# **Title page**

# **Why do patients take part in research? An overview of systematic reviews of psychosocial barriers and facilitators.**

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## Abstract

## Background

## Understanding why people take part in health research is critical to improve research efficiency and generalisability. The aim of this overview of systematic reviews was to identify psychosocial determinants of research participation and map them to psychological theory and empirical recruitment research, to identify effective strategies to increase research participation.

## Methods

## Qualitative and quantitative systematic reviews were systematically identified. No date or language limits were applied. Two reviewers independently selected reviews. Methodological quality was rated using AMSTAR and poor quality reviews (scoring 0-3) were excluded. Barriers and facilitators were coded to psychological theory (Theoretical Domains Framework) and empirical recruitment research (recruitment interventions that had been subjected to randomised controlled trial evaluation).

## Results

## We included 26 systematic reviews (429 unique primary studies), covering a wide range of patient populations and health settings. We identified five groups of facilitators, of which three were dominant (potential for personal benefit; altruism; trust) and appear to be relevant across research setting and design. We identified nine groups of barriers, which were more dependent on the particular study (context, population and design). Two determinants (participant information; social influences) were found to be both barriers and facilitators. Barriers and facilitators could be coded to the Motivation and Opportunity components of the Theoretical Domains Framework; only one was coded to a Capability component. There was some overlap between psychosocial determinants and empirical recruitment research, but some barriers and facilitators had not been tested at all.

## Conclusions

## Identifying effective recruitment strategies could increase the efficiency and generalisability of primary research. We identified a number of barriers and facilitators that could be addressed by researchers. There is a need for more research to identify effective recruitment strategies that draw on the psychosocial facilitators and barriers identified in this overview.

**Keywords:** recruitment. Research participation. Psychosocial. Systematic review. Overview. Consent.

## Background

Research is essential to the development of improved health care; however the recruitment of participants remains low (1-3). This is a particular problem for randomised trials which test the effectiveness of interventions aimed at prevention, diagnosis, screening or treatment (4). Suboptimal recruitment can result in underpowered and inconclusive studies, increased research costs and delay, and unrepresentative sampling (1, 5). There is a need to understand better the influences on participation in health research, particularly trials, and identify areas and strategies for intervention. Accordingly, the PRioRiTy study, a James Lind Alliance Priority Setting Partnership, recently concluded that one of the most pressing recruitment questions was to determine what motivates participation (6).

Research participation is determined by psychosocial factors (that is, the interrelationship of social factors and individual cognitions and behaviours) acting as barriers or facilitators to impede or increase individuals’ willingness to take part. These determinants will vary conceptually, including the instrumental (e.g. receiving financial compensation), attitudinal (e.g. being motivated by the potential for societal benefit), cognitive (e.g. believing that healthcare practitioners are virtuous) and emotional (e.g. fearing treatment change). Important social influences are likely to include the opinions of family and others whose views are valued. A number of systematic reviews have been undertaken to collate barriers and facilitators reported in primary studies, with most reviews focusing on specific conditions or patient groups.

The challenges experienced in recruitment have stimulated the production of a wide range of interventions to increase recruitment rates. Often these have been evaluated within SWATs (Study Within A Trial), using trial methods to provide rigorous evidence of impact. For recruitment to trials, SWATs have been meta-analysed by Treweek et al (2018); for recruitment to health research more generally, a systematic review was last undertaken in 2007 (7). Notable in the Treweek review was that despite a significant number of embedded trials (n=68) and a range of intervention types (n=72), in many cases there was no clear link between the tested intervention and reasons underpinning decisions to take part (8). Therefore there was an opportunity to review and collate a substantial evidence base on psychosocial determinants of research participation, and to look for features in the evidence that are generic or more context-specific. Making links between determinants and theory and recruitment interventions could strengthen the potency of interventions and, as a corollary, reduce levels of ‘research waste’ created by the evaluation of interventions without a clear rationale for possible effect.

