

BMJ Open Behavioural approaches to recruitment and retention in clinical trials: a systematic mapping review

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ABSTRACT

Objectives To identify studies that applied behavioural approaches to issues of recruitment and/or retention to trials; to describe these approaches; and to identify gaps for future research.

Design Systematic mapping review of research undertaken in clinical trials within peer-reviewed sources. Review participants were individuals involved in clinical trials, including trial staff, participants, potential participants and former participants.

Data sources MEDLINE, EMBASE, CINAHL, ERIC, PsycINFO, Web of Science and ASSIA from inception to 15 January 2020 with no date or language restrictions.

Eligibility criteria Studies within the context of clinical trials reporting the barriers/facilitators to recruitment and retention, or developing/evaluating solutions to said barriers/facilitators, using a behavioural approach.

Results 31 articles were included. Recruitment-focused studies (n=22, 71%) represented the majority. Studies tended to focus on participant behaviours (n=22, 71%). Underserved populations (n=11, 35%) were a notable subset of studies. Most studies (n=23, 74%) were exploratory but those that evaluated interventions (n=8, 26%) often did so within underserved populations (n=6). A majority of studies (n=30, 97%) did not specify their behaviours consistent with guidelines from behavioural scientists. The most used approaches were social cognitive theory (n=8, 26%), the theory of planned behaviour (n=6, 19%) and the theoretical domains framework (n=5, 16%).

Conclusions A range of behavioural approaches have been applied to recruitment and retention to trials. The multitude of recruitment research here is consistent with trials research generally and emphasises the need for research into retention. Authors report target behaviours minimally, which is not conducive to replication. Further research should build on lessons here, such as clearly specifying behaviours. Increased methodological rigour and transparency will lead to robust evidence bases and less research waste in poor recruitment and retention. Overall, trials informed by behavioural approaches promises to be efficient and more participant focused.

INTRODUCTION

Clinical trials are the backbone of evidence-based medicine, but they are complicated ventures.¹ Two of the most persistent

Strengths and limitations of this study

- A strength of this mapping review is the use of a protocol to ensure it was conducted systematically and can be replicated.
- The review has generated a database with relevant study data to allow further interrogation of this data in an accessible fashion.
- Considerable effort was placed in qualifying approaches as behavioural through referencing past expert consensus along with the expertise of the review so as to capture as broad a scope of relevant approaches as possible.
- Limitations include no formal quality appraisal of the included studies in their overall design or application of their behavioural approaches.

challenges when conducting trials are recruiting and retaining participants (ie, identifying potential participants, enrolling them and then keeping those enrolled on study until data collection is complete). Trials achieving prespecified recruitment targets range from 31% to 60% and nearly half of trials have a loss to follow-up of over 11%.²⁻⁴ Poor recruitment and retention have both scientific and ethical consequences, introducing uncertainty into the conduct and outputs of affected trials.^{2 5-8}

As recruitment and retention are such pervasive issues, both have been identified as top priorities for methodological research aimed at improving them.⁹ Recruitment and retention encompass many behaviours (eg, approaching a patient about a trial, signing a consent form, returning a questionnaire) performed by multiple actors (eg, patients, doctors, nurses) at various locations (eg, in hospital, at home) and across different time points. Therefore, many of the questions that trials researchers have about what promotes or inhibits recruitment and retention are suitable for investigation through a behavioural approach. Behavioural



theories provide a framework to understand what drives behaviour by defining key influences that contribute to that behaviour and how they interact.¹⁰ Those influences often include factors attributable to the individual (ie, beliefs, motivations, attitudes, capabilities) or to external influence (ie, relationships, environments, opportunities, resources).^{10–13} Investigations to understand a particular behaviour are looking to identify these influences and their relative contributions in driving the behaviour. Once researchers understand these relationships, they can then design strategies aimed at changing these behaviours.^{13 14}

Potential strategies that target modifiable behaviours are likely to be complex interventions because of their interacting influences and, therefore, should be directed by the UK Medical Research Council guidance on developing such interventions through the use of theory.¹⁵ A theoretical underpinning to an intervention can assist in understanding how an intervention is likely to cause the desired change by specifying the mechanisms of action believed to bring about that change.^{13 14 16–18} Behavioural theory does so by specifying the influences that drive the behaviour and the contexts the behaviour is meant to be enacted in, which includes information on who, where, when and with whom an individual enacts it.^{18 19} By carrying through this level of specification from initial investigation through to intervention development, it is easier to identify if the intervention is working through the proposed mechanisms on the proposed target influences of the behaviour.^{16–18} This more systematic process, as opposed to atheoretical interventions that do not specify proposed mechanisms as thoroughly, allows for a clearer understanding of the content of an intervention and its efficacy.^{13 15–18 20} That understanding then allows for replication and subsequent evidence synthesis, as well as the adaptation of successful interventions to new contexts/behaviours.^{13 17 18 21}

The extent to which behavioural approaches have been applied to understand and/or change the behaviours encompassed within recruitment and retention, however, is unclear. Thus, in order to establish the breadth of available literature on this application, we chose to conduct this review.

Rationale

The aim of this review was to identify examples of behavioural theory being used to guide explorations or develop interventions to address issues relevant to recruitment and retention to clinical trials. Our objectives were to generate a reproducible evidence base, identify gaps within the literature and inform future research.

METHODS

To address the above aim, a systematic mapping review was conducted. A mapping review seeks to describe the state of knowledge for a given question within a topic of interest and presents results narratively to answer said question, assisted by figures and population of a database

with included studies and their meta-data.^{22–24} The term ‘scoping review’ is often used interchangeably with the term mapping review due to their methodological similarities.²⁴ This review is identified as a mapping review as the authors consider it to be slightly more focused in seeking to answer a question, rather than broadly identifying the extent of the topic in published literature, as scoping reviews aim to do.^{22–24} A protocol was designed to ensure the review was conducted in a systematic and transparent fashion to increase reproducibility.

