**TITLE PAGE**

**Title:** Community midwives’ and health visitors’ experiences of research recruitment: a qualitative exploration using the Theoretical Domains Framework

**Corresponding author**

Dr Jennie Rose, Senior Research Fellow, Faculty of Health, Education, Medicine and Social Care, ARU, East Road, Cambridge, CB1 1PT, UK. Email: Jennie.Rose@aru.ac.uk. Telephone: 01223 695323

**AUTHOR INFORMATION**

**Jennie Rose**

Post at the time the work was completed: Research Fellow in Public and Community Health, Anglia Ruskin University

Current appointments: Senior Research Fellow in Public and Community Health, Anglia Ruskin University

Qualifications: PhD, BSc (Hons) Psychology, BSc (Hons) Zoology

**Kieran Lynn**

Post at the time the work was completed: Research Assistant, Anglia Ruskin University

Qualifications: BSc (Hons) Psychology

**Jane Akister**

Post at the time the work was completed: Reader in Social Work, Anglia Ruskin University

Current appointment: Emeritus Reader in Social Work, Anglia Ruskin University

Qualifications: PhD, MSc

**Fiona Maxton**

Post at the time the work was completed: Research Delivery Manager, NIHR CRN Eastern

Current appointment: Lead Nurse - Research & Development, and NIHR 70@70 Senior Nurse Research Leader, North West Anglia NHS Foundation Trust

Qualifications: RSCN, RN PhD

**Sarah A Redsell:**

Post at the time the work was completed: Professor of Public Health, Anglia Ruskin University

Current appointment: Honorary Associate Professor, School of Medicine, University of Nottingham

Qualifications: BSc (Hons), PhD, RGN, Rhealth visitor, CPsychol

# TITLE: Community midwives’ and health visitors’ experiences of research recruitment: a qualitative exploration using the Theoretical Domains Framework

# ABSTRACT

Background: Successful research is frequently hampered by poor study recruitment, especially in community settings and with participants who are women and their children. Health visitors and community midwives are well placed to invite young families, and pregnant and postnatal women to take part in such research, but little is known about how best to support these health professionals to do this effectively.

**Aim:** This study uses the Theoretical Domains Framework to explore the factors that influence whether health visitors and community midwives invite eligible patients to take part in research opportunities.

Method: Health visitors (n=39) and community midwives (n=22) working in four NHS Trusts and one community partnership in England completed an anonymous, online survey with open-ended questions about their experiences of asking eligible patients to take part in research. Qualitative data were analysed using directed content analysis and inductive coding to identify specific barriers and enablers to patient recruitment within each of the 14 theoretical domains.

Findings: Six key TDF domains accounted for 81% of all coded responses. These were (a) environmental context & resources; (b) beliefs about capabilities; (c) social/professional role and identity; (d) social influences; (e) goals; (f) knowledge. Key barriers to approaching patients to participate in research were time and resource constraints, perceived role conflict, conflicting priorities, and, particularly for health visitors, negative social influences from patients and researchers. Enablers included feeling confident to approach patients, positive influence from peers, managers and researchers, beliefs in the relevance of this behaviour to health care and practice, and good knowledge about the study procedures, its rationale and the research topic. The findings suggest that to improve research recruitment involving health visitors and community midwives a package of interventions is needed to address the barriers and leverage the enablers to participant approach.

# KEYWORDS

Recruitment; Theoretical Domains Framework; health visitors; community midwives

# BACKGROUND

Health care professionals play an important role in the recruitment of participants to research studies. In the UK, data protection legislation prevents researchers approaching potential participants directly (Redsell and Cheater, 2001; Preston *et al.*, 2016; Grady *et al.*, 2019) and therefore it is common practice for health care professionals to inform patients[[1]](#footnote-1) of research participation opportunities (Preston *et al.*, 2016). However, there is substantial evidence that when performing this function health care professionals approach only a proportion of eligible patients (Bonevski *et al.*, 2014; Hughes-Morley *et al.*, 2015; Tromp and Vathorst, 2015; Briel *et al.*, 2016; Preston *et al.*, 2016). This introduces biases to the sample as well as adversely affecting recruitment (Preston *et al.*, 2016; Rose *et al.*, 2017).

Whilst there is a growing body of research into the factors that influence recruitment to research, there has been less of a focus on community health care settings, particularly where the participants are perinatal women and young children. (Frew *et al.*, 2014). Yet research involving these participants can be especially susceptible to recruitment problems (Baxter *et al.*, 2012; Webster *et al.*, 2012; Jordan *et al.*, 2013; Pica and Bourgeois, 2016; Huntington *et al.*, 2017; van der Graaf *et al.*, 2018). Historically, women in their childbearing years were excluded from research participation in case it was detrimental to their future children, and a prevailing precautionary approach may be a contributory factor (Frew *et al.*, 2014). Policies changed decades ago, but research involving these participants remains susceptible to low rates of accrual (Pica and Bourgeois, 2016; van der Graaf *et al.*, 2018) and undersampling of socioeconomically disadvantaged and minority ethnic groups (Baxter *et al.*, 2012; Webster *et al.*, 2012; Jordan *et al.*, 2013; Huntington *et al.*, 2017). In the case of pregnant women, the narrow window of eligibility for recruitment presents a particular challenge {Coleman-Phox, 2013 #107). Other explanations also focus on issues that stem from the patients, such as lack of time (van Delft, 2013; Frew *et al.*, 2014) and competing priorities including childcare and work commitments (Daniels *et al.*, 2012; Carpenter, 2016). Much less attention has been paid to the health care professionals’ role in the recruitment process for this population (Tooher *et al.*, 2008). With early intervention to improve population health being high on the policy agenda in the UK and elsewhere, a greater understanding of the influence of health care professionals on the recruitment of perinatal women and children to research is needed.

