting of recruitment strategy trials nested within primary clinical trials [13–15]. They have also conducted priority setting exercises identifying key unanswered research questions, for example, how recruiters can effectively communicate with potential participants, what/how information should be provided to participants, and what barriers exist to involvement in trials [3, 16].

The application of theory, i.e. accumulated knowledge believed to explain the mechanisms of action of a phenomenon [17], in addressing complex problems has long been recognised as a means of improving both the design and outcomes of interventions [18]. By grounding interventions in theory, researchers can avoid ad-hoc approaches that may lack consistency and replicability [19]. A solid theoretical foundation also facilitates communication across disciplines, supports systematic evaluation, and enhances the cumulative development of knowledge [20]. In the context of clinical trial recruitment, theory can help explain why some recruitment strategies succeed while others fail, offering insights into the psychological, social, and environmental factors that influence trial participation.

We have proposed that higher quality, evidence-based guidance for trialists is likely to result from reframing research participation in terms of behaviour, subject to the same forces as other human behaviours [21]. When faced with similar challenges in the study of complex health interventions, implementation science moved to capitalise on theories, models, and frameworks from the behavioural sciences to design more effective, theory-informed interventions [22]. The reasoning was that without clear and explicit theory to describe and understand relevant mechanisms determining the behaviour (e.g., approaching patients, signing consent forms) of actors (e.g. recruiters, physicians, patients) in a complex system, interventions would inevitably be hit-and-miss. Using evidence-based behaviour change techniques, the active components of a behaviour change intervention [23] also allow trialists to understand why an intervention has no effect on recruitment, as this approach provides an explicit mechanism of action pathway that is being tested. In the absence of clearly defined theory use and behaviour change techniques, it is much more difficult to develop a cumulative science that describes why participation is so low in some studies, and which recruitment strategies (a planned, systematic approach using specific techniques) are more effective [22].

Our goal for the current work was to assess trial recruitment intervention studies in terms of (1) whether and how they have reported employing theories, models, and frameworks (TMFs) and (2) independent of explicit TMF use, the extent to which different theory-guided behaviour change techniques can be identified in tested interventions. Framing the literature in a way that is both cumulative, theory-informed, and uses standardised terminology to describe interventions will encourage evidence-supported intervention design, replication, and evaluation, rather than interventions that are context-specific and guided by individual experience. We also explored possible trends in TMF and behaviour change technique use over time.

## Methods

We used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement to support complete reporting of this study (Additional file 1, Appendix A) [24]. Our study was not registered in any repository, and we did not publish our study protocol.

### Study selection

We sought to identify studies that examine the effects of recruitment interventions on clinical trial participation; often these included studies embedded within a trial or studies using hypothetical trial scenarios to examine effects of different recruitment methods or materials [25]. Our study sources included studies identified in a previous Cochrane review [12] supplemented by searches in the Online Resource for Research in Clinical triAls (ORRCA) database [26]. These two sources used systematic methods to identify included studies from multiple databases. Since we were interested in the same sample of recruitment interventions included in the Cochrane review, we included all 68 studies from this review (complete to the end of 2015), and updated our review with a search of the ORRCA database using the same inclusion/exclusion criteria as the Cochrane review. ORRCA database searches were conducted on November 3rd, 2020 and August 11th, 2022. See Hudek et al. (2024) [25] for additional detail on source rationale and search methods.

#### *Inclusion and exclusion criteria*

In line with the Cochrane review, we included all published articles with the following PICOS (participant, intervention, comparator, outcome, study design) [27] inclusion criteria: *participants (P)* included potential trial participants; *interventions (I)* of interest included any intervention aimed at improving recruitment to the host trial; the *comparator (C)* could be either study recruitment methods as usual or another intervention aimed at improving recruitment; *outcomes (O)* of interest included the proportion or number of potential participants recruited to the host trial, or willing to participate; and *study designs (S)* included both randomised and quasi-randomised trials of recruitment interventions.

We excluded any articles where the host study was considered low risk (i.e., survey, observational cohort, biobank study) as these types of studies may not present the same recruitment challenges as those recruiting to trials where participants often consider a greater range of potential barriers, such as new treatments/procedures, unknown side effects, the uncertainty of randomisation, and time and financial burdens of multiple clinical visits [28].

### Data extraction

Detailed methods for data extraction are available from an earlier publication [25]. Briefly, two of three coders extracted data from each study (NH, KC, SS) into an Excel form, meeting regularly for consensus. A fourth coder (JCB) resolved any disagreements among coders. For each publication, we extracted data for up to three study arms (control/comparator = least intensive/recruitment as usual, intervention 1 = moderately intensive, intervention 2 = most intensive/resource heavy). Additional arms were not included in the extraction in order to maintain a manageable and interpretable amount of data. Papers reporting results from more than one study (i.e., different samples for the control/comparator) were treated as separate studies during coding and analysis. The data extraction form included 8 sections (background information, intervention details, use of shared decision-making, patient engagement, theory, model, and framework use, behaviour change techniques, recruitment outcomes). Background information and intervention details were published previously [25] and included year of publication, country, real vs. hypothetical trial decision, clinical specialty of host trial, and phase of host trial. Use of shared decision making and patient engagement is also published elsewhere [29]. In the current manuscript, we report on data extracted on theory use and behaviour change techniques. Due to resource limitations, we were unable to contact study authors for additional documents or study details and therefore limited extraction to what was available in the published study.