The aims of this research therefore were to:

- Undertake an overview of systematic reviews of psychosocial determinants of research participation among patients and the public.

- Summarise the reported determinants thematically and as barriers or facilitators.

- Map these determinants to a behaviour change theoretical framework.

- Map these determinants to interventions intended to increase participation in research.

## Methods

The review was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (9). The review was registered in PROSPERO: <http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017062738>.

### Data sources and searches

The search aimed to systematically identify reviews of psychosocial determinants of patient and public decisions on health research participation. The strategy was developed from one used in cancer trials (10) and was developed in MEDLINE (Ovid) before adaptation for other databases. No language, time or geographical limits were applied. Searches were limited to systematic reviews, using DARE search strategies (11).

The following databases were searched 7th- 8th June 2016: MEDLINE, MEDLINE In-Process, CINAHL Plus, Cochrane Database of Systematic Reviews (CDSR), Cochrane Methodology Register (CMR), Database of Abstracts of Reviews of Effects (DARE), EMBASE, Health Technology Assessment (HTA) database. PROSPERO was also searched for ongoing reviews. Results were imported into EndNote x7 and de-duplicated. Reference lists of included articles were scanned and forward citation searching was completed in Google Scholar. Searches were updated 4th December 2017 and 20th September 2019, retrieving a further 1,197 and 1,775 results respectively (total 2,972). (See Appendix 1 for the Medline search strategy).

### Inclusion and exclusion criteria

We included quantitative, qualitative or mixed methods systematic review reporting findings from studies exploring patient or public psychosocial determinants of health research participation. The focus of this review was on real research scenarios and not hypothetical research: work in this area often has mixed content and so at least two thirds of primary studies within a review needed to involve actual research scenarios for inclusion. No language or publication status restrictions were applied. Systematic reviews were excluded if they only reported the characteristics of research participants, or if limited to healthcare practitioners’ views on the determinants of participation.

### Screening

Titles and abstracts were screened independently by two authors (RS and PK) using predefined criteria. All potentially relevant articles were retrieved and independently screened (by RS and PK). Disagreements were resolved through discussion.

### Quality assessment

Two authors (RS and PK) used AMSTAR to assess the quality of reviews, and as an entry criterion (12). Ratings were undertaken independently and then an agreed score was reached through discussion. Items were scored 1 if the criterion was met and 0 if not met or unclear. One small modification to the recommended scoring was that, for criterion 5 articles only had to list included studies and not excluded studies (most reviews did not report excluded studies). A total AMSTAR score was calculated with review articles categorised as low (0-3), moderate (4-7) or high quality (8-11), and low quality reviews (scoring 0-3) were excluded (13).

### Data extraction and analysis

Data extraction was undertaken using a pre-designed form. Extracted data included review aims, study design, participant details and key findings. Information was extracted by one reviewer (RS) and checked for accuracy by PK, except for key findings which were independently extracted by both and reconciled by consensus. It was anticipated that the systematic reviews identified would include a variety of study designs and thus a narrative reporting method was used. RS first identified psychosocial themes reported in included reviews and then grouped the data within these categories, in consultation with PK; themes were considered to facilitate participation or act as a barrier, or to do both. We adhered to behaviour change guidance by inductively coding barriers and facilitators to research participation (RS, PK, JH) which were then considered in relation to two theories of behaviour change (the Theoretical Domains Framework (TDF) and COM-B model, described below) (14-16) and (ii) empirical research on interventions intended to increase rates of trial participation (8).

The TDF provides a comprehensive account of 14 domains which influence a person’s behaviour, and is used here because research participation is a behaviour. These 14 domains have been shown to cluster into three overarching constructs: capability, opportunity and motivation, which are defined in the behavioural science literature as the COM-B model (15, 17). The capability construct recognises how psychological and physical capabilities influence behaviour. It includes the following TDF constructs: knowledge; skills; memory, attention and decision processes; and behavioural regulation. The opportunity construct outlines how the social and physical environment shapes behaviour. It includes the following TDF constructs: social influences; and environmental context and resources. The motivation construct considers conscious and unconscious cognitive processes that influence behaviour. It includes the following TDF domains: social or professional role and identity; beliefs about capabilities; optimism; beliefs about consequences; reinforcement; intentions; goals; and emotion.

