

TITLE

Recruiting to cohort studies in specialist healthcare services: Lessons learned from clinical research nurses in UK cleft services.

ABSTRACT

Aim

This study aimed to explore the experiences of clinical research nurses recruiting patients in a large specialist care-based cohort study.

Background

Longitudinal studies are vital to better understand the aetiology and moderators of health conditions. This need is especially salient for congenital conditions, such as cleft lip and/or palate, where establishing large, comprehensive datasets from birth is vital to improve understanding and to inform interventions. Various barriers exist in recruiting patients to large cohort studies. The role of clinical research nurses embedded within health settings has grown over past decades to facilitate data collection, yet challenges remain.

Design

Qualitative descriptive study.

Methods

Individual semi-structured interviews with 12 clinical research nurses based in 10 National Health Service cleft services across the United Kingdom, recruiting to the Cleft Collective Birth Cohort Study.

Results

Out of seven emergent themes, three highlighted challenges to recruiting patients, another three described facilitative factors, and one theme overlapped challenges and facilitators. Challenges included: the life circumstances of potential participants; language barriers; and limited clinical research nurse time for study. Facilitative factors included: integrating research into clinical practice;

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patient information shared with clinical research nurses; and support from the university-based research study team. The theme ‘Method of data collection’ related to both challenges and facilitators.

Conclusions

The qualitative data from clinical research nurses recruiting to a large birth cohort study provide helpful practical detail for specialist healthcare teams, specialist nurses, clinical research nurses and researchers looking to optimise recruitment and data collection in longitudinal studies.

Relevance to clinical practice

The findings suggest the importance of specialist clinical services and research study teams cooperating to embed research into everyday clinical practice, without compromising care. This should facilitate patients’ willingness to participate in important research like the Cleft Collective study and provide them with a positive experience of research.

SUMMARY BOX

What does this paper contribute to the wider global clinical community?

- Highlights the importance of integrating cohort studies into specialist services’ healthcare provision to facilitate recruitment and data collection.
- Specialist practitioner nurses often hold a key role in facilitating research in cohort studies, as a trusted figure for patients and their families.

KEY WORDS

Research Implementation; Specialist Nursing; Research in Practice; Facilitators; Qualitative Approaches.

INTRODUCTION

Large-scale cohort studies offer an effective method for investigating causes and factors moderating the impact of complex medical conditions (Manolio, 2009). Alongside epidemiological studies recruiting from the general population according to environmental criteria (e.g. location), cohort studies can selectively sample individuals affected by or at risk of specific conditions to investigate aetiology and risk factors (Stock et al., 2016). In the case of complex conditions (e.g. Diabetes type 1; congenital craniofacial conditions), multi-site birth cohorts provide the most rigorous and reliable methodology for understanding gene-environment interactions implicated in their aetiology and the factors contributing to patients' adjustment to the condition, by maximising demographic diversity and accuracy of recall (Clayton & McKeigue, 2001; Stock et al., 2016).

A variety of challenges exist in recruiting participants from specialist healthcare services into cohort studies, as well as collecting data once individuals are recruited. In the United Kingdom (UK), for example, despite the National Health Service (NHS) Constitution pledge to offer all potentially eligible patients the opportunity to participate in research studies (Department of Health, 2015), organisational, financial and interpersonal barriers appear to hinder this promise from being delivered (Fenlon et al., 2013). Little formal research has investigated the challenges in recruiting and collecting data in cohort studies recruiting from specialist services. Fenlon et al. (2013) have, however, identified a lack of engagement from clinical gatekeepers, minimal administrative support and over-tasked clinical research nurses as barriers to recruiting to a UK-based colorectal cancer cohort study.

Studies of clinical nurses' and other clinical and research members' perceptions of recruiting to clinical research have identified facilitators of effective recruitment, including strong communication between research study teams, lead nurses and other healthcare staff (Baron, Hirani & Newman, 2016; Nurni et al., 2015; Peters-Lawrence et al., 2012; Reynolds et al., 2013); integrated clinical and

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academic teams on site and doctors mentioning the study within routine consultation (Newington & Metcalfe, 2014); and clinical teams holding positive attitudes toward research (Borschmann et al., 2014; French & Stravropoulou, 2016).

Clinical research nurses (CRNs), who are registered nurses trained to facilitate research, are typically embedded in health settings and support recruitment and data collection in research studies. Their main responsibilities generally involve screening potential participants, obtaining informed consent, collecting and recording data and coordinating with both clinical and research study teams (Spilsbury et al., 2007). At the forefront of recruitment, and as the main representative for studies to potential participants, CRNs are crucial to the success of research studies within specialist health settings. As such, CRNs can offer valuable insight into the challenges and opportunities of recruitment and data collection in cohort studies.

BACKGROUND

This study draws from a nationwide cohort study in the UK conducted in cleft care. Clefts can occur in the lip alone, both the lip and palate, or palate only, together known as cleft lip and/or palate (CL±P). Cleft lip and/or palate is a congenital condition that affects around 1.7 per 1000 babies globally and although not life-threatening in resource-rich countries, often confers feeding difficulties, hearing impairments, dental complications, speech and language problems and psychosocial challenges. Patients undergo multiple surgical procedures to repair the cleft and related malformations (Mossey et al., 2009; Berkowitz, 2013).