#### *Theory, model, framework (TMF) use*

We defined theory as a set of concepts and/or statements with specification of how phenomena relate to each other. Theory provides an organising description of a system that accounts for what is known, and explains and predicts phenomena [17, 30]. Models can be described as simplified explanations or specific aspects of a phenomenon; and frameworks provide a structured overview thought to account for a phenomenon using multiple descriptive categories and constructs/concepts [31]. We coded explicit and implied TMF use. We defined explicit use of a TMF if it was identified by name and included a reference. We coded for implied TMF use, constructs, and mechanisms of change more liberally, which required the TMF/construct/mechanism to be named or described in some way, but did not require a reference. We did not seek to distinguish theories from models or frameworks; we aimed to identify the presence of any TMF, by name, where available.

For studies with TMF use, we collected the TMF name, reference, and a quote describing the TMF use.

Multiple TMFs could be coded for a single study. Details of the area in which TMFs were used were captured using categories developed in previous work [30]. These seven areas of use included (1) justification—TMF used to support the study design/purpose; (2) intervention design—TMF used to inform the intervention design, conceptually, or by specifically influencing the design; (3) pilot testing—TMF used within the study to guide pilot testing of the intervention; (4) evaluation—TMF used to guide outcomes measurement or develop the evaluation strategy; (5) predictions—stated purpose of the study was to test the influence of a variable predicted to be relevant based on a given TMF; (6) post hoc—TMF mentioned in the discussion section to support or explain the results of the study; and (7) other—uses other than those mentioned previously. For studies with use defined as 'other', brief descriptions were collected to describe this use.

#### *Behaviour change techniques*

Behaviour change techniques (BCTs) were coded using the BCT taxonomy (v1) developed by Michie et al. (2013) [23]. This taxonomy is comprised of 93 BCTs used in behaviour change interventions, clustered into 16 groups. We specified the behaviour of interest using the AACTT (action, actor, context, target, time) framework [32] as action—any action focused on giving participants an opportunity to provide trial consent; actor—potential participants or study recruiters; context—recruitment to a clinical trial, not limited to specific clinical conditions; target—potential participants or substitute decision makers; time—any time frame up to when participants provide or decline consent. We extracted quotes that fit the taxonomy definition for specific BCT use from descriptions of any actual recruitment activity from the introduction and methods sections of each study, separately for each arm, counting the occurrence of each BCT only once per arm. We refer to these as 'implied' BCTs as they are not explicitly described as BCTs by the study authors and we cannot assume they are aware they are using such techniques. In cases where the same BCT was coded in multiple arms within the same study, we captured potential differences in frequency and intensity using brief descriptions of how the BCTs differed and the associated BCT codes.

#### *Risk of bias*

Risk of bias was assessed for each study using the Cochrane RoB 2 tool for parallel trials to assess reporting bias across five domains: bias during randomisation, deviations from the intended intervention, missing outcome data, measurement of the outcome, and selection of the reported results [33]. Risk of bias for each study was assessed by two of three independent coders, with all discrepancies resolved through consensus [25]. No studies were excluded from analysis based on risk of bias ratings. We did not assess bias due to missing results or conduct certainty assessments as it was not possible to determine whether the absence of TMFs or BCTs reflected non-reporting or actual non-use in the included studies. Additionally, no meta-analyses were conducted in which such assessments would be of value.

### Data analysis

TMF use, number of TMFs used, type of TMF used, and the seven areas of TMF use were described using frequencies and proportions. Presence of BCTs was also described using frequencies and proportions, by intervention arm and overall. We conducted Cochran-Armitage trend tests to explore the incidence of identified BCTs and TMF use over time (grouped by decade because year data was negatively skewed). Due to empty or low-frequency cells in the contingency table, year data were collapsed into three groupings for the TMF analysis: 1986–1999, 2000–2009, and 2010–2020.

## Results

The ORRCA searches resulted in 129 records to screen; 24 duplicates were removed, 51 records were excluded due to trial design, 5 had no usable outcome, and one had no comparator intervention (Additional file 1, Appendix B). In total, the initial set of 68 papers from the Cochrane review on the topic (Treweek et al., [12]) was supplemented with another 48 papers from the ORRCA database for a final sample of 116 papers [34–149]. We extracted data from 122 individual studies (Additional file 1, Appendix C) within the included publications as five papers reported on more than one study (see Hudek et al. [25] for more detail on study flow).

