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Patient advocacy and patient centredness in participant recruitment to randomized-controlled trials: implications for informed consent

Zelda Tomlin PhD,* Isabel deSalis PhD,† Merran Toerien PhD‡ and Jenny L. Donovan PhD‡

*Research Fellow, Department of Primary Care and Public Health, Cardiff University, Cardiff, †Research Fellow, School of Social and Community Medicine, University of Bristol, Bristol, ‡Research Fellow RCUK, Department of Sociology, University of York, York

Correspondence
Zelda Tomlin PhD
Research fellow
Department of Primary Care and Public Health
Cardiff University
Neuadd Meirionnydd
Heath Park
Cardiff CF14 4XN
UK
E-mail: tomlinz@cardiff.ac.uk

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Abstract

Context With the routinization of evidence-based medicine and of the randomized-controlled trial (RCT), more patients are becoming 'sites of evidence production' yet, little is known about how they are recruited as participants; there is some evidence that 'substantively valid consent' is difficult to achieve.

Objective To explore the views and experiences of nurses recruiting patients to randomized-controlled trials and to examine the extent to which their recruitment practices were patient-centred and patient empowering.

Design Semi-structured in-depth interviews; audio recording of recruitment appointments; thematic interactional analysis (drawing on discourse and conversation analysis).

Setting and participants Nurses recruiting patients to five publicly funded RCTs and patients consenting to the recording of their recruitment sessions.

Main outcome measures The views of recruiting nurses about their recruitment role; the extent to which nurse–patient interactions were patient-centred; the nature of the nurses' interactional strategies and the nature and extent of patient participation in the discussion.

Results The nurses had a keen sense of themselves as clinicians and patient advocates and their perceptions of the trial and its interventions were inextricably linked to those of the patients. However, many of their recruitment practices made it difficult for patients to play an active and informed part in the discussion about trial participation, raising questions over the quality of consent decisions.

Conclusion Nurses working in patient recruitment to RCTs need to reconcile two different worlds with different demands and ethics.

Evidence production, a central task in evidence-based medicine, poses a challenge to patient-centred practice and more research and relevant training are needed.

Background

As the number of randomized-controlled trials (RCT) expands and the health technology assessment (HTA) industry grows, many more patients – and their bodies – are likely to become 'sites of evidence production;'[1] the processes through which they are co-opted and enrolled as trial participants deserves careful scrutiny.

Patient recruitment has been studied extensively from a utilitarian stance, an interest generated by widespread difficulties in recruiting the required number of participants. Recruitment failures are common and have led to loss of resources or statistical power and sometimes to trial abandonment.[2–9] Several systematic reviews have registered the 'problem' of trial recruitment and the proposed strategies to resolve it.[10–12] Reluctance of clinicians to offer randomization and of patients to consent to it has emerged as a central issue in most published studies.

Randomization – allowing chance to determine the patient's course – requires an attitude of *indifference* as to which, if any, of alternative interventions the patient ends up receiving. This state of indifference – or 'maximum uncertainty' – has been termed personal equipoise.[13–16] The underlying logic of personal equipoise is that a clinician (historically a doctor) can only ethically offer randomization when he/she expects equivalent outcomes from all trial interventions. An expectation that one intervention may produce a better outcome would mean knowingly exposing the patient to harm (in case of allocation to another intervention), breaching the Hippocratic principle of non-maleficence.[17]

The concept of equipoise has dominated the discourse of research ethics for several decades despite mounting empirical evidence that clinicians and patients appear generally not to be in equipoise and find randomization difficult.[2,3,5,6,8,11] Rather than entering the recruitment pathway as tabula rasa, clinicians and patients have experiences, stories, ideas and emotions – or preferences – about the interventions being tested. Such preferences impact on RCTs. Clinician preferences can lead to failure to approach potential participants,[4,7] provision of differential or biased information[18] or dilution of interventions.[4] Patient preferences are seen as a major barrier to recruitment;[11] on the other hand, if patients with preferences do participate, these may interact with trial outcomes threatening validity (the so-called 'preference effect').[19,20] Participation of these patients also raises the possibility that their consent was obtained through subtle pressure or outright coercion.[19] The difficulties both clinicians and patients have with the practice of randomization and concerns over how preferences may impact on recruitment, intervention delivery and outcomes mean that clinicians and patients continue to be expected and encouraged to be in 'equipoise'.[15,21,22]

