Please see below for a link to the webinar recording for the Trials Methodology Research Partnership:

Recruiting pregnant women to clinical trials: the ENCOUNTER study

Vivienne Hanrahan (National University of Ireland Galway)

14 April 2021

On behalf of the Health Research Board Trials Methodology Research Network

The slides are also available below.

For any queries, please contact uktmn@nottingham.ac.uk

https://www.youtube.com/watch?v=pIxkXVX5seg

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ENCOUNTER Study

rEcruiter's experieNCe Of recrUiting pregNanT womEn to clinical tRials

v.hanrahan1@nuigalway.ie

@ENCOUNTERStudy

www.encounterstudy.ie

#trialmethodology

Vivienne Hanrahan, RM, BSc.

PhD Student

School of Nursing and Midwifery,
National University of Ireland, Galway

Health Services
Research Unit

Outline

- **Background**
- **Qualitative Evidence Synthesis**
- **Taking a Behavioural Approach**
  - Specifying, Diagnosing and Treating the behaviour
- **ENCOUNTER preliminary findings**
- **What's next?**

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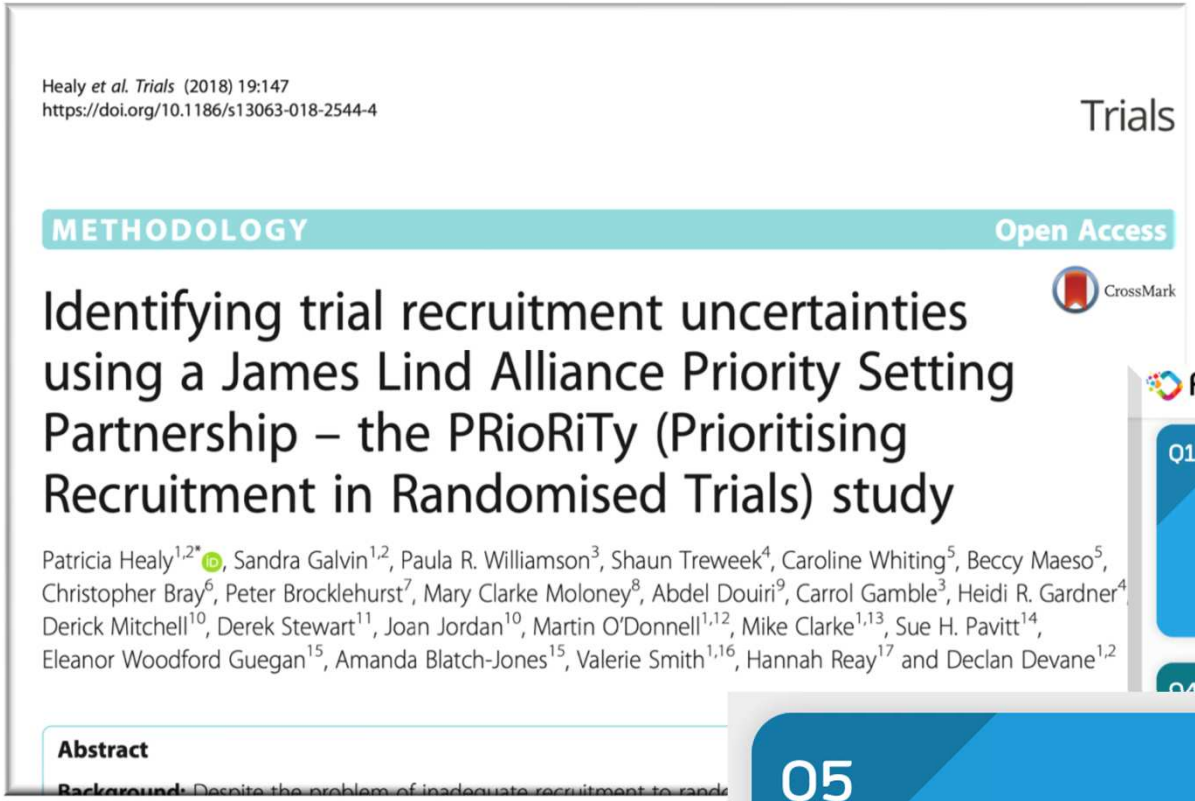
PRioRiTy Study Question 5



