**PROJECT DESCRIPTION:**

BACKGROUND:

As of March 16 2022[[1]](#footnote-1), there have been 61 857 cases of COVID-19 in the ACT. While most people diagnosed with COVID-19 recover well, approximately 10% of COVID-19 survivors are likely to develop post COVID-19 condition1 (also known as ‘long COVID’2), where symptoms persist for more than 12 weeks and negatively impact on activities of daily living3. From European studies, we know that frequent symptoms of post COVID-19 condition include fatigue, weakness4, breathlessness and cognitive problems2. These problems can occur in people who were hospitalized with COVID-19, but also those who were managed entirely in the community2. A recently published Australian study, including data from Canberran patients, showed that 39% of patients who survived an ICU admission with COVID-19 had new onset disability at 6 months5. Based on our current case numbers, the ACT could have *more than 4000* people at risk of developing persistent covid-19 condition and new disability.

Given the wide range of symptoms and body systems affected, a multidisciplinary approach to rehabilitation is recommended by the World Health Organization (WHO)6 and the UK-based NICE Guidelines for COVID-19 management3. From March 2022, the ACT commenced its new COVID-19 recovery rehabilitation service, based at the University of Canberra Hospital. Patients are referred following medical screening (via medical specialists or general practitioners) and undergo comprehensive assessments and treatments that are individualized to meet each patients’ unique problems and goals.

Although multidisciplinary rehabilitation is recommended by the WHO6 and NICE3 for COVID-19 recovery, there is very little evidence on which to guide the best approach to rehabilitation. Controversially, many rehabilitation services in Europe and the US have taken a conservative approach to managing these patients, recommending an energy-conservation approach, rather than the use of graded exercise therapy. However there is ***NO good quality evidence***on which to base this approach, rather anecdotal feedback from patients about the challenges of return to exercise. The NICE guideline3 states:

*“The panel discussed the ongoing debate over self-pacing and graded forms of exercise. The panel considered careful self-pacing of exercise to be an important element of self-management. However, the panel concluded that in the absence of evidence relating to people with ongoing symptoms from COVID-19 it could not make specific recommendations and it agreed to include a research recommendation to determine the effectiveness of exercise interventions for this population.” (p.73)*

In contrast, graded exercise therapy prescribed by trained therapists is highly efficacious in improving not just strength and exercise tolerance, but also functional independence, quality of life and mental health across a broad range of conditions. These improvements have been demonstrated in people with chronic lung disease7, chronic heart failure8, stroke9, and even ventilator-dependent patients in the ICU10 11. Here in Canberra, our research team has shown that individualized, prescribed exercise therapy improves both strength and quality of life even for very unwell ICU patients10. In this context, graded exercise therapy could be a highly valuable treatment for patients recovering from COVID-19, and it is surprising that, to our knowledge, no service is using this approach. In agreement with the NICE guideline, there is a pressing need to generate data demonstrating the impact of exercise on recovery for patients with post COVID-19 condition.

The COVID-19 rehabilitation service at the University of Canberra Hospital has been established in this context. The service hinges on sound principles of thorough patient assessment and medical screening12; individualized patient-centred care planning; carefully prescribed and supervised graded exercise therapy by trained therapists; and holistic management of a wide range of physical, cognitive, psychological and social problems to best meet the needs of our ACT people still struggling to recover from COVID-19. From benchmarking exercises, we know that there is no other established multidisciplinary COVID-19 recovery service in Australia. We are leaders in this space in Australia.

As a collaborative research team, we want to take this opportunity to capture data regarding this service’s *usual practice,* and hope to demonstrate that this novel approach to COVID-19 rehabilitation (including graded exercise therapy) is **feasible** and **safe**. Usual practice will include prescribed exercises where indicated, including retraining of respiratory muscles where these are weak (a potential contributor to breathlessness, particularly in ICU survivors). We also want to capture the patients’ experience of this service, to ascertain the **acceptability** of this model of care. If we can demonstrate that this approach does not harm patients, and is acceptable to patients, we may encourage COVID-19 rehabilitation clinics around the world to re-think their approach to COVID-19 recovery, and lead the world in generating the evidence needed to inform best practice.

