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ORIGINAL ARTICLE

Theory-guided interviews identified behavioral barriers and enablers to healthcare professionals recruiting participants to maternity trials

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Abstract

Objective: To conduct a behavioral investigation, using the Theoretical Domains Framework (TDF), to identify barriers and enablers to maternity healthcare professionals (HCP) inviting all eligible women to participate in a maternity care trial.

Study design and setting: We invited HCP recruiters from maternity care trials in high priority research areas including, diabetes, preeclampsia and breastfeeding, from across Ireland and the UK, to take part in a semi-structured interview. Data collection was informed by the TDF, followed by inductive thematic analysis and deductive mapping to the TDF.

Results: Twenty-two recruiters including midwives, nurses, allied health professionals and doctors were interviewed online or by telephone phone. Thematic analysis generated four global themes; *Availability and accessibility of resources, Navigating the recruitment pathway, Prioritising clinical responsibilities over research responsibilities and The influence of colleagues and peers*. Themes were mapped to the TDF, identifying 13 domains relevant to the behaviour.

Conclusion: This paper identifies the factors enabling or inhibiting maternity HCP recruiters to invite all eligible women to participate in a maternity care trial. The findings provide guidance for researchers designing trials for this population and the essential first step in developing a recruiter-focused behaviour change intervention to support recruitment to trials in maternity care.

Keywords: Randomised trials; Recruitment; Pregnancy; Maternity; Behaviour; Theory

What is new?

- This study demonstrates how a behavioural approach can be applied to assess factors that influence HCPs recruiting to trials in maternity care
- The study sampled across clinical trials in areas of high-priority research including, diabetes, preeclampsia and breastfeeding
- This study supports future development of a recruiter-focused behavioural intervention to address remaining uncertainties surrounding the most effective ways to offer maternity care trial participation to all eligible women

1. Introduction

Recruitment to clinical trials has long been recognised as a challenge to successful trial delivery(1). Clinical trials in maternity care present additional challenges for recruitment because they typically require large sample sizes to detect small clinically significant effect sizes [2] and evoke ethical concerns around the safety and perceived vulnerability of mother and baby [3]. The result of these challenges has been the underrepresentation of pregnant women in research and clinical trials, thereby limiting scientific knowledge on the effects of treatments for their health needs [4]. The COVID19 pandemic exposed disparities in the care of pregnant women, compared to the general population, highlighting the lack of available high-quality evidence [5]. This has led to an urgent call for proactive recruitment efforts to ensure fair and equitable inclusion of pregnant women of all ethnicities and socioeconomic backgrounds in clinical trials [6]. The ENCOUNTER (rEcruiter's experieNCe Of recrUiting pregNanT womEn to clinical tRials) Study, a multi-phased doc-

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toral research project, aims to generate evidence addressing the priority of offering all eligible women the chance to participant in a maternity care trial.

Evidence from trials both within and outside of the maternity setting suggest, as recruiters, HCPs only approach a proportion of those eligible to participate [7–9]. A growing body of literature exploring why this selective approach occurs has identified reasons such as; a bias towards protecting individuals perceived as vulnerable [10], healthcare providers poor understanding of trial methodology, and insufficient time and/or resources for recruitment [11]. While there is a need to understand the barriers and enablers that exist for HCPs recruiting to trials generally, it is especially important in maternity care trials if we are to enhance the representation of pregnant women in clinical trials [5]. Maternity HCPs, usually midwives, nurses, doctors, and allied health professionals, are often the first point of trial contact for pregnant women and frequently act as trial recruiter. Our previous qualitative evidence synthesis [9] identified the gap between the designed protocol for trial recruitment and the recruiter's lived experience of recruiting to the trial based on a range of influential factors. Many of the factors identified in our synthesis, and others reported to impact the trial recruitment pathway [10,11], can be considered as people performing (or not) a behaviour. For example, recruiters acting as gatekeepers choosing not to follow the recruitment protocol to include all eligible women in the trial [9]. Behaviours such as these are ubiquitous within trial recruitment, as there are multiple behaviours at several key stages. Developing an understanding of what influences these behaviours is necessary to identify what needs to be done differently to ensure the inclusion of pregnant women in clinical trials.