In order to map barriers and facilitators to research participation against empirical interventions intended to increase recruitment research, we drew on a relevant Cochrane review (8). The review included 68 trials, organised under six categories: trial design; trial conduct; consent process; modification to information; recruiter or recruitment site interventions; and incentives. The available evidence for the six categories varies considerably and the lack of evidence for some means there is considerable uncertainty about effectiveness. Of note, whilst the included studies assessed 72 different recruitment strategies, only seven were assessed by more than one embedded study.

## Results

6,374 records were identified and an additional eight through citation searching; 2,972 further records were identified via the search updates resulting in a total of 9,354 articles. We retrieved 156 articles for full text review and finally included 26 articles. Exclusions are detailed in Figure 1.

### Quality of the evidence

Six reviews (23.1%) were rated as high quality (AMSTAR 8-11) and 20 reviews (72.9%) were of moderate quality (AMSTAR 4-7) (see Table 1). Most involved a comprehensive literature search, employed duplicate study selection and data extraction and provided a list of included studies alongside their characteristics. The results of reviews were largely synthesised appropriately and most authors stated whether there were any conflicts of interest. Just over half of the reviews assessed the scientific quality of the included studies, but only two assessed publication bias. The majority of reviews did not provide any evidence of a priori design, such as a published protocol.

### Characteristics of included studies

The 26 reviews incorporated a total of 489 relevant primary studies, of which 179 (36.6%) had been undertaken in the USA; 80 (16.4%) in the UK; 19 (3.9%3.9%) in Australia; 17 (2.4%) in Canada; 12 (2.4%) in South Africa; 10 (2.0%) in Thailand; while 15 (3.1% ) had been undertaken in more than one country (see Table 1). Country of origin was not reported in the source review for 82 (16.8%) studies and the remaining 62 studies had been undertaken in one of 23 countries. Of the 489 primary studies, 56 (11.5%) were included in more than one review, leaving a total of 429 unique studies. . This degree of overlap in the primary studies is low, incorporating a covered area of 4.4% and a corrected covered area of 0.5% (18). Five (19.2%) reviews (10, 19-23) explicitly stated that they included only qualitative studies; the remainder included both quantitative and qualitative research. The focus of reviews varied in terms of health setting and types of research participation. Sixteen (61.5% ) reviews were limited to studies of trial participation (10, 20, 22-35) and the remaining ten either included a mix of primary research designs or it was unclear (19, 21, 36-43) . Fifteen (57.7%) reviews related to specific health conditions or settings: cancer (n = 6), HIV (n = 3), mental health (n = 2), chronic obstructive pulmonary disease (COPD), emergency medicine, pregnancy and bio-banking (each n = 1). Four studies focused on child or adolescent participants and their parents/caregivers; (21, 24, 25, 42); one study focused on ‘hard to reach’ older patients [26]; and four reviews focused on ethnic minority groups (29, 31, 35, 36). Fifteen reviews (57.7%) only included real research scenarios (19, 21-23, 26-29, 31-33, 36, 38, 40, 41); whereas eleven (42.3%) included both real and hypothetical scenarios. Most reviews (19; 73.1% considered both facilitators and barriers to research participation; three (11.5% ) were limited to facilitators and four (15.4% ) to barriers. The reviews were published 1999-2019; their included primary studies were published 1982-2016. Characteristics are further detailed in Table 1.

### Identified psychosocial themes

### *Facilitators of research participation*

A number of themes were identified which reported facilitators of research participation (Table 2); the most commonly reported was perceived personal benefits, including the perception of therapeutic benefits, closer monitoring, and access to new treatments (10, 19-23, 25, 27, 30-33, 35, 37-42).