Patient recruitment commonly centres on the recruitment encounter between the patient and the recruiting clinician (increasingly nurses) where trial information is provided, advantages and disadvantages of participation are discussed in the context of the patient's lifeworld and the patient is invited to consent to randomization. Exploration of patient beliefs and preferences is integral to these discussions; the aim is to inform the patient (dispelling any misinformation) and to allow the patient to weigh the advantages and disadvantages of participation in the light of the new insights gained during the discussion. The domination of the world of RCT practice by the equipoise discourse means that often, these discussions are framed by the requirement to ensure that the patient is 'in equipoise' before consenting to randomization.[21,22] This in turn implies that the patient is likely to or is encouraged to embark on a journey from a state of preference to a state of no (strong) preference or even indifference.

Trial recruitment is, therefore, a socially delicate interactional undertaking: whether and how the patient's agenda emerges and is handled by the recruiter is likely to impact on the quality of consent. Small and subtle interactional moments can significantly influence the patient's understanding, feelings and views about participation and the ethical standing of their decision. If patients find it difficult to voice their concerns, if these are ignored or if patients are subtly or explicitly pressured to change their minds, then there is a danger that their consent (or declination) is merely ritual rather than 'substantively valid' – genuinely informed, voluntary and autonomous.[23]

Despite the essentially interactional nature of informed consent,[24] there has been little empirical research into the processes, routines and ethical implications of informed consent encounters. The few published studies have shown that doctors can fail to explain the trial clearly,[25] while communications training can have limited success in changing their interactional styles.[26] The crucial role of the interaction has been illustrated in a study that found that patient preferences could change as a result of the discussion with the recruiting nurse.[27] Importantly, shared decision making has been identified as essential for informed consent in RCTs[28] but was found not to be routinely practised.[29] The importance of researching the recruitment encounter is underlined by the somewhat unsettling findings from studies that explore patient experiences of and reasons for participating in trials. For example, participants have remained unaware that they were participating in randomized research[30–32] or have been affected by the 'therapeutic misconception' – the failure to understand that the clinician's focus has shifted away from their individual care to scientific research and the care of populations.[33,34] Some have agreed to participate because, while wanting to help others, they believed that they would receive better care if they participated.[35]

This article reports from a study of trial recruitment. First, it charts the discursive struggle of nurse-recruiters to reconcile two potentially conflicting commitments, to patients as clinicians and to the trials as recruiters. Second, it examines the nurses' recruitment practices and the extent to which their interactions with potential participants were 'patient-centred'. The study concludes with implications for informed consent and suggestions for practice and research.

Methods

The data come from four RCTs that collaborated with the Quartet study (Qualitative research to improve recruitment to randomized-controlled trials, 2005-08) plus the ProtecT study.[36]

Setting and sample

The RCTs were selected purposively with an element of self-selection. All were funded by major UK public trial funding bodies and were expected to have recruitment difficulties. Consent was sought separately from the chief investigator, principal investigators (PIs) and recruitment staff (commonly nurses) to ensure voluntary participation and to avoid the perception of monitoring on behalf of the trial management group. The Quartet PI was also a Trial A PI; the Quartet researchers reassured trial A nurses that they were independent of the trial A management team and that only anonymized data would be shared with the PI.

Data collection

The recruiters were provided with digital recorders and audio-recorded recruitment interactions that they considered suitable, with the patient's consent. Following the last recording, the recruiters were individually interviewed in-depth, using a semi-structured design. Group discussion sessions were also held. All data were audio-recorded, fully transcribed and managed using the Atlas-ti software. The interviews lasted on average one hour and topics relevant to this study were the following: the rationale for the trial; views on trial arms; patient eligibility; patient preferences; recruitment difficulties.

Analysis

An ethnographic and constructivist perspective was adopted, enabling informant meanings to emerge[37] and paying attention to interactional and representational 'work'.[38,39] Thematic coding and constant comparison were used to analyse the data and coded segments were compared to formulate over-arching themes. Content and thematic analyses were conducted on the interactional data, paying attention to phenomena common to discourse and conversation analysis: pauses, interruptions, discordant talk, orientation, directiveness, etc.[40] The aim was to elicit the nature and extent of information provided and whether the patient participated actively in the discussion. Two interview and two interactional transcripts were coded independently by three researchers and differences discussed to construct a common coding frame. Data that appeared fundamentally different or contradictory were examined for instructive and plausible explanations.