The use of behavioural science in understanding challenges of trial conduct is gaining traction. Recent studies show promise in using behavioural science to understand factors that influence HCPs inviting potential participants to trials [12,13], and ultimately in developing behaviour change interventions to target modifiable behaviours. One behavioural framework commonly used in health research of this nature is the Theoretical Domains Framework (TDF). The TDF is an established framework that consolidates 33 theories of behaviour and behaviour change into 14 broad domains that obstruct or enable behaviour [14]. Fig. 1 presents each domain and definition.

This study aims to use behavioural science to specify and identify the barriers and enablers for HCPs to inviting all eligible women to participate in a maternity care trial and provide solutions to address the barriers. This paper reports one phase of the ENCOUNTER Study.

2. Methods

We used the TDF to inform our study design, specifically, data collection and analysis [15] and the Consolidated criteria for Reporting Qualitative studies to guide study reporting [16], see *Supplementary File 1*.

We applied the Action, Actor, Context, Target, Time (AACTT) framework [17] to define the behavior of interest for this study and to inform sampling by ensuring HCPs from all relevant clinical backgrounds were represented, and to focus the development of the interview topic guide. Table 1 presents the specified behavior.

2.1. Recruiting participants

Our comprehensive targeted recruitment strategy (described in *Supplementary File 2*) purposively selected trials in pre-specified high priority research areas for inclusion in this phase of the ENCOUNTER Study. Initially, 17 Principal Investigators (PIs) were contacted by email and invited to take part, eight expressed an interest and extended our invitation to HCP recruiters on their team. Three PIs contacted us directly through the ENCOUNTER Study Twitter account to participate in the study. In total, 24 HCP recruiters contacted the study team and were emailed study information packs, of these, 22 returned a signed consent form and were offered either online or telephone interview at a time convenient to them.

2.2. Data collection

In addition to the AACTT specification, the validated version of the TDF [14] informed our topic guide (*Supplementary File 3*), which followed previously published examples [18,19]. Two pilot interviews ensured comprehensibility and theoretical robustness. The guide was used adaptively, facilitating a conversational semi-structured interview, making inquiry about recruiter's experiences regarding challenges and opportunities, of recruiting eligible women to clinical trials. One-to-one interviews were conducted by VH between September-December 2020. Participants reconfirmed their consent and interviews were audio recorded.

2.3. Data analysis

Interviews were transcribed verbatim, and sent to participants to confirm accuracy and add any further comment, four participants wished to expand on their points. Anonymized transcripts were transferred to QSR NVivo 12. Thematic analysis [20] was used to generate initial codes and subthemes (VH), which were revisited and iteratively updated through a series of meetings (VH,LB,KG). Once the inductive thematic analysis was agreed, data within each subtheme were then categorized as either explicitly or implicitly linked to the specified behavior (VH,LB,KG). This categorization allowed us to carry forward to TDF analysis only data relevant to the behavior. To facilitate behavioral diagnosis, a TDF codebook was developed guided by published examples [18,19] and agreed

Domain definition All definitions are based on definitions from the American Psychological Associations' Dictionary of Psychology	**Constructs**
1. Knowledge (An awareness of the existence of something)	Knowledge (including knowledge of condition /scientific rationale), Procedural knowledge, Knowledge of task environment
2. Skills (An ability or proficiency acquired through practice)	Skills, Skills development, Competence, Ability, Interpersonal skills, Practice, Skill assessment
3. Social/Professional Role and Identity (A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting)	Professional identity, Professional role, Social identity, Identity, Professional boundaries, Professional confidence, Group identity, Leadership, Organisational commitment
4. Beliefs about Capabilities (Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use)	Self-confidence, Perceived competence, Self-efficacy, Perceived behavioural control, Beliefs, Self-esteem, Empowerment, Professional confidence
5. Optimism (The confidence that things will happen for the best or that desired goals will be attained)	Optimism, Pessimism, Unrealistic optimism
6. Beliefs about Consequences (Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation)	Beliefs, Outcome expectancies, Characteristics of outcome expectancies, Anticipated regret, Consequents
7. Reinforcement (Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus)	Rewards (proximal / distal, valued / not valued, probable / improbable), Incentives, Punishment, Consequents Reinforcement, Contingencies, Sanctions
8. Intentions (A conscious decision to perform a behaviour or a resolve to act in a certain way)	Stability of intentions, Stages of change model Transtheoretical model and stages of change,
9. Goals (Mental representations of outcomes or end states that an individual wants to achieve)	Goals (distal / proximal), Goal priority Goal / target setting, Goals (autonomous / controlled) Action planning, Implementation intention
10. Memory, Attention and Decision Processes (The ability to retain information, focus selectively on Aspects of the environment and choose between two or more alternatives)	Memory, Attention, Attention control. Decision making Cognitive overload / tiredness
11. Environmental Context and Resources (Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour)	Environmental stressors, Resources / material resources Organisational culture /climate, Salient events / critical incidents, Person x environment interaction, Barriers and facilitators
12. Social influences (Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours)	Social pressure, Social norms, Group conformity Social comparisons, Group norms, Social support, Power Intergroup conflict, Alienation, Group identity, Modelling
13. Emotion (A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event)	Fear, Anxiety, Affect Stress, Depression, Positive / negative affect, Burn-out
14. Behavioural Regulation (Anything aimed at managing or changing objectively observed or measured actions)	Self-monitoring, Breaking habit, Action planning