The majority of included publications ($n=78$; 64%) were published between 2010 and 2020 and two thirds ($n=78$; 64%) were recruiting to real clinical trials vs hypothetical decisions about trial participation. Most were conducted in the USA ($n=53$; 43%) or the UK ($n=40$; 33%), followed by Australia ($n=11$; 9%), Canada ($n=6$; 5%), France ($n=2$; 2%), Estonia ($n=2$; 2%), Italy ($n=1$; 1%), Austria ($n=1$; 1%), Denmark ($n=1$; 1%), Norway ($n=1$; 1%), Sweden ($n=1$; 1%), Tanzania ($n=1$; 1%), and internationally ($n=2$; 2%). Oncology was the most frequent clinical area for host trials ($n=36$; 30%), but overall, the clinical areas of host trials were diverse (e.g., psychiatry, smoking cessation, orthopaedics; Additional file 1, Appendix E: Supplementary Table 1). Among the 53% ($n=65$) of studies that reported on participant age, mean age ranged from 14.2–77.7 years; and among the 66% ($n=81$) of studies reporting sex and/or gender, mean percent female was 62%, with some studies including

only females ($n=17$; 14%) or males ($n=2$; 2%). The risk of bias ratings within the studies included low ($n=40$, 33%), some concern ($n=57$, 47%) and high risk of bias ($n=25$, 21%; Additional file 1, Appendix D) [25].

Table 1 describes TMF use among the 122 recruitment intervention studies in our sample. Only a minority ($n=23$; 19%) explicitly identified a TMF in any part of the publication, with another 17% ($n=21$) identifying specific constructs that implied consideration of TMF-informed mechanisms. Most ($n=78$; 64%) did not report that TMFs were considered in the study. The most common ways in which TMFs were used included informing the design of the intervention ($n=15$; 12%), helping justify the intervention ($n=14$; 12%), or making a theoretical prediction ($n=12$; 10%), with relatively few reported examples of TMFs informing pilot testing ($n=1$; 1%), evaluation of the intervention ($n=8$; 7%), or post hoc explanation of study results without other TMF involvement ($n=4$; 3%). The number of areas in which TMFs were used ranged from 1 ($n=7$; 6%) to 5 ($n=1$; 1%); no studies used TMFs in all 6 areas we coded for. We identified a total of 22 unique explicit

**Table 1** Theory, model, and framework (TMF) use among included studies ($n=122$)

| | | | Frequency (%) |
|---|---|---|---|
| **TMF use** | | | |
| None reported | | | 78 (63.9) |
| Explicit TMF use | | | 23 (18.9) |
| Implied TMF use/constructs/mechanisms of change | | | 21 (17.2) |
| **List of explicit TMFs used*** | | | |
| Theory of planned behaviour | | | 7 (5.7) |
| Prospect theory | | | 3 (2.5) |
| Grounded theory | | | 2 (1.6) |
| Theory of reasoned action | | | 2 (1.6) |
| Ottawa decision support framework | | | 2 (1.6) |
| Other (e.g. Andersen's health behaviour model, social cognitive theory) | | | 17 (13.9) |
| **List of implied TMFs/constructs/mechanisms used** | | | |
| Barriers to participation | | | 4 (3.3) |
| Patient engagement | | | 2 (1.6) |
| Framing | | | 2 (1.6) |
| Targeting | | | 2 (1.6) |
| Other (e.g., consumer principle, learning effect) | | | 10 (11.5) |
| **Total number of TMFs used** | | **Explicit** | **Implicit** |
| None | | 99 (81.1) | 101 (82.8) |
| One TMF | | 14 (11.5) | 21 (22.1%) |
| Two or more TMFs | | 9 (7.4) | 0 (0.0) |
| **Area of TMF use**** | **Definition** | | |
| Justification | *Theory is discussed in the background/literature review/objectives section and is used to support study design/purpose* | 14 (11.5) | 11 (9.0) |
| Intervention design | *The theory informed the intervention, either conceptually or by specifically influencing the design of the intervention* | 15 (12.3) | 13 (10.7) |
| Pilot testing | *Theory was utilized within the study to guide pilot testing of the intervention* | 1 (0.8) | 0 (0.0) |
| Evaluation | *The theory or constructs outlined in the theory were used to guide outcomes measurement or develop the evaluation strategy* | 8 (6.6) | 2 (1.6) |
| Predictions | *At least one stated purpose of the study was to test the influence of a variable predicted to be relevant based on a given theory* | 12 (9.8) | 4 (3.3) |
| Post hoc | *Theory was discussed in the discussion section for the purposes of supporting or explaining the results of the study* | 4 (3.3) | 0 (0.0) |
| Other | *Theory used in other ways (e.g., design of intervention trial, intervention production)* | 0 (0.0) | 2 (1.6) |

* Note: Does not add to 23 because some studies cited more than one theory, model, or framework

** Note: For one study (Nickell et al., 2019) area of theory use was unclear and not included in the frequencies reported here

TMFs. The most commonly identified TMFs included the theory of planned behaviour [150] (7 studies), prospect theory [151] (3 studies), grounded theory [152] (2 studies), the theory of reasoned action [153] (2 studies), and the Ottawa decision support framework [154] (2 studies). The other 17 TMFs cited appeared only once among studies. Among the 21 studies that implied TMF use or mentioned other TMF-based constructs/mechanisms of change, there was little consistency in the type of TMF, construct, or mechanism mentioned, ranging from large-scale research approaches (e.g. integrated knowledge translation [155]) to general psychological constructs (e.g., consumer principle [156], targeting [157]). While some studies used more than one TMF within the same study ($n=9$; 7%), none were used to test predictions of competing theories (see Additional file 1, Appendix E: Supplementary Table 2 for the full list of explicit and implicit TMFs).