NHS ethics committee and NHS trust R and D approvals were obtained.

Results

The RCTs

The five RCTs covered different clinical areas (Table 1). The nurses were: clinical nurse undertaking recruitment as an occasional extra task (Trial B and Trial E); directly employed by the trial (Trial A and Trial D); National Cancer Research Network (NCRN) nurse (Trial B and Trial C); non-clinical recruiter (Trial B – not individually interviewed). Trial A nurses had received training in recruitment strategies (prior to the current study) and could therefore be expected to have become sensitized to equipoise-related and interactional issues.[41] A total of seven nurses from three trials provided 23 recordings of recruitment appointments, nine nurses were interviewed individually and 30–34 nurses participated in four group sessions (Table 2). In the data extracts, letters stand for the specific trial and 'Rec' for recruiter.

We first report on the nurses' strong sense of themselves as clinicians, rather than recruiters, illustrated by the practice of reviewing and re-evaluating patient eligibility. We then show how nurse 'equipoise,' or more to the point, nurse preferences are inextricably and empathically linked to patient preferences. Next, we report on how some of the nurses' interactional practices constrained patient centredness and empowerment.

Clinicians or recruiters?

Throughout the interviews, the nurses spontaneously affirmed and emphasized their identity as clinicians 'first and foremost' and as patient advocates. That this identity might be replaced or encroached on by that of trial recruiter was unacceptable, regardless of whether their work had any clinical content.

> 'I think what you've got to remember is, we're nurses first and foremost and, and that's a huge difference between being a researcher [and a nurse]… as nurses, we care'(ARec5, focus group).

> '… [patients] have got our telephone numbers, they can ring us… once they get used to that, it's a sense of belonging…' (ARec2).

Table 1 Study RCTs and data collection

	Trial A cancer treatment	Trial B cancer treatment	Trial C cancer follow-up	Trial D childhood fever	Trial E mental health
Arms	3	2	4	3	2
Follow-up	10 years	5 years	5 years	5 days	2 years
Individual interviews	N/A	2 nurses	3 nurses	2 nurses	2 nurses
Group sessions	1 (7 nurses)	1 (3 nurses)	N/A	N/A	2 (10–12 nurses each)
Recorded appointments (some with the same patient)	N/A	2	9	12	N/A

Table 2 The battling patient

This patient's son reveals, 25 min into the 33-min session, that his father prefers laser surgery. The recruiter appears not to hear this, proceeding with a misaligned turn about the mechanics of randomization.

Son: I think you were under the impression that you were going to get the endoscope but [
Pat: [aye, well, I was hoping, you know, but as you explained to me that- consider some pure advice before it can be decided.
Nur: What I'll do today, if you agree to participate in the study, I would phone the centre and I would be able to tell you what that treatment was [to be

It becomes clear that the patient's preference is based on his earlier – positive – experience with endoscopic biopsy. His son and the nurse point out that laser *surgery* may have more side-effects. The patient appears not to accept this caveat. The nurse repeatedly reminds the patient that he can decide on the spot and the patient repeats his preference each time.

Following a break in the recording, the son suggests that radiotherapy may produce a better outcome. The patient says:

Pat: Oh, I think the endoscope is the best.

This is followed by more discussion between the son and the nurse about the potential superiority of radiotherapy. The patient says:

Pat: [Want to ( ) again
Nur: OK that's fine, the laser gun?
Pat: The laser gun
Nur: That's absolutely fine.

The son casts one last doubt over the decision:

Son: You would rather have that than the other?
Nur: Ok that's fine. So I can take your name…

The nurses on Trial D needed to advise the parents of seriously ill children to seek urgent help. One nurse regretted not acting quickly enough because she had temporarily allowed her recruiter identity to overshadow her clinician identity.

> 'I felt very, very guilty about something I don't think I'd actually done… I actually was very much in the research role, still thinking about the research; but still, at the same time, I was confronted with a child that I knew needed to get some help' (DRec1).

This nurse promoted her clinician identity when approaching potential participants.

> *Researcher*: 'You've all got the nursing background?'
>
> 'We do, yeah, and I do use it… because it's helpful initially because [the parents] know that… I do have a clinical responsibility, umm, to do my best for them in my role… It's a very different way to work, you know, [to what] I'm used to in the wards, as a nurse, in your uniform. You know, you've got a certain role and it's clear, respectful… and there's a lot of power with that as well. And then, to actually to have that taken away from you…'(DRec1).