Healy *et al. Trials* (2018) 19:147
https://doi.org/10.1186/s13063-018-2544-4

Trials

METHODOLOGY Open Access

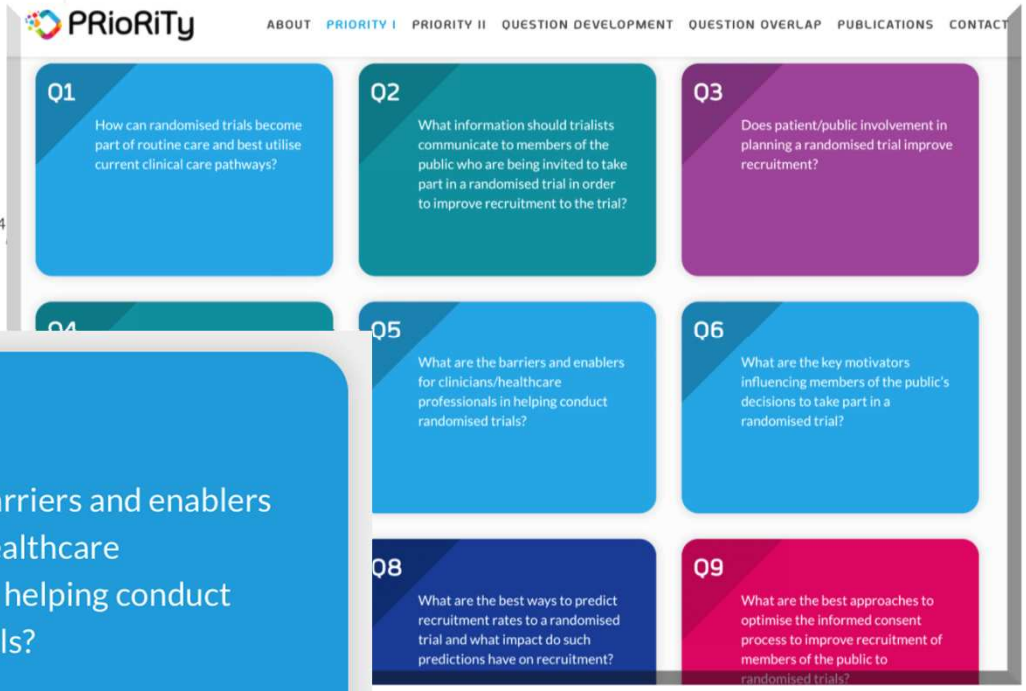
CrossMark

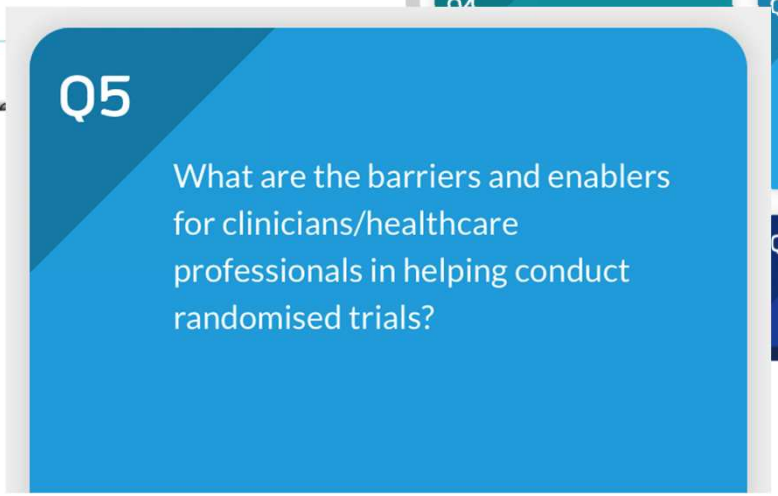
Identifying trial recruitment uncertainties using a James Lind Alliance Priority Setting Partnership – the PRioRiTy (Prioritising Recruitment in Randomised Trials) study

Patricia Healy[1,2*], Sandra Galvin[1,2], Paula R. Williamson[3], Shaun Treweek[4], Caroline Whiting[5], Beccy Maeso[5], Christopher Bray[6], Peter Brocklehurst[7], Mary Clarke Moloney[8], Abdel Douiri[9], Carrol Gamble[3], Heidi R. Gardner[4], Derick Mitchell[10], Derek Stewart[11], Joan Jordan[10], Martin O'Donnell[1,12], Mike Clarke[1,13], Sue H. Pavitt[14], Eleanor Woodford Guegan[15], Amanda Blatch-Jones[15], Valerie Smith[1,16], Hannah Reay[17] and Declan Devane[1,2]

Abstract

Background: Despite the problem of inadequate recruitment to rand





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Recruitment in pregnancy

What's different about it?

- Dyad of mother & baby offers an extra layer of complexity to the challenge of recruitment

Why does it matter?

HEALTH • COVID-19 VACCINE

Pregnant women aren't typically included in clinical trials, but that's changing with COVID

BY **SY MUKHERJEE**
March 19, 2021 8:15 PM GMT

FORTUNE

WHAT COMES NEXT

For Business • For the Economy • For the Battle Against COVID-19

VIEWPOINT

Involving Pregnant Individuals in Clinical Research on COVID-19 Vaccines

Diana W. Bianchi, MD
Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland.

Lisa Kaeser, JD
Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland.

Alison N. Cernich, PhD
Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland.

The continued global escalation of coronavirus disease 2019 (COVID-19) cases is of particular concern for pregnant and lactating individuals. While many cases of COVID-19 are asymptomatic or relatively mild, recent evidence suggests that pregnant people are at increased risk of hospitalization and have a 3-fold adjusted relative risk of needing intensive care (10.5 vs 3.9/1000 cases) and mechanical ventilation (2.9 vs 1.1/1000 cases) compared with age-matched nonpregnant individuals.[1] Pregnant people with laboratory-confirmed severe or critical COVID-19 disease have higher adjusted relative risks of cesarean delivery (1.57 [95% CI, 1.30-1.90]), postpartum hemorrhage (2.04 [95% CI, 1.19-3.4
nancy (1.64 [95
(3.53 [95% CI, 2.
These comp
are older, have a
medical comort
and ethnic disp
mortality amor
ment of COVID

been provided for nonpregnant patients. Efforts
Centers for Disease Control and Prevention thro
V-Safe registry[5] as well as industry and the Fo
Drug Administration will yield postmarket vacc
veillance information from pregnant people, in
evidence on the effects of the vaccine on pre
and infant outcomes. These data will be usefu
the meantime, pregnant people and their c
must make real-time decisions based on little o
entific evidence.

As noted in 2016, when the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) was established as part of the 21st Century Cures Act,[6] there is a continuing need to advance knowledge and research related to the de-

JAMA The Journal of the American Medical Association

A pregnant woman attends a celebration in Caracas. Data show that pregnant women face increased risks from SARS-

HOW DOES COVID AFFECT MOTHER AND BABY?

Pregnant women fare worse than others, although the risks to the[m] are slight. By Nidhi Subbaraman

Yalda Afshar was about two months pregnant when reports of COVID-19 began to emerge in the United States in February last year. As an obstetrician managing high-risk pregnancies at the University of California, Los Angeles, Afshar knew that respiratory viruses are especially dangerous to pregnant women. There was very little data on the effects of the SARS-CoV-2 virus and, as cases racked up, she felt like she was flying blind, both while advising her patients and in navigating her own worries about contracting the virus and passing it on to her baby and family. But her situation also brought her closer to the women she was treating. "I had this sense of solidarity that I've not felt before," she says. "It was an inspiration to just work harder and try to get answers faster."

Afshar launched one of the first registries in the United States to track women who had tested positive for the virus during their pregnancy, working with colleagues from across the country to recruit and follow participants. More than a dozen similar projects launched over the course of 2020.

Now, more than a year into the pandemic, research from groups a
shown that pregnant w
are at higher risk of hosp
disease than are women
are not pregnant. The rate
death are also higher in p
certain minority racial an
in those in non-minority g
situation in the wider pop
The good news is tha
spared a severe respiratory infection, and do
not often get sick. Samples from the placenta,
the umbilical cord and blood from mothers
and infants indicate that the virus rarely

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Health Policy

Inclusion of pregnant women in COVID-19 treatment trials: a review and global call to action

Melanie M Taylor, Loulou Kobeissi, Caron Kim, Avni Amin, Anna E Thorson, Nita B Bellare, Vanessa Brizuela, Mercedes Bonet, Edna Kara, Soe Soe Thwin, Hamsadvani Kuganantham, Moazzam Ali, Olufemi T Oladapo, Nathalie Broutet

Inclusion of pregnant women in COVID-1
improve maternal health, pregnancy, and birt
for pregnant women. We explored the inclu
international clinical trial registries at two ti
biological drugs for the April 7–10, 2020 ti
same registry search for the July 10–15, 202

"Without an explicit and proactive effort to recruit and retain pregnant women in clinical trials, the understanding of treatment effects, dosing, side-effects, and potential benefits of COVID-19 treatment for pregnant women will be limited. Inclusion of pregnant women is a matter of equity as much as efficacy and safety..."