AIMS:

To describe the feasibility and patient acceptability of a novel approach to COVID-19 recovery which is based on individualized assessment; patient-specific prescription of tailored graded exercise therapy; and holistic patient management designed to meet patients’ physical, cognitive, psychological and social needs.

HYPOTHESES:

We hypothesize that this novel approach to multidisciplinary COVID-19 rehabilitation will be:

1. Feasible to deliver in an outpatient setting, with minimal adverse effects for patients.
2. Acceptable to a heterogeneous group of patients who present with challenges of COVID-19 recovery

METHODS:

*Design & Participants:*

This observational study will analyze data routinely collected as part of the delivery of the ACT’s new multidisciplinary COVID-19 recovery clinic. All patients presenting for assessment in the clinic (June – December 2022), who meet the criteria below, will be eligible for inclusion.

* Referral via medical specialist or general practitioner with a history of presumed or actual COVID-19, and ongoing post-acute sequelae impacting on activities of daily living
* Aged 16 years or over
* ACT residents
* Willingness and capacity to participate in assessment and therapy, either in an outpatient setting at University of Canberra Hospital, OR in the patient’s own home if deemed appropriate by the assessment team

For the feasibility analysis, a waiver of consent will be sought through the Human Research Ethics Committee, such that all patients’ deidentified quantitative data can be analysed through a program-level lens. For the acceptability analysis, patients will be invited to participate in a survey and an individual interview about their experience of the program, and they may consent or decline participation in these as they wish.

*Setting:*

The COVID Recovery Rehabilitation service is based at the University of Canberra Hospital, as part of the Brindabella Day and Ambulatory Rehabilitation Service. The service commences in March 2022 and already has a waiting list. The service is currently funded to continue until end 2022. The skilled multidisciplinary team includes the following disciplines:

* Rehabilitation Medicine
* Physiotherapy
* Exercise Physiology
* Occupational Therapy
* Social Work

For patients identified as requiring specialised referral to clinical psychology, neuropsychology, speech pathology, nutrition and dietetics, these referrals can also be managed within the existing rehabilitation services.

*Intervention:*

Patients referred to the program will undergo comprehensive medical assessment and screening for their suitability to participate in rehabilitation. Where indicated, this will include assessment of the patient’s cardiopulmonary exercise capacity (VO2max and anaerobic threshold), as well as lung function testing (spirometry, maximum inspiratory pressure). Such tests have recently been shown to be safe and valuable in patients following COVID-1912. The medical specialist will then advise the rehabilitation team of any specific exercise limitations based on this testing (e.g. SpO2 targets).

Following a thorough patient-tailored individual assessment, the rehabilitation program received by a patient in the service could include any or all of the following, depending on the patient’s needs:

* Specialized care planning and care coordination (including social work input where relevant)
* Goal based short term rehabilitation interventions (e.g. supervised individually prescribed exercise therapy; inspiratory muscle training13; functional retraining for activities of daily living)
* Education to facilitate self-management
* Group rehabilitation including pulmonary rehabilitation and semi supervised group therapies
* Telehealth interventions as an adjunct to usual therapy where clinically safe and effective
* Where necessary, home-based assessment and treatment for goals relating to essential activities of daily living
* Individual therapy sessions involving clinical psychology, neuropsychology, dietetics, speech pathology etc as required

The novelty of this intervention approach is the inclusion of *therapist-prescribed supervised, individualized graded exercise therapy*, as opposed to purely energy conservation strategies.

*Outcome Measures:*

*Primary outcomes:*

**Feasibility** data will include:

* Number of patients completing an initial assessment
* Time between referral and completion of initial assessment
* Number and type of sessions attended per patient
* Actual completion of planned sessions (as a percentage of planned sessions), including frequency of unexplained non-attendance
* Safety: occurrence of adverse events (e.g. deterioration in presenting symptoms during course of program; worsening of physiological status during exercise; injury, serious disability or death during rehabilitation activities)
* Number of patients completing the program
* Size of waiting list across the life of the program (June – December 2022)

The clinic will be considered **feasible** *a priori* if it meets the following criteria:

* More than 75% of patients attend a minimum of 75% of planned sessions
* More than 75% of patients complete the individually prescribed rehabilitation program
* Safety: Adverse event rate will be < 10% of patients experiencing any minor adverse events (and **no** serious disability or death occurring as a direct result of rehabilitation activities)

**Patient acceptability** will be captured through voluntary completion of:

* Acceptability survey (bespoke design, based on the principles previously described by Sekhon et al) completed by participants on completion of the program
* Individual patient interviews conducted by a researcher not involved in delivery of the program (TB). This strategy should minimize bias in patient responses.

