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Functional recovery following hospitalisation of patients diagnosed with COVID-19: a protocol for a longitudinal cohort study

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ABSTRACT

Introduction COVID-19 is an international public health crisis with more than 132 million infections worldwide. Beyond acute infection, emerging data indicate patients diagnosed with COVID-19 may experience persistent sequelae similar to survivors of sepsis or acute respiratory syndromes, including mobility limitations and fatigue. However, there is limited evidence on the trajectory of functional recovery in those hospitalised with COVID-19. The primary aim of the Coronavirus Registry Functional Recovery (COREG-FR) study is to understand the trajectory of functional recovery among individuals hospitalised for COVID-19 over the medium (up to 6 months) and longer term (6–12 months) that will guide clinical care and optimal management of serious COVID-19 illness and recovery.

Methods and analysis COREG-FR is a multicentre longitudinal cohort study. We will enrol a minimum of 211 adults age 18 years and older with COVID-19 from five hospitals. Participants will be followed from admission to hospital as an inpatient, to hospital discharge, and at 3-month, 6-month, 9-month and up to 12-month post-hospital discharge. We will conduct telephone interviews at ward admission and discharge, and telephone interviews plus in-person assessments of physical function and lung function at all remaining follow-ups. Our primary outcome is the Activity Measure for Post-Acute Care mobility scale measured at all time points. We will conduct linear mixed effects regression analyses to explore determinants of functional outcomes after COVID-19 illness. Subgroup analyses based on age (≤65 vs >65 years), frailty status (Clinical Frailty Scale score ≤4 vs >5) and variants of concern will be conducted.

Ethics and dissemination COREG-FR has been approved by Research Ethics Boards at participating sites. We will disseminate this work through peer-reviewed manuscripts, presentations at national and international meetings and through the established COREG website (www.coregontario.ca). COREG-FR is designed as a data platform for future studies evaluating COVID-19 recovery.

Trial registration number NCT04602260; Pre-results.

Strengths and limitations of this study

- Coronavirus Registry Functional Recovery (COREG-FR) is a large, multicentre study collecting data five major hospitals in Southwestern Ontario.
- We will analyse data as they are available to inform pandemic care in real time.
- Data collection is not entirely prospective, with some information relying on retrospective patient recall.
- Our sample size may limit the ability to identify many prognostic factors in the regression analyses.
- There is potential for selection and attrition bias.

INTRODUCTION

First identified in late 2019, SARS-CoV-2 has caused a global pandemic with over 132 million infections and over 2.8 million deaths worldwide as of 31 March 2021.[1] In the Canadian province of Ontario, there have been more than 370 000 infections and 7475 deaths.[2] Importantly, the risk for hospitalisation and death due to COVID-19 increases steadily with age, with adults age 40 years and older accounting for 91% of hospitalisations and nearly 100% of deaths.[3] Although there has been a rapid and coordinated response to study the effects of COVID-19 in the acute stages, data focused on medium-term and long-term functional recovery is limited.

Survivors of serious illnesses, such as sepsis[4–6] and other acute respiratory syndromes,[7 8] are known to have a higher risk for long-term sequelae, including persistent mobility limitations. While such sequelae have been attributed to extensive bed rest and/or prolonged stays in the intensive care unit (ICU),[9–11] severity of illness and illness

pathology have also been identified as critical factors affecting functional recovery.[5] Emerging data suggest survivors of COVID-19 also experience persistent, long-term consequences. Indeed, a recent study by Huang *et al*[12] followed 1733 patients hospitalised due to COVID-19 for 6 months to characterise patient-reported symptoms, quality of life and physical function. Seventy-six per cent of patients reported at least one symptom at follow-up, with the most common being fatigue (76%), muscle weakness (63%) and sleep difficulties (26%).[12] Other studies evaluating shorter term outcomes (6–12 weeks) demonstrated similar results, including persistent symptoms of fatigue, dyspnoea and myalgia.[13–15] Chopra *et al*[16] followed patients for 60-day post-hospital discharge and reported that 39% of those hospitalised with COVID-19 were unable to return to previous activity levels, with 38% (n=75 of 195) reporting they were either unable to return to paid work due to their health (n=45) or returned at reduced hours or modified duties (n=30). We identified three cohort studies that followed patients for 12 months post-COVID-19 related hospitalisation with sample sizes ranging from 83 to 1276 patients.[17–19] All studies reported substantial improvements across the recovery trajectory in terms of symptoms, clinical findings (eg, chest CT) and physical function (as measured by 6 min walk distance, Barthel Index or Lawton-Brody Scale), with many domains returning to predicted values by 12 months. However, all studies reported a proportion of patients, up to 57%, with at least one persistent symptom at 1 year.[17–19] While these studies provide early evidence of the lasting consequences of COVID-19, comprehensive, prospective, long-term (ie, beyond 6 months) data using standardised outcome measures that track functional recovery are still limited. In addition, most studies to date have not included premorbid assessments of functioning. Furthermore, with the emergence of new variants of concern (VOCs), there is an urgent need to understand their impact on recovery and patient outcomes.