Search strategy

A search strategy was developed by the lead author (TC) and an information scientist (PM). The search strategy used terms informed by the respective Cochrane reviews on recruitment and retention along with incorporating behavioural theory terms informed by a scoping review of behavioural theories across the social and behavioural sciences.^{6 8 10} The list of search terms and complete search strategy can be viewed in online supplemental appendix 1. We searched the following databases: MEDLINE, EMBASE, CINAHL, ERIC, PsycINFO, Web of Science and ASSIA. These databases were searched from inception to 15 January 2020 with no date or language restrictions.

Eligibility criteria

To be eligible for inclusion, the studies needed to:

- ▶ Report the design, development and/or evaluation of behaviourally focussed recruitment/retention strategies (ie, explanatory studies).
- ▶ Identify barriers/facilitators to recruitment/retention (ie, exploratory studies) through a behavioural approach (see below for further clarification on what constituted a behavioural approach).
- ▶ Be set in the context of a clinical trial.

Exclusion

The following exclusion criteria were applied:

- ▶ Studies that evaluated a recruitment/retention strategy that did not have an explicitly defined behavioural approach.
- ▶ Studies that explored the challenges/solutions to poor recruitment/retention that did not use a behavioural approach to understand findings or develop strategy.
- ▶ Studies that aimed to improve adherence to an intervention rather than completion of a trial.
- ▶ Hypothetical trials without empirical data. Protocols were included when they described future studies that would generate empirical data.

Eligibility screening process

Citations and abstracts were collated and duplicates removed by PM and then migrated into RefWorks. The abstracts were screened independently by TC per the inclusion/exclusion criteria above. A select 10% of abstracts were divided and reviewed by members of the team (KG and HM) and any discrepancies were discussed between reviewers. Should an agreement still not have

been reached, it was taken to a meeting of the full review team for further discussion. All full-text papers identified from the abstract screening process were reviewed independently by TC. Each team member (KG, HM, EMD and LL) reviewed a quarter of the total full texts to affirm eligibility. Any disagreements for inclusion were discussed with the full review team. Systematic reviews identified in abstract screening were hand-searched for additional papers. Similarly, eligible full texts had references hand-searched for potentially relevant papers. Conference abstracts that described potentially relevant research were assessed as to whether there were full, peer-reviewed papers available and these were screened as above.

Determination of the application of a behavioural approach

Eligible papers needed to report the use of a behavioural approach explicitly within the text through direct mention of a behavioural theory or of a model/framework that draws constructs from such theories. For the sake of clarity, the term ‘behavioural approach’ is used throughout this review to encompass behavioural theory and models/frameworks. Approaches reported in potentially eligible studies were first checked against a published list that had been developed through expert consensus and systematic search to identify theories of behaviour and behaviour change across social and behavioural sciences.¹⁰ Davis *et al*¹⁰ identified such theories and also provided a list of excluded approaches that were identified in their search but were agreed through expert consensus to not be behavioural. The lead author of this paper (TC) identified approaches in potentially eligible studies that were not referenced in the review by Davis *et al*¹⁰ but appeared to be applicable to the scope of our review (ie, targeting behaviours associated with recruitment/retention in trials).¹⁰ The lead author (TC) applied the following criteria to such approaches as applied in the Davis *et al*¹⁰ review:

- ▶ The reported definition of theory: ‘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’.¹⁰
- ▶ The criteria that a behavioural approach would consider ‘individual behaviour as an outcome or part of the process leading to the outcome’ rather than exclusively at a group or community level.¹⁰ This idea provided the criteria that the approach had to be focusing on the individual, at least partly, when attempting to understand or alter recruitment/retention behaviour.

Additionally, although Davis *et al*¹⁰ did not include models/frameworks in their review, they still provided a definition for models/frameworks that was incorporated in our review. This definition was ‘organising structures of constructs that do not meet the definition of theory in that they do not offer predictions about how constructs relate to each other or allow prediction of outcomes’.¹⁰ As

the scope of this review was broad, we decided to include models/frameworks when we could establish that they had been developed from theoretical constructs from behavioural theories. Approaches that did not meet the definition for theory were then assessed for inclusion as a model/framework. Decisions as to whether the approach identified in the potentially eligible studies qualified as behavioural were presented to the review team for consensus.

Data extraction

Data were extracted by TC with a select 20% sample assessed for quality by members of the review team (KG and HM). The data extraction form was developed from the template of the ‘Data collection form for intervention review—randomised control trials (RCTs) and non-RCTs’ of the Cochrane Handbook.²⁵ It was amended to the needs of this review and is available in online supplemental appendix 2. The following summary data were extracted and summarised from each study: author details; year and journal of publication; country of origin; study type; study aim; sample size; behavioural approach reported; application of behavioural approach (ie, to develop intervention, to understand problem, to develop future strategy); patient and public involvement in the study and, where available, parent study context (eg, condition, trial design, intervention(s)). Data amenable to descriptive statistics were formatted into graphs. Other data were more amenable to narrative summaries to describe key points as well as to discuss similarities/differences between studies. Data from the extraction forms were collated into a database available in online supplemental appendix 3.

