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Identification of the ideal recruitment situation in pandemic research: learning from the RECOVERY trial in Northern England: a qualitative study

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ABSTRACT

Background In early 2020, little was known about treatments for COVID-19. The UK responded by initiating a call for research, leading to the formation of the National Institute for Health Research (NIHR) Urgent Public Health (UPH) group. Fast-track approvals were initiated and support was offered to research sites via the NIHR. The Randomised Evaluation of COVID-19 Therapy (RECOVERY) trial was designated UPH. High recruitment rates were required for timely results. Recruitment rates were inconsistent across different hospitals and places.

Purpose The Factors Affecting Recruitment to the RECOVERY trial study was designed to seek out the facilitators and barriers to recruitment across a population of 3 million served by eight different hospitals and suggest recommendations for recruitment to UPH research during a pandemic situation.

Methods A qualitative grounded theory study using situational analysis was used. This included a contextualisation of each recruitment site containing prepandemic operational status, prior research activity, COVID-19 admission rates and UPH activity. Additionally, one-to-one interviews using topic guides were completed with NHS staff involved in the RECOVERY trial. Analysis sought out the narratives that shaped recruitment activity.

Results An ideal recruitment situation was identified. The closer sites were able to move towards that ideal situation, the easier they found it to implement the most significant factor on recruitment: embedding research recruitment into standard care. The ability to move to the ideal recruitment situation was mediated by five significant elements: uncertainty, prioritisation, leadership, engagement and communication.

Conclusion Embedding recruitment into routine clinical care was the most influential factor on recruitment to the RECOVERY trial. To enable this, sites needed to attain the ideal recruitment situation. Prior research activity, size of site and regulator grading did not correlate with high recruitment rates. Research should be at the forefront of prioritisation during future pandemics.

INTRODUCTION

When COVID-19 appeared in the UK in early 2020, there was little information about effective treatments.^{1,2} Treatments had been suggested, but there were no data to confirm or refute if these aided recovery above standard care.³ Responding to this exceptional situation, the Department of Health and Social Care commissioned the National Institute for Health Research (NIHR) to set up an

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ At the outset of the COVID-19 pandemic, there were no evidence-based treatments.

WHAT THIS STUDY ADDS

⇒ Embedding research recruitment into standard care was the most influential factor on recruitment rates.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Research should be prioritised and resourced during a pandemic.

Urgent Public Health (UPH) group which reviewed studies that were submitted via a UK-wide portal. Projects considered most urgent and likely to deliver timely results were prioritised on behalf of the chief medical officer, designated UPH studies⁴ and supported by NIHR Local Clinical Research Networks. Once prioritised, studies became eligible for expedited review through the UK regulatory authorities, the Health Research Authority (HRA) and the Medicine for Health Regulatory Authority. United Kingdom Research and Innovation (UKRI) and the NIHR cofunded rapid research to support investigations into COVID-19.⁵

The Randomised Evaluation of COVID-19 Therapy (RECOVERY) trial was funded and approved prior to setting up the UPH group. It became the first key UPH study. It aimed to identify treatments for those hospitalised with suspected or confirmed COVID-19.³ It was funded by grants and donations from numerous sources including UKRI, NIHR and Wellcome, sponsored by the University of Oxford and approved on 11 March 2020.⁴ Prior to COVID-19, national trial set-up averaged 80 days. With the expedited systems, the RECOVERY trial completed set-up in 9 days.⁶ Imperative to timely results was rapid recruitment. To aid sites, trial procedures were reduced and streamlined. The regulatory authorities agreed that principal investigators and site research staff could complete short online study training, waiving the requirement to complete Good Clinical Practice certification. Eligibility criteria were rationalised. Enrolment and randomisation were completed online, with informed consent processes simplified. Follow-up was at a single time point and achievable via several routes. The platform design of the trial enabled multiple iterations of the protocol to be produced to keep pace with the fast-changing landscape of



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the pandemic. The initial four treatment arms each required a minimum of 2000 participants for robust findings. A recruitment rate of 1000 patients a week would lead to results in 5–7 weeks.⁷ By May 2020, the national recruitment rate was 13% of all COVID-19 admissions. By 14 January 2021, RECOVERY recruited over 28 000 patients with COVID-19 from 176 hospitals in the UK.⁸ In the Local Clinical Research Network (LCRN) area of the North East North Cumbria (NENC), recruitment rates varied from 7% to 51%, with a mean of 17%.⁹ It was this variance, the desire for high participant numbers and the aspiration to offer a research opportunity across the NENC that acted as the catalysts for the Factors Affecting Recruitment (FAR) study. The study was set up in the Local Clinical Research Network, North East and North Cumbria in September 2020, starting with a pilot across two Trusts with a view to using learning from earlier experiences of recruitment in the pandemic to positively influence recruitment in later waves (online supplemental information S1, FAR study protocol).

While regard was paid to the operational pressures that organisations were under, stronger recruitment rates were highlighted as important.⁷ Communications from the UK chief medical officers, NHS England and NHS Improvement emphasised that every eligible patient should be approached to enter a trial.^{10 11} In June 2020, the first major finding of the RECOVERY trial was announced,¹² identifying that dexamethasone reduced deaths by up to one-third in hospitalised patients with severe respiratory complications. The use of this drug became UK national policy within 4 hours of the announcement.¹³ As admission numbers increased during the second wave, there were further opportunities to recruit patients to support the rapid assessment of potential therapies.¹⁴ While it was acknowledged that delivery teams were affected by reduced numbers of staff, the need to recruit was highlighted with the RECOVERY trial being given the highest priority. From 14 December 2020, LCRNs were given a target to recruit 10% or more of COVID-19 admissions in their region to RECOVERY, with the ambition of 20%.¹⁴

In January 2021, the FAR study interim report was presented to the LCRN partnership group. With their agreement, the pilot was expanded to include all Trusts in the LCRN area. The objectives were to identify the facilitators and barriers to recruitment and offer recommendations for recruitment to UPH during a pandemic situation. Between April 2020 and March 2021, the national recruitment rate to the RECOVERY trial was 9% of all COVID-19 admissions. The LCRN region had an average recruitment rate across all sites of 15%, the highest in England.

The RECOVERY trial has gone on to be the biggest randomised clinical trial of COVID-19 treatments. It is internationally based with over 47 000 participants and 199 active sites.¹⁵

This paper presents the work of the FAR study and identifies the ideal recruitment situation in a pandemic. We currently know of no other empirical research that has explored the factors that influenced recruitment to clinical research during the COVID-19 pandemic. Recommendations are made to inform future work within healthcare systems should a similar situation arise.

METHODS

Theoretical framework

Grounded theory with situational analysis was used. Situational analysis, through analytical mapping, reveals the social processes and relationships within the area of inquiry.¹⁶ It was chosen to take into account both the human and non-human influences, identifying the prevailing dialogues that shaped recruitment to the RECOVERY trial. Situational analysis uncovered the

discourses that supported or silenced research recruitment, and explored their impact. This included information about each site from public sources, the COVID-19 daily situation report and the open data platform managed by NIHR. Recruitment at each site was set within a wider contextual picture including a pre-pandemic review of operational and research status. This backgrounding formed the initial stages in seeking out the factors that influenced recruitment. This information was used to generate the topic guides for the qualitative interviews and formed part of the analysis.

The authors have experience of situational analysis and qualitative methods (DC), NHS research management (SD), research and development (R&D) leadership and clinical trials investigation (CW) and quality improvement (CW and JS). This range of skills and backgrounds allowed a reflective group to focus on identifying the elements that proved conclusive in their influence. The methods are reported in accordance with the Consolidated Criteria for Reporting Qualitative Research guidelines.¹⁷ There was no prior patient or public involvement as the project focused on NHS employees. The project was reviewed by the hosting organisation's R&D department. It was deemed as service improvement and not requiring HRA approval. The project was registered on the clinical effectiveness register. Permission to approach staff was given by each site.