In the UK, following a national review in 1998 aimed at improving outcomes (Sandy et al., 1998), cleft services were centralized and organised into multidisciplinary teams (MDTs) comprising surgeons, clinical nurse specialists (CNSs), speech and language therapists, dentists, orthodontists and, in most cases, clinical psychologists (Scott et al., 2014). Specialised cleft care is often offered over the lifespan, or at least until early adulthood. Upon pre or post-natal cleft diagnosis, CNSs initiate contact with parents and remain the primary contact for families in the early years. For CRNs

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recruiting to research studies in cleft care in these early years, coordinated working with CNSs is therefore a priority.

Many parallels exist in terms of the clinical context and care delivery in which cohort studies are conducted between cleft teams and services for other complex conditions. Examples include congenital conditions like spina bifida, microtia, cystic fibrosis, diabetes type 1 and conditions associated with premature birth. In all of these specialities care is at least in part provided via an MDT, often with CNSs in closest contact with families, there is a long-term care pathway involving multiple interventions, and whole families are involved in the patient's care (particularly in childhood; NHS England 2015).

The participants in this study were CRNs involved in the UK-wide Cleft Collective research programme based at the University of Bristol (Stock et al., 2016). Initiated in 2012, the study has to date recruited more than 5,000 participants, comprising biological mothers, the mother's partner, affected children and a small number of siblings. By recruiting families shortly after the point of diagnosis (Birth Cohort) and additionally at the national five-year audit (Five-Year-Old Cohort), the study aims to address three key questions commonly posed by parents at the time of diagnosis: 1) What has caused my child's cleft? 2) What are the best treatments for my child? and 3) Will my child be OK (both now and in the longer term)? To address the first two questions, genetic data is extracted from affected children's blood and discarded lip or palate tissue (at cleft repair surgery) and saliva from parents, together with environmental information collected via questionnaires. To address the second and third questions, information on speech and language development, surgical treatment, psychological wellbeing, orthodontics, audiology and nursing is recorded via questionnaires, and data extracted from medical and educational records. The study aims to recruit as many participants as possible over the coming years, and to follow enrolled families as their child grows up.

Via adoption funding from the UK National Institute of Health Research (NIHR), RNs have been employed to facilitate recruitment and data collection in the majority of active research sites.

Following study protocol, the Cleft Collective research study team based at the University of Bristol (henceforth referred to as 'study team') provided study-specific training to all recruiters prior to site

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initiation and continue to visit teams and to supply regular study updates. The study team also hosted a workshop for recruiters in 2015 aimed at facilitating shared learning across sites. Recruitment rates to the cohort vary across sites and at this point in the development of the study, a better understanding the experiences of CRNs in this study has the potential to shed light on factors that aid and hinder recruitment and data collection. This information may also benefit other cohort studies carried out in specialist services for complex health conditions.

AIM

This study aimed to explore the perceptions of CRNs in relation to challenges and facilitators of recruiting to the Cleft Collective Birth Cohort Study by conducting semi-structured interviews with RNs.

METHODS

Design

This study employed semi-structured interviews to explore CRNs' experiences of recruiting to the Cleft Collective Birth Cohort Study.

Data collection

Sample and recruitment

All CRNs actively involved in recruitment to the Cleft Collective Birth Cohort Study between July and September 2016 were invited to participate in an interview. Those who expressed an interest were sent further information about the study, and a convenient interview date and time was subsequently arranged. If no response was received after two reminder emails, a refusal to participate was assumed ($n = 2$ teams).

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Procedure

Individual, semi-structured interviews using open-ended questions were conducted over the telephone by the second author between July and September 2016. Interview topics included: employment history, their experiences of interaction with families, cleft teams and the study team. Participants were also explicitly asked to identify key challenges and facilitators of recruitment and data collection, and to offer suggestions for how recruitment could be further enhanced. All interviews were audio recorded and later transcribed verbatim by the first author. Interviews ranged from 15-51 minutes in length, averaging 30 minutes (nine of the 12 interviews lasted 25-35 mins).

Data analysis

Interview data were analysed by inductive thematic analysis as described by Braun and Clarke (2006). The first and last authors familiarised themselves with the data through re-reading transcripts, and subsequently allocated codes to passages of text pertaining to perceived barriers and facilitators of recruitment and data collection, cross-referencing with already-coded transcripts throughout. Codes were then grouped into preliminary themes by searching across codes for overarching patterns, and the preliminary themes were then checked against the coded extracts and dataset for coherence. Sub-themes were mapped onto each theme and reviewed for best fit, in accordance with working definitions of each theme. Themes and subthemes were then refined to ensure internal homogeneity (within-theme coherence of data) and external heterogeneity (distinctiveness between data in different themes) (Patton, 1990). Any discrepancies in analysis between authors were resolved via discussion. To control for potential researcher bias toward the Cleft Collective Study, the analysis was led by the first author who was not part of the study team.