Fig. 1. Theoretical domains framework v2 (Cane *et al.*, 2012)

with two psychologists experienced in the TDF (ED,LL) (*Supplementary File 4*). Using the codebook, VH,LL independently coded the inductive analysis subthemes (explicitly) linked to the specified behavior to the TDF. Our method of analysis meant a frequency count of domains was not possible. Instead, the salience of each domain within the subtheme was discussed (VH,LL), with the major/minor domains influencing the specified behavior determined based on strength of beliefs and conflicting opinions. The results of this mapping exercise were then discussed with all members of the research team to ensure fidelity of the codebook. Similar to methods described in a recent study [13], subthemes were compared across relevant domains in order to identify any relevant patterns

Table 1. AACTT framework

	Specified behaviour
Action	Inviting all eligible women to participate in a trial
Actors	[1] Midwives/Nurses/AHP in clinical role [2] Midwives/Nurses/AHP in research role [3] Doctors in clinical role [4] Midwives/Nurses/AHP/Doctors in CI/PI role
Context	Clinic or hospital setting
Target	Pregnant/postpartum women
Time	During any episode of care

in the data, which were then grouped into global themes. These global themes (reported below) represent the most important factors impacting HCP recruiters' behavior to invite all eligible women to participate in a trial.

Details on research team characteristics and reflexivity are provided in *Supplementary File 2*.

3. Findings

We interviewed 22 HCP trial recruiters (nine Ireland based, 13 UK based) including research midwives/nurses, clinical midwives/nurses, allied health professionals, obstetricians, and endocrinologists, recruiting for nine different trials, across 14 individual sites. Recruiters were associated with trials in maternity care including clinical areas such as diabetes, preeclampsia, and breastfeeding. Participants included 20 female and two males, all had over 5 years clinical experience, 15 were experienced recruiters ($>$ 2 years), and seven novice recruiters ($<$ 2 years). One participant was known professionally to the researcher prior to interview. Twenty interviews were conducted online, two by telephone. The median time of interviews was 47 minutes (range 26mins - 88mins). Table 2 presents participant characteristics.

3.1. Overall findings

Four global themes were identified, these included 12 subthemes, and spanned 13 domains of the TDF.

1. *Availability and accessibility of resources* describes the barriers and enablers to HCP recruiters inviting all eligible women to participate in a maternity care trial that the availability and accessibility of resources presents.
2. *Navigating the recruitment pathway*, describes the practical considerations and strategies adopted by recruiters in carrying out the behavior.
3. *Prioritizing clinical responsibilities over research responsibilities*, describes the importance of recruiter's clinical background and the role it plays in their recruitment activity.
4. *The influence of colleagues and peers*, describes how support, or lack of, is influential on HCPs inviting all eligible women to the trial.

These global themes, associated subthemes, and TDF domains (in parentheses), are presented in Table 3 and described in detail below.

While themes have been presented as mutually exclusive, some are interlinked and overlap, with some themes having dependency on others. Exemplars of supporting data for each theme are provided in *Supplementary File 5*.

Global theme 1: Availability and accessibility of resources

(TDF domain: Environmental context and resources)

Most recruiters cited the availability and accessibility of resources as a barrier to inviting all eligible women to participate in a trial. Frequently the absence of a dedicated space to have a private conversation with potential participants was identified as a problem.