Sampling and recruitment

Purposive sampling¹⁸ was used to identify staff best placed to explore recruitment, interviewing a cross section of staff at each site. There were broad inclusion criteria, namely, NHS-employed individuals directly or indirectly involved in the set-up and running of the RECOVERY trial. In the initial pilot phase, we interviewed a range of individuals from differing roles. Directors were included to enable exploration at a strategic level and an understanding of the main issues within a site. Principal investigators and research nurses were invited to examine the recruitment processes, with managers and administrators able to give an insight into operational systems and levels of support.

Post the pilot phase, we focused recruitment on those who were best placed to converse about recruitment. These were R&D managers, principal investigators and research nurses.

Details of the interviewees are shown in [table 1](#).

Recruitment was facilitated by site R&D departments. Eligible staff were identified and given information about the study (Participant information sheet, online supplemental information S2). All participants gave verbal or written consent. Recruitment began in September 2020 and coincided with the rise in COVID-19 cases. Due to the local impact of COVID-19, recruitment was suspended in January–February 2021, then restarted and completed in March 2021. All eligible acute medical secondary care trusts in the region participated in the study.

Table 1 Description of Interviewees

| Role/job title | Interviewees (n) |
|---|------------------|
| Director level | 7 |
| Principal or associate principal investigator | 5 |
| Research nurse | 3 |
| Research and development manager | 3 |
| Administrator | 1 |
| Total interviewees | 19 |

There are 15 NIHR LCRNs across England. They support patient, public and organisations to participate in and deliver high quality research. The NENC area covers a population of 3 million serving both urban and rural population, with areas of high level deprivation and rising health inequalities exacerbated by COVID-19.

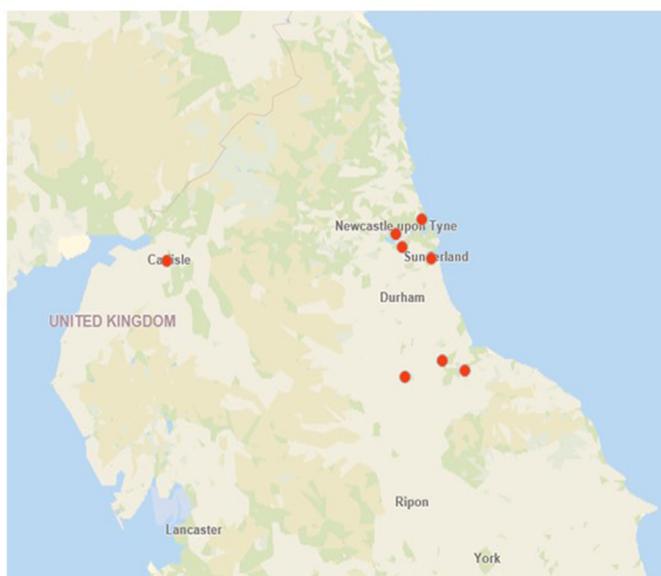
There were eight sites recruiting to the RECOVERY trial in the NENC area. They ranged from District General Hospitals to regional trauma and referral centres.

Two of the organisations had been the result of recent mergers. The smallest served a population of approximately 200,000 with the largest up to 3 million as a referral centre.

The most recent regulator gradings (UK Care Quality Commission) indicated 2 sites required improvement, 4 were good and 2 outstanding. All sites had identified similar risks in their recent annual reports: staff recruitment and retention, increasing demand and financial pressures.

Staff sickness rates pre-pandemic were reported as between 4.5-5%.

Previous research activity indicated 1 large active site with the remaining 7 recruiting an average of 16-22 participants per study opened.



Map of NENC region showing all Acute NHS Hospital Trusts

Figure 1 Geography and contextualisation. LCRN, Local Clinical Research Network; NENC, North East North Cumbria; NIHR, National Institute for Health Research; RECOVERY, Randomised Evaluation of COVID-19 Therapy.

Data collection and analysis

Topic guides were developed for the semistructured interviews and revised in line with the findings. The topic guides can be found in online supplemental informations S3, S4. All interviews were audio recorded using a video-conferencing platform, transcribed and anonymised, and salient concepts and ideas were coded.

Data analysis continued alongside data collection. DC read and coded all the interviews with salient concepts and ideas. These were shared among the wider team (CW and SD). The team's wider experience and differing roles enabled discussion and reflection on initial thoughts. At the end of the pilot phase, the interim analysis was shared with members of the RECOVERY trial team, lead LCRN and NIHR. Feedback from these meetings enabled the initial findings to undergo a period of confirmation and refutation, aiding the overall credibility of the findings.

RESULTS

The geography and main findings from the contextualisation of the sites are illustrated in [figure 1](#).

Nine interviews were completed during the pilot phase, and 10 were completed in the follow-up phase. All participating sites had staff interviewed for the study. The interviews ranged from 22 min to 61 min (mean 31 min). The interviews took the form of a conversation with open questions and extension questions where further information or clarification was required. Interviews were reflective in nature with participants looking back across the time of the pandemic.

Ideal recruitment situation

Analysis of the interviews produced a description of the ideal recruitment situation. The more elements of the ideal recruitment situation that sites were able to exhibit, the more likely they were to operationalise the most influential factor on recruitment: *embed research recruitment into standard care*. [Table 2](#) describes the five requirements of the ideal recruitment situation.

A strong and focused understanding that systematic research was required led to its resourcing. Leaders emerged and drove the process. This resulted in teams of staff working to their strengths, using wide-ranging communication routes. Where this was in place research recruitment became embedded into routine clinical care, resulting in high recruitment numbers.

Further analysis, in conjunction with the wider contextual findings, revealed the following factors that influenced the ability of a site to move to the ideal recruitment situation.

Uncertainty and prioritisation

All sites prioritised safe, effective patient care and staff safety. Prioritisation was influenced by uncertainty, uncertainty being centred on conflicting advice, procurement issues, available beds and the unknown time span of the initial pandemic wave. Uncertainty was intensified by events in Italy, increasing admission numbers, the impact of staff sickness and isolation, and the lack of known effective treatments. To prioritise within uncertainty, sites entered into mitigating actions. At some sites, this included the major redeployment of R&D staff. This removed R&D as a resource, reducing influence and power. The outcome was an

Table 2 Ideal recruitment situation

| Element number | Description |
|----------------|---|
| 1. | An understanding and engagement with the view that systematic research into COVID-19 was the only effective way to progress towards treatments |
| 2. | The ability to resource research |
| 3. | Leadership to drive the needed understanding, resourcing and systems |
| 4. | Teams of motivated, committed medical and research and development staff working to their strengths |
| 5. | Strong systems to enable those teams to work to their full potential and receive support when required, coupled with an inclusive communications strategy |

inability to move towards the ideal recruitment situation due to a lack of drive for UPH research, an inability to form teams with the required skill mix and a failure to reprioritise. This scenario inhibited the set-up of systems and processes to embed research into standard care (see supporting quotes in [box 1](#)).

Leadership

A further factor that influenced the ideal recruitment situation was leadership. Initially, leaders were senior medical staff; some were the principal investigators of the RECOVERY trial. These individuals had a strong grasp of the aetiology of the disease and/or research processes. They were able to influence prioritisation at a senior level during the time of uncertainty. They were transformational and collaborative and, above all, visible and active on the ground. Additional leaders emerged through the course of the pandemic. The result of effective leadership was a groundswell of interest, increased engagement and the formation of multiskilled teams with strong systems and processes. They drove the vision to embed recruitment (see supporting quotes in [box 1](#)).

Engagement

To move towards the ideal recruitment situation and establish recruitment in standard care, it was imperative that medical staff, who would not normally be involved in research, became engaged. Initially, non-engagement was identified where research was viewed as ‘something done by others’. The inhibitors to engagement were perceived as excessive workload, fear of catching COVID-19, lack of direct request and inaction. The outcome of non-engagement was an imbalance in team make-up, an individualistic approach and inefficiency. The engagement of medical staff with consenting participants enabled R&D staff, in particular research nurses, to support all other activities.

Enhanced engagement was seen where there were visible leaders, where research had been resourced, and where strong systems and processes had been put in place. The outcome of engagement was efficient teams, who routinely approached patients with recruitment in mind (see supporting quotes in [box 2](#)).