Understanding the medium-term (up to 6 months) and longer term (6–12 months) trajectory of functional recovery for adults hospitalised with COVID-19 is critical to inform health and rehabilitation interventions for survivors and improve patient outcomes. The Coronavirus Registry (COREG) Functional Recovery (COREG-FR) study (NCT04602260) is an extension of COREG (NCT04508959), a COVID-19 registry research platform capturing comprehensive data on all patients during hospitalisation with COVID-19 in the Waterloo, Niagara and Hamilton regions (seven hospitals) (www.coregontario.ca). The objectives of COREG-FR are to: (1) characterise the functional recovery of hospitalised adults (age 18+ years) diagnosed with COVID-19 at 3-month, 6-month, 9-month and up to 12-month post-hospital discharge in terms of mobility, daily activity, cognition, lower extremity function, pulmonary function and symptoms and (2) examine the determinants of functional outcomes after COVID-19 illness for hospitalised adults, including exploring the impacts of age, frailty status, comorbidities and new VOC.

METHODS AND ANALYSIS

Study design

This is a multicentre longitudinal cohort study that will prospectively collect data on individuals admitted to hospital with COVID-19 since the start of the pandemic. Patients hospitalised prior to study initiation in July 2020 will be recruited retrospectively; their follow-ups will be conducted prospectively starting with the first applicable time point after recruitment. Retrospective recruitment will go as far back as the first documented hospital admission date in the COREG database, which was 9 March 2020. Hospital admission and discharge data will be collected retrospectively. Figure 1 shows the study schema.

Study population

We will include adult patients, age 18 years and older who are either currently hospitalised or recently discharged due to COVID-19 infection in accordance with the International Severe Acute Respiratory and emerging Infection Consortium definition. Participants will be recruited from five hospitals in Hamilton and Kitchener-Waterloo regions. Participants must be able to communicate in English in order to provide informed consent and complete the follow-up assessments. We will exclude those who were previously institutionalised (eg, in long-term care), with premorbid severe mobility limitations (eg, unable to stand without physical assistance), and with cognitive impairment limiting their ability to complete follow-up assessments.

For individuals admitted to hospital prior to study initiation (July 2020), we will identify them through the COREG registry and approach consecutive patients that meet inclusion criteria. Prospectively, site leads will identify potential patients through daily Infection Prevention and Control data, either from confirming a positive case by nasopharyngeal swab or a confirmed case from the day of admission to a medical unit, emergency department or ICU. These patients will be concurrently entered into COREG and approached to participate in this extension study, either while still in hospital or shortly after discharge to home.

Patient and public involvement

The patients in this study were not involved in the development of the research question or design of this study. They will not be involved in recruitment or conduct of the study; however, we will include patient partners in the interpretation of results and dissemination of findings to ensure we represent what is most important to survivors, including how we define and describe long COVID-19.

Study procedures

Included hospital patients will be assessed on admission to a medical unit, at hospital discharge, and at 3-month,