"So, it can be quite difficult sometimes to have confidential conversations, which really is essential., I often spend time wandering around the hospital trying to find an empty cupboard to try and have a conversation in." 2RM

However, some recruiters felt that recruiting participants from the 'waiting area' was preferable as it made efficient use of the woman's time. Mobile technology was mentioned by some recruiters as helpful in inviting all eligible women to join a trial, as resources such as telephones and iPads enabled effective communication. Most recruiters talked about having sufficient staff, both clinical and research, as an enabler in granting both the opportunity and time to approach all eligible women, whilst acknowledging that being understaffed led to missed recruitment opportunities. Some recruiters also referred to trial funding as being influential to recruitment efforts, suggesting they placed greater emphasis on offering participation to all eligible women for trials backed by external funding.

Global theme 2: Navigating the recruitment pathway

Planning & preparation

(TDF domains: Behavioural regulation, Knowledge)

Many recruiters emphasised the importance of planning and preparing for trial recruitment. This organisation involved screening ward and clinic lists and accessing women's charts to gain background knowledge on potential participants.

Table 2. Participant characteristics

Participants (HCP recruiters)	**N = 22**
Based in Ireland	9 (41%)
Based in UK	13 (59%)
Professional Background	
Clinical midwife/nurse	4 (18%)
Research midwife/nurse	11 (50%)
Doctor	2 (10%)
Chief/Principal Investigator	5 (23%)
Gender	
Female	20 (90%)
Male	2 (10%)
Recruitment experience	
>2 years	15 (68%)
<2 years	7 (32%)
Clinical experience	
<5 years	0 (0%)
>5 years	22 (100%)
Associated selected trial	N=9
CTIMP	1 (11%)
Non-CTIMP	8 (89%)

"We screen all the lists ourselves, so we will often have a little bit of an idea of the woman's medical history, particularly her obstetric history… if there was like a previous stillbirth or something, there are certain things you would want to be a little bit kind of sensitive about. But I do like to go in with as much information as I can behind me, because I think it helps." 13RM

A 'two-stage' strategy (providing trial information initially and returning at a later point to discuss participation) was favoured by some recruiters, believing this strategy allowed women more time to assimilate trial information and make an informed decision about participation. Some recruiters highlighted that for Clinical Trials of an Investigational Medicinal Product (CTIMPs), additional planning and preparation was required.

3.1.1. Being visible

(TDF domains: Behavioural regulation, Intentions, Environmental Context and Resources)

The visibility of both the trial and the recruiter was important to inviting all eligible women to take part in a maternity care trial. Recruiters were motivated to use creative strategies to increase the noticeability of the trial, including posters, noticeboards and social media posts, promoting awareness of the trial among clinical staff and potential participants. One recruiter even described competing in a marathon to raise trial awareness and extend their reach in accessing potential participants that might otherwise have been missed. Some recruiters suggested sustaining a visible presence in the clinical area enabled recruitment, and was a helpful signpost reminding clinical colleagues to refer all potential eligible women to them.

"*We had posters up, we had things stuck to CTG machines* [Fetal heart rate monitors]… *labels reminding them* [clinical colleagues] *that it's still going on, we have this trial and we still have to do it! … It's like a continuous, 'bang' 'bang' on the drum". 20CI/PI*

3.1.2. Approach to recruiting

(TDF domains: Emotion, Skills, Beliefs about consequences, Environmental Context and Resources)

Most recruiters referred to the '*bespoke-ness*' of their approach to recruitment and emphasized that the invitation to participate in a trial should be '*gentle*' and sensitively appropriate to each woman's situation. Recruiters talked about the significance of choosing the 'right' time to approach which was seen as key to successful trial recruitment.

Recruiters also highlighted the importance of communicating the trial in a concise understandable way. Some recruiters revealed they developed and rehearsed a recruitment '*spiel*' for each trial. Interestingly, many recruiters indicated that intuition played a part in whether or not they approached all eligible women to participate in a trial, they described '*getting a vibe*' which could deter them from approaching a woman despite her meeting the eligibility criteria.