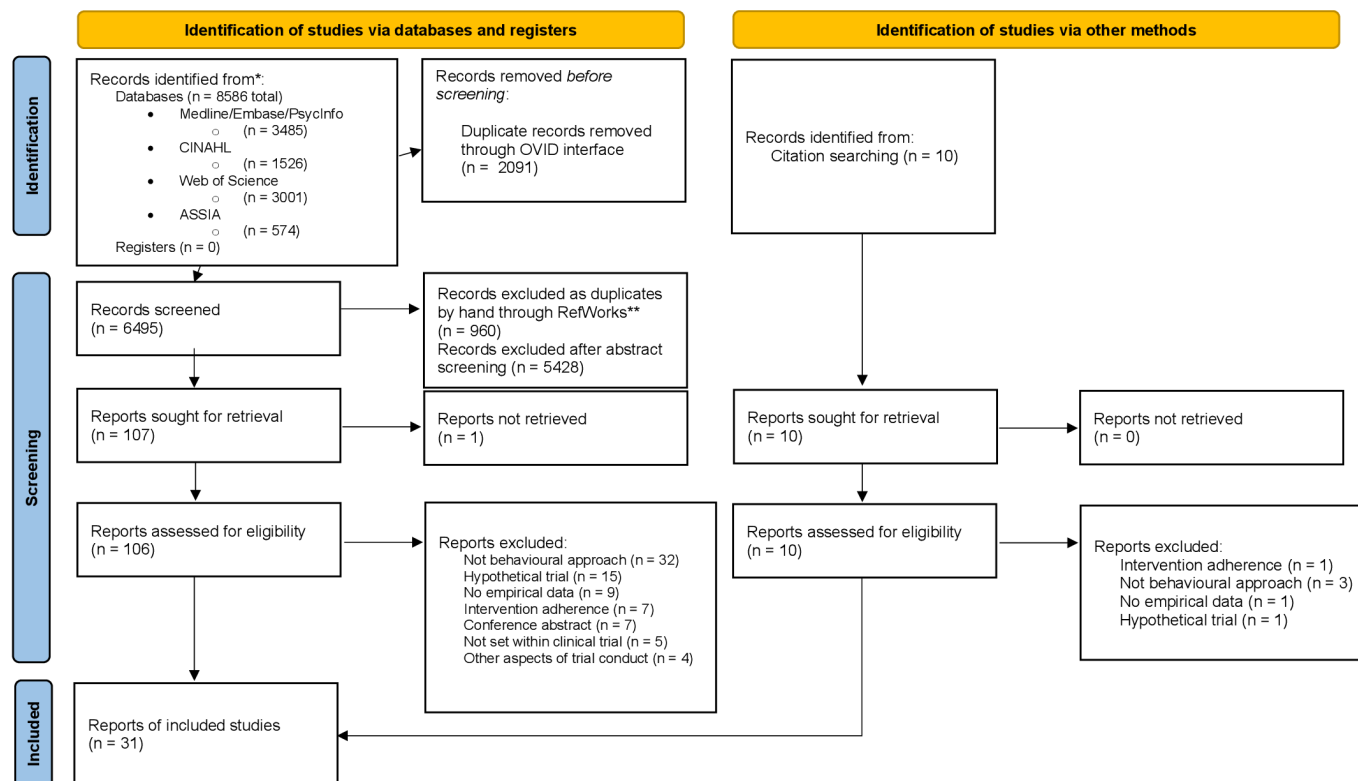
Behavioural specification

Included papers were assessed as to how authors specified the target behaviours of recruitment/retention and how these targets related to the chosen behavioural approach. Verbatim descriptions of how recruitment/retention were conceptualised were identified within the text by the lead author (TC) and were categorised as to whether they specified recruitment/retention broadly as their targets or further specified the targeted behaviours that comprise recruitment/retention. For example, a paper could give their aim as ‘understanding why participants enrol’, which is broad in that it can easily be broken down into further specific behaviours. In contrast, a specific behaviour could be reported as ‘understanding why participants do not return follow-up questionnaires to trial staff within designated follow-up windows’.

Patient and public involvement

Patients/the public were not involved in the design or conduct of this systematic review. It is not possible to disseminate the results of this review to the participants of the included studies.

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources



*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).

**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: <http://www.prisma-statement.org/>

Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram.

RESULTS

The results are summarised in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram in [figure 1](#).²⁶ A total of 6495 articles were identified from the primary search after deduplication. An additional 10 articles were identified by handsearching. A manual deduplication through the RefWorks software removed 960 articles. A total of 5428 abstracts were excluded with 106 articles moving to full-text review. Of those full texts, 85 failed to meet inclusion criteria with details given in the PRISMA diagram. Thus, a total of 31 full-text articles were eligible for inclusion in the review and progressed to data extraction.

Study characteristics

Of the 31 included studies, the majority (n=22, 71%) were conducted in the USA with others in Canada (n=2, 7%), the Netherlands (n=2, 7%), the UK (n=2, 7%), Australia (n=1, 3%), Kenya (n=1, 3%) and Puerto Rico (n=1, 3%). Publications spanned from 1995 to 2020 with half (n=16, 52%) being published within the 5-year period between 2015 and 2020. Publications over time based on their origin can be seen in [figure 2](#).

The host trials (ie, the trials that the reported studies were situated in/drew their populations from) were heterogenous in both phase and disease indication. Host trials ranged from early phase 1 trials through to

late-stage phase 3 trials. A large subset of papers (n=21, 68%) did not explicitly report the phase of the host trial, instead opting to name the trial or disease area being investigated. Those that did explicitly mention their host trial's phase (n=6, 19%) reported phase 1 (n=2), phase 3 (n=3) and 'early phase' (n=1). Other studies (n=4, 13%) that explicitly reported their host trial phase drew their populations from multiple trials. Many of the studies focused on cancer populations (n=11, 35%) with notable instances also within HIV/AIDS populations (n=5, 16%).

Study design

A majority of studies (n=23, 74%) were exploratory, looking to apply behavioural approaches to identify issues within recruitment/retention by assessing barriers/facilitators to their targets and predisposing characteristics of participants. They explored these barriers/facilitators through qualitative interviews and/or focus groups,²⁷⁻³⁹ intervention mapping,⁴⁰⁻⁴¹ surveys/questionnaires,²⁷⁻³¹⁻³²⁻³⁶⁻⁴²⁻⁴⁸ and secondary data analysis.⁴⁹ These studies identified potential strategies to address these insights, some only suggesting directions for future research while others developed interventions but did not formally evaluate them. The remainder of studies (n=8, 26%) did report evaluation of interventions. Of those eight studies, six (19% of total studies) evaluated their interventions using randomised comparisons. These