Health Policy: Inclusion of pregnant women in COVID-19 treatment trials: a review and global call to action

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The best science for better lives

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Correspondence to: L C Chappell
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Cite this as: *BMJ* 2020;370:m3305
http://dx.doi.org/10.1136/bmj.m3305
Published: 25 August 2020

Include pregnant women in research—particularly covid-19 research

Adapting interventions and changing attitudes will drive scientific progress

Marian Knight, [1] R Katie Morris, [2] Jenny Furniss, [3] Lucy C Chappell[4]

The UK Confidential Enquiries into Maternal Deaths have repeatedly highlighted inequities in the medical treatment of pregnant and postpartum women, noting that women are denied investigations and life preserving treatments simply because they are pregnant or breastfeeding.[1 2] These inquiries emphasise that the default position should be to investigate and treat pregnant and breastfeeding women in the same way as non-pregnant women, unless there are clear reasons not to.[1]

Clinical trials, particularly those of drug treatments, have typically automatically excluded pregnant or breastfeeding women, meaning data are unavailable on safety and effectiveness. These challenges were noted by the Task Force on Research Specific to Pregnant Women and Lactating Women,[3] which issued 15 recommendations, centred around tackling the cultural assumptions that limit scientific progress into preventive and therapeutic interventions for pregnant women.

This disparity in trial inclusion has been exacerbated in the covid-19 pandemic. A recent review reported that of 927 trials related to covid-19, 52% explicitly excluded pregnancy, 46% did not mention pregnancy, and only 1.7% specifically included pregnancy, of which just three were interventional trials.[4] The risks of untested interventions have been highlighted by others,[5] and the moral imperative to include pregnant women in such trials is obvious,[6] but the mechanisms to do so are less clear.

Dealing with safety concerns

The RECOVERY (Randomised Evaluation of Covid-19 Therapy) trial shows that excluding pregnant and breastfeeding women need not be the default option.[7] Inclusion of these women in trials has challenges, and approaches developed for the RECOVERY trial provide a template for other studies.

or breastfeeding allows safety concerns to be al for women, their families, and healthcare professionals.

Even if regulatory barriers have been overcor gatekeeping or inertia may occur if local ethi committees take an overwhelming precautic approach, overriding recognition of the pot benefits of including pregnant and breastfe women. This problem can be mitigated by network of maternity researchers, familiar delivering drug trials in pregnancy, who c rapidly mobilised to help implement stud

The pressure on health services in the pa necessitates streamlined approaches to cl The need to add data collection about pre infant outcomes is perceived as a disinc inclusion of pregnant women. However routinely collected information can eas basic follow-up data. If these data do n sufficient clinical nuance to address k questions—such as decisions around iatrogenic birth—additional linkage to data may provide a solution. The UK Surveillance System,[9] part of an inte network,[10] facilitated rapid roll-out observational studies of covid-19 in designed before the pandemic in re includes these extended data.

Changing the default

These examples show how some caused by regulatory and other tr be overcome to include pregnant women even within a rapidly evo increasing numbers of women are with pre-existing conditions an benefit from newer therapies, n default to including, rather thar

BMJ: first pl

Department of Health & Social Care
The Executive Office (Northern Ireland)
Scottish Government
Welsh Government

Policy paper

Saving and improving lives: the future of UK clinical research delivery

Published 23 March 2021

Contents

Ministerial foreword

The past year has delivered unprecedented challenges for us all. But through these dark times, UK clinical research has provided a beacon of hope.

The tireless efforts of our healthcare professionals, researchers, participants, regulators, medical charities and industry have helped us to lead the world in COVID-19 research. From the rapid delivery of innovative platform trials, like RECOVERY, to our massive contribution to the global vaccine effort, our research ecosystem has pulled together across the UK to provide us with a route back to normality.

This is testament to our strengths. The UK has long been at the forefro

Qualitative Evidence Synthesis

PLOS ONE

RESEARCH ARTICLE

Recruiters' perspectives of recruiting women during pregnancy and childbirth to clinical trials: A qualitative evidence synthesis

Vivienne Hanrahan[1]*, **Katie Gillies**[2], **Linda Biesty**[1]

1 School of Nursing and Midwifery, National University of Ireland Galway, Galway, Ireland, 2 Health Services Research Unit, University of Aberdeen, Aberdeen, Scotland, United Kingdom

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OPEN ACCESS

Citation: Hanrahan V, Gillies K, Biesty L (2020) Recruiters' perspectives of recruiting women during pregnancy and childbirth to clinical trials: A qualitative evidence synthesis. PLoS ONE 15(6): e0234783. https://doi.org/10.1371/journal.pone.0234783