In the UK, community midwives and health visitors (public health nurses) provide health care for women and their children, from pregnancy to five years of age. Delivering universal services, these practitioners have very high potential reach (Laws *et al.*, 2016) and are well placed to approach pregnant women, new parents and families about participation in research. However, where health visitors and community midwives have been involved in participant recruitment, disappointing recruitment and limited representativeness of the study sample has been an issue resulting from reluctance of the health care professionals to approach all eligible participants (Hoddinott *et al.*, 2007; Knight and Wyatt, 2010; Mytton *et al.*, 2014; Redsell *et al.*, 2017). In order to address these problems, it is necessary to understand the particular issues that concern community midwives and health visitors when they are tasked with informing families in their care of opportunities to take part in research. With the exception of one study which looked at barriers to community midwives identifying potential participants in a specific randomised controlled trial (RCT) ((Stuart *et al.*, 2015) there is little previous research exploring the research recruitment experiences of these community midwives and none that we could find focussing on the experiences of health visitors.

The aim of this study was to explore health visitors’ and community midwives’ perceived barriers and enablers to approaching patients about research participation. We used an established theoretical framework, the Theoretical Domains Framework (TDF) (Michie *et al.*, 2005; Cane *et al.*, 2012; Michie *et al.*, 2014) to guide data collection and analysis. This evidence-based tool provides a systematic approach to understanding health care professionals’ behaviours and identifying what needs to change.

# METHODS

We used the SRQR reporting guidelines (O'Brien *et al.*, 2014) to structure the reporting of this study.

# Design

We used a self-reported, anonymous, online, cross-sectional survey to collect data from the health visitor and community midwife participants. Eight questions gathered data about respondents’ professional and demographic characteristics. The remainder of the survey focussed on the specific behaviour of interest: approaching eligible patients about research participation. These questions were informed by the refined TDF (Cane *et al.*, 2012) (Table 1) . An initial set of questions designed to elicit responses covering all 14 TDF domains was piloted with a convenience sample of health care professionals. Feedback from the pilot respondents prompted the rewording of some questions, and the addition of others, resulting in a broader set of open-ended questions which sought to explore the possibility of barriers and facilitators that did not fit in any of the TDF domains as well as prompting the respondent to mention factors that would map to the theoretical domains (Supplementary file 1). The final questionnaire included 25 questions: 8 questions gathered demographic data and 17 questions invited free text responses to questions about approaching patients about research participation. The redrafted survey was entered onto the host site (Jisc’s Online Surveys) and tested for functionality and comprehensibility by five health researchers employed in the authors’ Faculty, none of whom were part of the study team.

**Ethical Approval**

Permission to conduct the study was provided by the Anglia Ruskin University Faculty of Health, Social Care and Education Research Ethics Panel (Reference FHSCE\_DREP-16-106) on 23rd February 2017 and Health Research Authority approval (REC reference 17/HRA/1753) was granted on 10th April 2017. Local R&D permission was granted by four NHS Trusts and one social enterprise contracted to the NHS.

# Participants and setting

We invited staff delivering community public health nursing (health visiting) and community midwifery services for four NHS Trusts and one social enterprise to complete the questionnaire. These organisations covered both rural and urban areas, in different regions of England. Prior experience of conducting research was required, however, the employing organisations did not have data which staff had that experience, so all community midwives and health visitors were informed of the survey. Those who were eligible were identified through an initial filtering question on the survey.

**Researcher characteristics and reflexivity**

At the time of data collection, the researchers included two registered nurses (SR and FM), one of whom is also a health visitor (SR), a social worker (JA) and a Research Fellow (JR). We all have experience working in non-academic roles with families, in clinical or community settings. We also all have experience of working with health and social care professionals to recruit participants to research projects, and these experiences prompted our interest in this study. Our application of an approach rooted in psychological theory to frame the study is influenced by our training as psychologists (JR, SR, KL).

# Data collection

Participating organisations sent an email to their health visitors and community midwives inviting them to take part in the study. A hyperlink in the email opened to the participant information sheet. Potential participants were informed that the survey was anonymous, no personally identifiable information would be captured and once submitted their survey answers could not be withdrawn. Recipients were asked to confirm their consent before starting the survey and again before submitting their completed surveys. The survey was open for four weeks, and a reminder sent after two weeks.

# Analysis

Data were downloaded from Jisc’s Online Surveys. Quantitative data were imported into SPSS Version 26 and analysed descriptively. Qualitative data were imported into NVivo Version 12 (QSR International Pty Ltd., 2018). Two researchers (JR and KL) independently coded text into each of the fourteen theoretical domains of the refined TDF (Cane *et al.*, 2012). Responses were also examined for any barriers and enablers to approaching eligible patients about research participation which did not fit within any of the domains of TDF. The coders agreed on 99.1% of their coding decisions. The few differences in coding were discussed, and a consensus opinion reached. Specific barriers and enablers to patient recruitment were then identified within each domain.