Table 2 describes the range of BCTs identified across 122 studies within our sample, along with example excerpts from the text coded to the BCT taxonomy. Out of 122 studies, we identified 87 (71%) which implied use of BCTs. Among those papers containing BCTs, we identified a range of 26 individual BCTs. The most commonly identified BCTs were *information about social and environmental consequences* ($n=30$), *information about health consequences* ($n=25$), *prompts/cues* ($n=25$), *credible source* ($n=18$), and *instructions on how to perform the behaviour* ($n=17$). Often, BCTs were not limited to the intervention arms of recruitment intervention studies; many BCTs (e.g., *information about health consequences* ($n=17$), *prompts/cues* ($n=15$), *material incentives* ($n=5$)) appear in both control and intervention arms as part of standard recruitment practice for the study. Over half of included studies ($n=66$, 54%) had one or more BCTs identified in only one intervention/control arm, ranging from one arm-specific BCT ($n=34$, 28%) to up to seven arm-specific BCTs ($n=2$, 2%). The most frequently identified arm-specific BCTs included *information about social and environmental consequences* ($n=28$), *information about health consequences* ($n=15$), *credible source* ($n=15$), and *instructions on how to perform the behaviour* ($n=12$; see Additional file 1, Appendix E: Supplementary Table 3 for a full list). The arm-specific BCTs also included instances where differences were noted in the frequency or intensity of some BCTs across intervention arms ($n=18$; 15%). BCT intensity varied most often across interventions exploring differences in *information about health consequences* ($n=7$; 6%; e.g., testing how much detail in which to describe side effects and outcomes across intervention arms) and other frequently observed BCTs (e.g., *information about social and environmental consequences* ($n=2$, 2%), *credible source* ($n=2$, 2%)).

Table 3 describes differences in the use of BCTs across studies that used TMFs explicitly, implicitly, and showed no evidence of TMF use. Implied BCTs were identified in all 23 studies (100%) reporting explicit TMF use, 81% ($n=17$) of studies with implied TMF use, and 60% ($n=47$) of studies with no reported TMF use. The studies with explicit TMF use also tended to have more implied BCTs present per study, with 39% ($n=9$) having 3 or more BCTs identified, compared to 19% ($n=4$) of studies with implied TMF use or 13% ($n=10$) of studies with no reported TMF use. Examining the types of BCTs used across different levels of TMF use, explicit or implied TMF use appears to use more goals and planning techniques. Studies reporting explicit TMF use also appeared to have a higher incidence of using natural consequences BCTs (e.g., information about health consequences, social and environmental consequences, salience of consequences). While use of rewards/threats (e.g., incentives and rewards) and prompts or cues were similar across TMF usage.

To further explore the 35 studies in which we were not able to identify use of any BCTs, we reviewed the recruitment/intervention methods for possible mechanisms of change implied by the authors. The majority described differing methods of how information was either displayed or delivered ($n=16$), but not in a way that outlined potential BCTs. Other studies appeared to use cognitive nudges ($n=3$) or modified the study design without explaining it to participants ($n=7$). Two studies appeared to emphasise improving patient understanding over recruitment per se and may therefore have been less likely to incorporate or report behavioural elements aimed specifically at enhancing recruitment [49, 74]. One study provided an unconditional £5 incentive with the study invitation meant to build credibility/trust between invitees and researchers, which does not fit the BCT taxonomy definition for incentives [158]. Finally, 6 studies described their methods very briefly and lacking detail that BCT use could not be determined. In addition, none of these studies mentioned use of any explicit theories and only 4 mentioned implied theories/mechanisms of change; these included barriers to participation, the consumer principle, picture superiority effect, and framing.

The Cochran-Armitage trend test indicated a significant trend in more reported TMF use over time, increasing from 17% to 28% and most recently 42% ($z=-2.03$, $p=0.042$; Table 4). The Cochran-Armitage trend test for identified BCT use over time was not statistically significant ($z=-0.19$, $p=0.499$; Table 5).