Editor: Tim Mathes, Universitat Witten/Herdecke, GERMANY

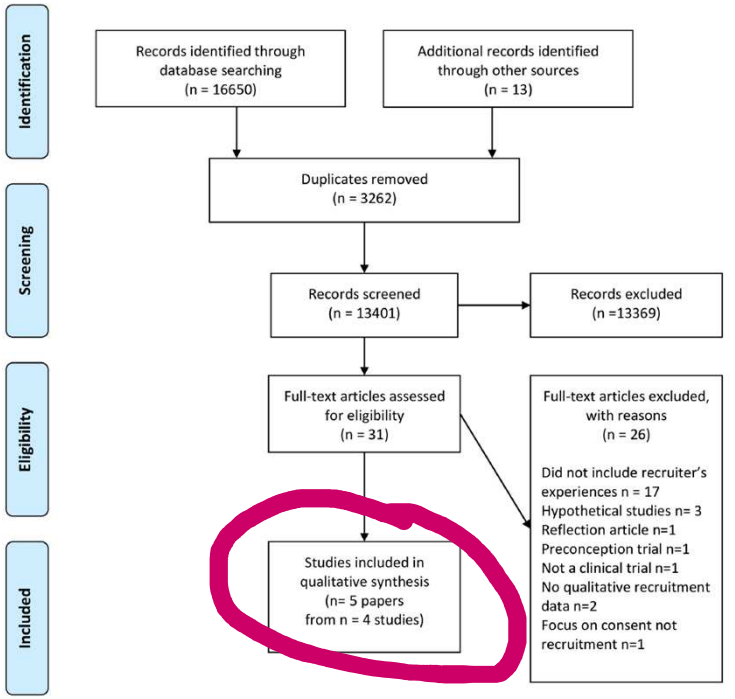
Abstract

Introduction

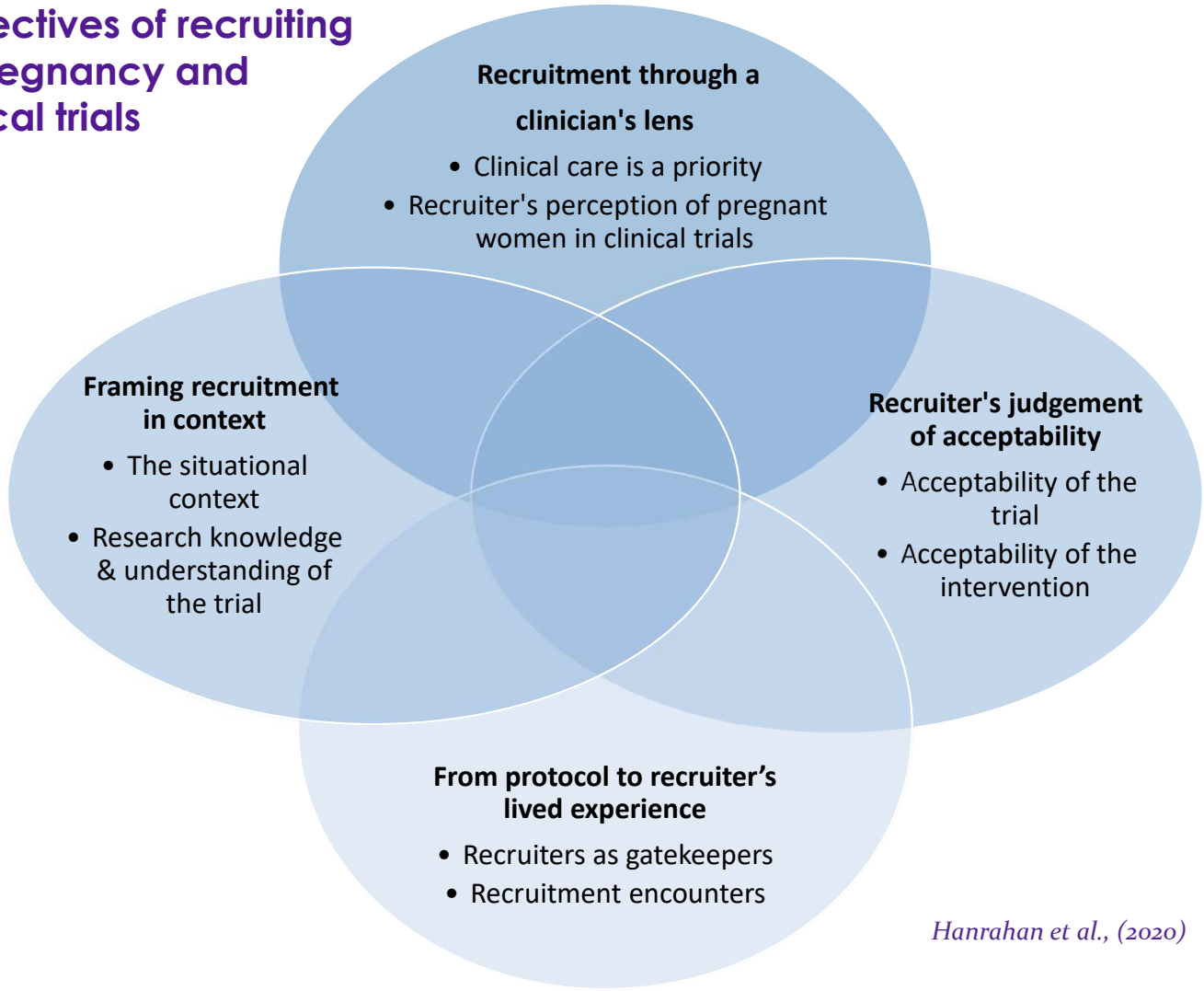
Research on research is key to enhancing efficacy in trial methodology. Clinical trials involving women during pregnancy and childbirth are limited, with a paucity of data guiding evidence-based practice. Following a prioritisation exercise that highlighted the top-ten unanswered recruitment questions, this qualitative evidence synthesis was designed specifically to focus on the barriers and enablers for clinicians/healthcare professionals in helping conduct randomised trials within the context of recruitment during pregnancy and childbirth.

Methods

The synthesis was undertaken using Thomas and Harden's three stage thematic synthesis



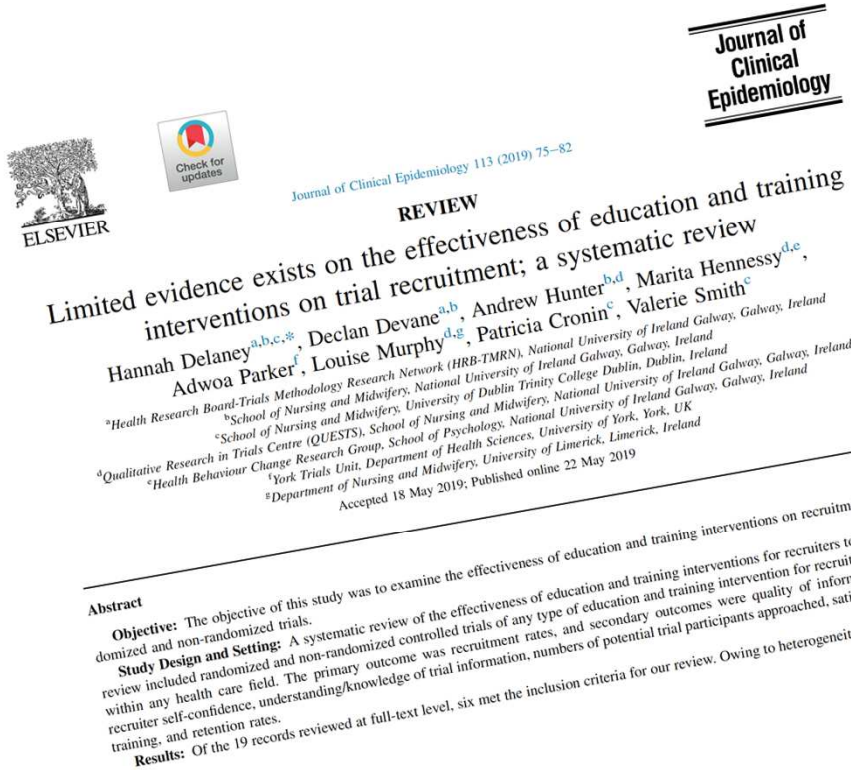
Recruiter's perspectives of recruiting women during pregnancy and childbirth to clinical trials



Hanrahan et al., (2020)

Takeaway from the QES

Recruiter focused recruitment interventions



Journal of Clinical Epidemiology

Check for updates

ELSEVIER

Journal of Clinical Epidemiology 113 (2019) 75–82

REVIEW

Limited evidence exists on the effectiveness of education and training interventions on trial recruitment; a systematic review