3.1.3. The 'right' participants

(TDF domains: Beliefs about consequences, Knowledge, Memory and decision processes, Intentions)

Table 3. Thematic analysis mapped to the Theoretical domains framework

Inductive thematic analysis	**Deductive analysis - Mapping of subthemes to Theoretical Domains Framework**	
Subthemes	Salient domain	*Linked domains*
Availability & accessibility of resources	Environmental Context and Resources	*None*
Planning & preparation	Behavioural Regulation	*Knowledge* *Memory, attention, decision-making processes*
Being visible	Behavioural Regulation	*Intentions* *Environmental Context and Resources*
Approach to recruiting	Emotion	*Skills* *Beliefs about Consequences* *Environmental Context and Resources*
The 'right' participants	Beliefs about Consequences	*Knowledge* *Memory, attention, decision-making processes* *Intentions*
Benefit of experience	Knowledge	*Beliefs about Capabilities* *Skills*
Putting women's clinical care and wellbeing first	Intentions	*Social/Professional Role and Identity* *Goals*
Acceptability of the intervention	Beliefs about Consequences	*Social/Professional Role and Identity*
Commitment to the research	Intentions	*Social/Professional Role and Identity* *Beliefs about Consequences*
Being supported	Social Influences	*Social/Professional Role and Identity* *Reinforcement*
Gatekeeping	Social Influences	*Intentions*
Recruitment targets	Goals	*Reinforcement* *Emotion* *Social Influences*

Recruiters clearly stated that, if eligible, all women should be offered the opportunity to join a trial and had the right to decide if they participated. Despite this, some recruiters indicated there could be difficulties in identifying potential trial participants. For example, some recruiters experienced ambiguity interpretating eligibility criteria and were concerned about the consequences of recruiting ineligible participants.

> *"I think, 'Oh, I can go to that person' And then you're kind of reading between the lines and go 'Oh, maybe I shouldn't?' 'Did we recruit all the wrong women because we didn't kind of get it?' You think you're having a great run of it and you recruit loads of people and then you're like, 'Oh, sugar, did I miss some of the criteria?' " 22CM*

While some recruiters sought the 'right' participants to invite to a trial based on their own judgement of the woman's suitability as a potential trial participant and whether they believed she had the capability to complete the trial.

3.1.4. Benefit of experience

(TDF domains: Knowledge, Beliefs about capabilities, Skills)

All recruiters indicated that having clinical experience in maternity care was advantageous to their role as trial recruiter. This was largely because they believed their clinical knowledge provided insight on the topic and rationale underpinning the trial, which better positioned them to answer women's questions. Recruiters described learn-

ing how to recruit to trials through experience. Using informal training methods such as shadowing more experienced colleagues, equipped them to manage '*rejection*' when the invitation to join a trial was declined. Most recruiters remarked that their competence in recruitment developed through practice, while some indicated their confidence increased alongside knowledge and understanding of the trial.

Global theme 3: Prioritising clinical responsibilities over research responsibilities

3.1.5. Putting women's clinical care and wellbeing first

(*TDF domains: Intentions, Social/Professional Role & Identity, Goals*)

Prioritising the clinical care and wellbeing of potential participants was paramount to all recruiters in the study. Inviting all eligible women to participate in a trial was a secondary consideration for HCPs presented with either women's physical or emotional needs. Most recruiters referred to their professional responsibility and duty of care towards women and sought to minimise any potential burden associated with participation.

> *"It would always be the woman… to be truthful now, a research study would always come second to a woman's needs…" 19CM*

3.1.6. Acceptability of the intervention

(*TDF domains: Beliefs about consequences, Social and Professional Role and Identity*)

Most recruiters indicated that they were more comfortable and thereby more willing to recruit to trials where they believed the intervention was acceptable to women. Recruiting for trials where the intervention did not align with their professional opinion was more challenging for recruiters. Furthermore, the recruiter's perception of acceptability varied depending on their clinical background.

> *"I think with the induction trials, quite often, doctors will get more recruits than midwives on those ones, because I think we're thinking a little bit more about the actual impact of induction and what that can lead to and whether that is really necessary to try this?" 15RM*

3.1.7. Commitment to the research

(TDF domains: Intentions, Social and Professional Role and Identity, Beliefs about consequences)

Some recruiters expressed a sense of ownership towards the trial and reported feeling *'invested'* in it. This engagement with the trial appeared to encourage recruiters to invite all eligible women to participate as recruitment success was important to them. Recruiters were keen to recruit to trials they believed to be worthwhile and showed promise in improving clinical care.

> *"If you have a frontline team, who love, who really want to improve maternity care, and who are selling your study as a potential advance in the field, then that's a huge benefit to recruitment. I think if you have a frontline team who are reluctant, they see it as a tick box exercise only, that's much harder." 4CP/PI*

Global theme 4: The influence of colleagues and peers

3.1.8. Being supported

(TDF domains: Social Influences, Reinforcement)

Support from peers across the trial setting was an important enabler for all recruiters in inviting all eligible women to participate in a trial. The collaboration of clinical colleagues allowed recruiters to gain access to all potential participants. Recruiters valued this support and paid attention to building and nurturing relationships with clinical colleagues. Recruiters described how the absence of such support prevented them from reaching all potential trial participants.