Ethics

As this study involved NHS staff participants and no patients nor their relatives or carers, Health Research Authority (HRA) approval via NHS Ethics Committee was not required, in accordance with HRA ethical standards (HRA, 2017). The study protocol and interview schedule were therefore

reviewed and approved by the Faculty Research Ethics Committee (Health and Applied Sciences) at the University of the West of England.

RESULTS

Two cleft teams did not have a CRN in post during the study period, and thus were unable to participate. Of these teams, one team opted to give an in-situ cleft clinical nurse specialist (CNS) responsibility for recruitment, and another team gave responsibility to an administrator. Two teams who did employ CRNs for the study did not respond to two invitation reminder emails. Interview data were finally included from 12 active CRNs, representing 10 of the 12 participating sites with CRNs in place at the time of invitation. All nations involved in the study were represented (England, Wales and Scotland).

All CRNs were female. Participants had worked in NHS research for an average of 30 months (range = 6 months – 6 years) and had worked on the Cleft Collective study for 15 months on average (range = 1 month – 3 years). All but one worked part-time recruiting to the Cleft Collective, dedicating an average of 2 days per week to the study (range = 1 – 4 days). Most ($n = 11$) had previous experience of working in paediatric care, including neonatal care ($n = 2$), cleft services ($n = 2$) and paediatric intensive care ($n = 1$). Full participant details are provided in Table 1.

[INSERT TABLE 1 HERE]

Participants' accounts were grouped into seven core themes, largely categorised under (i) facilitators or (ii) challenges to recruiting and collecting data. Subthemes were grouped in each core theme.

Figure 1 shows the thematic map. Table 2 provides the definition of each theme.

[INSERT FIGURE 1 HERE]

[INSERT TABLE 2 HERE]

Challenges to recruitment and data collection:

Potential participants' life circumstances

One of the key groups whom CRNs felt unable to approach about participation in the Cleft Collective study was families living with complex social issues:

“The ones that we deliberately haven't approached are the families that we know have safeguarding issues and things going on in their family where [participating] would just be too much...” (4)

CRNs also acknowledged the strain experienced by families of children receiving intensive or special care as a result of comorbid conditions, and often chose not to approach these families:

“Another challenge is when a child has another syndrome as well. It's so difficult for the parents to think about anything else...[they're] so exhausted.” (7)

Language barriers

Another perceived key barrier to recruitment was related to language, with CRNs reporting struggling to recruit families who were non-English speaking:

“I don't think the language thing helps [...], I think you've got to be careful because they consent possibly for life [...] and [they may not have] grasped what they're signing for...” (8)

CRNs acknowledged the usefulness of interpreters, while also suggesting they did not adequately resolve the language barrier when questionnaires were not already translated:

“...[even] if they've got an interpreter we don't tend to approach them because we don't have the questionnaires in another language. I think we've got them in Polish and that's it.” (3)

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“My feeling is if the interpreter was going to be interpreting and writing the questionnaire, you’re not going to get the parents’ true feelings.” (2)

In addition to spoken language barriers, CRNs highlighted the challenge of illiteracy:

“...there are interesting obstacles to recruiting in [our catchment area], that covers a very vast and diverse area. There are foreign patients who can’t read English, [and] I’ve got English patients who can’t read and write” (2)

Limited CRN time for study

All but one CRN were assigned to the Cleft Collective study on a part-time basis. Participants discussed the difficulties of fitting their workload into their allotted hours. Participants felt that the limited staffing resource committed by their organisation to the study meant they missed opportunities to recruit families:

“It’s a big study with a lot of recruitment- I don’t always have enough time... I’m not here all the time and there are patients going to theatre on Friday mornings, and I don’t work Fridays.” (2)

“...if I had more time I’d be able to do more, because you could probably then contact parents at home [...] and maybe prep them a little bit more before they come into clinic...” (4)

In the context of CRNs’ limited hours working on the study, some CRNs with more autonomy in how they allocated their time to the study said they had to be flexible in order to reach as many families’ clinics or other hospital appointments as possible, and thus gain opportunities to recruit:

“I have to juggle my hours around, my days around really, to fit in with clinics and op days...” (5)

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“[clinics] do get changed... so I try to be flexible... you kind of fit in with everyone else” (2)

CRNs also commented on the challenge of completing the time-consuming study paperwork typical of large-scale studies within their allocated hours:

“...[clinic] would almost [take up the whole day]. I often stay late [...] making sure all the paperwork and stuff gets done.” (9)

“There is a lot of paperwork, but then that’s par for the course.” (1)

Method of data collection (a)

CRNs observed that families often did not complete data collection forms once they have taken them home:

“...people are quite enthusiastic initially. Sometimes I think they go home and they just shove it in the drawer and forget about it.” (8)

Facilitators of recruitment and data collection

Method of data collection (b)

In response to disappointing return rates of questionnaires from families’ homes, CRNs expressed their preference for taking consent and data completion in person, on site:

“There have been parents who have [completed questionnaires and given saliva samples] there and then, because obviously it’s a lot easier to get them there and then.” (6)

CRNs also suggested using an online questionnaire may facilitate greater data completion:

“...if the questionnaires were online... a unique link where they’d have that option [would result in more participants completing the questionnaires]” (1)

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Integrating research into clinical practice

