

**Title:** Increase in recruitment upon integration of trial into a clinical care pathway: an observational study

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**Introduction:** Clinical care pathways (CCPs) aim to translate clinical guidelines into care processes within a healthcare institution. Traditionally, clinical research is used to inform the evidence base and hence the architecture of such pathways. Where the evidence is unclear however using such pathways may aid recruitment to clinical trials. In this study, we aim to assess the effect of integrating clinical trial recruitment into a CCP.

**Methods:** RECOVERY-RS is an ongoing UK-wide clinical trial assessing the efficacy of non-invasive respiratory support for patients with severe COVID-19. Recruitment commenced at the Queen Elizabeth Hospital Birmingham on 20<sup>th</sup> April 2020. On 11<sup>th</sup> January 2021, a Respiratory Support Unit (RSU) was established to provide enhanced respiratory support for severe COVID-19 patients. As part of this, a CCP was developed for escalation of COVID-19 patients on general wards to RSU. The recruitment process into RECOVERY-RS was integrated into the RSU CCP and recruitment data to the trial were collected between 20<sup>th</sup> April 2020 and 28<sup>th</sup> Feb 2021. This was compared with the number of patients with COVID-19 disease admitted to the hospital and the number admitted to critical care.

**Results:** As of 28<sup>th</sup> February 2021, a total of 158 patients were recruited into the RECOVERY-RS trial at QEHB. 108 (68.4%) of them were recruited after RSU was opened. In the pre-RSU period, 101 patients were initiated on CPAP or HFNO with 35 (33.7%) of them via trial randomisation. Post-RSU, 73 patients were initiated on CPAP or HFNO; all of them (100%) through trial randomisation ( $p < 0.001$ ).

The proportion of patients recruited into the RECOVERY-RS trial relative to the number of COVID-19 hospital admissions and ITU admissions were 2.7% and 17.2% respectively pre-RSU. Post-RSU, there was a significant increase in both the proportion of recruited patients relative to the number of COVID-19 hospital admissions (9.1%;  $p < 0.0001$ ) and ITU admissions (52.4%,  $p < 0.001$ ).

**Conclusions:** CCPs represent an opportunity to recruit patients into clinical trials. This is important in areas where the evidence base is scarce. In order to succeed, all parties involved in patient care have to agree to equipoise between trial treatment arms.