> *"I think often I felt a little bit like they could almost do with not having me there… it* [trial recruitment] *sort of was like an extra thing, an extra sort of interruption." 13RM*

Support from other trial recruiters encouraged recruiters to extend the trial invitation. Most recruiters reported that regular communication with the trial team was helpful, while onsite support from the team was especially appreciated.

3.1.9. Gatekeeping

(TDF domains: Social Influences. Intentions)

Most recruiters mentioned experiencing some form of logistical or active clinician gatekeeping at trial sites. While some recruiters accepted clinician gatekeeping as well-meaning and did not challenge it, many others expressed frustration and believed clinician gatekeeping denied eligible women trial participation. Resolve to find ways to overcome gatekeeping ensured recruiters reached all potential participants.

> *"And I would routinely discuss it with a woman first, and then if she showed interest, I would go to the consultant and say "I've offered her the research because she was eligible, and because I do not require you to gatekeep, to give me permission to offer research to an eligible woman" 1CI/PI*

3.1.10. Recruitment targets

(TDF domains: Goals, Reinforcement, Emotion, Social Influences)

Many recruiters described recruitment targets as positive and found having targets encouraged them to invite all eligible women to join a trial. The competition created between trial sites was also generally well received as most recruiters appreciated the opportunity to benchmark their recruitment performance and celebrate successes.

"They [trial teams] *do occasionally try and push us a bit by saying, 'Oh, another site is getting more than you this month'. I like seeing those numbers you know, we're hitting targets, and I like a bit of competition. So actually knowing about the other sites might be quite useful." 10RM*

However, the element of competition served as a disincentive for some recruiters as they felt *'under pressure'* to meet what they considered to be an unachievable recruitment target.

4. Discussion

This study aimed to use a behavioural science approach to investigate the challenges and opportunities for recruitment to trials in maternity care from the perspectives of maternity healthcare professionals. Our findings pointed to several important factors determining whether or not recruiters invited all eligible women to participate in a trial which will directly inform a future intervention. Recruiters in our study were aware of their responsibility to invite all eligible women to participate in a trial, however, for a number of reasons they often had difficulty following through on the invitation. Below we detail key findings and suggest potential practical solutions to target recruitment barriers in Table 4.

One of the most commonly reported barriers to inviting women to participate in a trial stemmed from the availability and accessibility of resources. Lack of resources resonates widely in trial recruitment literature across clinical areas. Several recent studies highlight the inadequacy of essential resources such as time, staffing and physical space [12,21-23]. Notably, the lack of time available for recruitment appears to mostly impact clinical midwife/nurse recruiters [21–23]. An explanation for this might be that, unlike medical colleagues, midwifery/nursing staff are often not allocated protected time to support research activity. A potential solution to this is granting midwives/nurse dedicated time away from clinical duties for the specific purpose of recruitment. Interestingly, the UK National Institute for Health Research have introduced designated members of staff to help improve recruitment to research studies [24]. However, it is difficult to assess how many of these roles are dedicated to trials in maternity care as there is currently no data on the actual number of clinical research nurses/midwives across the UK and Ireland [25].

Recruiters navigated the recruitment pathway by adopting a mixture of strategies to overcome anticipated practical challenges. This included recruitment planning and preparation, ensuring visibility of the trial in the clinical environment, and tailoring their recruitment approach for each potential participant. A Cochrane systematic review of strategies designed to help healthcare professionals to recruit participants to research studies identified three main recruitment strategies; using a potential participant alert system, additional input to study sites and having additional personnel to support recruitment. The authors suggest using a combination of strategies to be most effective, as there is minimal evidence for any one single component [7]. Combining recruitment strategies proved successful in a recent study recruiting underserved pregnant participants, where the flexibility of HCPs to adapt to complex interventions and real-world challenges improved trial recruitment [26].

Having difficulty finding the 'right' participant is frequently reported by HCP recruiters throughout the literature, with the practice of choosing not to approach all eligible patients commonplace [8,27]. This participant selection bias is problematic for a number of reasons, it infringes upon the scientific validity of clinical research and is counterfactual to evidence-based care in that treatment is based on preference, not evidence [28]. Preston *et al.*'s highlight the importance of finding solutions to overcome this issue in all healthcare research [7]. A potential solution could be to frame research as part of clinical care and emphasize the importance of generating evidence on the best treatment.