Hannah Delaney[a,b,c,*], Declan Devane[a,b], Andrew Hunter[b,d], Marita Hennessy[d,e], Adwoa Parker[f], Louise Murphy[d,g], Patricia Cronin[c], Valerie Smith[c]

[a]Health Research Board-Trials Methodology Research Network (HRB-TMRN), National University of Ireland Galway, Galway, Ireland
[b]School of Nursing and Midwifery, National University of Ireland Galway, Galway, Ireland
[c]School of Nursing and Midwifery, University of Dublin Trinity College Dublin, Dublin, Ireland
[d]Qualitative Research in Trials Centre (QUESTS), School of Nursing and Midwifery, National University of Ireland Galway, Galway, Ireland
[e]Health Behaviour Change Research Group, School of Psychology, National University of Ireland Galway, Galway, Ireland
[f]York Trials Unit, Department of Health Sciences, University of York, York, UK
[g]Department of Nursing and Midwifery, University of Limerick, Limerick, Ireland

Accepted 18 May 2019; Published online 22 May 2019

Abstract

Objective: The objective of this study was to examine the effectiveness of education and training interventions on recruitment to randomized and non-randomized trials.

Study Design and Setting: A systematic review of the effectiveness of education and training interventions for recruiters to trials. The review included randomized and non-randomized controlled trials of any type of education and training intervention for recruiters to trials, within any health care field. The primary outcome was recruitment rates, and secondary outcomes were quality of informed consent, recruiter self-confidence, understanding/knowledge of trial information, numbers of potential trial participants approached, satisfaction with training, and retention rates.

Results: Of the 19 records reviewed at full-text level, six met the inclusion criteria for our review. Owing to heterogeneity of outcomes

Townsend et al. Trials (2015) 16:432
DOI 10.1186/s13063-015-0908-6

RESEARCH

TRIALS

Open Access

CrossMark

A systematic review of training programmes for recruiters to randomised controlled trials

Daisy Townsend*, Nicola Mills, Jelena Savović and Jenny L. Donovan

Abstract

Background: Recruitment to randomised controlled trials (RCTs) is often difficult. Clinician related factors have been implicated as important reasons for low rates of recruitment. Clinicians (doctors and other health professionals) can experience discomfort with some underlying principles of RCTs and experience difficulties in conveying them positively to potential trial participants. Recruiter training has been suggested to address identified problems but a synthesis of this research is lacking. The aim of our study was to systematically review the available evidence on training interventions for recruiters to randomised trials.

Methods: Studies that evaluated training programmes for trial recruiters were included. Those that provided only general communication training not linked to RCT recruitment were excluded. Data extraction and quality assessment were completed by two reviewers independently, with a third author where necessary.

Results: Seventeen studies of 9615 potentially eligible titles and abstracts were included in the review: three randomised controlled studies, two non-randomised controlled studies, nine uncontrolled pre-test/post-test studies, two qualitative studies, and a post-training questionnaire survey. Most studies were of moderate or weak quality. Training programmes were mostly set within cancer trials, and usually consisted of workshops with a mix of health professionals over one or two consecutive days covering generic and trial specific issues. Recruiter training programmes were well received and some increased recruiters' self-confidence in communicating key RCT concepts to patients. There was, however, little evidence that this training increased actual recruitment rates or patient understanding, satisfaction, or levels of informed consent.

Conclusions: There is a need to develop recruiter training programmes that can lead to improved recruitment and informed consent in randomised trials.