Whilst altruism was the second most commonly reported factor, discussed in terms of benefiting science (10, 19, 27, 31, 35, 37-42), helping others (10, 19-23, 27, 37-40, 42) or altruism more generally (25), this was sometimes linked to personal benefit (20, 33, 39). For example, patients with depression were less likely to participate if it might risk their own mental health, despite wanting to help others (20). Further, two reviews highlighted that the desire to help others was not always concerned with helping all people, but specifically benefiting people who were personally important (32, 40). Finally, a review involving research with children and adolescents concluded that the importance of altruism depended on the child’s health state; altruistic motives were given as a primary reason for participation by parents with healthy children, but for parents whose children had life threatening conditions, altruism was secondary (21).

The influence of others was also important. Potential participants’ confidence in the physician and/or the research was motivating (20, 22-24, 28, 30, 32, 33, 36, 38-41). Having a positive, trusting relationship with the doctor was commonly cited as a facilitator; for example, the idea that the ‘doctor knows best’ was expressed (34). The opinions of family and friends also facilitated participation (20, 22, 31, 36, 37, 42).

The impact of the potential participant’s knowledge of trials and the quality of the study information was mixed. For example, knowing you could leave the trial increased participation (10), but one review highlighted that enhanced knowledge and understanding could decrease participation (32). A study with children and parents highlighted the need for age-appropriate information (24), whilst another highlighted the need for cultural appropriateness (29). However knowledge could act as a barrier when too much complex information was provided (10, 25, 38) or when information was vague (41). Gaining knowledge of their health condition was a participation facilitator for children (42) and those invited to biobank studies (40).

Financial benefits were discussed in three reviews, but did not appear to be a primary determinant (19, 31, 42); rather, financial benefits were seen as an added bonus (19). However financial constraints and costs could inhibit participation (35, 36, 42).

### *Barriers to research participation*

Fear was identified as a barrier in a large number of reviews, often related to perceived risks of treatments or interventions being tested, and possible side effects (19-22, 25, 26, 30, 33, 35, 37, 39, 41-43). Assessment of risk varied with the severity of the patient’s illness (21), for example, patients with a life-limiting diagnosis were more tolerant of research risk, potentially because of the access that participation granted them to new medication (21). This was also linked to a perceived lack of choice imposed by the terminal diagnoses: patients stated the view that there seemed no option but to participate (21-23, 42). More specific fears regarding the safety of interventions were common in reviews of HIV vaccine trials (26, 31): potential trial participants were concerned about vaccine efficacy, or whether it could increase their susceptibility to HIV (31). Other fears included discovering their HIV status (19) or being reported to immigration (35).

Distrust in research was common across patient groups (19, 20, 29, 31, 32, 35, 37, 38, 42, 43), but was particularly prominent among minority ethnic groups (20, 35), minority indigenous populations (29) and people in sub-Saharan Africa (19). In one review distrust was linked to a lack of knowledge and understanding (31). Specific distrust concerns included potential breaching of privacy or confidentiality (29, 31, 43), being a ‘guinea pig’ (38, 42) and a general mistrust of researchers’ intentions (19). Nevertheless, trust in the safety of research was also reported as a motivating factor (21, 42).

Treatment preference, either for or against a specific treatment, was a reported barrier in several reviews (10, 30, 32, 34, 42). Preferences included not wanting to change medication, or not wanting to receive a placebo or experimental treatment (34). However, preference for a specific treatment could also be a facilitator; in one mental health systematic review participants wanted access to the non-pharmaceutical, talking therapies on offer (20).

Perceived stigma was a commonly reported barrier to recruitment to trials in HIV (19, 26) or mental health (20, 43). People did not want others to know their HIV status, or to assume it as a result of trial participation (19, 26). In mental health studies, stigma was largely due to people not wanting to be perceived as ‘crazy’, ‘weak’ or ‘vulnerable’ (20).