When the researcher commented that her current role did not include clinical duties, one nurse said:

> 'I actually take a bit of offence at that really, because I do feel that I'm hands on… I'm seeing them when they're… feeling absolutely rotten and I am holding the vomit bowl… you know, and caring for their immediate needs. You don't just switch that off and get someone else to do that' (CRec1).

Patient eligibility and empathic preferences

Most nurses, except those on Trial E,[8] were convinced of the trial rationale and expected useful clinical knowledge to emerge from it. However, the nurses viewed particular arms as less desirable for certain types of patients. These views were formed in the course of assessing patient *suitability* for trial participation, a concept that included but went beyond clinical eligibility to encompass the patients' lifeworld, or beliefs, circumstances, relationships, plans, hopes, fears, expectations, psychological features and values. This intimate 'knowledge' was derived from the patient's appearance, clinical notes and interaction with the nurse. The conclusions reached appeared to determine the nurses' views about the trial arms. We term this 'empathic preferences'.

The nurses' empathic preferences covered both the processes and the outcomes of trial interven-

tions and were broadly in two directions: less intervention was associated with potentially worse *outcomes* and more intervention was associated with unacceptably burdensome *processes*. Relevant factors included the patient's age, presenting features (e.g. tumour size or location), circumstances, psychology and motivation.

'*More*' *is better*

Less intervention could lead to undetected deterioration of the condition, in this case cancer, potentially ruling out curative intervention.

> '[The MDT] said that he was suitable for randomisation; he was in his 50s and I didn't – it didn't sit comfortably with me at all and so… first and foremost you're a nurse and… I actually talked to a consultant about it first' (ARec1).

This nurse watched patients on the less intensive monitoring arm 'like a hawk' to detect any deterioration. There were also psychological consequences for the nurses, as shown by the following focus group extract:

> 'If you give a patient surgery or radiotherapy, right, even if they go on to progress and die because of the disease, you've done absolutely everything you can' (ARec3).

> 'But have you, really?'(ARec1).

> 'Well, that's how it goes, though. You've really tried to cure them, haven't you? If you just leave them on monitoring, you know– what are you really doing? (ARec3).

Informal 'suitability' criteria had been formulated by some recruiters on Trial C (cancer follow-up).

> '… particularly younger patients, I often won't even raise [trial participation] in the MDM [multidisciplinary team meeting] for young, fit patients in their 50s' (CRec3).

In Trial E (mental health), patients on the control arm were seen as 'rejected' (Howard *et al*. 2008).

> 'And sometimes you can feel a bit, umm, ''have I let this client down?''… maybe I set them up to fail, thinking that they'd be randomly selected and be given that extra support and they haven't and I can feel a bit disappointed…' (ERec1).

Nurses' views also led to some dilution of interventions. In Trial C, those on the symptomatic arm (no regular follow-up) were given the telephone number of the hospital nurse specialist; in Trial E, some patients on the control arm were referred to the innovative service.

Trial as burden

By contrast, the more intensive trial *processes* were perceived as too burdensome for some patients.

> I've had a chap recently who wanted to be monitored because his wife had died a year ago… and he didn't like being in the house... he said, ''if I had an operation, I'll be at home, [if] I had radiotherapy, I'll be at home and I can't cope with that'' (ARec7).

> '… you do get a sense, when you meet people, of, for example, how fit they are… if I see somebody being wheeled in by carers or something, then, for a trial where they may need] … extra follow-up visits, then you're probably going to think, maybe this person isn't suitable anyway' (CRec2).

> 'I think I know which parents to approach and when and which not to… there are particular people that you just know straight away that it's not a good time' (DRec2).

Occasionally, nurses expressed ethical unease about trial recruitment *per se*:

> … they come in quite happily with, you know, wanting their monitoring, and then you've thrown a real spanner in the works by giving them the information; they've gone away without knowing what the hell they want… And you think, ''oh, maybe I should have just left them…'' (ARec1, focus group).

One nurse thought that patients were affected by the therapeutic misconception.

> … there are still some patients who say, ''well, [the doctor] wouldn't have offered it to me if he didn't want me to do it.'' And sometimes you just have a feeling – especially with some of the trials where you're doing more aggressive things – that's not the best way to go with this patient (BRec1).