Keywords: Trials, Communication, Recruitment, Training, Randomisation, Equipoise

Behavioural approach

Specify

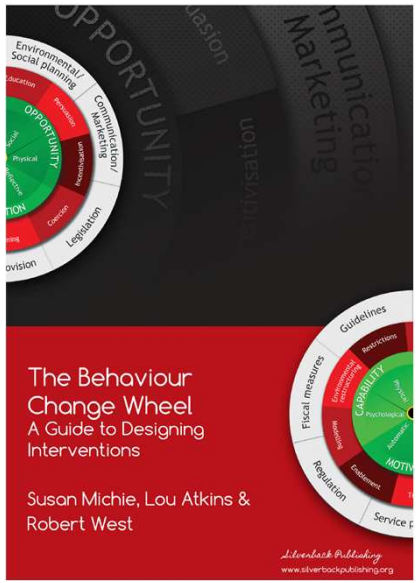
Diagnose

Treat

Applying behavioural theory

- **Behaviour Change Wheel**

  Michie *et al., 2014*

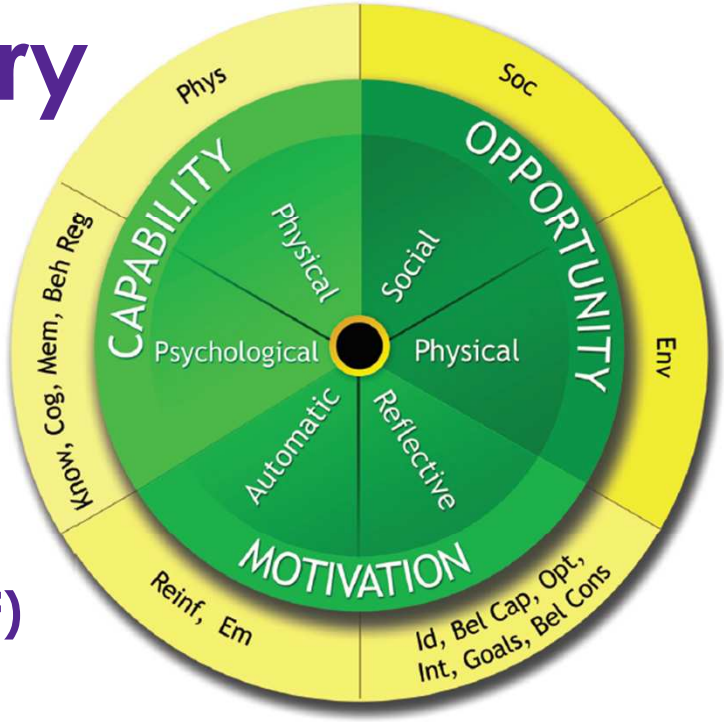


- **Theoretical Domains Framework (TDF)**

  Cane *et al.*, 2012

✓ 33 psychological theories

✓ Arranged into 14 domains

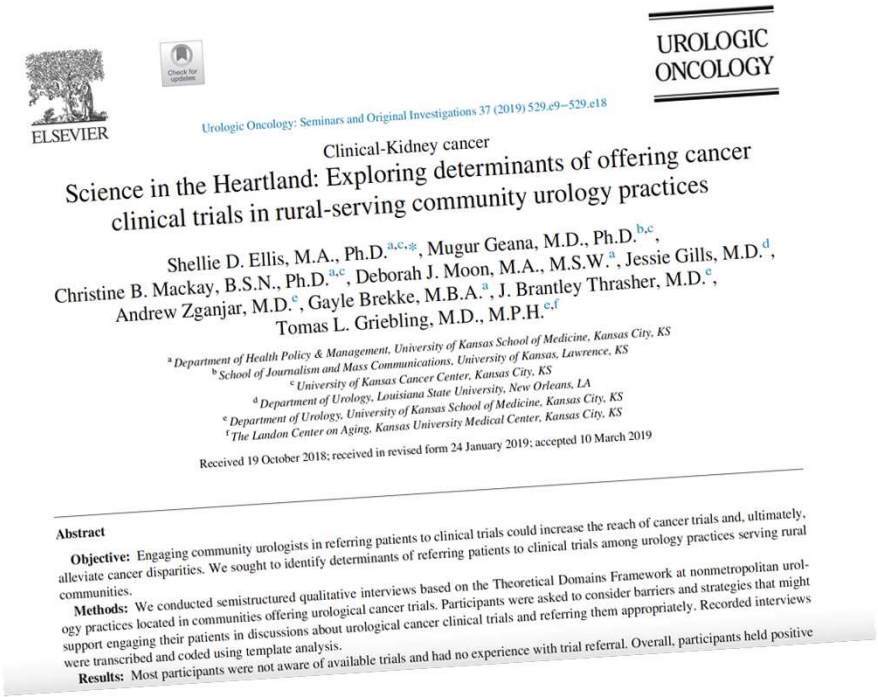


Sources of behaviour

TDF Domains

Soc - Social influences
Env - Environmental Context and Resources
Id - Social/Professional Role and Identity
Bel Cap - Beliefs about Capabilities
Opt - Optimism
Int - Intentions
Goals - Goals
Bel Cons - Beliefs about Consequences
Reinf - Reinforcement
Em - Emotion
Know - Knowledge
Cog - Cognitive and interpersonal skills
Mem - Memory, Attention and Decision Processes
Beh Reg - Behavioural Regulation
Phys - Physical skills

Previous application of the TDF in trial recruitment



ELSEVIER

Urologic Oncology: Seminars and Original Investigations 37 (2019) 529.e9–529.e18

UROLOGIC ONCOLOGY

Clinical-Kidney cancer

Science in the Heartland: Exploring determinants of offering cancer clinical trials in rural-serving community urology practices

Shellie D. Ellis, M.A., Ph.D.[a,c,*], Mugur Geana, M.D., Ph.D.[b,c], Christine B. Mackay, B.S.N., Ph.D.[a,c], Deborah J. Moon, M.A., M.S.W.[a], Jessie Gills, M.D.[d], Andrew Zganjar, M.D.[e], Gayle Brekke, M.B.A.[a], J. Brantley Thrasher, M.D.[e], Tomas L. Griebling, M.D., M.P.H.[e,f]

[a] Department of Health Policy & Management, University of Kansas School of Medicine, Kansas City, KS
[b] School of Journalism and Mass Communications, University of Kansas, Lawrence, KS
[c] University of Kansas Cancer Center, Kansas City, KS
[d] Department of Urology, Louisiana State University, New Orleans, LA
[e] Department of Urology, University of Kansas School of Medicine, Kansas City, KS
[f] The Landon Center on Aging, Kansas University Medical Center, Kansas City, KS

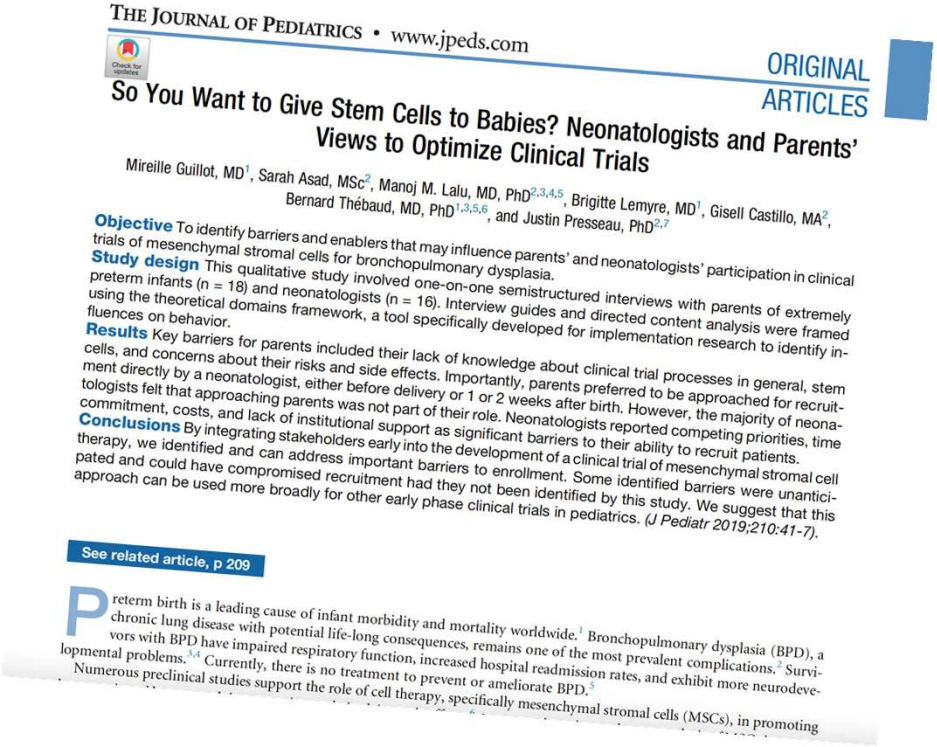
Received 19 October 2018; received in revised form 24 January 2019; accepted 10 March 2019

Abstract

Objective: Engaging community urologists in referring patients to clinical trials could increase the reach of cancer trials and, ultimately, alleviate cancer disparities. We sought to identify determinants of referring patients to clinical trials among urology practices serving rural communities.

Methods: We conducted semistructured qualitative interviews based on the Theoretical Domains Framework at nonmetropolitan urology practices located in communities offering urological cancer trials. Participants were asked to consider barriers and strategies that might support engaging their patients in discussions about urological cancer clinical trials and referring them appropriately. Recorded interviews were transcribed and coded using template analysis.