**Table 2** Frequency of BCTs identified in any of the intervention groups ($n = 122$)

| BCT | Control frequency (%) | Intervention frequency (%) | Total frequency (%)* | Example text from study |
|---|---|---|---|---|
| 1. Goals and planning | | | | |
| 1.2 Problem solving | | 1 (0.8) | 1 (0.8) | "For example, facilitators engaged participants in an interactive discussion on attitudes and beliefs toward clinical trials (ie, "Why Bother with Clinical Trials?"), dealing with negative social appraisal of involvement (ie, "Inspiration, Information, and Motivation to Act"), and forming behavioral intentions (ie, "Clinical Trial Update: Progress in Drug Development and Prevention Research")."[66] |
| 1.4 Action planning | | 1 (0.8) | 1 (0.8) | "In addition, all participating HSSCs were asked to designate a person to liaise between the homecare and research teams." [68] |
| 1.5 Review behaviour goal(s) | | 2 (1.6) | 2 (1.6) | "The purpose of the values clarification component is to help people clarify how they feel about the different consequences of options, which consequences are relevant to their personal circumstances, and what trade-offs they need to make to arrive at a choice."[35] |
| 1.6 Discrepancy between current behaviour and goal | | 1 (0.8) | 1 (0.8) | "Emails to the clinical sites from the central trial coordinators generally contained highly-tailored site-specific information about recruitment performance relative to goals,…" [93] |
| 1.9 Commitment | | 1 (0.8) | 1 (0.8) | "23 of the 33 eligible HSSCs were contacted during the pre-engagement phase, to ask for a letter describing their support for the study and their intention to participate should it be funded." [68] |
| 2. Feedback and monitoring | | | | |
| 2.1 Monitoring of behaviour by others without feedback | | 1 (0.8) | 1 (0.8) | "During on-going visits, the trial monitors reviewed the inclusion criteria and protocol compliance of each patient,…" [84] |
| 2.7 Feedback on outcome(s) of behaviour | | 1 (0.8) | 1 (0.8) | "The additional communication strategy from the central trial coordinators to the clinical sites involved frequent email contact, regular personalised mail-outs of league tables and graphs describing recruitment performance relative to other centres,…" [93] |
| 3. Social support | | | | |
| 3.1 Social support (unspecified) | 1 (0.8) | 6 (4.9) | 7 (5.7) | "The purpose of the CI was to provide flexible, individualized, nondirective basic education and support for patients in order to create a context of trust that promoted clinical trial enrollment." [62] |
| 3.2 Social support (practical) | 1 (0.8) | 3 (2.5) | 3 (2.5) | "In arm C of the AAMEN Project, transportation to the church project session sites is provided." [59] |
| 4. Shaping knowledge | | | | |
| 4.1 Instruction on how to perform the behaviour | 5 (4.1) | 17 (13.9) | 17 (13.9) | "…and the addition of bullet points to clarify what to do if the participant wished to take part." [47] |
| 4.2 Information about antecedents | | 1 (0.8) | 1 (0.8) | "An implicit values clarification statement signposts the need for patients to engage with and evaluate this full information, possibly enabling patients to employ more appropriately their intuitive or usual processes to reach the decision." [35] |
| 5. Natural consequences | | | | |
| 5.1 Information about health consequences | 17 (13.9) | 24 (19.7) | 25 (20.5) | "The risks of participation (e.g., side effects, risks of uterine cancer) were also discussed in each session." [90] |

**Table 2** (continued)

| BCT | Control frequency (%) | Intervention frequency (%) | Total frequency (%)* | Example text from study |
|---|---|---|---|---|
| 5.2 Salience of consequences | 1 (0.8) | 6 (4.9) | 6 (4.9) | "However, the computer-based presentation also included interactive, explanatory features; these included text boxes linked to keywords, to providing further explanation, hyperlinks to diagrammatic and pictorial presentations of procedures, and a video clip of a live right heart catheterisation procedure." [78] |
| 5.3 Information about social and environmental consequences | 6 (4.9) | 26 (21.3) | 30 (24.6) | "The education session emphasized the benefits of participation, the lack of financial burden, and the need for minority participation in clinical trials." [90] |
| 5.6 Information about emotional consequences | | 2 (1.6) | 2 (1.6) | "Some participants find the MRI sound quite aversive, so we believe it to be a particularly relevant part of disclosed information when consenting to a study involving MRI evaluations." [77] |
| 6. Comparison of behaviour | | | | |
| 6.1 Demonstration of the behaviour | | 2 (1.6) | 2 (1.6) | "The study itself was then described including: the manoeuvre, showing actual patients receiving each treatment…" [117] |
| 6.2 Social comparison | | 3 (2.5) | 3 (2.5) | "The SMS reminder message (see text below) was designed to provide key enrollment information as well as including a peripheral cue based on the concept of social proof (looking to the actions of others for reassurance in situations of uncertainty) to encourage action by the study participants." [43] |
| 6.3 Information about others' approval | 3 (2.5) | 3 (3.5) | 6 (4.9) | "Quotations by PPIR [patient and public involvement in research] members described why they thought the study was important." [72] |
| 7. Associations | | | | |
| 7.1 Prompts or cues | 15 (12.3) | 25 (20.5) | 25 (20.5) | "Patients randomized to telephone follow-up received up to three telephone calls from the same study nurse,…" [119] |
| 9. Comparison of outcomes | | | | |
| 9.1 Credible source | 4 (3.3) | 17 (13.9) | 18 (14.8) | "First, in arms A-C, the first contact potential participants had with the AAMEN Project was in the form of an enhanced recruitment letter written by, and including the photograph of, a prominent local African American man, who is a former professional basketball player and owner of a Detroit-based company that employs many African Americans." [59] |
| 10. Reward and threat | | | | |
| 10.1 Material incentive (behaviour) | 5 (4.1) | 8 (6.6) | 8 (6.6) | "The invitation letters contained either the offer of the £100 incentive payment if the patient consented to be screened or a standard invitation letter with no incentive offer." [76] |
| 10.2 Material reward (behaviour) | 2 (1.6) | 1 (0.8) | 2 (1.6) | "To maintain equity, the £100 incentive was paid to all patients who signed a consent form for any of the studies (without regard to whether the incentive offer was in the invitation letter)." [76] |
| 10.10 Reward (outcome) | | 1(0.8) | 1 (0.8) | "The additional communication strategy from the central trial coordinators to the clinical sites involved … individualised certificates acknowledging achievement of recruitment milestones,…" [93] |
| 12. Antecedents | | | | |
| 12.1 Restructuring the physical environment | | 2 (1.6) | 2 (1.6) | "In arms A and D, baseline information was gathered via mailed packet; in arm B, baseline information was gathered via telephone interview, and in arm C, this information was gathered during church-based project sessions." [59] |