Communication

The final influencing factor was communication. Communication channels were both formal and informal. The most spoken-about method of communication was WhatsApp groups. These were internal to the site and also across sites. They had a feel of being grade/job-specific and at times excluded those not within the grade or job. There were also ‘daily huddles’ where teams were able to review the situation and plan actions. On a wider level, some sites used their Twitter feeds and online newsletter systems. These were used to update and engage staff with the progress of research studies and highlight ‘good’ news. Communication also covered the daily government briefings where interviewees talked about the rising profile of research, both within sites and at a national level. However, there was very limited evidence to suggest the national communication impacted on public awareness and drive to access UPH studies. The main news that appears to have had a positive effect was from the RECOVERY team about treatments. This acted as a validation of the study and the sacrifices individuals were making. For some staff, the outcome of these streams of communication was increased engagement, feelings of self-worth and pride (see supporting quotes in [box 3](#)).

Box 1 Supporting quotes for uncertainty, prioritisation and leadership

Uncertainty and prioritisation

I think the biggest challenge, was the uncertainty, no-one really knew what we were going into, we just don't know how bad things are going to get, we had vision of intensive care being overrun and hospitals being saturated and not being able to cope, so I think there was panic right at the top, in terms of how do we plan for this. P2

At that point [(outset of pandemic)], we were not sure whether we were going to be completely overwhelmed, or whether it was something we were going to be able to cope with...the difficulty we had was just not knowing how big it was going to be the other thing that we found really challenging was the conflict in advice we were receiving into the trust the infection prevention stuff...we also had issues around accessing PPE we were uncertain about whether we could get hold of critical equipment for critical care...[(Priority)] changed in a number of ways, first of all this was a group of [(Research delivery)] staff that we could use clinically, so some of them did get re-deployed. P4

Everybody was absolutely terrified, or just totally didn't know what to do
[(Talking about impact of redeployment)] ... it was very disruptive, and some of their hours were still in research so they were going on the wards and may be coming back for a day, day and half a week, back into research. P15

In the first wave there was a very key prioritisation of COVID-19 research over everything else, we certainly found a lot of people research nurses, some doctors who had been involved in other research, suddenly available to help with COVID-19 studies and urgent public health ones. At the beginning it was very uncertain, it was very hard to get research nurses anywhere near a patient, let alone in the same room as them, it took a long time to persuade the managers to let them, the research nurses, to actually go into a room and give the information sheet to a patient with COVID-19, which they do much more now, but there are still notable exceptions, people won't go into a room or [(are)] very wary. P16

In the early days, quite a lot of staff were redeployed, we did identify staff who wouldn't be redeployed who would support RECOVERY, but I think we just didn't envisage the workload involved in RECOVERY, it soon became clear that we had to get those staff who were redeployed back. P10

We were much more protective of research in wave two than we were in wave one. P19

Leadership

That takes us to an important point about leadership and communication, I think in hindsight there were probably failings on both counts, I can think of some justification as to why that might happen, and the uncertainty is probably the biggest reasons behind this, because research or RECOVERY, research in general around COVID-19 and RECOVERY trial in particular were not seen high enough on the priority ladder at that point by the trust management. P2

The fundamental issue with RECOVERY was the junior doctors were so busy that adding this in, was just that one thing too many, we realised quickly that it needed research nurse and data manager support, so that the consultant or the junior doctor was just literally speaking to the patient, consenting, doing what they

Continued

Box 1 Continued

needed to do and then the research nurse and the data manager would pick up the baton and run with it. P5

[(talking about a local leader)]...[(they)] have had to be very resilient, and got very thick skinned to walk onto a different hospital ward where nobody knows you, you are not necessarily getting the support of your colleagues as you are seen as stepping on people's toes, but [(they)] had the right knowledge and was very much the best person to do the job at the time, but I think without [(them)] the study would not have been as successful as it has been. P10

We planned recruitment based on the fact that there was an acceptance from everyone that this disease, there was no treatment, there was lots of possibilities of treatments but we don't know, therefore putting the patient into the RECOVERY trial was the correct thing to do for their benefit, so there was an acceptance at the medical directorate level, medical director, chief executive, effectively that we as a service see participation in RECOVERY as a standard aspect of any individuals clinical care. P7

Those sites that positively addressed the five factors recruited at a higher rate than those who were unable to. In successful sites, the discourse was to recruit as many participants as possible, which became the driving force. This itself created an energy with a power to produce systems which embedded recruitment. Where recruitment stalled, the driving force and energy to embed were missing. This was due to one of more of the five factors acting as an inhibitor or brake. The five factors (*uncertainty, prioritisation, leadership, engagement and communication*) were the primary influences on the ability of sites to attain the ideal recruitment situation. Once these were in place, recruitment to the RECOVERY trial became embedded in routine clinical care. This then became the norm with staff themselves identifying strategies to enhance the processes and systems in place.

Ongoing contextualisation revealed the supporting work of the LCRN. Each site had a senior manager single point of contact who, at the height of the pandemic, made weekly contact with site R&D leadership. These meetings communicated national updates, discussed local challenges and identified national and local resources that could be redeployed to support activity. These included funding a weekend working pilot and launching an associate principal investigator scheme to aid the identification of additional leaders. Local staff were also redeployed into regional organisations to facilitate research activity. In response to feedback received from sites, the local management team delivered bespoke learning packages to aid research training, including a bitesize piece about taking consent in personal protective equipment. By 1 July 2021, this has been accessed by 2255 people.

During the summer of 2020, admission rates dropped and sites were able to enter a period of reflection and reprioritisation; this included the repatriation of R&D staff and the commitment not to redeploy in further waves. As admissions started to rise from September 2020 onwards, sites were able to draw on their experiences of the first wave. Those who had attained the ideal recruitment situation instigated their systems again; others added in additional measures to move them nearer the ideal recruitment situation. These were primarily in the form of improved systems and processes. One site, with the aid of

Box 2 Supporting quotes for engagement

Engagement

Trying to engage some of our colleagues to get active in research has been a challenge because they see it as an additional burden on top of their clinical work,

[What changed?]. . . The RECOVERY trial was literally embedded in the standard activity, we publicised this in a number of ways, having regular directorate meetings, email contacts with all our medical staff and in our COVID areas display boards at a trust level, luckily they did not withdraw the research nurses back into clinical care, so it meant that we had a research team that could support the clinical team it was that combination of literally this is the right thing to offer the patients. P7

I was having this conversation with another physician in a corridor saying we could do more to recruit people into the RECOVERY trial and [their] question was, how can you think about RECOVERY trial when we are really stretched off our feet, the consultant workforce is depleting, we are in unimaginable stressful condition RECOVERY isn't the top of my priority list, I'm really sorry to have to say this, but I just can't. And at that point I thought OK, I'm not going to push you on that. If somebody like the Chief Executive or the Medical Director sends out an email to everyone, saying this is very important I urge everyone to contribute as much as they can, because for the NHS for our trust this is absolutely critical it might just make people who are sitting on the fence change their attitude. P2

We've had a lot of doctors who have turned round and you know, it's not my responsibility, I don't get involved in research, we've had cases where the PI would argue why can't the junior doctors be more involved in this and a senior consultant say no, it's not their responsibility they shouldn't have to deal with this. P10

We don't feel the trust sees research as important, I mean yes, they protected us in the second wave because they said the research was important, but we had to fight for it, I'm sure we would have recruited more if the medics had been on board, I mean they weren't even telling them [the patients] about it the first time a patient would hear about it was when we [Research nurse] turned up. P14

The ethos of our trust is that they do not promote research. It's not on the agenda, that is the biggest barrier. It was there pre-COVID, will probably be there post-COVID and was certainly there throughout.