Results: Most participants were not aware of available trials and had no experience with trial referral. Overall, participants held positive



THE JOURNAL OF PEDIATRICS • www.jpeds.com

ORIGINAL ARTICLES

So You Want to Give Stem Cells to Babies? Neonatologists and Parents' Views to Optimize Clinical Trials

Mireille Guillot, MD[1], Sarah Asad, MSc[2], Manoj M. Lalu, MD, PhD[2,3,4,5], Brigitte Lemyre, MD[1], Gisell Castillo, MA[2], Bernard Thébaud, MD, PhD[1,3,5,6], and Justin Presseau, PhD[2,7]

Objective To identify barriers and enablers that may influence parents' and neonatologists' participation in clinical trials of mesenchymal stromal cells for bronchopulmonary dysplasia.

Study design This qualitative study involved one-on-one semistructured interviews with parents of extremely preterm infants (n = 18) and neonatologists (n = 16). Interview guides and directed content analysis were framed using the theoretical domains framework, a tool specifically developed for implementation research to identify influences on behavior.

Results Key barriers for parents included their lack of knowledge about clinical trial processes in general, stem cells, and concerns about their risks and side effects. Importantly, parents preferred to be approached for recruitment directly by a neonatologist, either before delivery or 1 or 2 weeks after birth. However, the majority of neonatologists felt that approaching parents was not part of their role. Neonatologists reported competing priorities, time commitment, costs, and lack of institutional support as significant barriers to their ability to recruit patients.

Conclusions By integrating stakeholders early into the development of a clinical trial of mesenchymal stromal cell therapy, we identified and can address important barriers to enrollment. Some identified barriers were unanticipated and could have compromised recruitment had they not been identified by this study. We suggest that this approach can be used more broadly for other early phase clinical trials in pediatrics. (*J Pediatr 2019;210:41-7*).

See related article, p 209

Preterm birth is a leading cause of infant morbidity and mortality worldwide.[1] Bronchopulmonary dysplasia (BPD), a chronic lung disease with potential life-long consequences, remains one of the most prevalent complications.[2] Survivors with BPD have impaired respiratory function, increased hospital readmission rates, and exhibit more neurodevelopmental problems.[3,4] Currently, there is no treatment to prevent or ameliorate BPD.[5]

Numerous preclinical studies support the role of cell therapy, specifically mesenchymal stromal cells (MSCs), in promoting

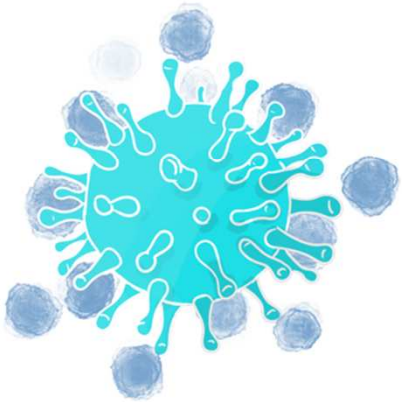
Specifying the behaviour

- **A**ction - Behaviour that needs to change
- **A**ctor - Person/people that do(es) or could do the action targeted
- **C**ontext - Setting in which the action is performed
- **T**arget - To whom or for whom the action is performed
- **T**ime - When the action is performed

Presseau *et al.,* (2019)

“Healthcare professional recruiters inviting all eligible pregnant women to participate in a trial”

ISLAGIATT principle



Three Phased Recruitment Plan

ENCOUNTER Study
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www.encounterstudy.ie

Diagnosing the behaviour

- 22 Semi-structured online interviews

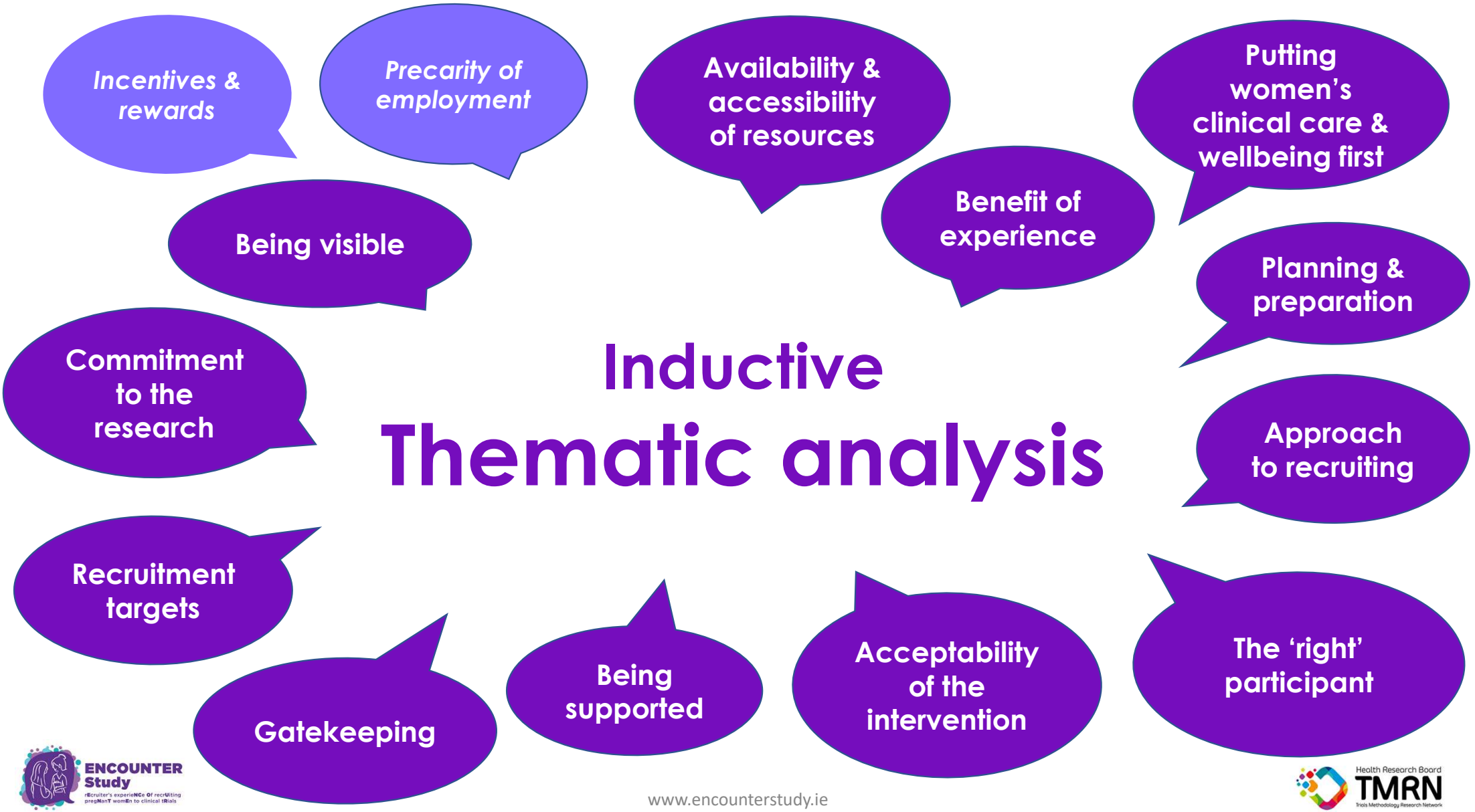
Broad range of clinical backgrounds

8 individual trials (covering 15 different sites) in Ireland & UK

- Inductive & deductive analysis

Our findings

- This is still a work in progress… but **preliminary** findings suggest…



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Deductive analysis
Mapping inductive themes to the TDF