**Table 2** (continued)

| BCT | Control frequency (%) | Intervention frequency (%) | Total frequency (%)* | Example text from study |
|---|---|---|---|---|
| 12.5 Adding objects to the environment | 1 (0.8) | 5 (4.1) | 5 (4.1) | "The inclusion of pens within trial invitation packs may not only improve recruitment rates through encouraging reciprocal positive behaviour, but the convenience of a pen being readily available may prompt rapid completion and return of trial documentation." [146] |
| 16. Covert learning | | | | |
| 16.3 Vicarious consequences | | 1 (0.8) | 1 (0.8) | "An actual trial participant then described why she had participated in the study and the contribution she felt she had made to medical science and to future pregnant women." [117] |

* Note: Total frequency is not a sum of intervention and control arms as some studies used the same BCTs in each arm and were only counted once in the total

## Discussion

We reviewed randomised evaluations of recruitment interventions in their reported use of TMFs and evidence-based behaviour change techniques. We found that over half of included studies did not report the use of any TMF, either by explicitly referencing the TMF or by mentioning use of theory-informed constructs. From this, it appears that many interventions are being developed without much explicit consideration of theories, models, or frameworks. Further, there is very little consistency in what might be considered relevant TMFs in this area, as the most frequently mentioned theory, the theory of planned behaviour, was only referenced in 7 studies, constituting 6% of the studies in our sample. Instead, 22 different TMFs were found in our sample, perhaps reflecting a new literature where the most useful theoretical frameworks have yet to be determined. Our findings support those of another systematic review examining behavioural approaches to recruitment and retention in trials, which found the most frequently used theories included the theory of planned behaviour, social cognitive theory, and the theoretical domains framework [159].

While some studies appear to use TMFs to support the design and development of their recruitment interventions, very few studies tested predictions based on TMFs and we did not find any evidence of studies testing competing TMFs. Rather than testing logistical issues for which the relevant underlying mechanism is unspecified (e.g., whether consent forms are printed on quality paper in a coloured folio [34], whether having a computer-assisted consent process helps [78]), testing theory-relevant constructs leverages evidence from other literatures in a way that will lead to a more coherent and cumulative knowledge base.

This sample of studies apparently utilised a small subset of BCTs, many of which are common in standard recruitment activities [160] such as providing instructions on how to participate, information about the risks and benefits to participating, reminders, and information being delivered by a credible source. Less frequently identified BCTs included goal-focused techniques, such as those related to eliciting health outcome-related goals (i.e., shared decision making), feedback on recruitment success for recruiters, and providing or arranging social support for participation decisions. These may be important areas of exploration for the recruitment literature. For example, focusing on patients' health goals through shared decision making is a relatively new concept for trial participation decisions, but well established in health care. Shared decision making may be well suited to encouraging trial participation decisions that support patient goals, as it may lead to improved decision making [161–164], understanding patient experience, and may even reduce health inequalities [162–164]. Studies of shared decision making in trial participation are rare [165], and are a potentially useful area for future work.

We identified 26 individual BCTs out of a possible 93 present in the BCT taxonomy (v1) within the included interventions. While this may suggest a wide range of underused BCTs, the literature is yet unclear as to which BCTs might be both effective and appropriate to the context of trial recruiting, or within the specific contexts of different trials. However, tools exist to help intervention developers select potentially effective BCTs based on theory and potential mechanisms of action [166]. We would encourage interested trialists to engage with these tools when designing recruitment interventions in order to design interventions grounded in theory and further the knowledge base in this area.