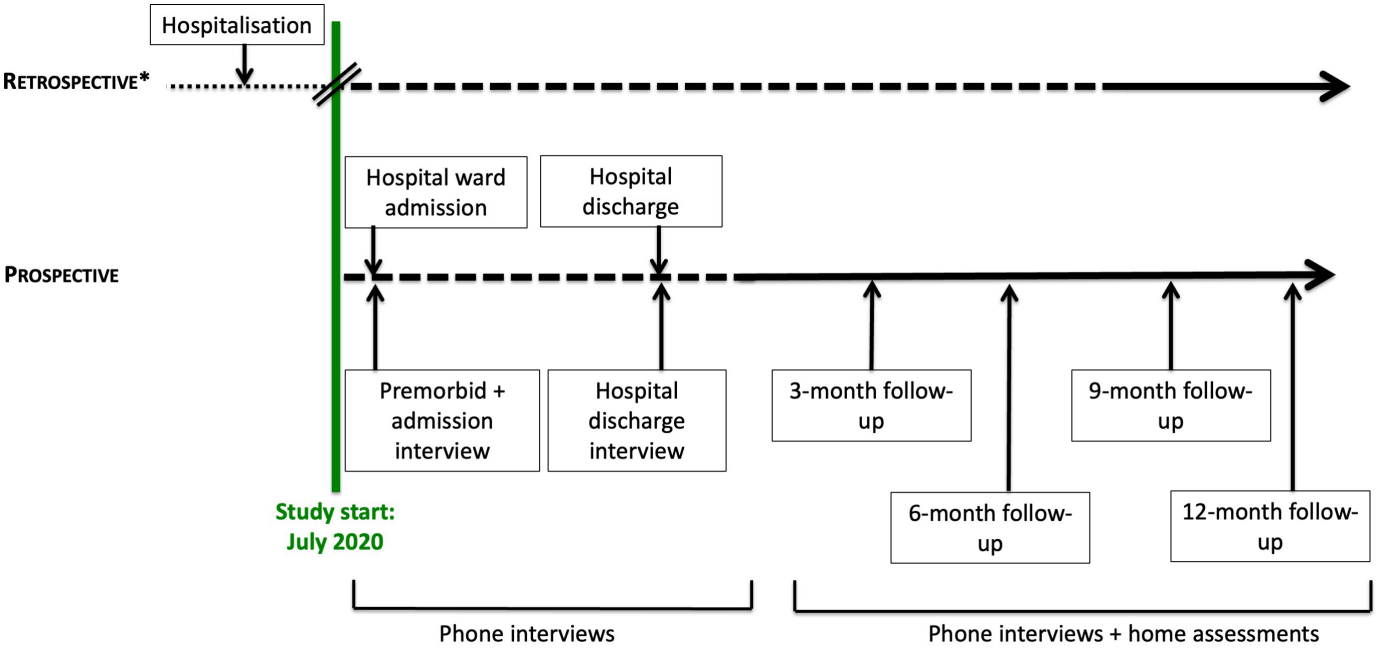

Figure 1 This figure depicts the study schema, including points of entry and follow-ups. *Patients hospitalised prior to study initiation; hatched lines represent window of enrolment (retrospective patients are enrolled at their next available time point, up to 9 months post-hospital discharge. Premorbid, admission and discharge data are then collected retrospectively).

6-month, 9-month and up to 12-month post-hospital discharge. Hospital admission and discharge data will be collected by review of the medical record and by telephone interviews as described further. post-hospital discharge assessments will consist of telephone questionnaires and home visits to assess physical function and lung function. Two research physiotherapists affiliated with the study will conduct the home assessments. Both the physiotherapists and participants will be screened for symptoms of COVID-19 prior to the home visit and personal protective equipment will be worn by both parties, except during the spirometry tests where the participant will not be able to be masked. Table 1 outlines study measures and time points.

Patients admitted to hospital due to COVID-19 prior to study initiation in July 2020 will similarly be prospectively assessed at 3, 6, 9 and up to 12 months after hospital discharge, starting with the closest time point after recruitment. Hospital admission and discharge data will be collected retrospectively. After consent (or coinciding with the consent phone call per the patient's preference), patients will receive one phone call to complete premorbid, hospital admission and hospital discharge questionnaires.

In the case of future surges in COVID-19 infections and the possibility for reinstitution of strict lockdown measures, home visits may be paused. In that event, or in the event that a patient declines home visits, follow-ups will be conducted by phone only and will include the standardised patient-reported questionnaires typically administered during the home visit (see table 1). Spirometry and physical function measures will not be completed remotely at this time.

Data and measures

At baseline, we will collect demographic and health information from COREG, including age, sex at birth, ethnicity, comorbidities, onset date of first or earliest COVID-19 symptoms, as well as data related to VOC (from the medical record as available) and vaccination status. We will extract COVID-19 illness symptoms from hospital admission (eg, fever, cough, myalgia, nausea or vomiting, etc), vital signs (eg, temperature, heart rate, blood pressure, etc) and data on patients' COVID-19 hospitalisation, including length of stay, ICU admission (including the need for oxygen therapy and mechanical ventilation), medications (eg, dose and duration of steroids), complications and any other documented treatments (eg, prone positioning).