[What could have improved engagement] . . . a statement coming out from the trust board, we did have many discussions with our medical director and [they] did send some WhatsApp's for me, and some emails for me and things like that, but it was more can you help out, it was not a directive. It's making those decisions at a level, are we going to get on board with research? We were just in the middle doing a bit of a balancing act really. I thought why would you not get onboard with a study when you have got no treatments to offer people, I could not understand why clinicians would not get onboard with that. P15

The main barrier [to getting key personnel involved] to that was general business, fatigue etcetera, I think they just felt overwhelmed at the time and asking them to do another thing was really just beyond quite a lot of them. . . If I was planning to do it all again, I think I would be more proactive in terms of trying to establish a responsibility for this type of research being part of the acute service, in other words if you are an acute

Continued

Box 2 Continued

medicine consult or acute medicine registrar involved in that side of things, it's made pretty clear it is not a choice you take part in research, it is an obligation, because I think we would have got more people into the trial if that had been the case, if it had been a core part of peoples activity. P16

additional local funding, employed two clinical research fellows. Two sites significantly improved their recruitment numbers; however, for others, skill mix and the numbers of engaged personnel remained problematic.

Later interviews covered the second wave of the pandemic, where interviewees contrasted recruitment during the first and

Box 3 Supporting quotes for communication

Communication

The communication around it wasn't great, people within R&D were aware, the clinical teams, very few of them were aware.... there should have been even more done from the top by the very top, to each Trust saying research is high priority so I think there were failings at multiple levels...communications from the government maybe should have come out to the wider public, saying that a lot of research is going on, if anyone is admitted to hospital please ask about the trial, or about participating in research'. 'I get hold of every junior doctor I can see and say have you heard about RECOVERY are you interested, I have got RECOVERY on the junior doctors educational teaching timetable so that they are made aware of it and got involved...I would have liked to see that [shared learning from another site] happening on a much wider scale, being facilitated by the network, where people could learn from each other's experiences, so good practice could have been much more widely shared. P2

The newsletter and communications that went out to staff really focus on the success factor associated with the RECOVERY trial, and there was a lot of news about the value of Dexamethasone for example as soon as that was known. P3

One of the positives from the pandemic, if I can call it that, looking back and you know when we were watching the briefings every day and they started saying, you know, research is the key, research is the answer to this issue, you know, Professor Van-Tam and Chris Whitty and everyone kept saying we are moving out of this phase and we are going into a research phase because that is how we are going to solve this and come up with a vaccine people started to really notice that and link COVID with research. P5

We were just seeing in real time value of the work that you were doing, as well seeing it reinforced on some of the Downing Street briefings, they were talking about RECOVERY, dexamethasone, it was out there in the public domain and people were seeing, and you were able to explain too your family well yes that's because of the work we were doing, so you did feel like there was real value in what you were doing. P8

The trial itself was very heavily trailed in the senior medical WhatsApp group, I think we would have really struggled without a WhatsApp group, I've gone back and looked at my WhatsApp for this time last year and yeah heavily heavily trailed, but you know up to 100 messages a day going around that WhatsApp group. P19

Barriers

Fatigue
Restarting of routine clinical work including research studies
Change in investigative products offered by the RECOVERY trial. More knowledge required, increased workload, concern about efficacy and equipoise.
Lack of capacity in pharmacy
Patient decline
Speed of recovery from illness
Eligibility of participants

Facilitators

Familiarisation with process and system
Instigation of improved process and system
Reduced levels of uncertainty
Additional protected research delivery staff
Associate principal investigators
Site to site learning
Additional funding to support extra hours
Changes in site staff

Figure 2 Wave 2 specific influences. RECOVERY, Randomised Evaluation of COVID-19 Therapy.

second waves. This enabled second wave-specific influences to be identified; the most significant factor identified was fatigue, coloured by a sense of frustration. In contrast to the initial interviews, which were upbeat, later interviews conveyed a sense of weariness and at times exasperation. The second wave-specific influences can be seen in [figure 2](#).

DISCUSSION

In March 2021, it was estimated that treatment with dexamethasone had saved 1 million lives worldwide.¹⁹ The major factor that influenced recruitment to the RECOVERY trial was the embedding of recruitment into routine clinical care. This was facilitated by moving towards the ideal recruitment situation, which was affected by the five factors described, and the power they exerted over the actions taken at the site. The interaction of these factors and their associated elements can be seen in [figure 3](#). In addition, in the UK, regional research infrastructures (eg, NIHR LCRN in England) engaged with sites to enable rapid deployment of resource and shared learning.

We know of no other published work that has explored the influential factors on recruitment to clinical research at site level during the COVID-19 pandemic. Works have highlighted the positive role of the national and regional research organisations in enabling urgent pandemic research.²⁰ Additional works²¹⁻²⁴ have praised the methodology and processes of the RECOVERY trial and suggested this shows how research and healthcare can be combined. As a result, in March 2021, placing research at the centre of patient care became UK government policy.²⁵ Our findings support these works. Previous work²⁶ shows a link between clinical trial activity, the number of participants enrolled in interventional research, improved regulator grading and improved mortality rates. Interestingly, we identified that size of site, previous research activity and current regulator (UK Care Quality Commission) grading did not affect recruitment.

Uncertainty and its effects have been widely covered in the recent literature²⁷⁻²⁹ as has leadership³⁰⁻³²; our findings concur with these works. Uncertainty generates anxiety and requires clear, reliable, adaptive communication.³² There were elements of uncertainty in this scenario that could have been controlled. Conflicting advice from central bodies and initial lack of equipment are areas where the impact could have been limited earlier. This would have helped to reduce the confusion and provide a stronger sense of direction. This, in turn, would have facilitated space for longer-term strategic decisions and may have prevented the reactive redeployment of staff. Sites themselves realised that the redeployment of R&D staff was counterproductive and that it should not have been initiated, a move supported by Mourad *et al* and NIHR.^{33 34} We would strongly endorse this stance.