# RESULTS

# Sample characteristics

A total of 22 community midwives and 39 health visitors with experience of approaching patients about participation in research completed the survey. Employing organisations did not have data on the numbers of eligible staff and it was therefore not possible to calculate a response rate. Participant characteristics are shown in Table 1. Most of the participants were females (n=59, 97%) and 31 (52%) had more than 10 years’ experience. Overall, the majority of participants were white British (n=42, 69%) and working in urban environments (n=39, 64%). Fifty percent of community midwife participants were BAME (Black, Asian and Minority Ethnic), as compared to 21% of health visitors. Sixty nine percent of health visitors were working in economically deprived communities, as compared to 18% of community midwives.

**Barriers and enablers to inviting eligible patients to take part in research**

Across the dataset, 408 responses mapped to the 14 TDF domains. Table 2 summarises the frequency of responses mapped to each of the 14 TDF domains for health visitor and community midwife participants. Across all 14 TDF domains, 21 barriers and 31 enablers were identified, plus 9 factors that could act as either a barrier or an enabler. We did not find any barriers or enablers that did not fit into one of the TDF domains (see Supplementary Material for the complete list of barriers and enablers identified in all 14 TDF domains).

For both health visitors and community midwives six key domains accounted for 81% of all coded responses. These were (a) environmental context & resources; (b) beliefs about capabilities; (c) social/professional role and identity; (d) social influences; (e) goals; (f) knowledge. The barriers and enablers for these key domains are detailed below, with example quotations.

*(a) Environmental context and resources*

Across the dataset, environmental context and resources was the most frequently identified domain, and was apparent in the responses of 27 (69%) health visitors and 18 community midwives (81%). Specific barriers identified were heavy caseloads leaving insufficient time, insufficient staff, language barriers and challenging clinical situations. The most frequently cited barrier in this domain, evident in the responses of 48% of health visitors and 61% of community midwives, was heavy caseloads leaving insufficient time. Respondents felt they lacked the time to talk to patients about research opportunities. Staff shortages, leading to increased individual workloads, compounded the challenge of workload pressures, making it more difficult for health visitors and community midwives to find the time to talk to patients about research opportunities.

‘It is difficult when the unit is busy and the time constraint, workload is high and staffing levels are poor’ (community midwife)

‘I find it difficult to find the time to enrol families for research due to busy workload’ (health visitor)

Health visitors and community midwives mentioned that language could also be a barrier when attempting to inform patients who spoke little or no English about potential research opportunities.

*‘*It is a difficulty when English isn't their first language’ (health visitor)

The enabling effect of comprehensive and accessible study information was evident for both health visitors and community midwives; it was particularly important given the workloads and time constraints of these staff. They needed to feel equipped to answer the questions of patients about the research without having to find additional time in their schedules to read around the research topic.

‘It’s fine as long as I have been given appropriate info myself in a concise form’ (community midwife)

‘A lot of the time due to time constraints and pressure from management we have little time to find out information so that we are able to answer questions that families may have. (health visitor)

Some respondents suggested that if additional staff with specific responsibility for research were made available, more patients could be informed about research opportunities. Others felt that research funding should, but often didn’t, cover the financial cost of staff time needed to approach patients about research participation. These respondents felt that the cost was being borne by themselves, as it was added to their existing duties without the allocation of additional staff time to cover this work.

‘Banging on again... TIME resource explicit and funded up front whether through bid process or combination of NHS Trust and monies from bid and CRN as required. But key weakness as appears Chief Investigators do not acknowledge the 'cost' of what NHS 'jobbing' clinical midwives need to be able to freely enjoy and support consistent good quality research recruitment’ (community midwife)

‘There should be payment to providers of care for payment of additional time for the research study recruitment’ (health visitor)

*(b) Social and professional role and identity*

The second most frequently identified domain for both professional groups was professional role and identity. Across the dataset there were different ways in which the respondents’ professional role and identity influenced their participant recruitment behaviour. There was an enabling belief expressed by both community midwives and health visitors that supporting research is integral to their professional role. However, some health visitors felt strongly that it was not part of their professional role - this should be the researchers’ responsibility. A different subset of the health visitors were somewhat ambivalent, suggesting that the research topic needed to relate to their role and practice, and noting there was potential for conflict with their professional role.

‘I see it as a professional endeavour and one avenue into understanding the need of clients’ (health visitor)

‘It is part of my job description’ (community midwife)

‘Researchers should stop imposing on us and sort it out themselves’ (health visitor)

‘I approve of encouraging participation in research as a general rule but am very respectful of the boundaries of roles, expectations and service policy’ (health visitor)

*(c) Social influences*

Social influences could act as both barriers and enablers to patient approach. This was more common for health visitors than community midwives, with 59% of health visitor participants compared to 45% of community midwives having responses that mapped to this domain. The social influence of patients, which acted as a barrier, was much more frequently cited by health visitors (n=12, 31%) than by community midwives (n=2, 9%). These respondents actively chose whether to inform an eligible patient about a research study; it was a judgement based on the health care professionals’ perception of the patient’s situation rather than implementation of the study’s eligibility criteria.