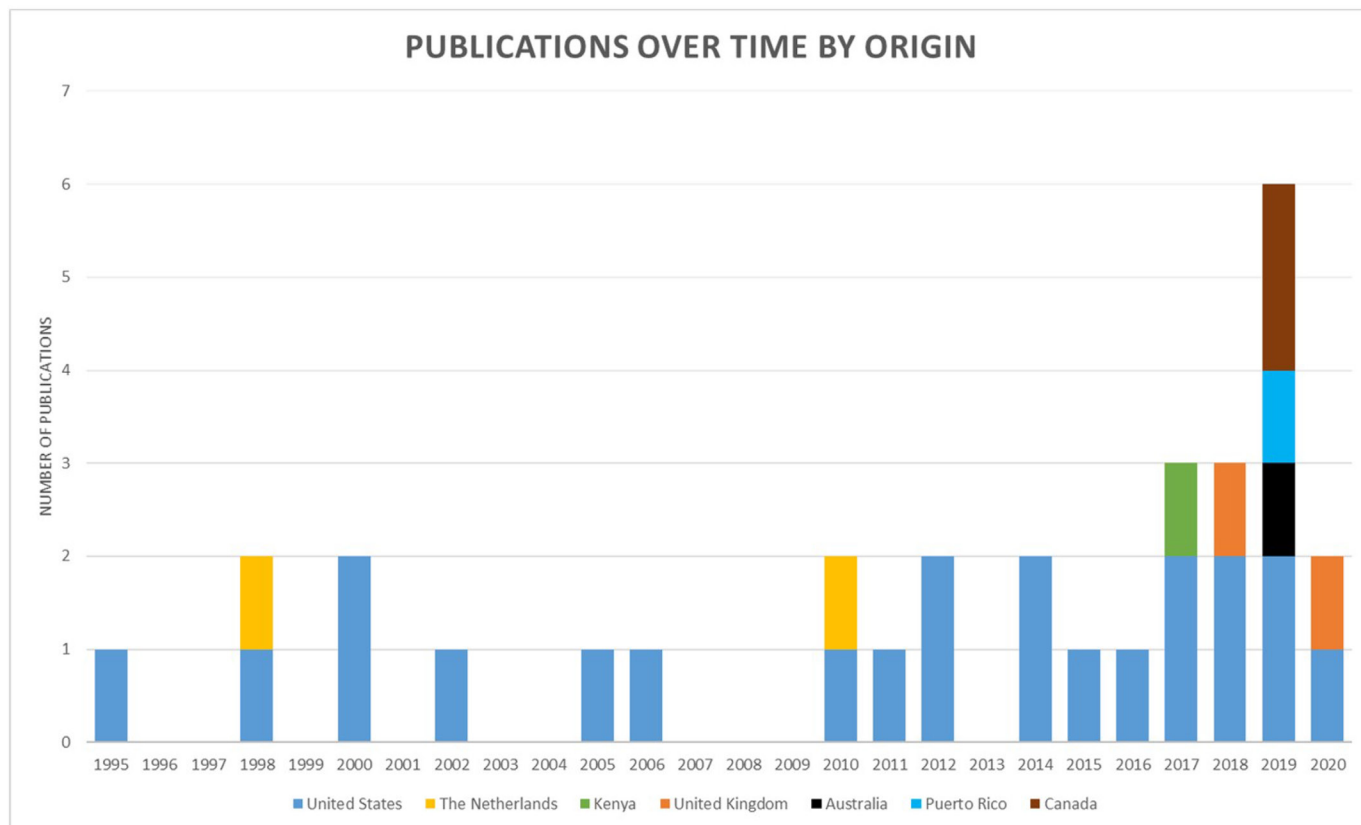


Figure 2 Origin of studies mapped over time.

were either cluster randomised (at the level of trial centre (n=2) or peer recruiter (n=1)) or randomised at the level of individual participants (n=3). One study (3% of total studies) evaluated two interventions, one randomised at the level of participants and the other as a within-subject interrupted time series of clinicians. One study (3% of total studies) evaluated their intervention through a non-randomised pretest/post-test design at the level of participants.

Recruitment vs retention

Researchers have historically focused on recruitment over retention, with a greater proportion of studies exploring retention from 2010 onwards compared with the 15 years prior (figure 3). Overall, the studies showed a clear focus on the use of behavioural approaches to understand trial recruitment with 22 (71%) of the studies focusing solely on recruitment and a further three (10%) studies looking at both recruitment and retention (figure 4).

Target population

The target population was considered to be the group of individuals whose behaviour was being targeted by the behavioural approach. As seen in figure 5, included studies tended to investigate the behaviour of trial participants vs staff. A majority of articles (n=22, 71%) focused solely on trial participants with a further four (13%) studies addressing them at least partially. Some studies collected data from other populations that were not the target of the behavioural approach. For example, a study

could aim to understand the behaviour of participants but explore the experiences of trial staff to inform their results.

Under-served populations

A notable subset of the papers (n=11, 35%) sought to apply behavioural approaches to understand, or develop solutions to, issues of recruitment/retention that affect ethnic minority groups and other groups underrepresented in trials. These groups will be referred to as ‘underserved groups’, per guidance from the INCLUDE project.⁵⁰ The term is preferred by stakeholders, of which these groups are members, as it reflects that the groups are not at fault for their lack of representativeness and are similarly motivated to participate in trials as others.^{50 51} All 11 of these studies sought to address recruitment of underserved groups, five targeting only participants, four targeting both participants and trial staff, and two targeting only staff. Of these 11 papers that focused on under-served groups, seven involved trials in HIV/AIDS and cancers. This represented nearly half (n=7) of all studies that drew from these disease populations (n=16). Of the eight total studies (26% of total studies) that evaluated interventions in this review, six evaluated interventions aimed at increasing recruitment of under-served groups. Five of these evaluations utilised a randomised design.