Thus, the nurses believed that they were acting as clinician-advocates even when their job was to recruit participants and had no clinical

component. As clinicians, they scrutinized eligibility decisions made elsewhere (by the consultant or the multidisciplinary team) and the more they knew about the patient-as-person, the more they developed empathic preferences for trial interventions on behalf of the patient. We now report on the nurses' recruitment practices.

Recruitment interactions

The analytic focus here was the extent to which the interaction was patient-centred and the patient's voice was heard. These themes are illustrated through particular roles that the patients assumed or were cast into and particular communicative strategies that the nurses employed, more or less consciously. Although short data segments are presented in the tables, the interpretation draws on the entire session and sometimes also other interactions between the parties. Problematic interactional practices and suboptimal information delivery are contrasted with patient-centred practices and more comprehensive and proactive information giving.

The battling patient – Appointment 1

This role indicates a patient who struggles to have his/her voice heard and agenda acknowledged; discursive alliances between the recruiter and significant others present can exacerbate this. In this extract, the patient has a preference but has to deal with several attempts to promote the other intervention or trial participation. His preference is accepted after he repeats it five times Table 3.

Table 3 The silenced patient

Pat: I think that at my age [( )
Nur: [what age are you?
Pat: [guess
Nur: 62?
Pat: Thanks very much.
Nur: What age are you?
Pat: 74.
Nur: Oh my goodness, you look very well. You certainly [don't look….

Table 4 The acknowledged patient

Pat: only ( ) (.) why have the [laser
Wfe: [Hah hah
Pat: if I'm going to finish up having the other one as well
Nur: Because there's a good chance that you're going to get away without having the radiotherapy [and the other
Pat: [Right
Nur: thing that they could do is that they can go back in and take another little piece out with the laser…erm, it depends what happens when it goes over to the lab and when they look
Pat: [(What it is)
Nur [if it's just a few tiny little cells they might just go in and take another tiny piece with the laser
Pat: [Oh right
Nur: [(and it-) and you may not need the radiotherapy after all
Pat: I see
Nur: erm, so, it's not- it's not a certainty that you're going to end up having the radiotherapy as well, it's a small chance
Pat: Yeah
Nur: [So
Wfe: [O-
Nur: Go on
The patient's wife wonders if remedial radiotherapy would be the 'full course' and the nurse explains that this would depend on laboratory results.
Nur: So
(Pause)
Pat: That's fine.

The silenced patient – Appointment 1

This is a patient who is – possibly unintentionally – prevented from putting across his or her concerns/wishes. In this extract, the same patient introduces the topic of his age, which he appears to think is relevant to the treatment options. Following the nurse's interruption, the two proceed to joke about his youthful appearance. The conversation then moves on; neither the nurse nor the patient returns to the topic of age and the patient's thoughts remain unexplored Table 4.

The acknowledged and informed patient – Appointment 2

This is a patient whose concerns and questions are heard and answered in a direct and comprehensive fashion. In this extract, the patient also actively engages with the recruiter's response, confirming his understanding.

Table 5 The partially informed patient

Pat: It's got here, the more intensive follow-up schedules may find any recurrent cancer at an early stage, which may or may [not be to an advantage, what does
Nur: [Right
Pat: That mean?
Nur: Well, what it means is that, umm, it's possible that you could develop a polyp or something like that which might mean that you had extra investigations
Pat: Oh, right
Nur: But it might not necessarily, umm, be something that needs treatment
Pat: Oh right, well, that doesn't matter does it?

The relevant passage reads:

'*The more intensive follow-up schedules may find any recurrent cancer at an earlier stage which may or may not be an advantage. They may also find other changes that are not cancer and which don't need treatment. This may mean that you have more investigations than necessary and this can cause inconvenience and anxiety.*'

The nurse only addresses the second part, leaving unexplained the first sentence about recurrent cancer – the one that the patient is confused about. Compare this with another nurse's successful specification of the ambiguous phrase 'may or may not be an advantage', unprompted by the patient.

Nur: Now, what we know with [this] cancer is that, if it comes back, the likelihood of us being able to cure it is very small… erm, what we'd be looking at is controlling it… for a few people, if it comes back and it came in the [organ] which is- if it's going to come back, it's a common place for it to come - that for a few people you can do surgery and for a few of those, it will cure it, but they're only a small proportion.

Additionally, the patient's wife is promptly heard and acknowledged by the nurse who foregoes her conversational turn and proceeds to answer the new question in the same comprehensive way. The pause at the end allows the wife to confirm that her question has been satisfactorily answered Table 5.