Practical difficulties were highlighted including the perceived inconvenience of trial participation (for example, additional procedures and appointments) (20, 25, 26, 32, 34, 42), a lack of time (26, 32, 34, 36, 37), travel or transport issues (10, 26, 29, 30, 32, 34-37, 39, 43), costs (10, 30, 34-36, 42), as well as employment (10, 35) or childcare responsibilities (10, 36).

Concerns about trial methods were highlighted as barriers, including the inherent uncertainty (10, 21, 34, 41) and randomisation (20, 25, 32, 33, 37, 41, 42). Potential participants also stated concerns about possible unknown side effects (10) and uncertain treatment effectiveness (21, 34). There was some evidence of confusion about the meaning of randomisation (32), whilst other reviews noted that patients understood the concept but felt that randomisation signified a loss of control (30, 34) or that the doctor should choose treatments based on clinical expertise. In contrast to the inhibiting effects of concern about trial methods and the practical implications of research, the perception of a trial as low burden or convenient tended to facilitate participation (31, 40, 42).

Whilst knowledge could facilitate research participation, a lack of knowledge and understanding of clinical research could have a negative effect (29, 31, 38, 42), and participants identified a need for more information (34). This lack of knowledge was sometimes linked to limitations of the informed consent process (38).

Finally, the patient’s health state at the time of invitation to participate was important in some reviews. Some patients felt too ill to participate (20, 36, 43), others who were happy with their current health were less likely to participate for fear of disrupting this (20). However, adverse health could favour research participation: one review of trials in acute conditions found that patients in pain said they were willing to agree to anything (38).

*The thematic pattern of barriers and facilitators*

It is notable that the identified barriers and facilitators include cognitive, emotional, social, practical and instrumental factors.

We identified a smaller number of facilitators than barriers, and three facilitating factors were dominant: the potential for personal benefit; altruism; and trust. Each of these was identified in a majority of the 26 included systematic reviews. These three factors were evidenced across different health settings and different research designs: they appear to be generic factors in being potentially important influences on individuals’ decisions about research participation whatever the context.

Barriers to participation were larger in number and more disparate. Their influence also appears to relate to the research design and to individual circumstances. For example, patients had stated treatment preferences or a current stable state of health, both of which might be disrupted by research involving a change to treatment. In patients with HIV or mental illness, research participation could be seen as threatening to self-identity or other’s perception of them. Distrust of research was reported and was often culturally-specific, being reported most often in minority and ‘low power’ population groups. Practical difficulties associated with research were related to individuals’ circumstances, such as the impact of research on transport costs, childcare or paid work: the impact of these factors on participation will vary considerably across the population. Many stated barriers were specific to trial-based research, with expressed dislike of randomisation, uncertainty and possible treatment change.

### Determinants and their links to the Theoretical Domains Framework

The identified barriers and facilitators from the 26 systematic reviews each link to at least one TDF domain although there is a clustering on knowledge, social influences, optimism (or pessimism), goals and beliefs about consequences (see Table 2). Each of these domains was then mapped to the overarching constructs outlined in the COM-B model. Among the inductively identified facilitators of research participation the three most common included: personal benefit; altruism; trust. All the facilitators including the three most common, map to different facets of the Motivation component of the COM-B model. .

Among the 11 inductively identified barriers all are linked to Motivation facets (both reflective and automatic), with two also linked to Opportunities. One barrier was linked to Physical Capabilities. The two factors that could operate either as facilitators or barriers, (other people’s influence; information quality and participant knowledge) were mapped to Motivation and Opportunity components, respectively.