Many of the influential factors for HCPs inviting all eligible women to participate in a trial appeared rooted in prioritizing clinical responsibilities over those of research. It is perhaps inevitable recruiters accord primacy to women's care and well-being, aligning with the bioethical principles of beneficence and non-maleficence. Hays-Smith *et al*. found this may be unavoidable as trial recruitment involves patterns of behavior typical of a clinician-patient interaction. The authors suggest regular review of HCPs research obligations to ensure that clinical and research roles are not artificially separated in trial protocols [29].

In our study, recruiters' appraisal of the acceptability of the intervention influenced whether or not they offered the trial to all eligible women. It should be noted however, that this finding is contrary to an earlier review of (dis)incentives for clinicians participating in RCTs, which found no association between the perceived nature of the intervention and recruitment rates [30]. We suggest that it may be helpful to involve HCPs earlier in the trial design process and to include midwife/nurse representation in the trial management team from the outset [22]. Including PPI contribution at this early phase could also help disperse recruiter's doubts surrounding intervention acceptability [31].

The influence of colleagues both enabled recruiters to invite all eligible women to participate in a trial, and acted as barrier through clinician gatekeeping. Clinician gatekeeping, either active or passive, is a well-recognised recruitment barrier in healthcare research [8–10]. It is problematic not only in selection bias (as discussed), but also in undermining the woman's autonomy, by removing choice or steering decision making [11]. One strategy used to preserve autonomy in palliative care trials and thereby circumvent clinician gatekeeping, is to inform patients directly about the possibility of being asked to join a trial [32].

Table 4. Potential solutions to target barriers for healthcare professionals inviting all eligible women to participate in maternity care trials

TDF domain	Specified behaviour		Possible solutions to target barriers
	Barrier	Enabler	
Knowledge *example*	√ Understanding eligibility criteria	√ Having clinical experience	Trial team training with all staff responsible for recruitment/frequent updates/opportunities for peer learning both within and across sites, etc
Skills *example*	*X*	√ Recruiting is learned through experience	*Barrier not identified*
Social/Professional Role and Identity Example	√ Opinions based on clinical identity	√ Having a sense of ownership increased commitment	Ensure separation of HCPs clinical and recruitment role Provide training on how to maintain equipoise in trial recruitment
Beliefs about Capabilities *example*	*X*	√ Competence in recruiting grew with experience	*Barrier not identified*
Optimism	*X*	*X*	
Beliefs about Consequences *example*	√ Difficulties finding the 'right' participant	√ Belief that trial will result in improved clinical care	Ensure eligibility criteria and importance of trial are clear on training Review and feedback on screening logs
Reinforcement *example*	*X*	√ Acknowledging others for their assistance	*Barrier not identified*
Intentions *example*	√ Deciding not to approach 'unsuitable' participants Recruitment is secondary to clinical care	√ Following the recruitment protocol	Review and feedback on screening logs Reinforce research as part of clinical care to generate evidence on best treatment. Emphasise that counterfactual is to provide a treatment based on preference not evidence
Goals *example*	√ Feeling pressurised to meet targets	√ Motivated to achieve targets	Discuss targets with site teams to set realistic targets Regular review of targets and active support from trial team to achieve them
Memory, Attention and Decision Processes *example*	√ Remembering eligibility criteria	*X*	Visual reminders such as posters, credit cards, lanyards that list the eligibility criteria
Environmental Context and Resources *example*	√ Insufficient resources	√ Recruiting from waiting room	Ensure trial recruitment is adequately resourced with staff and has the place, space and privacy necessary for the recruitment encounter.
Social Influences *example*	√ Gatekeeping by clinical colleagues	√ Having the support of clinical colleagues	Team meetings to discuss the trials – similar to MDT meetings to get buy in from cross specialty
Emotion *example*	√ Intuitive recruitment	√ Being responsive to individual women	Reduce negative emotions through building peer network – discussing the balance between protecting women's interests while supporting them to benefit from evidence based care Embed the offer of trial participation into every care interaction.
Behavioural Regulation *example*	*X*	√ Determining own strategy for recruitment	Give recruiters space to plan and develop recruitment strategies tailored to each trial and each site.
X = no data reported, √ = data reported	Identified domain most salient to behaviour	Identified domain less salient to behaviour	Not identified

Table design adapted from examples in Newlands *et al*. 2021, 'Why trials lose participants: A multitrial investigation of participants' perspectives using the theoretical domains framework. J Clin Epidemiol. 2021;137:1-13

Similar to Kars *et al*., we suggest collaboration between recruiters and clinicians is key in finding the balance between protecting women's interests while supporting them to benefit from evidence based care.