Many CRNs spoke of the importance of the specialist cleft teams being actively involved in the recruitment process within their clinical roles, which often related to key clinical staff holding positive attitudes towards research:

“...we’re quite lucky here because all our consultants support [the study], they’re really proactive. I’ve worked with other studies where [the clinical team’s] completely separated, and they don’t engage with you and it makes it difficult to sort things out” (3)

CRNs described the valuable input they received from the clinical team and CNSs in particular, who develop a bond with families at an early stage, and who often inform patients about the study early on in the treatment pathway:

“When [cleft CNSs] have that initial contact and let [families] know [about the study], they are more aware and more open to the idea of participating” (7)

“[Parents] have a good bond with the cleft nurses, so they’ll mention the study and give a good insight of what it’s going to be like.” (12)

CRNs believed that embedding a specific timeslot and dedicated room to discuss the study with families during multidisciplinary clinics would help establish the cohort study as being a part of routine care:

“[At another research site the CRNs] have a room in Outpatients and [the families] get told they’re going to have a session with the research nurse. And I honestly feel if we had that, we would get more recruits [...], if we could be properly integrated into the clinic day” (9)

By physically integrating the study into practice, CRNs gain more face-to-face access to families. CRNs highlighted the importance of meeting families in person and building rapport, which they believed enhanced the likelihood of recruiting:

“I just think the one-to-one in-person contact, it’s so much more, because you build a good rapport. That’s important [to recruitment] I feel.” (7)

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CRNs also thought that the clinical teams' level of integrating the study into practice, and hence recruitment, benefited from their own efforts to engage the clinic team in the study:

"...I've had a few presentations to [the cleft team] about what the Cleft Collective is [...] I went out with the CNS's and saw what their job was a bit more, so I had that interaction..." (11)

Patient information shared with CRNs

CRNs cited the usefulness of having timely access to electronic patient records for the purpose of identifying eligible families:

"...more often than not I look at the computer system and have a look at who's coming in the clinics- we can see them months in advance" (8)

"[The online system is] quite helpful in finding out what appointments [families are] going to [...]. Really good for being able to screen patients and work out numbers and read all their multi-disciplinary records." (11)

Some CRNs talked about timely information-sharing from the clinical team, especially CNSs, as being helpful in planning to meet with patients, also drawing on their specialist expertise:

"I do find it very helpful to have a handover from the nurse specialists so that I have a heads-up about who can or can't be recruited..." (2)

"If I want to know anything about a patient, [the clinical team] are very good at letting me know" (5)

Support from the study team

CRNs mentioned the usefulness of the study-specific training, which was provided by the study team in advance of each site commencing their recruitment:

"Before this [study] even opened we were going to all the meetings [...] All training was done beforehand." (7)

"[The training] wasn't just all diagrams and talking. It was a nice mixture ...you could look back [at the materials] later, so it was really useful." (12)

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All CRNs recalled positive encounters with the study team and appreciated the study team's responsiveness, the provision of regular updates, and practical support to navigate the intricacies of applying the study protocol in practice:

"[The Cleft Collective team] are fantastic- always at the end of the phone and always willing to help... They've provided a solution to anything I've had to be honest." (3)

"I always get [...] updated with any site file changes, any amendments, which is really good from the protocol point of view [...]. On a monthly basis we get [a report with figures] and I have a look at what's mine and what's been sent" (7)

CRNs highlighted the benefit of shared learning across sites from a one-day workshop for recruiters organised by the study team:

"...the follow-up day in [a London hospital] was really useful. Another day like that would be good... because [we're] still finding problems. We'd like to [learn from other teams] to see if there's something we can do differently" (10)

DISCUSSION

This study employed interviews with CRNs to better understand their experiences of recruiting to the Cleft Collective Birth Cohort Study, with particular reference to their perceptions of the facilitators and barriers to recruiting participants. Clinical Research Nurses highlighted a variety of challenges of financial and/or organisation nature that limit the time they are able to dedicate to the study. They highlighted a complex social context and/or physical health complications as making a recruitment approach less likely. Facilitative themes centred around RNs' two-way collaboration with clinical teams in order to gain timely and physical access to potential participants, the effective training by study team, and efforts to facilitate the embedding of the study into routine clinical practice as part of the study protocol, rather than being an entirely separate, additional 'duty' for clinical teams and

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families to complete. Many of these themes apply more broadly to cohort studies and clinical research across specialist health settings internationally.

Challenges

In CL±P as with many other complex conditions, those with comorbid health problems, complex social issues and/or language barriers to receiving care are simultaneously some of the most vulnerable to poor health outcomes and the least well represented in research (Feragen & Stock, 2014; Gill, Plumridge, Khunti & Greenfield, 2012). It is therefore an important goal of research in specialist health services to recruit representative samples of all patients (Fenlon et al., 2013). The Cleft Collective study has highly inclusive eligibility criteria with this goal in mind, yet clearly CRNs felt unable to recruit some of the most vulnerable patients and families. In the case of social and medical complexities, CRNs described discomfort in approaching families whom they considered as overwhelmed by their circumstances. This could be explained by CRNs' heightened awareness of the emotional turmoil families with medical and/or social complexities can face, as the result of their previous clinical nursing experience (many in paediatric care) and strong empathy for such families. The CRNs' views suggest there is a challenging balancing act between ensuring that socially and medically vulnerable patients and their families are represented in research, while also ensuring study protocols and those recruiting to the studies respect such potential participants' need for true informed consent, privacy and dignity (Bagheri et al. 2012; Dickert & Kass 2009; Nurmi et al, 2015).

