

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