Behavioural specification

Overall, 13 (42%) of the papers described their study targets broadly as recruitment/retention using language

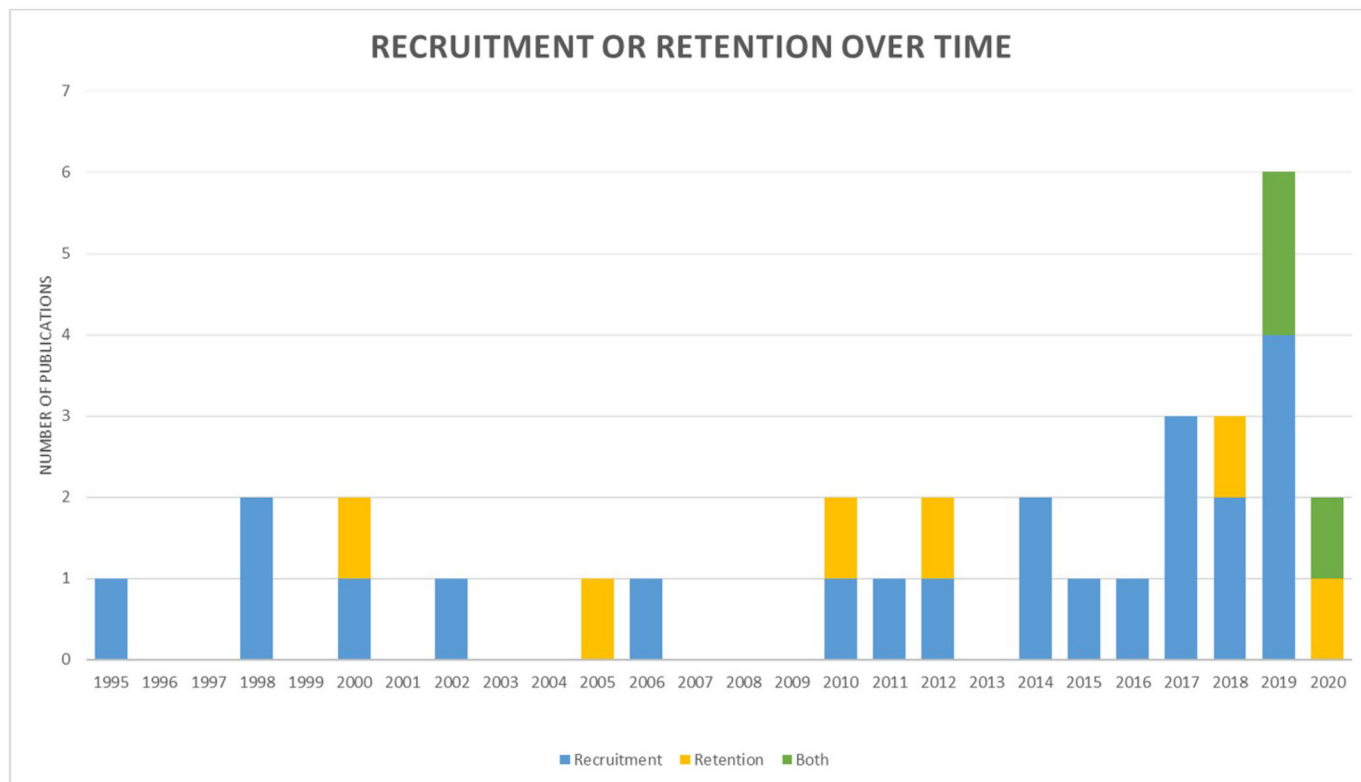


Figure 3 Instances of recruitment, retention or both being the objective of included studies mapped over time.

such as ‘enrolment’ or ‘participation’ in the host trial. These studies were often exploratory and sought to identify influences for participating in host trials generally without focusing on specific actions within participation. A majority of studies (n=18, 58%) included targets defined at the level of specific behaviours. Specific behaviours were defined as observable actions within the processes of recruitment/retention, such as attending a screening visit or completing follow-up questionnaires. Studies varied in the detail of description of these targets, with some focusing on the actions while others provided more information on their contexts (eg, time and place of action). However, only one paper³⁵ made use of recommendations to specify information about their behavioural targets in

a way consistent with recommendations from behavioural scientists.¹⁸

Application of behavioural approaches across included studies

The timing of the application of the behavioural approach, whether prospectively (ie, incorporated at the research question stage and study design), or retrospectively (ie, considered during analysis only as a mechanism to help understand the data) was assessed across all included studies. A majority of studies (n=24, 77%) had a clear prospective application of their behavioural approach while a smaller subset opted for a retrospective application (n=6), or a combination (n=1) (figure 6).

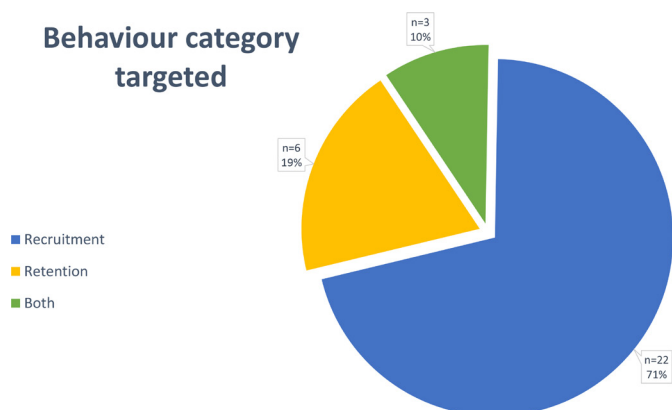


Figure 4 Whether recruitment, retention or both, were the category of behaviours targeted within the included studies.

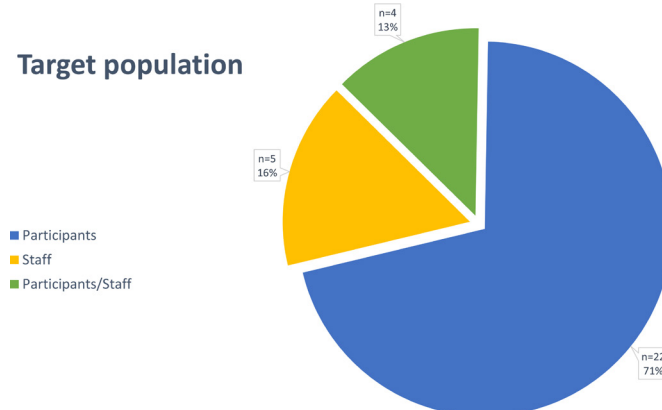


Figure 5 Which population of individuals and their behaviours were the target of included studies.