The issue of achieving truly informed consent was also highlighted by CRNs when discussing language barriers, including those relevant to people from minority population groups. Some research has suggested that people from ethnic minorities choose to participate in research as much as those from majority groups, as long as they are invited to do so in a language they understand (Mason et al., 2003; Wendler et al., 2005). However, while non-English speaking families were eligible for inclusion in the Cleft Collective Cohort Studies, informed consent relied on local NHS resources supplying interpreters to aid CRNs, and this appeared to be limited. Some CRNs also raised concerns about relying on interpreters to accurately represent families' views when translating questionnaires. Clearly pre-translated materials are preferable in longitudinal studies using questionnaires, and in

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addition, this facility also affords participants a greater level of privacy as this can dispense with the need for a translator. The costs associated with pre-prepared translations appropriate for a nationwide study are considerable and it may be more financially feasible to translate questionnaires in localised studies where the numbers of non-English languages may be limited to particular communities (e.g. prevalence of Urdu and Mirpuri speakers in the Born in Bradford cohort study; Raynor et al., 2008).

Clinical Research Nurses expressed frustration about having limited time in which to work on recruitment and administration for the Cleft Collective study. This follows previous qualitative findings that CRNs feel overstretched, working across multiple studies and sites (Fenlon et al., 2013). CRNs expressed concern at not being able to give all patients the opportunity to participate in research because they don't have the time to attend all clinics or families' hospital appointments. As with social, medical and language barriers, this thwarts the NHS Constitution's promise to offer all potentially eligible patients the chance to participate in research. Further, insufficient time to proactively prepare families in advance of data collection in clinic or surgery, as raised by some CRNs, may compromise patients' positive experience of research. There is therefore a need for research funders and organisations covering research support costs to ensure that local sites appropriate resources in a way that allows CRNs to access all potential participants and give them the best possible experience of participating in research.

Facilitators

Clinical Research Nurses described a preference for collecting data for the Cleft Collective on site wherever possible (including saliva samples and questionnaires) to maximise the chances of data being returned and to ensure their own availability to answer any questions, while also recognising the need to allow families time, privacy and dignity to complete the participation process. Optimum recruitment strategies will vary according to the needs of the target population and the structure of local clinics as well as the research methodology employed (Newington & Metcalfe, 2014). Wherever possible, though, and without compromising participants' experience, the RNs' view that immediate data collection aids return rates is likely to be generalisable to research studies in a range of specialist

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health services. The optional use of online questionnaires may also reduce participant burden compared to completing and returning paper copies, as noted by CRNs in this study.

Clinical Research Nurses conveyed the importance of specialist clinical staff and especially CNSs (given their prominent role in the early years of cleft care) introducing the study to families early on, so that the research appears embedded in routine care rather than presenting it as an 'add-on'. RNs also felt the CNSs' strong relationship with families conferred credibility to the study. The research questions underpinning data collection in the Cleft Collective Cohort Studies intentionally represented the questions most often asked by families in the early stages following CL±P diagnosis (also see Petit-Zeman and Cowan, 2013), meaning CNSs could often introduce the study in response to families' questions. This demonstrates the value of research studies being informed by patient experience, and in being introduced at a time and in a way that fits potential participants' naturally-occurring considerations.

Clinical Research Nurses linked stronger integration of research into clinical practice to the attitudes held by clinical teams towards research, and particularly their senior members. This may reflect a sense that the extent to which trusted clinicians take research seriously will, in turn, influence how seriously it's taken by families. Clinicians' views are likely shaped in part by previous experience of being involved in studies as well as their interactions with CRNs in any given study. As some CRNs described, by proactively engaging with clinical teams (and especially CNSs in cleft care), CRNs can help nurture research cultures in clinical teams for the benefit of current and future research studies. Some interview participants also valued the integration of the study into practice by having a dedicated study timeslot in clinics. Importantly, in cohort studies which typically involve participation over many years, sufficient time is needed to explain the ongoing commitments associated with participation. A separate room in which to discuss this and potentially to collect data also offers participants privacy and dignity. A dedicated appointment within clinic would also facilitate the building of rapport with a family, judged by some CRNs to improve the chances of successful recruitment.

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In the context of competing demands from other studies on which they may be working, having advance access to relevant patient information, such as clinic lists and appointment details was described by CRNs as helpful in planning the time necessary to approach participants efficiently. As noted by some CRNs, however, appointments and clinics can be cancelled or rescheduled at short notice, so communication from staff booking appointments/clinics will also be invaluable to ensuring CRN time is productively spent. CNSs and other clinical staff who know patients, their families and their condition well can also help by advising CRNs about families beyond information in patient records, such as their interpersonal styles, personal circumstances and openness to participating in research.