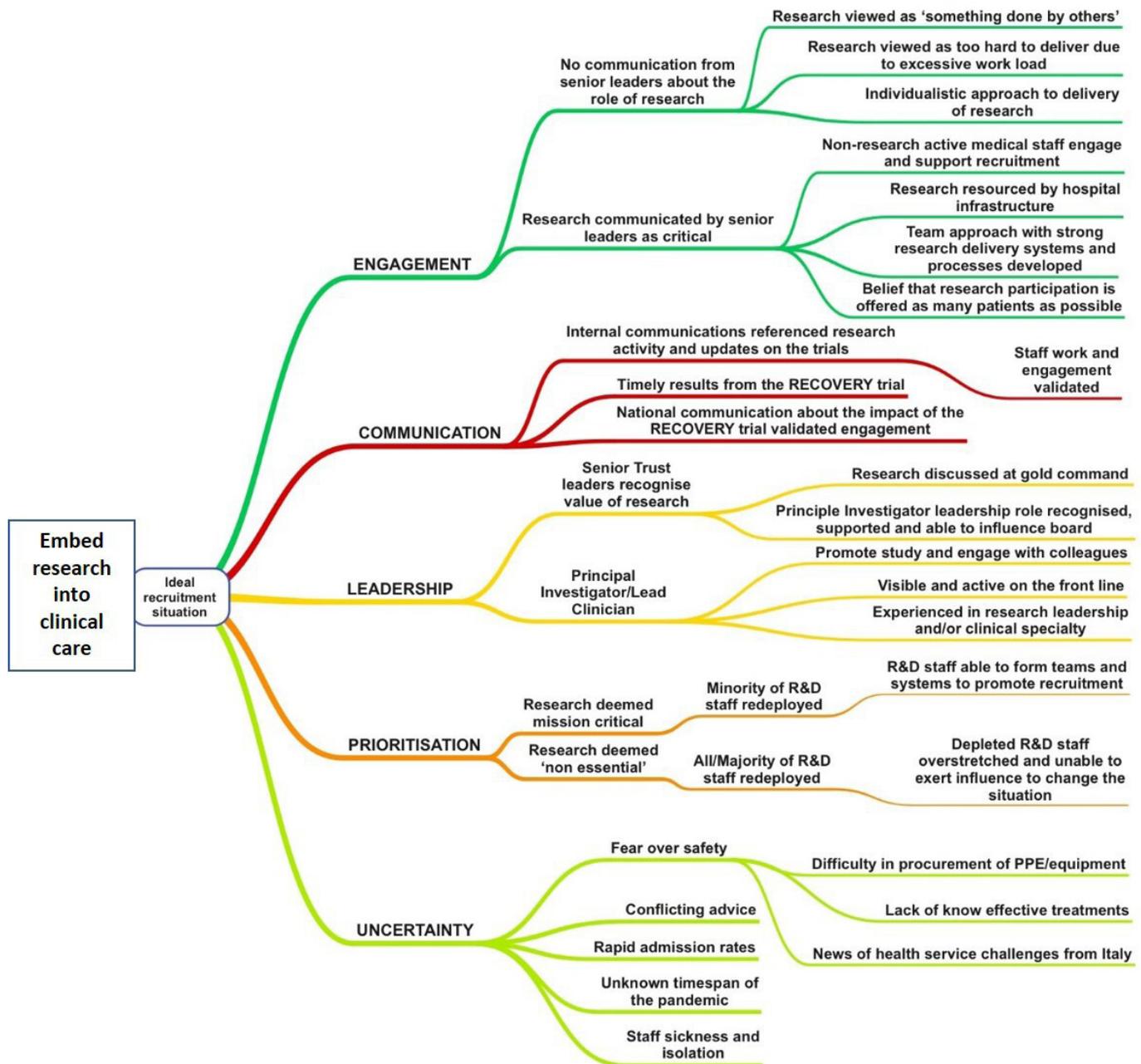


Figure 3 Situational analysis of the interacting factors impacting on recruitment. R&D, research and development; RECOVERY, Randomised Evaluation of COVID-19 Therapy.

Leadership proved pivotal in reaching the ideal recruitment scenario. There is limited knowledge about crisis leadership in this type of situation with most models centring on man-made disasters.³¹ We suggest the most effective leaders were transformational³⁵ in nature, being able to articulate requirements, engage and build teams with appropriate skill mix, and inspiring confidence by their personal example. This leadership style promoted solidarity within a site and therefore increased engagement. These elements should be taken into consideration by sites when facing a pandemic. Our work suggests that in future similar situations, recruitment teams be resourced so that all members can work to their strengths. If sites do not resource in this way, an ineffective, inefficient individualist approach will transpire. Part of the wider leadership role includes the communications strategy; it is known that positive reinforcement

acts as appreciation and affirmation.³¹ We propose that closer regard be paid to the inclusive nature of the internal site-specific communication routes where elements of interprofessional and intraprofessional conflict arose. More transparent real-time communication routes could be facilitated by local research infrastructure clinical and managerial leads, with a focus on problem-solving and sharing solutions locally (and potentially nationally). Sites were innovative in their problem-solving approaches to issues that arose. Real-time sharing of solutions would have aided those sites who had not yet resolved similar issues. Research leaders (eg, LCRNs in England) should proactively seek out recruitment outliers to offer bespoke support and resources.

Interviewees of all grades suggested that more medical staff should have been used in the drive to recruit to RECOVERY. At

sites where medical staff took the responsibility of consenting participants, the recruitment rates were higher. There is evidence at some sites that more medical staff, in particular junior medical staff, became involved in research processes. This successful model was replicated in multiple sites across the UK. However, we believe more could have been done. For example, if research participation had a higher profile in public awareness, then more individuals would have requested participation, resulting in a patient-led drive. There were very limited examples of this, in sharp contrast to the vaccine studies, where numerous individuals volunteered.³⁶ There are also elements of consent that are worthy of further investigation. Interprofessional conflict and differing opinions were illuminated, which focused on who was best placed to obtain consent, the informed nature of the consent, equipoise and the impact these elements may have had on the cohort of RECOVERY participants.

Additional areas that are worthy of further work centre on how the change in investigative products impacted on recruitment and how this could have been mitigated against. Also, the impact of introducing a national 10% recruitment target on sites, how this affected sites below 10% and the methods used for calculating this percentage.

This work has shown the factors that create the ideal recruitment situation during a pandemic situation. It has illustrated the factors that impact on a site's ability to move towards that ideal situation.

The main limitations of this work centre on the number of and role of interviewees. The total number of interviews was limited by the workload of those eligible and the waves of the pandemic in the UK. We would have liked to include more research nurses and trainee doctors; however, despite invites, limited numbers came forward. We feel those interviewed gave insightful comments that enabled strong conclusions to be drawn. We note the findings do not include the views of those medical staff who did not take part in the RECOVERY trial, participants or the relatives of participants.

CONCLUSION

Recruitment was most successful where research was embedded into routine clinical care. Should a similar situation arise in the future, sites should be supported to move towards the ideal recruitment situation described in this paper. To do this, due regard needs to be taken of the influence on sites by uncertainty, prioritisation, leadership, engagement and communication. Prior research activity, size of site and regulator (UK CQC) grading did not correlate with recruitment success, suggesting that all sites have the potential to achieve the ideal recruitment situation during a pandemic. In England, all hospitals are supported to be research active through NIHR, with different mechanisms for this activity in the UK devolved nations. This strength in infrastructure, illustrated by the rapid changes to support research, positively influenced the treatment options and outcomes during the pandemic. It is clear that during the assessment of priorities, research should be at the forefront of resourcing. Multiskilled teams, with a strong transformational leader, of both medical and R&D staff should be formed. Attention needs to be paid to inclusive transparent communications strategies with a strong national message to health organisations and the public.

Contributors DC, CW and SD developed the proposal. DC designed the project, conducted and transcribed the interviews, led the analysis and was lead author of the paper. SD contributed to the conception and design of the project, assisted in the analysis and contributed to the drafting and revision of the paper. JS contributed to the findings of the project, the drafting and revision of the paper. CW contributed

to the conception and design of the project, conducted interviews and assisted in the analysis, and contributed to the drafting and revision of the paper. All authors approved the final version of the paper for submission. DC as the lead author and CW as the chief investigator are the guarantors. They had the final responsibility for the decision to submit for publication and accept full responsibility for the work and conduct of the study. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Competing interests All authors have posts in the Local Clinical Research Network, North East and North Cumbria (LCRN NENC). Time to develop and complete this study was approved by the LCRN NENC executive and partnerships group.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was reviewed by the research and development department of the Newcastle-upon-Tyne Hospitals NHS Foundation Trust. It was deemed as service improvement and not requiring HRA ethical approval. The participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Data are available upon reasonable request from the corresponding author.

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Full study Title: Factors Affecting Recruitment to the RECOVERY study during the COVID-19 Pandemic.

Short study title: Factors Affecting Recruitment: FAR Study.

PROTOCOL VERSION NUMBER AND DATE

Version number 3.0 18.12.20

This protocol has regard for the HRA guidance

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor’s SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature:

.....

Date:

...../...../.....

Name: (please print):

.....

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KEY STUDY CONTACTS

| | |
|---|---|
| Chief Investigator | xxxx |
| Study Co-ordinator/Co-ordinator/Principal Investigator. | xxxx |
| Registered body | Newcastle Upon Tyne Hospitals NHS Foundation Trust. Clinical Effectiveness Register. |
| Funder(s) | National Institute for Health Research North East North Cumbria Clinical Research Network. (NIHR, CRN NENC) |
| Key Protocol Contributors | xxxx |
| Committees | xxxx |

STUDY SUMMARY

| | |
|--|---|
| Study Title | Factors Affecting Recruitment to the RECOVERY study during the COVID-19 Pandemic: A Pilot Study. |
| Internal ref. no. (or short title) | FAR Study |
| Study Design | Qualitative |
| Study Participants | NHS staffs who are or were employed in an organisation that delivering the RECOVERY study during the COVID-19 pandemic in the United Kingdom. |
| Planned Size of Sample (if applicable) | Up to 15 participants at each site. |
| Follow up duration (if applicable) | N/A |
| Planned Study Period | October 2020-February 2020 |
| Research Question/Aim(s) | To explore the factors that affected recruitment to the RECOVERY trial during the COVID-19 pandemic in the United Kingdom. |

FUNDING AND SUPPORT IN KIND

| FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study) | FINANCIAL AND NON FINANCIAL SUPPORT GIVEN |
|--|--|
| NIHR CRN NENC. | Financial support. |

ROLE OF STUDY SPONSOR AND FUNDER

The study does not require a sponsor. It is registered on the Clinical Effectiveness Register of the Newcastle Upon Tyne Hospitals Foundation Trust.