### Reported reasons for/against research participation and links to empirical recruitment research

There is a lack of overlap between the barriers and facilitators we identified and the interventions tested, both in terms of the distribution of studied strategies and their impact. Whilst treatment preference was an important barrier to participation, only one study tested a strategy (patient preference trial design) which could be mapped to this theme. For a number of identified barriers, including condition stigma and distrust, we identified no related interventions. Similarly, no identified studies appeared to analyse strategies which may improve recruitment by impacting on altruistic motives. Additionally there were no tested interventions linked to the patient’s confidence in the physician and the influence of family and/or friends, although the influence of recruitment via the Church or endorsements by previous participants have been studied.

Three tested recruitment strategies (phone reminders; recruitment primer letters; increased contact during recruitment in person or by phone) were not linked to any identified psychosocial determinants. Phone reminders act as a prompt to memory while primer letters act by raising awareness, with neither cited as a barrier to participation. Increased contact during recruitment could potentially act on knowledge, although its intended action is not made clear. A fifth strategy not linked to the identified psychosocial determinants (strategies aimed at recruiters or recruitment sites) is intended to change the behaviour of recruiters not participants. Also of note is that our overview identified three systematic reviews that investigated barriers or facilitators in relation to recruitment to paediatric research, and yet only one of the intervention studies included in the Treweek review (8) assessed recruitment to paediatric trials.

**Discussion**

### Statement of principal findings

### This overview found that a small number of psychosocial facilitators were evident, spanning settings and demographic groups. Psychosocial barriers were larger in number and more sensitive to research context and individual circumstances. When psychosocial determinants were mapped to the TDF and COM-B model, there was clustering on the opportunity and motivation domains. When determinants were mapped to recruitment strategies there was incomplete overlap and a number of determinants had no clear link to any evaluated recruitment interventions.

**Strengths and weaknesses of the study**

Overviews offer the potential for clarity in areas of significant systematic review activity (44), and may also identify consistencies and inconsistencies in primary evidence, and relative levels of importance (45). This overview has clarified the psychosocial determinants of research participation and also identified clear opportunities to develop recruitment science by drawing on theory and empirical evidence. Some strengths of this overview are the searching of multiple databases, use of dual independent assessors throughout, and including reviews not published in English. Excluding low quality reviews (n=4) increased rigour but reduced the number of included reviews and primary studies. We also excluded four reviews when we could not separate findings derived from patients and practitioners, and 22 reviews because less than two thirds of their included studies reported real research scenarios; in both cases this potentially reduced the total evidence base. In none of these cases do we think the exclusions have introduced bias or significantly limited findings. For example, AMSTAR has recently been shown to identify low quality reviews for exclusion from an overview, without introducing bias (46). Although overviews have been published for more than a decade, they continue to be subject to methodological debate particularly around primary study duplication (18, 47). Fifty-six (11.6%) of the primary studies in this overview were included in more than one review and we did not adjust the findings to take account of this; our rationale was that we were reporting findings thematically and not undertaking pooling of quantitative data. However primary study duplication may have led to overstatement of some determinants. The overview focused on barriers and facilitators of participation in health research broadly but mapped them against recruitment interventions to trials; we acknowledge the mismatch but there is no recently published systematic review of interventions to increase participation in non-trial health research.

**Strengths and weaknesses in relation to other studies, highlighting important differences in results**

For the first time this overview has brought together evidence on the determinants of health research participation from a wide range of settings and methods. One of its key contributions is to clarify the relatively small number of psychosocial factors that have a consistent, positive influence on patients’ decisions. That these three factors (potential for personal benefit, altruism and trust) are key determinants is an important insight, as is the finding that their influence spans health setting and type of research design. They are evident both in qualitative and quantitative primary studies. In itself this speaks to the value of an overview; this pattern would not be evident in an individual systematic review. The barriers identified by the overview are more context-specific, such as the stigma associated with certain conditions, the practical demands that some research can place on participants, and the suspicions felt by some minority ethnic groups about some clinical research. Again, this finding of context-specificity could not be derived from a single-setting systematic review. Mapping identified psychosocial determinants onto a theoretical framework and assessing the overlap of psychosocial determinants with recruitment interventions, has provided novel insights.