The data also point to the key role played by study teams in supporting the efforts of CRNs to recruit effectively. In this study the study team was described as giving timely, clear answers to CRNs' queries, preventing recruitment opportunities from being lost in doing so, and providing timely study updates including protocol amendments, recruitment figures and PPI feedback to ensure CRNs remain fully informed in their work and feel involved in the study. Participants reported that a study-wide workshop run by the study team was also a very helpful forum in which to discuss best practice with those recruiting at different sites. As a result of these findings the study team ran a second workshop in 2017.

Limitations

As is common in interview studies, the sample of CRNs were self-selecting (Robinson, 2014) and hence may represent those with more time to offer, and/or those more engaged with the study than CRNs who did not participate. Two cleft teams with an CRN recruiting to the study at the time of invitation were not represented, although this only accounts for one sixth of the total number of sites. The interview data were not matched to each CRN's actual recruitment figures, and hence it was not possible to observe any trends between participants' comments and their actual performance. The decision not to make these links was based on differences in the amount of time each recruitment site had been open, differences in recruitment targets between clinics and the variability in the amount of time each CRN had been allocated to this particular study. In relation to the potential generalisability

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of the results to other areas of medicine and different countries, we acknowledge that not all specialist healthcare is centralised to the same degree as UK cleft care. Topics discussed such as the utility of embedding research appointments into full-day MDT clinics may also relate to the fact that these clinics are partly designed to minimise travel for families, given the large distance many travel to reach their region's cleft care hub. However, such travel considerations apply to many people with complex conditions living in rural areas to access specialist services across the globe, and so much of the interview data presented above refers to issues independent of service structure.

Conclusions

This article reports findings from interviews with CRNs recruiting participants to a nationwide cleft birth cohort study, focusing specifically on the factors the CRNs consider influential in determining recruitment success. Emergent themes offer reflections on good practice and specific suggestions of what might be done by research study teams, clinical teams, the organisations in which they operate and CRNs themselves to optimise recruitment rates and data collection, while also working to ensure a good experience for those participating in research. The findings apply to specialist healthcare services beyond cleft care, as many of the themes refer to issues common to both cohort studies and clinical research in specialist healthcare settings.

Relevance to clinical practice

According to the CRNs with whom we spoke, clinical teams and particularly CNSs also play a key role in facilitating recruitment to a birth cohort study. While the structure of clinical teams and the specific role played by CNSs may differ between specialisms, the CRNs' observations hold relevance beyond cleft care in the UK. Making use of specialist-specific knowledge and relationships with patients and their families, clinicians can support recruitment and data collection by sharing pertinent information about potential participants with recruiters, promoting a positive research culture across the team. Clinicians can also make efforts to introduce the study to potential participants as early as possible and allocate space in clinic for CRNs to meet with potential participants.

Word count: 5,696.

REFERENCES

- Bagheri, H., Yaghmaei, F., Ashktorab, T., & Zayeri, F. (2012). Patient dignity and its related factors in heart failure patients. *Nursing ethics*, 19(3), 316-327.
- Baron, J., Hirani, S., & Newman, S. (2016). Challenges in patient recruitment, implementation, and fidelity in a mobile telehealth study. *Telemedicine and e-Health*, 22(5), 400-409.
- Berkowitz, S. (2013), *Cleft Lip and Palate: Diagnosis and Management*, 3rd ed. Springer Heidelberg: New York.
- Borschmann, R., Patterson, S., Poovendran, D., Wilson, D., & Weaver, T. (2014). Influences on recruitment to randomised controlled trials in mental health settings in England: a national cross-sectional survey of researchers working for the Mental Health Research Network. *BMC medical research methodology*, 14(1), 23.
- Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative research in psychology*, 3(2), 77-101.
- Clayton, D., & McKeigue, P. M. (2001). Epidemiological methods for studying genes and environmental factors in complex diseases. *The Lancet*, 358(9290), 1356-1360.
- Department of Health. The NHS Constitution for England. 2015.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/480482/NHS_Constitution_WEB.pdf. Accessed 18 July 2017.
- Dickert, N. W., & Kass, N. E. (2009). Understanding respect: learning from patients. *Journal of medical ethics*, 35(7), 419-423.
- Fenlon, D., Seymour, K. C., Okamoto, I., Winter, J., Richardson, A., Addington-Hall, J., ... & Foster, C. (2013). Lessons learnt recruiting to a multi-site UK cohort study to explore recovery of health and well-being after colorectal cancer (CREW study). *BMC Medical Research Methodology*, 13(1), 153.

RESEARCH NURSES IN COHORT STUDIES

Feragen, K. B., & Stock, N. M. (2014). When there is more than a cleft: psychological adjustment when a cleft is associated with an additional condition. *The Cleft Palate-Craniofacial Journal*, *51*(1), 5-14.

French, C., & Stavropoulou, C. (2016). Specialist nurses' perceptions of inviting patients to participate in clinical research studies: a qualitative descriptive study of barriers and facilitators. *BMC medical research methodology*, *16*(1), 96.

Gill, P. S., Plumridge, G., Khunti, K., & Greenfield, S. (2012). Under-representation of minority ethnic groups in cardiovascular research: a semi-structured interview study. *Family Practice*, *30*(2), 233-241.