**Table 3** Differences in the number and type of BCTs used between studies that used TMF explicitly, implicitly, and did not use TMFs ($n = 122$)

| | **Explicit ($n = 23$)** | **Implied ($n = 21$)** | **No TMF ($n = 78$)** |
|---|---|---|---|
| | **Frequency (%)** | | |
| BCTs identified | 23 (100.0) | 17 (81.0) | 47 (60.3) |
| Total number of BCTs identified | | | |
| 0 | 0 (0.0) | 4 (19.0) | 31 (39.7) |
| 1 | 11 (47.8) | 6 (28.6) | 26 (33.3) |
| 2 | 3 (13.0) | 7 (33.3) | 11 (14.1) |
| 3 | 6 (26.1) | 3 (14.3) | 7 (9.0) |
| 4 | 1 (4.3) | 0 (0.0) | 0 (0.0) |
| 5 | 0 (0.0) | 1 (4.8) | 2 (2.6) |
| 6 | 1 (4.3) | 0 (0.0) | 0 (0.0) |
| 7 | 1 (4.3) | 0 (0.0) | 1 (1.3) |
| BCTs identified | | | |
| 1. Goals and planning | | | |
| 1.2 Problem solving | 1 (4.3) | | |
| 1.4 Action planning | | 1 (4.8) | |
| 1.5 Review behaviour goal (s) | 2 (8.7) | | |
| 1.6 Discrepancy between current behaviour and goal | | | 1 (1.3) |
| 1.9 Commitment | | 1 (4.8) | |
| 2. Feedback and monitoring | | | |
| 2.1 Monitoring of behaviour by others without feedback | | | 1 (1.3) |
| 2.7 Feedback on outcome(s) of behaviour | | | 1 (1.3) |
| 3. Social support | | | |
| 3.1 Social support (unspecified) | 1 (4.3) | 2 (9.5) | 4 (5.1) |
| 3.2 Social support (practical) | 1 (4.3) | 1 (4.8) | 1 (1.3) |
| 4. Shaping knowledge | | | |
| 4.1 Instructions how to perform the behaviour | 4 (17.4) | 2 (9.5) | 11 (14.1) |
| 4.2 Information about antecedents | 1 (4.3) | | |
| 5. Natural consequences | | | |
| 5.1 Information about health consequences | 7 (30.4) | 5 (23.8) | 13 (16.7) |
| 5.2 Salience of consequences | 3 (13.0) | | 3 (3.8) |
| 5.3 Information about social and environmental consequences | 12 (52.2) | 8 (38.1) | 10 (12.8) |
| 5.6 Information about emotional consequences | 2 (8.7) | | |
| 6. Comparison of behaviour | | | |
| 6.1 Demonstration of the behaviour | | | 2 (2.6) |
| 6.2 Social comparison | 2 (8.7) | | 1 (2.6) |
| 6.3 Information about others' approval | 2 (8.7) | 1 (4.8) | 3 (3.8) |
| 7. Associations | | | |
| 7.1 Prompts or cues | 6 (26.1) | 3 (14.3) | 16 (20.5) |
| 9. Comparison of outcomes | | | |
| 9.1 Credible source | 5 (21.7) | 4 (19.0) | 9 (11.5) |
| 10. Reward and threat | | | |
| 10.1 Material incentive (behaviour) | 1 (4.3) | 3 (14.3) | 4 (5.1) |
| 10.2 Material reward (behaviour) | 1 (4.3) | | 1 (1.3) |
| 10.10 Reward (outcome) | | | 1 (1.3) |
| 12. Antecedents | | | |
| 12.1 Restructuring the physical environment | | 1 (4.8) | 1 (1.3) |
| 12.5 Adding objects to the environment | 1 (4.3) | 2 (9.5) | 2 (2.6) |

**Table 3** (continued)

| | Explicit (*n* = 23) | Implied (*n* = 21) | No TMF (*n* = 78) |
|---|---|---|---|
| | | Frequency (%) | |
| 16. Covert learning | | | |
| 16.3 Vicarious consequences | | | 1 (1.3) |

**Table 4** Contingency table for Cochran-Armitage trend test for theory, model, and framework (TMF) use over time (*n* = 122)

| TMF use | Year (frequency (%)) | | | |
|---|---|---|---|---|
| | 1980–1999 | 2000–2009 | 2010–2020 | Total |
| Yes | 2 (16.7) | 9 (28.1) | 33 (42.3) | 44 (36.1) |
| No | 10 (83.3) | 23 (71.9) | 45 (57.7) | 78 (63.9) |
| Total | 12 (100.0) | 32 (100.0) | 78 (100.0) | 122 (100.0) |

**Table 5** Contingency table for Cochran-Armitage trend test for behaviour change techniques (BCTs) identified over time (*n* = 122)

| BCT use | Year (frequency (%)) | | | | |
|---|---|---|---|---|---|
| | 1980–1989 | 1990–1999 | 2000–2009 | 2010–2020 | Total |
| Yes | 1 (100.0) | 5 (45.5) | 27 (84.4) | 54 (69.2) | 87 (71.3) |
| No | 0 (0.0) | 6 (54.5) | 5 (15.6) | 24 (30.8) | 35 (28.7) |
| Total | 1 (100.0) | 11 (100.0) | 32 (100.0) | 78 (100.0) | 122 (100.0) |