This study has demonstrated how a behavioral approach can be applied to assess the factors that influence a key recruiter behavior: inviting all eligible women to participate. We have enhanced knowledge of the barriers and enablers for HCPs inviting all eligible women to participate in a maternity care trial using data from several trials. The majority of current non-emergency trials in maternity care are in the areas of diabetes, preeclampsia and breastfeeding, we sampled across trials in these areas, making our findings specifically relevant to these high-priority research areas. Exploratory studies such as ours are usually embedded within a single host trial, whereas this study included recruiters across nine trials, thereby enhancing transferability of findings. Furthermore, while participants were asked explicitly about their experiences recruiting for the specific trial in question, many drew on experiences beyond this, making our findings more broadly applicable across trials. The spread of participants in this study represented clinical professions and trial backgrounds from hospital-based research facilities across Ireland and the UK, means that these findings reflect a European, high-income, facility-based perspective, which may not be generalizable to other contexts or settings. Nonetheless, it is worth noting that whilst this phase of the ENCOUNTER Study focused on recruitment to maternity care trials exclusively, this study could also provide learnings for the recruitment of pregnant women to clinical trials outside of maternity care.

4.1. Strengths and limitations

Social distancing measures imposed due to the pandemic made it necessary to conduct interviews online, this may have limited some HCPs willingness to participate, however, we believe this did not significantly impact the richness of the data. Interviewees were self-nominated and therefore more likely to be engaged in trial recruitment, contributing to a possible bias. Being interviewed by a midwife working in the field of research may have led participants to give socially desirable responses. However, this can also be considered a strength, as experiential understanding of the topic area helps develop rapport and probe where appropriate, potentially contributed to a richer data set. We acknowledge that the gender and make-up of the research team is likely to have influenced our analysis, however, we consider our reflexivity throughout has strengthened the validity and rigor of this empirical research.

A key methodological strength to our study was using a validated theoretical framework [14] to guide the design and analysis phases. Our topic guide followed conversational flow, which allowed interviews reflect more natural conventions [33]. We conducted reflexive thematic analysis [20] prior to deductively mapping themes to the TDF, we believe this approach strengthens our findings by facilitating concept and theme generation uninfluenced by the TDF [33]. Our sample was larger than typical TDF interview studies, as we adopted the 'Information power' model, taking into account; use of established theory, quality of dialogue, and analysis strategy, as an appropriate sample size model for this study [34].

5. Conclusion

Our study identified the factors that influence behavior, either enabling or inhibiting HCP recruiters to invite all eligible women to participate in a maternity care trial. Given that trials including women during pregnancy and childbirth make up only a small proportion of clinical trials taking place, it is important that these findings are used to support researchers and the progression of research in this population. Our findings are useful to researchers in two ways. Firstly, in helping trial designers to consider the barriers and enablers for HCPs inviting all eligible women to participate in a trial, thereby preventing problems before they emerge. Secondly, these findings can be used to develop a recruiter-focused behavioral intervention to address remaining uncertainties surrounding the most effective ways to offer maternity care trial participation to all eligible women.

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Ethics approval

Ethical approval for the all phases of the ENCOUNTER Study was granted by National University of Ireland, Galway (R20.Jun.08). The study was deemed NHS REC exempt in England, Scotland, Wales & N. Ireland by NHS Health Research Authority. Written informed consent was obtained from all participants.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jclinepi.2022.01.015.

CRediT authorship contribution statement

Vivienne Hanrahan: Conceptualization, Methodology, Investigation, Formal analysis, Writing – original draft, Writing – review & editing, Visualization, Project administration. **Linda Biesty:** Conceptualization, Methodology,

Formal analysis, Writing – review & editing, Visualization, Supervision. **Louisa Lawrie:** Formal analysis, Writing – review & editing. **Eilidh Duncan:** Methodology, Formal analysis, Writing – review & editing. **Katie Gillies:** Conceptualization, Methodology, Formal analysis, Writing – review & editing, Visualization.

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