Health Research Authority. Research requiring NHS review but not ethical review, 2017.

<http://www.hra.nhs.uk/resources/before-you-apply/research-requiring-nhs-rd-review-but-not-ethical-review/>. Accessed 18 July 2017.

Manolio, T. A. (2009). Cohort studies and the genetics of complex disease. *Nature genetics*, *41*(1), 5-6.

Mason, S., Hussain-Gambles, M., Leese, B., Atkin, K., & Brown, J. (2003). Representation of South Asian people in randomised clinical trials: analysis of trials' data. *Bmj*, *326*(7401), 1244-1245.

Mossey, P. A., Little, J., Munger, R. G., Dixon, M. J., & Shaw, W. C. (2009). Cleft lip and palate. *The Lancet*, *374*(9703), 1773-1785.

Newington, L., & Metcalfe, A. (2014). Factors influencing recruitment to research: qualitative study of the experiences and perceptions of research teams. *BMC medical research methodology*, *14*(1), 10.

NHS England. Service Specification for Cystic Fibrosis (Children) (2015).

<https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/01/a01-spec-cystic-fibrosis-child.pdf>. Accessed 10 July 2017.

RESEARCH NURSES IN COHORT STUDIES

Nurmi, S. M., Pietilä, A. M., Kangasniemi, M., & Halkoaho, A. (2015). Nurse leaders' perceptions of the ethical recruitment of study subjects in clinical research. *Journal of nursing management*, 23(8), 1020-1028.

Patton, M.Q. 1990: Qualitative evaluation and research methods, second edition. Sage.

Peters-Lawrence M.H., Bell M.C., Hsu L.L. et al. (2012) Clinical trial implementation and recruitment: lessons learned from the early closure of a randomized clinical trial. *Contemporary Clinical Trials* 33, 291–297.

Petit-Zeman, S., & Cowan, K. (2013). Patients/carers and clinicians can set joint priorities for research in cleft lip and palate. *Journal of Paediatric Otorhinolaryngology*, 77(3), 309-10.

Raynor, P. (2008). Born in Bradford, a cohort study of babies born in Bradford, and their parents: protocol for the recruitment phase. *BMC Public Health*, 8(1), 327.

Reynolds L.C., Crapnell T., Zarem C. et al. (2013) Nursing perceptions of clinical research in the neonatal intensive care unit. *Newborn and Infant Nursing Reviews* 13, 62–66.

Robinson, O. C. (2014). Sampling in interview-based qualitative research: A theoretical and practical guide. *Qualitative Research in Psychology*, 11(1), 25-41.

Sandy, J., Williams, A., Mildinhall, S., Murphy, T., Bearn, D., Shaw, B., ... & Murray, J. (1998). The Clinical Standards Advisory Group (CSAG) cleft lip and palate study. *Journal of Orthodontics*, 25(1), 21-30.

Scott, J. K., Leary, S. D., Ness, A. R., Sandy, J. R., Persson, M., Kilpatrick, N., & Waylen, A. E. (2014). Centralization of services for children born with orofacial clefts in the United Kingdom: a cross-sectional survey. *The Cleft Palate-Craniofacial Journal*, 51(5), e102-e109.

Spilsbury, K., Petherick, E., Cullum, N., Nelson, A., Nixon, J. and Mason, S. (2007). The role and potential contribution of clinical research nurses to clinical trials. *Journal of Clinical Nursing*, 17, pp. 549-557.

RESEARCH NURSES IN COHORT STUDIES

Stock, N. M., Humphries, K., Pourcain, B. S., Bailey, M., Persson, M., Ho, K. M., ... & Sandy, J. (2016). Opportunities and challenges in establishing a cohort study: an example from cleft lip/palate research in the United Kingdom. *The Cleft Palate-Craniofacial Journal*, 53(3), 317-325.