‘I feel that you have to pick clients who you know would be willing to participate’ (health visitor)

‘I wouldn’t ask them if I thought the client's reaction might not be positive’ (community midwife)

Researchers who fail to engage with and support the health professionals were a barrier to the involvement of health visitors, whereas community midwives identified communicative and supportive researchers as an enabler. These health care professionals felt that it was the researchers’ responsibility not only to provide the information and physical resources for recruitment, but also to provide support and encouragement in person.

‘We need more involvement from the researchers rather than just handing it to us!’ (health visitor)

‘Researchers being visible and approachable, using easy to- understand language and making it relevant to our clinical area, and help in the recruitment process is important’ (community midwife)

A desire to contribute to the team was an enabler for both health visitors and community midwives. However, only health visitors mentioned the influence of managers, which could act as both an enabler and a barrier to patient approach.

‘I do this as it supports my colleagues’ (community midwife)

‘We share enthusiasm about research and how it impacts on all of us, practitioner and patient alike’ (health visitor)

‘Some managers encourage participation whereas others are mindful of time restraints’ (health visitor)

*(d) Goals*

Introducing research opportunities to patients was not a high priority for respondents. Both health visitors and community midwives emphasised that patients’ needs always take precedence, but these respondents did not include a patient’s right to be informed of research opportunities among these needs. Commissioned targets took precedence, and since these did not include contributing to research, approaching patients about research opportunities fell to the bottom of the list of activities to be completed during a busy clinical encounter.

I just about have time to do the job of health visiting. We have targets to meet. A very demanding caseload. Extensive safeguarding. Typing up complex patient notes. Worrying about the lack of resources to actually support the dire needs of my caseload. Sorting out other people’s research is the last thing I need or want to do (health visitor)

‘Due to the volume of topics we already have to discuss within a limited time, research would likely slip to the bottom’ (community midwife)

However, 23% of the community midwives and 15% of the health visitors commented that even in the face of competing clinical targets, they considered approaching patients about research participation to be a priority because practice and care is improved by research, and good research evidence requires participation by their patients. Thus, a belief that research underpins high quality care meant that the goals domain could also act as a counterbalancing enabler to research recruitment behaviour.

‘Research into maternity services is a growing area and it is important that all are involved to ensure the service moves forward with robust clinical findings to support out work’ (community midwife)

‘Despite the time constraints, in order to gather evidence of effective interventions, good practice etc., we need to be doing research’ (health visitor)

*(e) Beliefs about capabilities*

For the most part, beliefs about capabilities acted as an enabler for both professional groups. Feeling confident to approach patients was mentioned by 55% of community midwives and 26% of health visitors, and this was the most frequently cited enabler. However, this domain overlapped with the domain of environmental context and resources, and the domain of knowledge. Thus, some respondents expressed a lack of confidence in approaching patients in certain situations, such as more challenging clinical situations or when time was short. Others explained that their confidence in approaching patients about research participation was contingent on their knowledge about the study.

‘I feel competent and confident and know where to access support’ (community midwife)

‘I am confident, if I was allocated time and resources’ (health visitor)

‘I am relatively confident, except in labour’ (community midwife)

‘I am confident if I know enough to offer a brief explanation or can signpost’ (health visitor)

*(f) Knowledge*

Knowledge could act as a barrier or enabler for both health visitors and community midwives. A need for good procedural knowledge about the study was mentioned by 11 health visitors and five community midwives, whilst the importance of knowledge of the scientific rationale for the study was emphasised by nine health visitors and three community midwives. Two health visitors and two community midwives mentioned needing knowledge of the research topic.

‘Knowing that participation is voluntary and that participants can with-draw within defined boundaries gives me greater confidence in approaching patients. Understanding the process of ethical approval and how research projects are planned, their protocols laid out etc. gives me greater confidence in explaining participation to others. I would also want to understand the research project objectives and the implication/commitment required from participants to feel confident that I could then 'sell' this to a patient’ (health visitor).

(g) Other domains

Of the remaining eight TDF domains, only four (Beliefs about consequences; Emotion; Reinforcement; Intentions) were coded for more than 10% of health visitor participants, and only two (Beliefs about consequences; Reinforcement) were coded by more than 10% of community midwife participants (Table 3). Nine health visitors and seven community midwives expressed views that indicated an enabling belief that approaching eligible patients about research participation was an important contribution to research, and hence to improvements in practice. For example, one midwife commented that “*Research into maternity services is a growing area and it is important that all are involved to ensure the service moves forward with robust clinical findings to support out work*” (Community midwife). Counterbalancing the enabling effect of this belief about consequences, nine health visitors, but no community midwives, expressed concerns about negative consequences for their relationship with patients.

The influence of the domain Emotion was evident in the responses of a higher proportion of health visitors than midwives. (Table 3). Five health visitors reported that approaching eligible patients about research participation made them feel stressed, two said it made them feel guilty and four expressed feelings of positivity and enthusiasm when undertaking this activity. One midwife mentioned feeling stressed and one reported feeling apprehensive when approaching eligible patients about research participation. Under the domain Reinforcement, we coded comments from three community midwives and five health visitors all of which were aimed at enabling the target behaviour. They included being able to offer incentives for staff, monitoring by management and feedback from patients. There was limited evidence for the importance of the domain Intention, with comments from five health visitors and two community midwives being coded to this domain, whilst the domains Skills, Optimism, Memory, attention & decision processes and Behavioural regulation were rarely evident in the dataset for both professional groups.