The partially informed patient – Appointment 3

This is where the patient is given information that is either inaccurate or, as in this extract, while technically accurate, contextually amounts to misinformation. This patient has telephoned the hospital to confirm that she would like to participate, but is confused about a statement in the written information sheet. The nurse's explanation is correct but refers to a different topic. Crucially, the patient accepts the nurse's explanation; this is an important misalignment as the sentence in question appears to contain important outcomes information Table 6.

Table 6 The misled patient

Pat: And, as I say, you're from the, the research? The cancer research then-
Nur: Yes we, we actually work for the [cancer research network
Pat: [Yes, well, I always -that's the one thing I always pay into, [so-
Nur: [Lovely thank you
Pat: And I always have done, I mean, even before- you know, long- we've always done that but, umm, when I was reading, I thought 'oh right'- so I'll go through with that then [okay
Nur: [Well thank you ((name)).

The misled patient – Appointment 3

This is a patient whose misbeliefs are unattended to because the recruiter fails to seize a clearly marked opportunity to spot and correct them. The extract is from a later section of the telephone conversation above and the patient is clearly confusing the National Cancer Research Network (NCRN), the nurse's employer, with a charity, most likely Cancer Research UK, to which she makes regular donations. This is an important failure because her mistaken belief has played a part in the patient's decision to consent. The nurse's failure to attend to this mistake may result from inattentiveness or it may represent a conscious decision to allow it to pass because correcting it might change the patient's mind about participating Table 7.

Therapeutic misconception – allowed or dispelled – Appointments 5 and 4

Patient beliefs that individual clinical features and welfare needs continue to determine the options provided even in research contexts pose a major obstacle for informed consent. Here, two recruiters deal very differently with this phenomenon, the first allowing it to persist and the second proactively attempting to prevent it Table 7.

Table 7 Therapeutic misconception allowed or dispelled

Appointment 5

Hsb: This can only be a good thing can't it?

Nur: That's what we hope yes, yeah, yeah

Appointment 4

The nurse has just finished outlining the trial arms and the clinical uncertainties.

Nur: And that is why the study is being done

Pat: Yeah

Nur: Umm, so you know, we can't say there'll be any kind of benefit to you being in anyone- one of these arms, all we know is that in the future we will know what is the best way [for people

Pat: [Best way for people, yeah. Hmm

Nur: So, it will be helping other people, but it isn't really something we can say will help you.

Pat: No.

The extracts show patterns of interaction that are likely to impact significantly on the quality of patient decision making. Interruption and digression, incomplete or inaccurate information and inattentiveness to patient feelings and concerns make it difficult for the patient voice to be heard or considered. By contrast, pauses, comprehensive and accurate information, checking understanding and satisfaction and dispelling the therapeutic misconception are likely to go some way in ensuring that the final decision is as 'good' as possible[22] (Wade *et al.,* 2009). Additionally, these practices are discordant with the nurses' discourse of advocacy, understood as providing patients with accurate and comprehensive information as well as opportunities to express their concerns, ideas and feelings, taking these seriously and discussing their implications.

Discussion and conclusion

This study provided valuable empirical data on how nurses and patients 'do' informed consent for RCTs. Through promoting themselves as clinicians, the nurses seemed to hope that their actions as recruiters would be morally defensible but their interview-based discourses of empathy and advocacy contrasted with their interactional practices that limited the possibilities for patient empowerment and meaningful patient participation in consent decision making. While there were instances of patient-centred practice, there were many others where the patient agenda and voice were suppressed – if unintentionally – and information delivery was unsatisfactory. These practices are likely to impair the consent process. Ness *et al.*[42] have also suggested that misaligned interactional 'frames' or expectations can lead to therapeutic misconception and adversely affect informed consent. There are also implications for trial findings: dilution of trial interventions may impact on the validity of findings; 'supplementing' eligibility criteria with informally developed suitability criteria may introduce significant but undetected differences into the groups, with implications for generalizability.

Nurses working in trial recruitment face the formidable challenge of reconciling the conflicting worlds of clinical practice and experimental science and the corresponding deontological (duty based) and utilitarian (consequentialist) ethics.[43,44] They must learn to side-step their own and what they understand to be patients' preferences in the interests of fairness, discovering and managing their own unrecognized emotions in the process.[45] Most recruiters work in isolation and 'muddle through': while they complete the International Committee on Harmonization (ICH) good clinical practice course,[46] they receive little or no specific training in interactional strategies or ethical reasoning (although nurses working on cancer trials complete a communications course).[47] Recruitment encounters are thus likely to involve professional, ethical and situational discomfort and awkwardness which may go some way to explain practices that hinder patient centredness.

