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# RAPID RESEARCH IN COVID-19 PROGRAMME

## CARP: COVID-19 Advanced Respiratory Physiology Platform

## AIMS

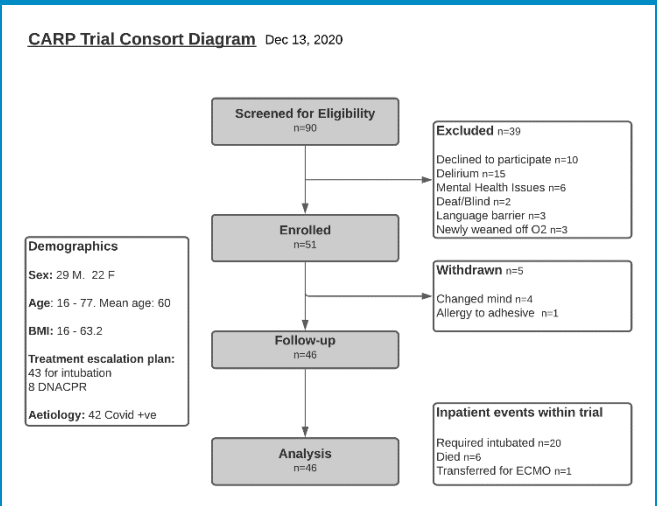
Patients with COVID-19 pneumonia are at risk of sudden deterioration, and a key challenge during the pandemic is to monitor unprecedented numbers of patients. Our aims were to complete technical development and governance requirements to commence a study establishing feasibility and exploring early utility of monitoring COVID-19 patient's breathing using wearable sensors, with all of the relevant data being presented in an easy-to-understand format, and which can be used to identify patterns which correlate with particular patient outcomes.

## KEY FINDINGS

- We achieved project milestones, establishing connectivity between wearable respiratory sensor and an internet-based clinical database hosted by NHS GG&C eHealth, and acquisition of all required ethics approvals.
- The COVID-19 Advanced Respiratory Physiology platform (CARP) study(clintrials.gov registration pending) commenced on 29th September 2020. 54 patients have been recruited over first 12 weeks, providing 5800 hours of continuous respiratory physiology monitoring data, as per the flow diagram (Figure 1).
- Comparison between respiratory rate data from either wearable sensors, or observations made by clinical staff, have allowed refinement of the sensor measurements improving accuracy of the wearable respiratory rate data.
- Data analysis comparison between wearable respiratory rate and ward-based respiratory rate observations will now be undertaken. It is anticipated that wearable data will improve accuracy of national early warning score measurements.
- Preliminary data review has highlighted that a sustained respiratory rate >20/minute or peak respiratory rate >25/minute associates with COVID-19 patient deterioration. These respiratory rate threshold insights have been shared with respiratory support clinicians in Scotland to contribute to iterations of COVID-19 patient escalation guidance.

- Planned interim analysis of CARP trial data will be in q1 2021. Data scientist review of recruitment, event rate, and volume of sensor data will determine appropriate timing of utilising computer-based algorithms to identify correlations between respiratory rate sensor data and patient outcomes. The study data will be aggregated with NHS-held clinical data, with the aim of establishing risk predictive scores and monitoring thresholds for clinical deterioration.
- The CARP trial remains open for recruitment at least until September 2021, with endowment funding supporting continued activity. Recruited patients will be followed up at 90-days post discharge. Qualitative patient user experience, detailed physiology sub-study and association of physiology results with post-discharge outcomes will be further explored. Interim data analysis and COVID-19 prevalence during the following months will prioritise recruitment strategy to maximise the acquisition of early utility data from this study which involved observing patients only (i.e. no interventions were made).
- Prospective benchmarking of sensor accuracy and further validation of CARP-derived physiology insights and predictive models will be required, but is anticipated that these insights will directly inform COVID-19 and non-COVID-19 respiratory failure triage, monitoring and management in the near future.