# DISCUSSION

We have used the TDF (Cane *et al.*, 2012) to identify the factors perceived by health visitors and community midwives as influencing whether they approach patients about research participation. Key barriers included time and resource constraints, perceived role conflict, conflicting priorities, and, particularly for health visitors, negative social influences from patients and researchers. Enablers included confidence to approach patients, social influence of peers, managers and researchers, and beliefs in the relevance of this behaviour to health care and practice. With this analysis in place, it is possible to use a matrix of behaviour change techniques which, according to expert consensus, link to each of the TDF domains (Michie *et al.*, 2014). Using this approach, we have mapped the key TDF domains to behaviour change techniques to produce recommendations to overcome the modifiable barriers and enhance the enablers (Table 4). These are discussed below alongside the discussion of the key barriers and enablers.

The most commonly reported barrier was heavy caseloads and staff shortages, which left insufficient time for health visitors and community midwives to approach eligible patients about research participation. Time constraints, staff shortages and heavy workloads are widely reported barriers to research recruitment across health specialities and services in the UK, Finland and US (Hoddinott *et al.*, 2007; Sullivan-Bolyai *et al.*, 2007; Nurmi *et al.*, 2015; Skea *et al.*, 2017; Daly *et al.*, 2019). In the present study, respondents clearly communicated the need for health care professionals to be allocated sufficient time to deliver this activity, and that in turn demands funding for the staff resource it uses. Whilst there is an established mechanism for the recovery of costs of research in the NHS (Department of Health, 2012), it is important that any salary support funding is visible to the healthcare professionals involved in patient approach. Counterbalancing the challenge of finding time to approach eligible patients about research opportunities, there was an enabling influence of comprehensive and accessible study information, evident for both health visitors and community midwives. Previous studies of factors affecting the recruitment activity by midwives have reported that inaccessible study materials present a barrier to recruitment activity by health care professions (Halkoaho *et al.*, 2012; Stuart *et al.*, 2015; Daly *et al.*, 2019). By facilitating a good understanding of a study, accessible study materials could support health care professionals to approach patients about research by influencing their perception of the time it would take as well as shortening the actual time taken. Our findings suggests that good study materials should be leveraged to ensure that the study burden is minimised.

The professional role and identity of participants was the second most frequently identified domain affecting the patient approach behaviour, with an enabling belief that supporting research is integral to their professional role evident for both community midwives and some health visitors. However, for some health visitors there were barriers in this domain, including concern about role conflict and, for some, an outright rejection of the relevance of this activity to their professional role. Previous research has found that some clinicians from a range of professional groupings, including midwives, find that navigating the dual role of researcher and health care provider can be a challenge (Newington and Metcalfe, 2014; Skea *et al.*, 2017; Daly *et al.*, 2019). There are, however, important developments in policy that could help to address these barriers. In England this includes the Chief Nursing Officer for England’s (CNO) national strategy for supporting, developing and embedding research (2020-2022) (NHS England, 2020) and the creation of a new nursing, midwifery and care staff research portfolio which showcases the contribution of nursing, midwifery and care staff are making to transforming health and care. By recognising and championing the roles played by nurses and midwives in clinical research, these developments could help to address the issue of role conflict reported here and elsewhere in the literature. It could also be key to delivering the goal set out in the NHS Long Term Plan (NHS, 2019) to increase patient participation in clinical research in order to facilitate evidence-based policy, improve health outcomes and reduce inequalities.

Our analysis suggests that leveraging an enabling belief in the link between successful research recruitment and improvements in health care could help to address the difficulty of navigating research responsibilities alongside a clinical role. This could be delivered through training at study set up, and reinforced over the course of the study recruitment period by researchers, who in providing timely support would also leverage the enabling effect of their social influence on the behaviour. We suggest that training at study setup also needs to build strong procedural knowledge of the recruitment and study processes, and provide health visitors and community midwives involved in the study with a good understanding of the study rationale and the research topic. Evidence from systematic reviews of strategies to improve the recruitment activity of clinicians (Fletcher *et al.*, 2012; Newington and Metcalfe, 2014) supports our finding that increasing research knowledge offers a promising route to improved recruitment. However, other systematic review evidence suggests that researcher visits and additional training alone are not sufficient to change patient approach behaviour of health care professionals (Preston *et al.*, 2016; Delaney *et al.*, 2019). This could indicate that the training and support offered by researchers did not meet the needs of health care professionals. Indeed, others have found that inadequate support from researchers poses a barrier to research recruitment (Nurmi *et al.*, 2015). Researchers could address this possibility by involving relevant health care professionals in the design of the study, the study materials and the training and support for healthcare professionals. Further, the training and support offered by researchers to healthcare professionals should be thoroughly evaluated to ensure it meets the needs of the staff who receive it.