	Theoretical Domains													
	Kn.	Sk.	S/PRI	Cap	Opt.	Con	Rein.	Int.	Goal.	MADP	ECR	SI	Em.	BR
1. Availability & accessibility of resources											√			
2. Benefit of experience	√	√	√	√										
3. Putting women's clinical care & wellbeing first			√					√	√					
4. Planning & preparation	√									√				√
5. Approach to recruiting		√				√					√		√	
6. The 'right' participant	√					√				√				
7. Acceptability of the intervention			√			√								
8. Being supported												√		
9. Gatekeeping			√					√				√	√	
10. Recruitment targets						√	√		√				√	

Theoretical Domains Framework - salient domains

- **Environmental context and resources**

> *"So, it can be quite difficult sometimes to have confidential conversations, which really is essential. So, I often spend time wandering around the hospital trying to find an empty cupboard to try and have a conversation in. Which, I mean you manage it, but it's not ideal."* 2RM

Theoretical Domains Framework - salient domains

- **Social/Professional Role & Identity**

"I feel like in the hospital, we're not quite second-class citizens, but… you'd never take precedence explaining your study over a nurse coming in, or a midwife coming into the room to a patient, you know, giving them their medication or taking their temperature, you'd always step back." 17RN

Theoretical Domains Framework - salient domains

- **Beliefs about Consequences**

"If you're doing a trial, where they were having to attend for more visits, that might not suit someone, though some women like that, and it is a reason they might take part in a trial. But, you know, that could be a little bit of a burden on them, an extra burden." 20CI/PI

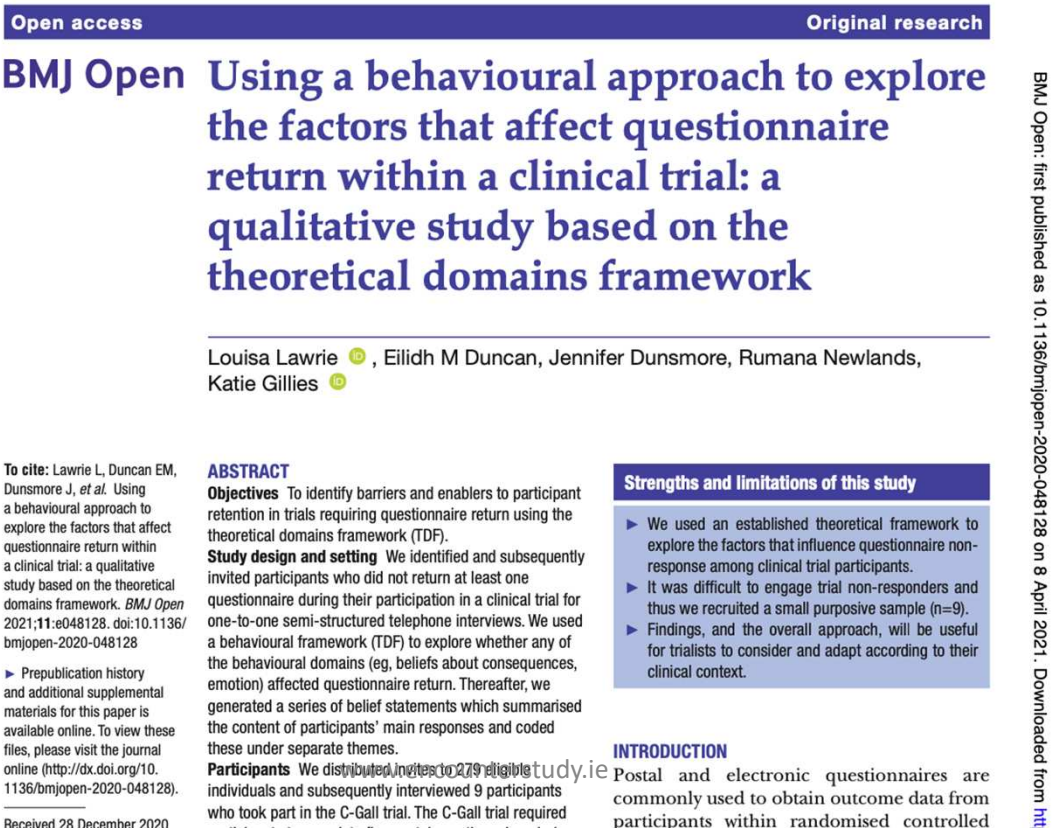
Treating the behaviour

- **Co-design** an intervention through online workshop
- **Testing** the intervention

- Applying learning from behavioural science provides a framework to rigorously **specify**, **diagnose** and **treat** behavioural problems in trials.

- It enables learning from one study to another to be maximised by application of a common set of principles

Behavioural approach beyond recruitment



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Using a behavioural approach to explore the factors that affect questionnaire return within a clinical trial: a qualitative study based on the theoretical domains framework

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ABSTRACT

Objectives To identify barriers and enablers to participant retention in trials requiring questionnaire return using the theoretical domains framework (TDF).

Study design and setting We identified and subsequently invited participants who did not return at least one questionnaire during their participation in a clinical trial for one-to-one semi-structured telephone interviews. We used a behavioural framework (TDF) to explore whether any of the behavioural domains (eg, beliefs about consequences, emotion) affected questionnaire return. Thereafter, we generated a series of belief statements which summarised the content of participants' main responses and coded these under separate themes.

Participants We distributed invites to 279 eligible individuals and subsequently interviewed 9 participants who took part in the C-Gall trial. The C-Gall trial required

Strengths and limitations of this study

- ► We used an established theoretical framework to explore the factors that influence questionnaire non-response among clinical trial participants.
- ► It was difficult to engage trial non-responders and thus we recruited a small purposive sample (n=9).
- ► Findings, and the overall approach, will be useful for trialists to consider and adapt according to their clinical context.

INTRODUCTION

Postal and electronic questionnaires are commonly used to obtain outcome data from participants within randomised controlled

ENCOUNTER Study

rEcruiter's experieNCe Of recrUiting pregNanT womEn to clinical tRials

Thank you

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Trials Methodology TMRP Research Partnership

Health Research Board TMRN Trials Methodology Research Network

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