**Meaning of the study: possible explanations and implications for clinicians and policymakers**

Clarification of the main themes in psychosocial determination is itself useful knowledge for a number of stakeholders, including clinicians, researchers and research ethics organisations. It should be possible for researchers to use this knowledge to enhance recruitment, for example by drawing on the power of trust by using personal endorsements, or role models from the same cultural background, or acknowledging the credibility of the people and organisations involved in research. However, interventions emphasising altruism (the potential for others to benefit from one’s actions) or the potential for personal benefit (when that could be uncertain in research, particularly in a controlled trial), could raise ethical challenges. Furthermore, it was notable that social influences – the effects of family, the doctor and other people seen as important – could act either as a barrier or a facilitator for a person deciding whether to participate in health research.

Identifying barriers to research should make it possible for adjustments to be made to the design and operationalisation of research, particularly if barriers are specific to study design and setting. Participant information, participant knowledge and social influences were found to act both as barriers and facilitators and this perhaps presents a problem; first, researchers are unlikely to be able to control for social influences; second, information to inform research participation is mostly universal in provision and highly regulated (48), and yet among patients there can be strong, individual preferences for the quantity and complexity of information (49-52). The opposing forces of universalism and individual preferences can be hard to reconcile, although digital provision does increase the potential for information to be tailored or personalised, whether by the originator or recipient.

Mapping identified determinants to theory offers the potential for greater understanding of individuals’ decisions, and opportunities for linkage. Carey et al (2018) systematically mapped the evidence for behaviour change techniques to mechanisms of action from hundreds of research studies (16). They showed that the mechanism of action ‘beliefs about consequences’, which we linked to a number of participation determinants, had strong empirical links to the following: information about health consequences; information about social and environmental consequences; pros and cons; information about emotional consequences; and comparative imagining for future outcomes. Any of these could guide recruitment interventions.

The lack of complete overlap between psychosocial determinants and empirical recruitment research also offers the potential to guide intervention development. Recruitment interventions could focus on altruism (noting potential ethical concerns); the stigma associated with the health condition; or distrust of research or researchers; none of which have been tested in recruitment interventions. Furthermore many other determinants, such as treatment preferences; fear and perceived risk; confidence or trust in the physician or research; and desire for choice; have had little or no evaluation in recruitment research.

**Unanswered questions and future research**

Mapping of the psychosocial determinants onto recruitment interventions offers the potential for new research, as outlined above, and the possibility of applying an empirical framework to explain and predict the actions of recruitment interventions. While the application of the TDF and COM-B models to the identified psychosocial determinants has produced new insights, it assumes that research participation is an explainable behaviour; this assumption would benefit from empirical and theoretical evaluation. Very many published recruitment interventions have been atheoretical and with a lack of clarity about possible mechanisms of action; there is an opportunity in future recruitment research to incorporate the growing science of behaviour change.

This overview included 26 systematic reviews reporting more than 400 primary studies but areas for development remain. For example, almost two-thirds (59.9%) of primary studies in the reviews had been undertaken in just four countries, all of them English-speaking (although a proportion of reviews did not report country of origin). It was surprising that separate reviews had not been conducted in primary care settings or healthy person screening, since the experience of research participation may be very different from emergency care or long-term health conditions, for example. We excluded much research using hypothetical scenarios and,. given the volume of real scenario research that we did include, the value of new hypothetical scenario research is questionable. Finally a significant proportion of the included reviews and primary studies used qualitative methods and it is possible that narrative synthesis, an area of rapid methodological development, has potential to offer new insights into the determinants of research participation.

**Conclusions**

We identified a number of psychosocial barriers and facilitators to research participation, of which several spanned patient groups and settings, while the effect of others was more context-specific. These could be addressed by researchers when planning and implementing recruitment to studies. There is a need for more research to identify effective recruitment strategies that draw on theory and the psychosocial facilitators and barriers identified in this overview.

[4928 words]

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