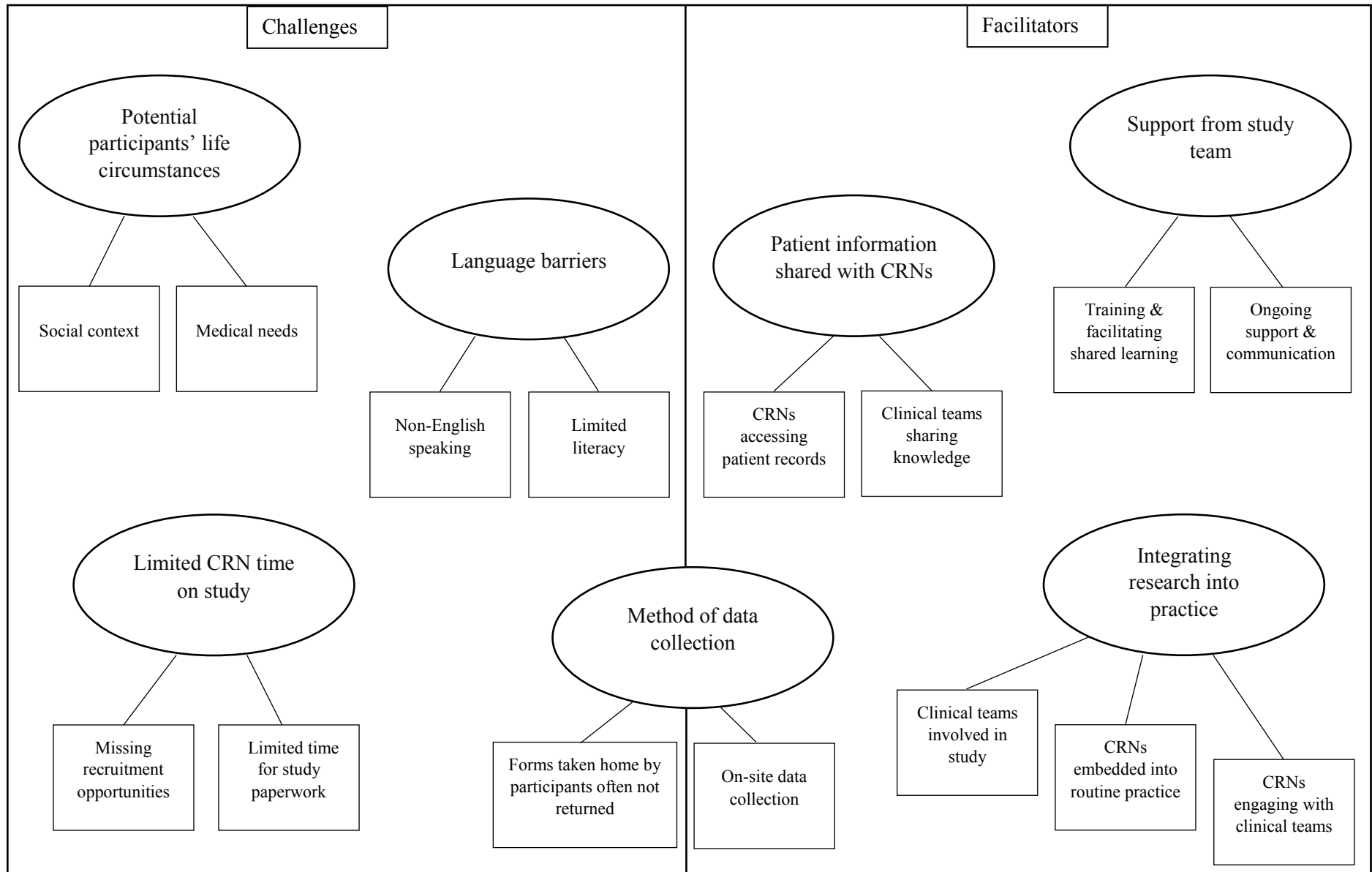
Wendler, D., Kington, R., Madans, J., Van Wye, G., Christ-Schmidt, H., Pratt, L. A., ... & Emanuel, E. (2005). Are racial and ethnic minorities less willing to participate in health research?. *PLoS medicine*, 3(2), e19.

Table 1. Characteristics of CRN participants.

Participant no.	Research site	Length of time worked on study (months)	Length of time as CRN (months)	Time allocated to study (days per week)	Clinical nursing background
1	1	18	30	1	Paediatrics
2	2	18	60	1	Paediatrics
3	3	5	6	1	Neonatal care
4	4	6	12	1	Paediatrics
5	5	24	24	1	Cleft care
6	1	3	18	1	Paediatrics
7	6	30	48	5	Paediatrics
8	7	14	72	1.5	Paediatrics
9	3	24	54	1	Neonatal care
10	8	36	24	2	Cleft care
11	9	1.5	2	3	PICU
12	10	2	12	1.5	General medicine

Figure 1. Thematic map of interview data.

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Table 2. Definitions of themes

	<i>Theme</i>	
<i>Challenges</i>	Potential participants' life circumstances	An expressed concern that families with complex social and/or medical issues lack emotional and/or physical capacity to participate in research. This led to CRNs being reluctant to approach such families.
	Language barriers	Difficulties in gaining informed consent from non-English speaking parents and families with limited literacy. CRNs also voiced an ethical stance that only true informed consent should be sought.
	Limited CRN time on study	Frustration that working part-time on the study (2 days per week on average) prevent CRNs from utilising all recruitment opportunities (e.g. attending all clinics), and that they often need to work beyond their allocated hours to complete study paperwork.
<i>Facilitators</i>	Patient information shared with CRNs	CRNs being given pertinent patient information to facilitate approaching and recruiting families, mainly via electronic patient record systems and direct information-sharing from cleft health professionals.
	Support from study team	The study team providing ongoing support by responding to CRNs' queries quickly and giving nationwide study updates. Study teams providing adequate training to CRNs prior to site initiation, and facilitating shared learning across sites via nationwide workshops.
	Integrating research into practice	Making the study part of routine clinical practice, helped by: the clinical team being actively involved in promoting and recruiting for the study; the study being factored into clinic timetables; and CRNs promoting the study to clinical teams.
<i>Challenge / Facilitator</i>	Method of data collection	An expressed preference for collecting data on hospital site to ensure it is completed, and frustration with parents taking data collection packs home and not returning them. Suggestion of electronic questionnaires as an alternative.