The study funder is National Institute for Health Research Clinical Research Network North East and North Cumbria. They will provide funding to employ a band 7 Project Manager who will act as the Principal Investigator for the study. They will provide funding to cover the summary costs associated with the study.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

The following functions falling under the responsibility of the Chief Investigator (CI).

R&D approval.

Good Clinical Practice (GCP) and study conduct.

Administration of study funding.

The CI will have overall responsibility for the conduct of the study. These responsibilities can be delegated to the Principal Investigator at a local level, they include:

Study conduct and welfare of the participants.

Familiarity with the study processes.

Compliance with the protocol, documentation and reporting any deviations.

Screening and recruitment of participants.

Obtaining local approval and abiding by the policies of Research Governance.

Compliance with Good Clinical Practice (GCP), the Research Governance Framework for Health and Social Care, the General Data Protection Regulations and any other legislation and regulatory guidance.

Ensuring that no participant is recruited into the study until all the relevant regulatory permissions and approvals have been obtained.

Obtaining consent from participants prior to any study specific procedures.

Ensuring staff are appropriately qualified by education, training and experience to undertake the conduct of the study.

Available for meetings in the case of study audit.

Maintaining study documentation and compliance with report requests.

Maintaining site files, including copies of approvals, lists of participants and signed informed consent forms (if used).

Ensuring data collection is accurate, timely and complete.

Providing updates on the progress of the study.

Ensuring participant confidentiality is maintained during the project and archival period.

Ensuring archiving of the study documentation for a minimum of 5 years following the end of the study.

Study Management:

A study management committee will be appointed and will be responsible for overseeing the progress of the investigation. The day-to-day management of the project will be

coordinated by xxxx, Project Manager and Principal Investigator. Members of the study management group are:

xxxx

PROTOCOL CONTRIBUTORS

xxxx: Chief Investigator

Initial conceptualisation of the project. Contributed to the study design and production of study materials. Data collection processes. Qualitative data analysis and dissemination strategy.

xxxx:

Initial conceptualisation of the project. Contributed to the study design and production of study materials. Qualitative data analysis and dissemination strategy.

xxxx:

Author of the protocol. Contributed to the study design and production of the study materials. Conducted the literature review and data collection. Principle analyst of the qualitative material. Production of the final project report. Dissemination strategy

Keywords: research, recruitment, COVID-19, RECOVERY Study.

STUDY FLOW CHART

| Timeline | | | | | | | | |
|----------------------------------|--------|--------|--------|--------|--------|--------|--------|--------|
| | Sep-20 | Oct-20 | Nov-20 | Dec-20 | Jan-21 | Feb-21 | Mar-21 | Apl-21 |
| Protocol production and updating | ■ | ■ | ■ | ■ | | | | |
| Approvals gained | | ■ | ■ | ■ | ■ | | | |
| Recruitment | | ■ | ■ | ■ | ■ | ■ | | |
| Interviews | | ■ | ■ | ■ | ■ | ■ | | |
| Analysis | | | ■ | ■ | ■ | ■ | ■ | |
| Report writing | | | | ■ | ■ | ■ | ■ | ■ |
| Review of pilot phase | | | ■ | ■ | | | | |
| Dissemination of findings | | | | | ■ | ■ | ■ | ■ |

STUDY PROTOCOL

Factors Affecting Recruitment to the RECOVERY study during the COVID-19 Pandemic.

BACKGROUND

When Coronavirus disease (COVID-19) appeared in the United Kingdom in early 2020 there was little information about effective treatments. A number of potential treatments had been suggested but there was no data to confirm or refute if these were aiding recovery above the usual standard of care (1). In response to this, the National Institute for Health Research (NIHR) and United Kingdom Research and Innovation (UKRI) co-funded rapid research to support investigations into COVID-19 (2). In conjunction with this the Health Research Authority (HRA) and NIHR enhanced support for the approvals application processes to speed up regulatory review (3). If successful, projects that went through this process were designated Urgent Public Health Studies (3). The Randomised Evaluation of COVID-19 Therapy study (RECOVERY) aimed to identify treatments for those hospitalised with suspected or confirmed COVID-19 (1) and was designated an Urgent Public Health Study. The study was approved on 11th March 2020, funded by NIHR/UKRI and sponsored by the University of Oxford (4). At the end of 2020 there were 74 Urgent Public Health Studies registered, 60 being open for recruitment (4).

Imperative to timely results was a strong recruitment strategy. Initially there were four arms to the RECOVERY study and each required a minimum of 2000 participants per arm. It was suggested a recruitment rate of 1000 patients a week could lead to results in 5-7 weeks (5). By May 2020 the recruitment rate was 13% of all admissions, regard was paid to the operational pressures organisations were under, but stronger recruitment rates were highlighted as important (5). Further communications from the joint Chief Medical Officers and the National Medical Director emphasised that every eligible patient should be approached to enter a trial and discouraged the use of off-licence treatments outside of trial participation (6,7).

The protocol produced by the RECOVERY study team drew attention to the need for timely recruitment (8). To aid sites that were taking part in the study during the pandemic they cut down trial procedures. The eligibility criteria were streamlined. Enrolment and randomisation were completed online, with informed consent processes simplified. Follow-up was at a single timepoint and achievable via a number of routes.

Across the North East and North Cumbria (NENC) Clinical Research Network (CRN) area eight NHS Foundation Trusts recruited to the RECOVERY study. As of the end of August 2020, a period of time covering the first wave of the pandemic, 903 patients had been recruited with a mean average of 112 per site and a median average of 104, the range being 34-223 (9).

The FAR study will investigate how organisations managed the set-up of, and conducted the processes of the RECOVERY trial. In the pilot phase three separate trial sites situated in the North East of England were approached to take part in interviews. Staffs who were directly and indirectly involved in the set-up, running and recruitment to the RECOVERY study were approached to take part in semi-structured interviews. These interviews built up a picture of the situation within the organisation immediately prior to and through the initial phases (to the end of August 2020) of the COVID-19 pandemic. The interviews explored how elements within that time period affected the recruitment to the RECOVERY study. Whilst recruitment had been difficult the interviews had proved a source of rich information. This had been combined and analysed with data from the CRN, NENC, the COVID-19 daily situation reports and the publicly accessible information regarding the sites. From this, conclusions have been drawn and initial recommendations have been made regarding improving and maintaining recruitment in a comparable situation.

After the initial pilot phase, the study team and interesting parties from NIHR and the RECOVERY study reviewed the methods and initial findings. This protocol (v3.0) is a result of that review.

RATIONALE

The project aims to explore the factors which affected the recruitment rates to the RECOVERY study during the COVID-19 pandemic. A number of strategies were put in place during the pandemic to rapidly fund and approve studies deemed as urgent to the public's health (2,3,8). Once these strategies were in place it was crucial in participating sites that timely set-up, recruitment and follow-up was achieved. The CRN NENC offered all sites an equivalent level of support, but from statistics available there is wide variance in the number of participants recruited at each site (9). During the pilot phase of the project looked at three broadly comparable sites where the recruitments rates differed. Initial findings suggest that sites adopted a comparable organisational structure in response to the pandemic. They prioritised safe and effective care and made decisions to ensure their prioritisation was operationalised. The decisions made were influenced by the degree of uncertainty expressed and compounded by the number of admissions of COVID-19 positive patients. It was further suggested that the clinical lead of the project had a significant influence on the

operationalisation of the study, the communication and the leadership, all of which influenced recruitment.