**CARP Trial**
Screening & recruitment summary
Week commencing Dec 7th 2020




## WHAT DID THE STUDY INVOLVE?

Respiratory rate is a key predictor of clinical deterioration in patients with COVID-19 and other illnesses. The wearable respiratory rate sensor (made by study partners, Altair) and computer algorithms can accurately and non-invasively measure respiratory rate. The CARP study involved:

- the production of a sensors and hubs to monitor a cohort of patients with respiratory failure, in the CARP clinical trial.
- Establishing connectivity between these hubs through NHS GG&C medical device wi-fi network to cloud-based database and dashboard.
- Co-design and development of an easy-to-use format (a 'dashboard') to manage identity and data linkage, document core clinical summary and event data and aggregate and present this with the respiratory sensor data.
- Development of the CARP clinical trial protocol and associated documentation, with acquisition of sponsor, ethics and NHS Research and Development management approvals to commence trial recruitment September 2020.

**CARP clinician dashboard:** Specimen clinical and respiratory sensor data.


## WHAT WERE THE RESULTS AND WHAT DO THEY MEAN?

An exemplar eHealth infrastructure, with all required governance for detailed evaluation of wearable respiratory sensor for the monitoring of COVID-19 patients has been established.

The CARP study has proven the feasibility of wearable respiratory sensor monitoring in hospital in-patients with COVID-19 and respiratory failure.

Preliminary results have shown an association between sensor measured high respiratory rates and adverse clinical events in COVID-19 patients. CARP trial recruitment and analyses will continue.

Initial data validation has correlated wearable respiratory sensor data with the current standard critical care monitoring equipment. This has allowed improvement in the computer programmes for the wearable sensor respiratory rate calculations.

The CARP clinical trial will continue, and the planned analyses will determine which components of sensor monitoring and clinical data are most valuable. It is anticipated that the utility data will inform improvements in clinical practice, expanding the evidence base for accurate early warning systems and thresholds for escalation in COVID-19 and nonCOVID-related respiratory failure.

The CARP study has provided the infrastructure for aggregating detailed historical clinical data (from NHS SafeHaven), wearable sensor data, detailed physiology data, clinical event and follow up data in patients with respiratory failure, and conducting AI-based analyses of these. The final CARP trial data will demonstrate the utility of this. This infrastructure can be easily extended to other clinical use cases, other physiology measurements and to other organisations.

## WHAT IMPACT COULD THE FINDINGS HAVE?

The CARP study has provided an advanced respiratory physiology platform with potential to undertake simultaneous evaluations of a wide range of emerging technologies, applied to a wide range of clinical conditions.

The preliminary CARP trial analyses are promising, and it is anticipated that the final analyses will directly inform clinical practice and improve monitoring of patients with COVID-19 and non-COVID related respiratory failure.

If the final analyses are as anticipated, wearable sensor respiratory rate could be established as an approved output for clinical trials of investigational medical products for COVID-19 and other infections.

## HOW WILL THE OUTCOMES BE DISSEMINATED?

The CARP clinical trial will continue recruitment until September 2021. The results to date will be combined with the interim analyses and reported at Scottish Thoracic, British Thoracic and European Respiratory Society meetings 2021. The CARP clinical trial protocol will be published. Results will be submitted for peer-reviewed publication, with pre-pub website availability and media linkage where appropriate.

## CONCLUSION

The CARP study has successfully established and advanced respiratory physiology platform for the study of COVID-19 related respiratory failure. Promising early data with wearable respiratory sensor monitoring has been obtained, and the CARP clinical trial data will continue to establish this utility over the next 12 months.

## RESEARCH TEAM & CONTACT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| **Name**<br>Dr Chris Carlin | **Email address**<br>christopher.carlin@ggc.scot.nhs.uk |
| **Address**<br>Department of Respiratory Medicine<br>Queen Elizabeth University Hospital<br>Glasgow | **Phone number**<br>07989 928636 |


## ADDITIONAL INFORMATION

CARP study: 22/06/2020 – 20/12/2020. CSO funding of £123,850 provided.

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