Whilst researcher training and support is clearly important in supporting community midwives and health visitors to approach patients about research opportunities, there are a number of other barriers that need to be addressed using different measures. From the findings in the present study, a package of interventions would need to target key barriers including time and resource constraints, conflicting priorities, role conflict and negative social influences whilst leveraging enablers including social influence of peers, managers and researchers, training and resources and beliefs in the relevance of this behaviour to healthcare and practice. Such an approach would provide an opportunity to address our finding that some health visitors and community midwives choose not to approach all eligible patients about research opportunities, a tendency which is apparently quite widespread among other health care professionals (Bonevski *et al.*, 2014; Crocker *et al.*, 2015; Hughes-Morley *et al.*, 2015; Stuart *et al.*, 2015; Tromp and Vathorst, 2015). Such selection bias necessarily undermines the representativeness of the study sample, the generalisability of the findings and the scientiﬁc and social value of the study. There is therefore a strong case for developing and evaluating a complex intervention which changes this behaviour.

*Strengths and limitations*

Data collection for TDF analysis can be done using interviews, focus groups or surveys (Michie *et al.*, 2014; Atkins *et al.*, 2017). Our use of an online survey with open-ended questions, combined the advantages of yielding qualitative data appropriate for an under-researched topic, whilst minimising the burden of the study for the health care professionals and the host organisations. Our respondents were generous in their free-text responses, providing ample material to enable us to apply the TDF to analyse the behaviour in question. However, interviews would have yielded richer data and thicker descriptions of the health professionals’ experiences of recruiting participants to research. The anonymity of the online survey may have enabled us to collect a broader range of responses than would have been possible had we conducted interviews. For example, our finding that some respondents chose who to approach about research opportunities based on their perception of the patient’s situation rather the study’s eligibility criteria might not have been volunteered in the presence of the researcher, where demand effects for socially desirable responses would be more keenly felt. Our survey did include some broad open-ended questions to provide an opportunity for respondents to discuss factors that they deemed to be most relevant, an approach recommended by McGowan *et al.*(2020) as supporting an understanding of the behaviour from the participants’ perspectives. However, interviews would have offered the opportunity to probe further the participants’ motivations for selecting particular patients to approach about research opportunities, and to explore views pertinent to the less frequently coded domains, such as skills and emotion.

The lack of a respondent denominator is a limitations as it meant we were unable to calculate an overall response rate and the sample sizes, though adequate for a qualitative study using the TDF (Atkins *et al.*, 2017), are small for samples collected via an online survey. The survey respondents were self-selecting and consequently open to response bias. But the samples were diverse with respect to the range of environments where the respondents were practicing and their experience in their professional role. Further, the gender and ethnicity profile of respondents was in line with the demographics of the NHS workforce in these specialisms. Nevertheless, collecting data about research is from health professionals who are not interested in research is by its nature problematic. Here, the anonymity of the survey may have helped; we received responses from participants with a wide range of views on research, including negative, ambivalent and positive views. Nonetheless, a larger sample size may have further increased the range of views expressed, providing greater insight into the perceptions of the wider population of community midwives and health visitors.

Although the TDF is widely used in implementation science to understand the behaviour of health care professionals, to our knowledge this is the first attempt to use it to understand participant recruitment behaviour. Our use of the TDF enabled us to systematically explore social, environmental, affective and cognitive influences on patient approach by health visitors and community midwives, and, importantly, to explore enablers as well as barriers to his activity.

**CONCLUSIONS**

This study uses a theory-informed approach to gain new insights into improving research recruitment where health visitors and community midwives invite patients to take part in a study. We found that inadequate time, poor study materials, research which seems to be irrelevant to their professional role, unsupportive researchers, and competing priorities all act to hinder research recruitment activity by community midwives and health visitors. These barriers could be countered by the enabling effects of confidence, positive social influence from researchers and team members, and a belief in relevance of participant approach to improvements in care and practice. Given the strong evidence for the importance of social and professional factors influencing whether health visitors and community midwives approach patients about research, we suggest that further work to improve research recruitment could usefully employ a participative approach. The aim would be to develop co-produced interventions tailored to the needs and specific context of each health care profession which should then be rigorously evaluated for effectiveness.

# Acknowledgements

The authors would like to thank the staff who agreed to take part in this study and completed the survey, the NHS Trusts and managers for help with recruitment, the Royal College of Midwives and the Institute of Health Visiting for promoting the study to their members.

# Financial Support

This research received no specific grant from any funding agency, commercial or not-for-profit sectors.

**Conflict(s) of Interest**

None.

# Ethical Standards

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional guidelines on human experimentation (the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social Care, 2005) and with the Helsinki Declaration of 1975, as revised in 2008. Permission to conduct the study was provided by the Anglia Ruskin University Faculty of Health, Social Care and Education Research Ethics Panel (FHSCE\_DREP-16-106) on 23rd February 2017 and Health Research Authority approval (17/HRA/1753) was granted on 10th April 2017. Local R&D permission was granted by four NHS Trusts and one social enterprise contracted to the NHS. Once launched, the online survey opened the participant information sheet (PIS). All participants indicated that they had read the PIS and consented to take part in the study, and this was recorded in the survey responses.

# REFERENCES

**Atkins L., Francis J., Islam R., O'Connor D., Patey A., Ivers N., Foy R., Duncan E. M., Colquhoun H., Grimshaw J. M., Lawton R. and Michie S.** 2017: A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. *Implementation Science* 12: 77.