The pilot phase was completed during the second wave of the pandemic. Interviewees naturally moved to making a comparison between the situation during the first wave and the second wave. Data from the CRN NENC is still showing a wide variance in recruitment rates, a pattern reflected nationally (10). The RECOVERY study remains a crucial part of rapidly assessing the efficacy of therapies (11). The ongoing pandemic and a potential for further waves in early 2021 have led NIHR to give local clinical research networks minimum targets for recruitment to RECOVERY (11). These are currently 10% of COVID-19 admissions, with an aim for 20% in the future. If LCRN's are not recruiting to that target they will need to produce a strategic plan to address this. With this in mind the study team have expanded the scope of the FAR study to add a further 5 sites. It continues to explore the factors that are affecting recruitment, but is taking in the second and any potential subsequent waves of the COVID-19 pandemic.

THEORETICAL FRAMEWORK

In order to explore the factors that affected the recruitment to the RECOVERY study the project aims to build up an in-depth picture of what is happening at the sites. Some of this information is available from public sources, such as annual reports and Care Quality Commission reports. Other information is available from the CRN NENC, but a large proportion of detail will only be uncovered by speaking to those who are experiencing the situation themselves. With this in mind a qualitative approach utilising situational analysis is being taken (12). Situational analysis is a specific data analysis approached used in conjunction with Grounded Theory (13). Taking this approach will allow the project to be iterative and adaptable, producing findings grounded in the data collected. This work will take the interviews of the participants and bring to the fore their narratives and views on the processes undertaken to recruit study participants to the RECOVERY study. The findings will not be an exact replication of the processes but an interpretation of the narratives. This interpretive analysis will make sense of the experiences of all those involved and lead to suggestions and recommendations for the future.

RESEARCH AIM

To explore the factors that affected recruitment to the RECOVERY trial during the COVID-19 pandemic in the United Kingdom.

Objectives

Identify the factors that inhibited or assisted in the recruitment of participants to the RECOVERY study at sites within the area covered by the Clinical Research Network, North East and North Cumbria.

Outcome

Make recommendations to aid timely recruitment to research studies.

STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

The project will primarily utilise a qualitative approach. To augment that approach information will be gathered from public sources and the CRN NENC. This material will aid the formation of topic guides to be used during the semi-structured interviews. It will also assist in drawing a comparison between the sites and placing them within the wider context. This will be achieved by desk-based research conducted by the principal investigator.

Qualitative data collection:

To add depth to the desk-based research and allow the aim to be achieved semi-structured interviews will be conducted with employees of the participating sites who were involved directly or indirectly in the RECOVERY study. Each interview will follow a topic guide; however, the semi-structured format will allow for each to be tailored to the individual's responses and role. Topic guides will be reviewed during the interview process and refined to confirm or refute emerging thoughts. The interviews will explore what each individual felt aided or inhibited the recruitment of participants. They will explore what was happening in the organisation, site or department prior to and during the COVID-19 pandemic and what impact this may have had. They will go on to examine the processes adopted during the pandemic and if these could have been changed to affect the recruitment of participants. The aim of these interviews is to build a narrative that describes, from the perspective of the sites, the similarities and differences in the particular situation of recruitment during the COVID-19 pandemic versus recruitment out with this period.

Interviews will be carried out in a way which adheres to current COVID-19 restrictions. It is envisaged the majority will be conducted via a video or audio call facilitated via Microsoft Teams. Should it be required and within guidelines they may also be conducted in a face-to-face format with interviewer and interviewee present in the same room. Interviews will be digitally recorded utilising the internal voice recorder on the laptop or via a handheld digital recorder. They will be stored on a password protected trust laptop. Interviews will be transcribed and anonymised by the principal investigator; digital recordings will be destroyed once the transcription is completed and checked for accuracy.

Qualitative data analysis:

Grounded theory is concerned with findings that can be traced to the data collected. It has evolved into a group of strategies that are employed from a mainly pragmatic perspective. The situational analysis model is being employed to reveal the prevailing discourses in the situation of recruitment to the RECOVERY study. Situational analysis not only allows the human influences (actors) to be taken into account, but also the non-human (actants) influences (14). This allows the conflict, contentions, refusals and denials to be identified. That process goes on to uncover the narratives that disciplined the actors and actants during the situation under study. These narratives can either strengthen or constrain the situation and will illuminate the factors which inhibited or assisted with recruitment. The interview data will be coded with a focus on identifying areas of influence.

To enhance credibility and trustworthiness of the findings data analysis clinics will be held with the core research team (15,16). Data will be stored for 5 years.

STUDY SETTING

The study is being run by the NIHR CRN NENC which is situated in the Newcastle Upon Tyne Hospitals NHS Foundation Trust.

The sites being investigated are NHS FT's situated in the area covered by the CRN NENC. The participants will come from the employees of NHS FT's.

The research and development departments of each trust will review the project and agree it's conduct. The PI or CI for the study will conduct the interviews. Participants will be accessed via the Trust research and development departments. Additionally, participants may be identified through direct contact with the CI.

SAMPLE AND RECRUITMENT**Eligibility Criteria**

The participants will be made up from those employed in an NHS FT during the COVID-19. They will have been involved in the either directly or indirectly in the RECOVERY study.

Inclusion criteria

Employed by an NHS FT during the COVID-19 pandemic.

Willing to give consent to an interview.

Exclusion criteria

Not currently employed by an NHS FT.

Not willing to give informed consent.

Sampling

All participants will be volunteers. Information about the study will be sent to eligible participants via the Research and Development department of the respective FT's or directly from the research team. The information will invite prospective participants to contact the principal investigator directly to arrange an interview.

Size of sample

During the pilot phase it was hoped to interview up to 15 volunteers at each site. Review of recruitment has suggested that in the current climate this is not possible, neither is it required to achieve the aim of the study. It has therefore been decided to carry out a more targeted recruitment strategy. Where possible interviews with a senior leader, a member of the research and development staff and the principal investigator of the RECOVERY study will be completed. If these individuals decline participants then their deputies will be contacted.

Grounded theory interviews are iterative in nature. Initial interviews will collect general information to aid formation of theory. Later interviews will become more focussed to allow for confirmation, or not, of emerging thoughts. It may also be necessary to return to participants to carry out a second interview where thoughts and ideas from earlier interviews are discussed.

Sampling technique

The sampling technique will be purposive, to enable the researchers to seek out those who are best placed to provide information about specific areas, strategic priorities and operational processes (17). In addition, there may be an element of snowball sampling, caused by word of mouth (18).

Recruitment

Information about the study will be provided to the Research and Development departments of each participating trust, or directly from the research staff. This information will be disseminated, via email, to employees who were involved directly or indirectly in the RECOVERY study. The information will then direct the potential participants to contact the researcher directly to arrange an interview. These will give information to allow potential participants to self-identify to the researcher

Sample identification

Potential participants will be identified by the Research and Development departments of the participating trusts. Additionally, the CI of the project may approach potential participants. Identification may be possible by accessing the delegation and training logs of the RECOVERY study. Interviewees will be drawn from some or all of:

Medical director, non-executive director, research and development manager, clinical governance manager, study set up staff, principal investigator(s), research nurses, additional staff identified on study logs as trained to take consent, administrative staffs involved in the RECOVERY study and staff working for the local clinical research network.

Consent

Informed consent will be obtained prior to any study activity.

A participant information sheet (PIS), (appendix I), will aid the verbal discussion between interviewer and interviewee. The PIS will be reviewed by the trust Research and Development departments. The potential participants will be given an opportunity to ask questions and, as much time as they require to make their decision on whether or not to take part in the research.

The consent processes will be proportionate to the type of study and risk profile (19). This study is deemed as low risk. Due regard will be taken of the current restrictions on face-to-face meetings during the COVID-19 pandemic. All potential interviewees will receive a copy of the PIS and consent form (Appendix II). If possible, the signed consent form will be returned to the researcher prior to the interview. If this is not possible verbal consent will be audio recorded and documented by the interviewer prior to the interview taking place.

Contact between interviewer and interviewee will only take place via the medium the interviewee puts forward. This is most likely to be via a secure NHS personal email addresses or telephone lines.

Consent forms will be stored on a secure password protected intranet. Hard copies, if supplied, will be scanned and stored as electronic versions, the hard copy destroyed once scanning has been completed.