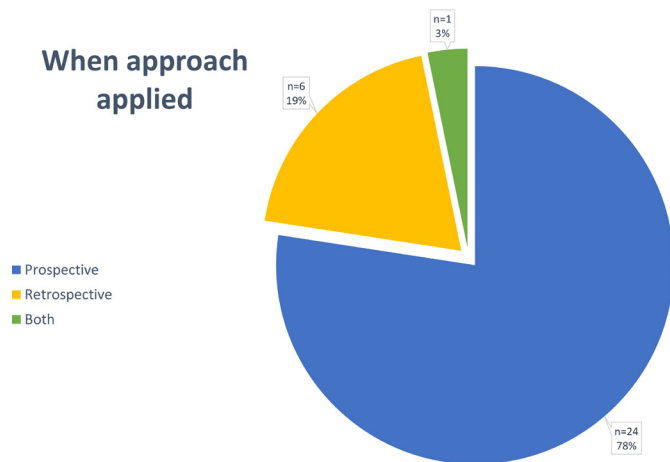


Figure 6 When the behavioural approach was applied in the study design of the included studies.

There was a range in the type of behavioural approaches applied, as can be seen in table 1. Most approaches (n=11, 69%) reported across the 31 included studies qualified as theory, per the definition utilised. Four approaches were considered models/frameworks. All models/frameworks are reported as described in table 1 and do not contribute to frequency counts of their component theories. Papers that used more than one theory but did not describe them as integrated into a model/framework were reported as individual theories (see table 1).

The most frequently reported behavioural approaches in the included studies were: social cognitive theory/social learning theory (n=8, 26%), the theory of planned behaviour (TPB)/reasoned action (n=6, 19%) and the theoretical domains framework (TDF) (n=5, 16%). Figure 7 provides detail on the frequency that each approach was used in understanding recruitment, retention or both. Summaries of each behavioural approach and its application in the included studies are presented below.

Social cognitive theory/social learning theory

Social cognitive theory (SCT), formerly social learning theory, was first advanced by Albert Bandura in 1986 and posits that human behaviour is influenced by personal, cognitive and environmental factors.⁵² Of the papers that used SCT, six focused on recruitment and two focused on retention. All six of the recruitment-focused papers were prospective in their application of SCT, as was one of the two retention-focused papers. Three papers^{40 41 53} applied intervention mapping to guide their design, implementation and evaluation, if applicable.⁵⁴

Five of the SCT papers that focused on recruitment developed educational interventions delivered through video,⁵⁵ web-conferencing^{40 53} or in-person sessions.^{40 41 53 56} Bradley⁴⁶ did not develop an intervention, rather looking to identify whether participants chose to enter a clinical trial based on principles from SCT. Bowen *et al*⁵⁷ designed incentives based on principles from SCT and randomly allocated participants to them. Coday *et al*²⁷ compiled

existing retention strategies, solicited from trial staff, into categories based on SCT principles.

TPB/theory of reasoned action

The TPB, an extension of the theory of reasoned action, was designed to predict and explain behaviour in specific contexts.⁵⁸ It argues that behaviour can be predicted by measuring intentions, which are influenced by an individual's attitudes, subjective norms and perceived behavioural control.⁵⁸ Of the five papers that used the TPB, all did so prospectively. All five targeted recruitment, while two^{29 34} also targeted retention.

Quinn *et al*³⁸ used the TPB to understand the decision-making process of those who enrolled in/declined a lung cancer trial. Kinney *et al*⁴³ assessed the effect of clinician recommendation on participants' decisions to enrol in/decline a chemoprevention trial. Vandenburg⁴⁷ queried participants about their decision to enrol in a glaucoma trial through a self-report survey along with assessing attitudes to see how those measures may inform decisions. Manton *et al*³⁴ and Arriens *et al*²⁹ both queried participants about their decisions to participate through interview or focus groups. Manton *et al*³⁴ focused on healthy volunteers within phase 1 trials, while Arriens *et al*²⁹ conducted focus groups with lupus patients.

Theoretical domains framework

The TDF was first articulated in 2005⁵⁹ with further refinement in 2012.⁶⁰ It is an amalgamation of 128 explanatory constructs drawn from 33 psychological theories that were deemed relevant to understanding and changing the behaviour of healthcare professionals.^{59 60} The TDF was designed to simplify psychological theories relevant to behaviour change and to make it accessible to those looking to design or evaluate interventions.^{59 60} The five papers that used the TDF were distributed between recruitment (n=2) and retention (n=2), with one assessing both. All five papers applied the TDF prospectively with one also doing so retrospectively. All the papers reported qualitative interviews assessing barriers and facilitators to their target behaviours. Gillies *et al*,³⁵ a study protocol, described a plan to assess the experiences of those who have dropped out of a trial and those who have considered dropping out through TDF-based interviews with the aim to develop interventions to address drop-out. Ellis *et al*²⁸ conducted TDF-based interviews with rural urologists to identify barriers and strategies that would support them in discussing and referring patients to urological cancer trials. Guillot *et al*³⁹ used TDF-based interviews to identify barriers and enablers for parents and neonatologists to enrol preterm infants in a future stem cell trial. Fahim *et al*³¹ analysed eligible participants surveyed as part of routine monitoring for their reasons for accepting/declining a surgical complication prophylaxis trial. Reported reasons were mapped to the TDF to identify mediators that influenced participants' decisions.³¹ An intervention was then developed by mapping these TDF domains to the Capability, Opportunity, and Motivation