**Baxter J., Vehik K., Johnson S. B., Lernmark B., Roth R. and Simell T.** 2012: Differences in recruitment and early retention among ethnic minority participants in a large pediatric cohort: The TEDDY Study. *Contemporary Clinical Trials* 33: 633-640.

**Bonevski B., Randell M., Paul C., Chapman K., Twyman L., Bryant J., Brozek I. and Hughes C.** 2014: Reaching the hard-to-reach: a systematic review of strategies for improving health and medical research with socially disadvantaged groups. *BMC Medical Research Methodology* 14: 42.

**Briel M., Olu K. K., von Elm E., Kasenda B., Alturki R., Agarwal A., Bhatnagar N. and Schandelmaier S.** 2016: A systematic review of discontinued trials suggested that most reasons for recruitment failure were preventable. *J Clin Epidemiol* 80: 8-15.

**Cane J., O'Connor D. and Michie S.** 2012: Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implementation Science* 7: 37.

**Carpenter R. E.** 2016: Recruitment of pregnant women to an exercise-intervention study. *J Obstet Gynaecol* 36: 200-207.

**Crocker J. C., Beecham E., Kelly P., Dinsdale A. P., Hemsley J., Jones L. and Bluebond-Langner M.** 2015: Inviting parents to take part in paediatric palliative care research: a mixed-methods examination of selection bias. *Palliative medicine* 29: 231-240.

**Daly D., Hannon S. and Brady V.** 2019: Motivators and challenges to research recruitment - A qualitative study with midwives. *Midwifery* 74: 14-20.

**Daniels L. A., Wilson J. L., Mallan K. M., Mihrshahi S., Perry R., Nicholson J. M. and Magarey A.** 2012: Recruiting and engaging new mothers in nutrition research studies: lessons from the Australian NOURISH randomised controlled trial. *Int J Behav Nutr Phys Act* 9: 129.

**Delaney H., Devane D., Hunter A., Hennessy M., Parker A., Murphy L., Cronin P. and Smith V.** 2019: Limited evidence exists on the effectiveness of education and training interventions on trial recruitment; a systematic review. *Journal of Clinical Epidemiology* 113: 75-82.

**Department of Health**. 2012: *Attributing the costs of health and social care Research & Development (AcoRD)*. Available at: <https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research>.

**Fletcher B., Gheorghe A., Moore D., Wilson S. and Damery S.** 2012: Improving the recruitment activity of clinicians in randomised controlled trials: a systematic review. *BMJ Open* 2: e000496.

**Frew P. M., Saint-Victor D. S., Isaacs M. B., Kim S., Swamy G. K., Sheffield J. S., Edwards K. M., Villafana T., Kamagate O. and Ault K.** 2014: Recruitment and retention of pregnant women into clinical research trials: an overview of challenges, facilitators, and best practices. *Clinical Infectious Diseases* 59: S400-407.

**Grady K., Gibson M. and Bower P.** 2019: Can a ‘consent to contact’ community help research teams overcome barriers to recruitment? The development and impact of the ‘Research for the Future’ community. *BMC Medical Research Methodology* 19: 195.

**Halkoaho A., Vähäkangas K., Häggman-Laitila A. and Pietilä A.-M.** 2012: Views of midwives about ethical aspects of participation in placental perfusion studies. *Midwifery* 28: 131-137.

**Hoddinott P., Britten J., Harrild K. and Godden D. J.** 2007: Recruitment issues when primary care population clusters are used in randomised controlled clinical trials: climbing mountains or pushing boulders uphill? *Contemporary Clinical Trials* 28: 232-241.

**Hughes-Morley A., Young B., Waheed W., Small N. and Bower P.** 2015: Factors affecting recruitment into depression trials: Systematic review, meta-synthesis and conceptual framework. *Journal of Affective Disorders* 172: 274-290.

**Huntington C., Newton J. T., Donaldson N., Liossi C., Reynolds P. A., Alharatani R. and Hosey M. T.** 2017: Lessons learned on recruitment and retention in hard-to-reach families in a phase III randomised controlled trial of preparatory information for children undergoing general anaesthesia. *BMC Oral Health* 17: 122.

**Jordan S., Watkins A., Storey M., Allen S. J., Brooks C. J., Garaiova I., Heaven M. L., Jones R., Plummer S. F., Russell I. T., Thornton C. A. and Morgan G.** 2013: Volunteer Bias in Recruitment, Retention, and Blood Sample Donation in a Randomised Controlled Trial Involving Mothers and Their Children at Six Months and Two Years: A Longitudinal Analysis. *PLoS One* 8: e67912.

**Knight B. A. and Wyatt K.** 2010: Barriers encountered when recruiting obese pregnant women to a dietary intervention. *Nursing times* 106: 20-22.

**Laws R. A., Litterbach E. K., Denney-Wilson E. A., Russell C. G., Taki S., Ong K. L., Elliott R. M., Lymer S. J. and Campbell K. J.** 2016: A Comparison of Recruitment Methods for an mHealth Intervention Targeting Mothers: Lessons from the Growing Healthy Program. *J Med Internet Res* 18: e248.