ETHICAL AND REGULATORY CONSIDERATIONS

This study is classed as research as it will produce transferable findings (20). It does not require HRA NHS ethical review as it is research which involves NHS staff recruited as research participants by virtue of their professional role. The project has no material ethical issues.

Assessment and management of risk

There is a small risk that during the interview process the participants may identify poor practice. If this is the case the interviewer will report this to the relevant trust using their safe guarding procedures. This scenario will be discussed in the PIS and form part of the consent discussion and process.

Regulatory review & reports

The project is registered by Newcastle Upon Tyne Hospitals NHS Foundation Trust on their Clinical Effectiveness Register.

The project has been reviewed and approved by the participating trusts via their Clinical Governance and Research and Development departments.

No study processes will be undertaken until approval is obtained.

Any amendments to the protocol will be submitted to the sites for approval before their implementation.

The CI will inform the approving bodies if the study is stopped prior to completion.

A final report will be published and an abstract will be made available to the approving bodies.

Regulatory Review & Compliance

Peer review

The study has been reviewed with the team of the CI. Where appropriate feedback has been acted upon.

Protocol compliance

The CI has overall responsibility for compliance to the protocol. Any breaches or deviances will be reported to the sponsor.

Accidental protocol deviations can occur at any time. They will be documented and reported to the CI and sponsor immediately they become apparent.

Multiple deviations may be classed as a serious breach of the protocol.

Data protection and patient confidentiality

Storage arrangements of all relevant data material will be in accordance with the General Data Protection Regulation 2018. Personal data will be regarded as strictly confidential. All data retained will be identified by a unique study ID. The participant log will be the only document which contains personal details. Access to participant information will be restricted to the interviewer. All paper documentation contained participant information will be kept at all times in a secure way with restricted access. Any data held or transferred on electronic devices will be kept on a password protected device and only transferred on encrypted systems. The data will be stored for 5 years. The custodian of the data will be the sponsor.

Indemnity

Indemnity will be provided by Newcastle Upon Tyne NHS Foundation Trust.

Access to the final study dataset

Access will be via the CI.

DISSEMINATION POLICY**Dissemination policy**

The data arising from this project is owned by CRN NENC.

The study will culminate with the completion of a final study report. It will be available on the CRN NENC website. An abridged version will be supplied to the participating trusts. The findings may form part of articles published via peer review journals, conferences or presentations.

Authorship eligibility guidelines and any intended use of professional writers

Authorship of the final report will be from within the study team.

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APPENDICIES

Anonymised



Factors Affecting Recruitment to the RECOVERY study during the COVID-19 Pandemic.

Invitation and brief summary:

We would like to invite you to take part in a research study. Please read this information leaflet which tells you why the research is being done and what you will be asked to do. You are welcome to ask us about anything that is unclear or for further information.

The project is looking at what factors may have affected recruitment to the RECOVERY study during the COVID-19 pandemic. We are doing this by interviewing people who were involved in either the set-up and running of the study or the recruitment of participants. The RECOVERY study was an Urgent Public Health Study where strategies were put in place to speed up approval, study processes and recruitment. We would like to find out if these worked and what else, if anything could be done to aid set-up, running and recruitment, should the situation arise again.

You have been identified as someone who was involved, directly or indirectly, in the set-up, running or recruitment of participants to the RECOVERY Study. We are hoping to interview about 15 people at each research site.

What would taking part involve?

You will be contacted by one of the research team who will arrange a convenient time for you to take part in an interview. During the interview you will be asked to talk about your experiences of the RECOVERY study during the COVID-19 pandemic. The interview will most probably take place over a video call or a telephone call. It will last about 30 minutes. The interview will be recorded on a digital recorder.

Do I have to take part?

No, you don't. It is up to you decide whether you want to take part or not. Even if you decide at first to join in, but change your mind, you can leave the study at any time. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. Once your interview has been transcribed and anonymised it becomes impossible to remove it from the study.

What are the possible benefits?

There are no real benefits to you personally. Hopefully we will be able to make some suggestions to researchers and organisation involved in research to aid set-up and recruitment of urgent studies in the future.

What are the possible disadvantages and risks of taking part?

We do not feel there are any disadvantages to taking part. There is a very small risk that during your interview you tell us about poor practice. Should this happen we will need to inform the Trust through their safeguarding procedures.



How will my information be kept confidential?

All information you provide we will be stored securely and kept strictly confidential. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Your interview will be transcribed by the research team and all the material that may identify you, colleagues or the trust anonymised. This means it will be replaced by a code. The code, and what it represents will only be seen by the research team.

In any reports or publications that may come from the study you, your colleagues or the Trust will not be identifiable.

Who is running the study?

The research is being run by the North East and North Cumbria Clinical Research Network. It is registered by Newcastle Upon Tyne Hospitals National Health Service Foundation Trust on the Clinical Effectiveness Register.

What happens now?

If you decide to take part in the project please contact xxxx on xxxx

Or xxxx

She will arrange a time for your interview and send you a consent form. You will need to sign the consent form before the interview. You can return it to xxxx and your consent will be recorded before the interview.

If you have any questions please contact xxxx on xxxx

Or xxxx

If you want to find out more about how your information will be used please see:

www.hra.nhs.uk/patientdataandresearch

If you have any complaints about the project please contact the project Chief Investigator: xxxx

Alternative you can contact the Patient Advisory and Liaison Service at Newcastle Upon Tyne Hospitals National Health Service Foundation Trust:

Freephone: 0800 0320202 Text/SMS: 07815500015

Email: northoftynepals@nhct.nhs.uk Post: Freepost PALS: RLTC-SGHH-EGXJ

The FAR Study.

Topic Guide. September-December 2020.

Could you give us a brief overview of your current role and responsibilities in the Trust?

Can you tell us how your felt the trust was operating in the late 2019's and early 2020's prior to the COVID-19 pandemic?

What would you have seen as its major challenges as that time?

Had there been any changes in personnel in the trust leadership group?

How did these change during the time period March-July 2020?

What became the major challenges?

Were any of the leadership group lost during that time period (employment move/sickness)?

What was the most challenges aspect(s) of dealing with the COVID-19 pandemic in the trust?

Prior to the COVID-19 pandemic where did research fit into Trust priorities?

How was research activity reported to the board and how often did this occur?

When the COVID -19 pandemic started how did this change?

Were you aware of any research work force redeployment to the frontline (medical, nursing or other)?

If so do you think there were any other alternative options at the time?

How were you and/or the board informed of COVID-19 research activity?

Did this information change the priority research had at board level?

How did knowledge of the COVID research activity in the Trust make you feel?

How often were you aware of staff talking about the RECOVERY study (or any other COVID research) between themselves?

If so, was it mentioned everyday / was information about the study displayed in clinical areas or communicated in the Trust comms?

How did knowledge of the COVID research activity in the Trust make you feel?

What do you feel aided recruitment?

What were the main challenges to recruitment?

Did staff sickness impact?

Did patient numbers impact?

How were these things addressed during the main recruitment period?

What do you feel drove recruitment? Who do you think drove recruitment?

Did patients / relatives ask about research studies?

Would there have been anything other that could have been done to aid further recruitment?

Is there anything else you feel is important to say regarding the RECOVERY study and the recruitment of participants to it?

How would you like to see urgent public health research such as the Recovery Trial develop within the Trust and what are the main barriers to this?

Thanks.

Questions/topic guide. From January 2021 onwards.

Role and responsibilities, general and RECOVERY.

How have the **pressures** on the Trust altered across the timeline of the COVID-19 pandemic?

How has this **affected the priorities**/prioritisation/emphasis.

What or who **drove recruitment**.

Who **led on recruitment**, medical staff or research nurses? Model ?

What were/are the **barriers to** recruitment.

How have **they changed**

Competing interests?

What learning was there from the first wave that has been used in the second and subsequent waves?

What do you think about the processes of **RECOVERY study?**

How have **the changes to the RECOVERY study impacted on recruitment?**

Have any **patients asked** directly to be entered onto a research study.

How does it make you **feel being part of UPH** research.

Any other factors that have affected recruitment to the RECOVERY study that have not been touched on?

Thanks.