**Table 1** List of approaches within included studies

Approach name	Theory or model/framework	Inclusion criteria (for review team consensus)	Instances (first author, publication year)
Behavioural Model of Health Services Use	Theory	Within Andersen (1995), the theory is described as being able to both predict and explain individual's health services use. Predisposing factors to services use, and their relations to one another, are described.	Smith GC, 2016, Zapka J, 2014; Roche CC, 2012
CHOICES Conceptual Model	Model/Framework	The model was developed with Social Cognitive Theory and the Stages of Change Model. The model does not relate the factors that contribute to behaviour to one another.	Chalela P, 2018
Capability, Opportunity, and Motivation Model of Behaviour (COM-B model)*	Theory	N/A	Fahim C, 2019
Goal Setting Theory*	Theory	N/A	Amorrortu RP, 2018, Tilley BC, 2017
Health Belief Model*	Theory	N/A	Nyaoke BA, 2017; Kinney AY, 1998; Verheggen FW, 1998, Yeomans-Kinney A, 1995;
Health Promotion Model*	Theory	N/A	Sample DA, 2002
Model of Cancer Clinical Trial Decision making	Model/Framework	The model was developed using the Transtheoretical Model of Behaviour Change. The model does not relate factors the that contribute to behaviour to one another.	Wenzel JA, 2015
Rotter's Social Learning Theory and Locus of Control	Theory	Included paper describes in detail the factors that this theory identifies as relevant to behaviour, how they interact, and how they can be used to predict behaviour.	Bradley JM, 2006
Self-regulation/Goal Theory	Theory	The included paper cited a review of theories as the source of what it called 'self-regulation/goal theory'. However, no theories reported in this source matched this description. Instead, the authors of this review, who are also the authors of the included study, seem to describe an amalgamation of these theories. That description gave sufficient detail about factors that contribute to behaviour and how they relate to each other to predict behaviour.	Huisman S, 2010
Social Cognitive Theory/Social Learning theory*	Theory	N/A	Ortiz AP, 2019, Amorrortu RP, 2018, Tilley BC, 2017, Gwadz MV, 2010, Coday M, 2005, Bradley JM, 2006, Bowen D, 2000 Corbie-Smith G, 2012
Theoretical Domains Framework	Model/Framework	This framework is known to the authors and the cited sources confirmed that it is derived from several behavioural theories.	Gillies K, 2018; Ellis SD, 2019 Guillot M, 2019, Fahim C, 2019, Goulao B, 2020
Theory of Planned Behaviour/Reasoned action*	Theory	N/A	Manton KJ, 2019, Quinn GP, 2011; Kinney AY, 1998 Arriens C, 2020; Vandenberg AM, 2000; Corbie-Smith G, 2012
Integrated Theoretical Model	Model/Framework	This model was developed using the Theory of Triadic Influence*. The model does not relate factors the that contribute to behaviour to one another.	Gwadz M, 2014
Transdisciplinary Theoretical Model	Theory	This theory describes individual attitudes and beliefs and how they interact to inform decisions of trial participation (behaviour).	Eggy S, 2017
Transtheoretical Model of Behaviour Change/Stages of Change Model*	Theory	N/A	Clark LT, 2019, Amorrortu RP, 2018, Tilley BC, 2017

*Referenced in Davis *et al.*¹⁰
N/A, Not applicable .

Model of Behaviour (COM-B).³¹ Finally, Goulao *et al.*⁶¹ evaluated three interventions designed to increase questionnaire response rates within a dental trial. The interventions were developed through mapping barriers to questionnaire return, elicited through trial staff interviews, to TDF domains.⁶¹

DISCUSSION

This systematic mapping review reports how behavioural approaches have been utilised to understand or address issues of recruitment/retention to trials to date. A

systematic mapping review was conducted due to the high degree of heterogeneity between study designs and populations, along with the understanding that different behavioural approaches were likely to structure results in notably distinct ways. Our search identified a larger evidence base than anticipated in both the quantity of papers and number of approaches. Much of the work to date has taken place within the USA with others spread across Europe, Africa and Australia. This is in contrast to the high volume of research on recruitment/retention that typically originates from the UK.^{6 8} The included

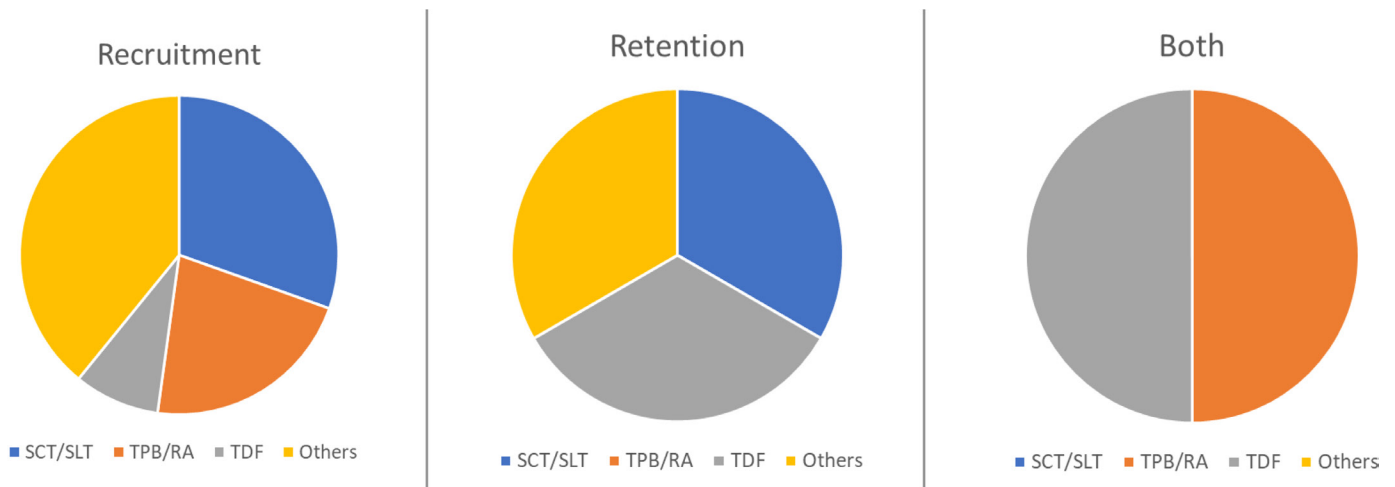


Figure 7 The top three most used approaches and how they were applied. Left: how the top three approaches were represented when studying recruitment; centre: how the top three approaches were represented when studying retention; right: how the top three approaches were represented when studying both. SCT/SLT, social cognitive theory/social learning theory; TDF, Theoretical Domains Framework; TPB/RA, theory of planned behaviour/reasoned action.

studies drew their populations from a range of disease and clinical contexts with a focus on addressing recruitment/retention in underserved populations and for those with cancers or HIV/AIDS. Studies focusing on recruitment outnumbered retention and often focused on changing the behaviour of participants. Most studies were exploratory, some examining barriers while others developed recommendations for future strategies or interventions for further evaluation. Those studies that did evaluate interventions tended to be randomised by design.