**McGowan L. J., Powell R. and French D. P.** 2020: How can use of the Theoretical Domains Framework be optimized in qualitative research? A rapid systematic review. *British Journal of Health Psychology* 25: 677-694.

**Michie S., Atkins L. and West R.** 2014: *The behaviour change wheel: a guide to designing interventions,* London: Silverback Publishing.

**Michie S., Johnston M., Abraham C., Lawton R., Parker D. and Walker A.** 2005: Making psychological theory useful for implementing evidence based practice: a consensus approach. *Quality and Safety in Health Care* 14: 26-33.

**Mytton J., Ingram J., Manns S., Stevens T., Mulvaney C., Blair P., Powell J., Potter B., Towner E., Emond A., Deave T., Thomas J., Kendrick D. and Stewart-Brown S.** 2014: The feasibility of using a parenting programme for the prevention of unintentional home injuries in the under-fives: a cluster randomised controlled trial. *Health Technology Assessment* 18: 1-184.

**Newington L. and Metcalfe A.** 2014: Researchers' and clinicians' perceptions of recruiting participants to clinical research: a thematic meta-synthesis. *Journal of Clinical Medicine Research* 6: 162-172.

**NHS England**. 2020: *Nursing research and evidence underpinning policy dialogue and system transformation*. Available at: <https://www.england.nhs.uk/nursingmidwifery/research-and-evidence/>.

**Nurmi S. M., Pietila A. M., Kangasniemi M. and Halkoaho A.** 2015: Nurse leaders' perceptions of the ethical recruitment of study subjects in clinical research. *Journal of Nursing Management* 23: 1020-1028.

**O'Brien B. C., Harris I. B., Beckman T. J., Reed D. A. and Cook D. A.** 2014: Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med* 89: 1245-1251.

**Pica N. and Bourgeois F.** 2016: Discontinuation and Nonpublication of Randomized Clinical Trials Conducted in Children. *Pediatrics* 138.

**Preston N. J., Farquhar M. C., Walshe C. E., Stevinson C., Ewing G., Calman L. A., Burden S., Brown Wilson C., Hopkinson J. B. and Todd C.** 2016: Strategies designed to help healthcare professionals to recruit participants to research studies. *Cochrane Database of Systematic Reviews* 10.1002/14651858.MR000036.pub2.

**QSR International Pty Ltd.** 2018: *NVivo 12*. <https://www.qsrinternational.com/nvivo-qualitative-data-analysis-software/home>.

**Redsell S. A. and Cheater F. M.** 2001: The Data Protection Act (1998): implications for health researchers. *Journal of advanced nursing* 35: 508-513.

**Redsell S. A., Rose J., Weng S., Ablewhite J., Swift J. A., Siriwardena A. N., Nathan D., Wharrad H. J., Atkinson P., Watson V. and et al.** 2017: Digital technology to facilitate Proactive Assessment of Obesity Risk during Infancy (ProAsk): a feasibility study. *BMJ Open* 7.

**Rose J., Redsell S. A. and Akister J.** 2017: Do families with experience of mental ill health have a voice? Gatekeeping in health and social care research. In: Diggins M. (ed) *Parental Mental Health and Child Welfare Work.* 35-38. Brighton: Pavilion Publishing.

**Skea Z. C., Treweek S. and Gillies K.** 2017: 'It's trying to manage the work': a qualitative evaluation of recruitment processes within a UK multicentre trial. *BMJ Open* 7: e016475.

**Stuart J., Barnes J., Spiby H. and Elbourne D.** 2015: Understanding barriers to involving community midwives in identifying research participants; experience of the first steps randomised controlled trial. *Midwifery* 31: 779-786.

**Sullivan-Bolyai S., Bova C., Deatrick J. A., Knafl K., Grey M., Leung K. and Trudeau A.** 2007: Barriers and strategies for recruiting study participants in clinical settings. *Western journal of nursing research* 29: 486-500.

**Tooher R. L., Middleton P. F. and Crowther C. A.** 2008: A thematic analysis of factors influencing recruitment to maternal and perinatal trials. *BMC Pregnancy Childbirth* 8: 36.

**Tromp K. and Vathorst S.** 2015: Gatekeeping by Professionals in Recruitment of Pediatric Research Participants: Indeed an Undesirable Practice. *The American Journal of Bioethics* 15: 30-32.

**van Delft K.** 2013: Recruitment of pregnant women in research. *J Obstet Gynaecol* 33: 442-446.

**van der Graaf R., van der Zande I. S. E., den Ruijter H. M., Oudijk M. A., van Delden J. J. M., Oude Rengerink K. and Groenwold R. H. H.** 2018: Fair inclusion of pregnant women in clinical trials: an integrated scientific and ethical approach. *Trials* 19: 78.

**Webster G. M., Teschke K. and Janssen P. A.** 2012: Recruitment of Healthy First-Trimester Pregnant Women: Lessons From the Chemicals, Health & Pregnancy Study (CHirP). *Maternal and child health journal* 16: 430-438.

1. We use the term ‘patient’ to refer to the recipients of the health care that community midwives and health visitors deliver, rather than the alternative terms ‘client’, ‘consumer’, ‘customer’ and ‘service user’, because a recent scoping review has shown that overall healthcare recipients prefer the term ‘patient’ (Costa *et al.,* 2019). [↑](#footnote-ref-1)