*Secondary outcomes:*

While this study design cannot demonstrate efficacy, patient progress during the program will be captured through the following outcome measures, as appropriate to their presenting symptomatology, at a minimum on commencement and completion of their rehabilitation program:

* Lung function: inspiratory muscle strength, Borg scale of breathlessness
* Physical strength: quadriceps, biceps and grip dynamometry; Oxford scale globally
* Blood pressure / oxygen saturation (based on need identified in medical screening)
* Functional measures: 6MWT, Timed Up and Go Test and / or 1 minute Sit to Stand (depending on functional level)
* Quality of life: EQ-5D scale
* Fatigue: Brief Fatigue Inventory
* Depression and Anxiety Stress Scale: DASS-21
* Return to Work / Occupation
* Disability: PICUPS Screening Tool (PICUPS or PICUPS Community version)
* Demographic data: including time since COVID-19 diagnosis, duration of symptoms, COVID-19 strain, hospitalization, age, sex, co-morbidities etc (these may be relevant to subsequent analysis)

*Sample size*

The sample size for this study is not pre-determined due to the pragmatic nature of this observational study. Rather, we will capture all patients admitted to the service between 1st June 2022 and 31st December 2022. We anticipate this will include between 50 and 100 patients, depending on demand. If there is excessive demand for the service, this study will capture the first 100 patients admitted to the service during this time frame.

For the patient acceptability interviews, we anticipate 10-15 patients will be required to achieve data saturation, but the process will continue until no new themes are identified in participant feedback.

*Statistical analysis:*

For quantitative analysis, all routinely collected patient data will be entered into a patient data management system (REDCAP) hosted through the University of Canberra. The data will be deidentified from the point of data entry, and only the primary research team will have access to this data, with password-protection limiting access. Where appropriate, data will be normalized to adjust for age and sex (e.g. maximum inspiratory pressure values14). Descriptive statistics will be used to analyze the primary outcome data, and feasibility will be calculated (e.g. percentage of completed sessions relative to planned sessions).

If sample size allows for the secondary outcomes, regression analysis may be used to identify relationships between demographic data (e.g. hospitalization with COVID-19, or time since infection) and outcomes in the service (e.g. functional tests like 6MWT). Analysis will be conducted using the R statistics program in collaboration with an experienced health statistician at the University of Canberra.

For qualitative analysis, the interviews will be transcribed verbatim and analysed using the framework described by Braun and Clark15. Themes will be identified and synthesized, using patient voice as much as possible to describe the experience and acceptability of the rehabilitation service. Patients will be de-identified in this analysis, but will be potentially re-identifiable to the research team. Results of this analysis will be shared with participants on request.

FEASIBILITY OF THE PROJECT:

This project is highly feasible, with the clinic already underway as of March 2022. We have applied for ethics through ACT Health (March 9 2022). The quality of dataset will be optimised through the appointment of a dedicated data entry research assistant, who will be responsible for entering data into the REDCAP database, cleaning the data and checking for missing data.

The research team has previously used the outcome measures described (including EQ-5D, DASS-21 etc) and are confident that these can be implemented as a routine part of assessment without being burdensome to clinicians or patients. The measurement of spirometry and inspiratory muscle strength will be included in initial medical screening.

The data analysis will be provided by the University of Canberra, and thus will not be an impost on clinicians’ time. Rather, the research experience and time of the Faculty of Health at UC will ensure rapid analysis and dissemination of the results of the study (early 2023). This team already has a strong collaboration with the Faculty of Health statistician (Dr Andrew Woodward) and can access this expertise to ensure analysis is robust.

Furthermore, the academic contributors (BB and TB) are award-winning research-communicators, and have published numerous practice-changing papers in the field of ICU rehabilitation, and in high-quality journals (e.g. NEJM). We are confident in our ability to produce high-quality research which will be published and referenced widely, paving the way for others to consider implementation of our Canberra approach to COVID-19 recovery.

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1. As per ACT Health social media reports, March 16 2022 [↑](#footnote-ref-1)