Underserved populations, particularly ethnic minorities, were the target of a number of papers. These papers often reported specific barriers to underserved groups involved in trials. Disparities in the levels of accessibility of trials, whether geographic, socioeconomic or cultural, were described in most papers applying behavioural approaches to the recruitment/retention of underserved populations. Lasting tensions that have arisen from historical and current mistreatment of underserved groups at the hands of medical research were a recurrent theme discussed by participants in included studies as influencing their behaviours. One-third of the included studies reported behavioural approaches being applied to recruitment/retention of under-served populations. These results echo findings from a mapping review on digital interventions for recruitment/retention that found 16 studies (15% of their total included studies) addressing under-served populations.⁶² Their findings also showed that research in these populations is primarily recruitment focused.⁶² About half of the included papers that applied behavioural approaches and focused on underserved populations evaluated interventions, in randomised comparisons, meant to improve recruitment. This represented 75% of all included studies that were designed to evaluate an intervention. This is at odds with the Cochrane reviews on interventions to improve recruitment/retention to trials, which highlight that

included studies are biased towards predominantly white population participants (where reported).^{6 8} Learning from these studies that apply behavioural approaches could be extended to the trials methodology community to encourage design and evaluation of interventions that aim to improve representativeness and access to research across populations, of which critical need has been identified.^{51 63 64}

The review identified a larger number of applications, as well as a greater diversity of approaches, than anticipated. An impression by the team that there is a preoccupation with participant-focused recruitment research was affirmed by this review, with indications that retention is slowly being incorporated in the methodology research agenda. This reaffirmation has informed the development of a future project looking to better understand how staff behaviours influence retention and the potential ways that behaviour change techniques can modify these behaviours. We identified a breadth of behavioural approaches that informed research into recruitment/retention. These approaches and the key information extracted from the included papers have been populated to a database available in online supplemental appendix 3. This database serves to both supplement the results and to serve as a tool for other researchers to further investigate the data and extend its application beyond the scope of this review.

The most frequently used approaches in this review were SCT, the TPB and the TDF. SCT and TPB share many similarities in how they conceptualise behaviour but are subject to differences in how they describe the constructs and processes that contribute and predict it.^{52 58} The TDF was an attempt to consolidate such differences so that a common language could be employed when discussing behaviour and acknowledges the contributions of each theory.^{59 60} This review identified a total of 15 approaches, but the three approaches presented here are present in



nearly two-thirds of the included papers. This shows a clear preference for these approaches in understanding and developing solutions to issues of recruitment/retention. Whether they present the most appropriate approaches to use, or represent those that are popularised, remains to be addressed. Potential reasons for their popularity may be that each of these three approaches have published manuals to aid in their implementation.^{65–68} Additionally, the TDF is explicitly linked to intervention development through the Behaviour Change Wheel, which guides selection of appropriate behaviour change techniques.^{14 17}

Specification of behavioural targets in this review was informed largely by ideas from Martin Fishbein and Icek Ajzen⁶⁹ and later refined into what is known as the Action, Actor, Context, Target, Time (AACTT) framework.¹⁸ However, virtually none of the papers made specific reference to such a framework. The papers ranged considerably in the amount of specificity in which they described their targets. A minority did so broadly at the level of the processes that are recruitment/retention. The remainder targeted specific behaviours within recruitment/retention but did not often tie them explicitly to the contexts in which they are embedded. Frameworks for specifying behaviour, such as the AACTT, can facilitate the design and evaluation of interventions. Specifying behaviour in detail facilitates the description of who needs to do what differently, understanding what may help or hinder them from doing so, how to address barriers, and how to determine if that support was effective.¹⁸ This also allows for a deeper connection between the behaviour under investigation and the theoretical constructs that may predict it.¹⁸ The papers that were not specific in their target behaviour were noticeably more difficult to understand how their behavioural approach informed their investigations. And finally, a clear specification of behaviour enables synthesis of what strategies are effective for particular behaviours.¹⁸ For these reasons, adherence to behaviour specification guidelines should be considered best practice for research that uses a behavioural approach.

Strengths and limitations

First, the review was intended to be accessible and transparent and was largely informed by methods from the Cochrane Handbook.²⁵ This was achieved through the use of a protocol that established the systematic methods for the review and was made publicly available. This review has also generated a database as an accessible means for others to probe the results in greater detail.

The limitations of this review are shared with other mapping reviews, such as no formal quality assessment or assessment of applicability or usefulness of identified theories for trials methods research. The review team applied existing expert consensus on behavioural approaches and extended these criteria in order to be deliberately more inclusive to collate behavioural approaches beyond pure theories. It was outside the scope of this review to contact authors for further details in order to interrogate

approaches that were not clearly linked to prespecified behavioural theories. Instead, every effort was made to reference the source material of the approach provided by authors and cross-reference that with the content of the papers themselves to reach an informed decision within the timeline of this review.

CONCLUSIONS

This review successfully identified how behavioural approaches have been applied to issues of recruitment and retention to trials. The evidence map generated through this review can inform a future research agenda around the behavioural specification of recruitment and retention problems in clinical trials and be used to inform the development of targeted solutions. This review has identified gaps in the research, especially in the reporting of these studies based on recommendations for good practice with regard to behaviour change. It is also important to consider how to maximise the potential of behavioural approaches to recruitment and retention of underserved populations and how this learning can be applied more broadly across trials. As behavioural science is poised as a means to systematically diagnose issues and develop solutions, the trials community will likely continue to see it being used to contribute to this evidence base. Overall, clinical trials have much to gain from behavioural approaches and their promise of a more efficient, and potentially participant focused, trial landscape.

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Contributors TC was responsible for the overall conduct of the review and is responsible for the overall content as guarantor. The guarantor accepts full responsibility for the finished work and/or the conduct of the study, had access to the data, and controlled the decision to publish. TC screened abstracts, extracted data, designed figures and tables, and was the main author of the work. KG and HM screened a select percentage of abstracts for quality assessment and also assessed a select sample of data extraction for quality. LL, KG, EMD and HM provided supervision and expertise in the formulation of the review, independently screened full texts to affirm eligibility and provided ongoing support through revisions.

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