A number of studies did not appear to contain any identifiable BCTs, which is counterintuitive given that these studies implemented interventions intended to promote trial participation. This likely reflects the absence of a common nomenclature and the limited precision with which recruitment interventions are currently reported. For example, a small number of interventions appeared to rely on behavioural nudges—elements of choice architecture that influence behaviour in predictable ways without restricting options [167]—but seemed to fall outside the precise definitions of the BCT taxonomy [23]. Imprecise descriptions around such nudge components may stem from journal word limits, lack of understanding that such nudges affect behaviour, or even attempts to avoid ethical scrutiny, particularly where the acceptability of nudges is debated [168]. It remains to be seen whether newer frameworks under development (e.g., the Behaviour Change Technique Ontology [169]), seeking to more precisely describe the full range of behaviour change strategies now being explored, can help clarify these issues.

Out of the 87 studies with BCTs identified, 66 (76%) had at least one difference in identified BCTs across arms, suggesting most studies were testing identifiably different behaviour change strategies as part of their interventions. However, for many studies not incorporating evidence-based TMFs and BCTs, the mechanisms of action within the interventions may remain unclear. In a meta-analysis examining BCT and theory use in physical activity interventions, researchers found that although theory use alone did not display larger effect sizes than no-theory interventions, those that included theory use also used more BCTs (3 + on average), which was associated with significant intervention effects [170]. This suggests that consideration of both theory use and BCTs may be associated with intervention effects. While it was beyond the scope of the current study to investigate the relationship between theory or BCT use and actual intervention outcomes, this is an essential next step in exploring the benefits of using theory-informed behavioural approaches to trial recruitment interventions.

Finally, we explored whether TMF and BCT use was becoming more prevalent over time. While BCT use showed no such relationship, results indicated TMF use is increasing over time. We observe in the literature that more recent trials have begun to incorporate behavioural theory in particular [21, 158, 159]. With better guidance on the design, conduct, and reporting of recruitment interventions, future research may be better positioned to harness the cumulative benefits of theory-informed strategies and behaviour change techniques, ultimately leading to more effective, transparent, and replicable approaches to improving trial recruitment.

### Limitations

Our study focused primarily on trial participation, while any recruitment process is almost certainly comprised of multiple behaviours (e.g., screening, initial approach, seeking consent, providing consent) from multiple actors (e.g., potential participants, recruiters) [159]. We defined target behaviours in this study loosely, to include any activity related to potential participants signing a consent document, including behaviours of potential participants and recruiter behaviours. In previous work using the same sample, 67% (*n* = 82) of included interventions were classified as modified

information or consent processes targeting potential participants based on ORRCA intervention categories [12]. Only 8% ($n=10$) were classified as recruiter/site level interventions; the remaining 25% involved trial design, procedural changes, or incentives [25]. As most studies emphasised patient-focused interventions, and recruiter behaviours would typically be reported only when they were the intervention focus (i.e., in 8% of studies), we were unable to capture differences between recruiter and participant specific behaviours during data extraction. Future work should capture these differences by reviewing additional materials beyond the final study report (e.g., study protocols, consent documents, ethics documents) to obtain a deeper understanding of the techniques used during recruitment and how or when they are best utilised to improve trial recruitment (i.e., which BCTs work at which points in the recruitment process, and for whom).

## Conclusion

We found less than one quarter of recruitment intervention studies reported using any theories, models, or frameworks explicitly in their work. While most studies enabled identification of at least one behaviour change technique as a component of their intervention, many identified techniques were those commonly used in recruitment procedures and considered standard practice. More complete descriptions of recruitment interventions, framing them as behaviour change interventions, using standardised terminology to describe relevant BCTs, and employing theory-informed rationales should facilitate future work exploring the impact of TMF and BCT use on recruitment intervention outcomes, and in turn, support efficient development of effective and replicable trial recruitment strategies.

### Abbreviations

| | |
|---|---|
| AACTT | Action, actor, context, target, time |
| BCTs | Behaviour change techniques |
| ORRCA | The Online Resource for Research in Clinical triAls |
| PICOS | Participant, intervention, comparator, outcome, study design |
| PRISMA | Preferred Reporting Items for Systematic Reviews and Meta-Analyses |
| TMFs | Theories, models, and frameworks |

## Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-026-09664-w.

Additional file 1: Appendix A (PRISMA checklist), Appendix B (PRISMA flow diagram), Appendix C (List of publications included in the review), Appendix D (risk of bias summary), Appendix D (Supplementary Tables 1, 2, and 3).

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### Authors' contributions

JCB, JP, JG, DAF, KG, IDG, and MT were responsible for the conception of this project and provided guidance and expertise throughout the project. NH, KC, and JCB completed study screening. NH, KC, and SS completed data extraction. NH completed data analysis. NH and JCB drafted the manuscript. All authors reviewed and approved the final version of the manuscript.

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### Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

## Declarations

### Ethics approval and consent to participate

Not applicable.

### Consent for publication

Not applicable.

### Competing interests

The authors declare that they have no competing interests.

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