The nurses' investment in their clinician identity as an ethical safeguard can be seen as a subliminal adaptive strategy, but is clearly inadequate as an actual safeguard to potential trial participants. Deconstructions of the idealistic nursing discourse suggest that nurses' capacity to act as patient advocates may be limited because they are just as much part of the 'system' as doctors and managers and their actions are bound with the interests of both the system and their own careers.[48–51] The 'knowing

and advocating' nurse may – unwittingly – limit patient autonomy by gatekeeping inappropriately.[52,53] For example, empathic preferences as identified in this study may mean that eligible and willing patients are excluded, hesitant (but silent) ones included and information distorted, inappropriately tailored or censored.

As this study has demonstrated, patient recruitment is a delicate interactional task and genuine informed consent (or declination) must be contingently and collaboratively constructed by the patient, significant others present and the recruiting clinician. The moral adequacy of this process depends on the integrity, knowledge and interactional skills of individual recruiters. The macro and meso regulatory frameworks governing research practice – the ICH, the World Medical Association's Declaration of Helsinki[54] and local ethical scrutiny – while necessary are not sufficient to gain purchase on the micro world of patient recruitment. This can only be achieved through developing, first, a systematic understanding of the recruitment encounter and the specific challenges it poses and, second, equipping each recruiting professional with relevant interactional perspectives and skills.

The trial recruitment interaction has been largely neglected by the health professional–patient interaction and shared decision-making literature. In contrast to a large and expanding body of work on patient centredness and shared decision-making in usual clinical practice,[55,56] little attention is paid to whether and how these concepts are relevant to trial recruitment. This may be partly explained by the difficulty in accommodating these concepts in the RCT context: while the *application* of evidence can be 'judicious'[57] and permit shared decision making,[58] the *production* of evidence may not afford similar flexibility because it depends fundamentally on adherence to rigid rules in pursuit of rigour. Patient preferences, a valuable if complex[59] resource in everyday clinical decision making, are thus reconfigured as problematic intruders in RCT practice. But it is because of these tensions that empirical research, critical enquiry and training in RCT recruitment practice are needed.

The notions of relational ethics[60] and relational autonomy,[61] stipulating respectively that ethics resides in the moral agency of practitioners, their emotions and their relationships with patients[62] and that people cannot step outside structural inequalities to engage in 'rational deliberation'[61] offer appropriate conceptual and methodological tools for this. Empirical sociological and normative perspectives need to be combined in the developing tradition of empirical ethics[63] to develop standards and a universal training infrastructure for trial recruitment. The training should help recruiting clinicians to reflexively delineate their clinical and recruitment roles, avoid the therapeutic misconception (both for the patient and for themselves) and engage with patients as partners in evidence production. Additionally, consideration may need to be given to the option of using non-clinical staff in trial recruitment.

This study had some limitations: the trials were less diverse than desired, with three of five focusing on cancer; the nurses agreeing to collaborate may have differed systematically and significantly from those who did not; the number of interviews and recorded interactions was small; the selection of interactions for recording was not systematic but left to the nurses' discretion; ethics was not the central research focus and more in-depth exploration may have demonstrated higher levels of 'moral distress'.[64] Nevertheless, our findings were similar to those of others who also reported that nurses routinely assessed patient suitability and wanted to protect 'vulnerable' patients,[65] engaged in a 'therapeutic discourse'[66] and prioritized clinical roles and concerns over research[67] as well as those that found problems with patients centredness[29] and interactional misalignments.[42]

This study contributes to the body of knowledge on how trial recruitment is conceptualized by nurse recruiters and how informed consent is enacted and has demonstrated some shortcomings. It has suggested further research that could lead to the development of new standards and a universal training module for recruiting clinicians with the involvement of trialists, clinicians, patients, social scientists and ethicists. The

overarching aim of good trial recruitment may not be to attain an apparently unattainable state of 'equipoise' but to help patients reflect clearly on their options and to enable patients and recruiters to co-construct 'good' consent decisions free of regret, guilt and coercion.

Conflicts of interest

The authors declare that they have no conflicts of interest.

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