At the first phone call, we will collect premorbid medical information, including alcohol use, smoking status and history, and medication use. We will also collect premorbid data on physical function (eg, falls history, gait aid use and basic mobility status), socioeconomic status (eg, household income, level of education and employment situation), living situation (eg, type of dwelling and living alone), cognitive status and frailty status (for those age 60+ years only).

At all subsequent follow-ups, we will collect data on any changes in the baseline information outlined previously, and any persistent or new symptoms. We will also collect data on functional outcomes as described further. Outcome measures were chosen in consultation with frontline clinicians and based on international consensus recommendations.[20 21] Physical function measures were selected based on the following criteria: (1) administration time <5 min, (2) easily conducted by clinicians and

Table 1 Schedule of events for this longitudinal cohort study

Instrument	Premorbid*	Admission (to ward)*	Hospital discharge*	3 months	6 months	9 months	12 months
COREG demographics		✔					
COREG symptoms and hospital stay info		✔	✔				
Demographics and medical info	✔	✔					
Symptoms		✔	✔	✔	✔	✔	✔
Follow-up interview				✔	✔	✔	✔
Clinical Frailty Scale (only for 60+ years)	✔		✔	✔	✔	✔	✔
AM-PAC Inpatient (6 Clicks)		✔	✔				
AM-PAC Outpatient	✔†			✔	✔	✔	✔
Post-COVID-19 Functional Status Scale				✔	✔	✔	✔
Functional Independence Measure				✔	✔		
MRC Breathlessness Scale				✔	✔	✔	✔
In-person home visit measures							
Fatigue Visual Analogue Scale‡				✔	✔	✔	✔
Impact of Event Scale‡				✔	✔	✔	✔
Hospital Anxiety and Depression Scale‡				✔	✔	✔	✔
EQ-5D-5L‡				✔	✔	✔	✔
Pulmonary Function Tests				✔	✔	✔	✔
Short Performance Physical Battery				✔	✔	✔	✔

*Data will be collected at the first phone interview.
†Only mobility and cognition subscales are collected premorbid.
‡These outcome measures can be administered by telephone in the event that home visits are paused.
AM-PAC, Activity Measure for Post-Acute Care; EQ-5D-5L, EuroQoL-5D-5L; MRC, Medical Research Council.

nurses if needed, (3) commonly used by clinicians in respiratory rehabilitation or in hospitalised settings and (4) evidence for their psychometric properties in adults.

Primary outcome

The Activity Measure for Post-Acute Care (AM-PAC),[22] specifically its basic mobility domain, is our primary outcome. The AM-PAC is a patient-reported activity limitation instrument based on the International Classification of Functioning, Disability, and Health[23] that assesses three domains: basic mobility, daily activities and applied cognition. Each item is scored from 1 (unable to perform) to 4 (none or no difficulty) with lower scores indicating lower levels of function (ie, patients have much difficulty or are unable to perform certain tasks). The AM-PAC can be clinician administered or patient-reported and has been validated for patients receiving postacute care services. It has shown to be more responsive to change than the commonly used Functional Independence Measure (FIM).[24 25] There is both an inpatient and outpatient version of the AM-PAC, with the inpatient version shortened to 6-items (AM-PAC 6 Clicks).[25–28] The AM-PAC Mobility and Cognition subscales will be administered in reference to premorbid functioning. We will use these premorbid scores to define functional recovery. The 6 Clicks questionnaire will be administered at hospital admission and discharge to measure current functional status, and the full AM-PAC will be administered at all follow-up time points. Individual domain scores are converted to a standardised score, which allows comparison across the different forms (eg, daily activities inpatient scores can be compared with daily activities outpatient scores). Furthermore, by allowing comparison of domain scores across forms, the transformed scores can be used to assess change over time.[26]

Secondary outcomes

We will assess a number of secondary outcomes to characterise the functional recovery trajectory of patients with COVID-19.

Supports and activity

We will record information not captured in COREG, including health-related or emotional supports

individuals are receiving or wish they were receiving, any follow-up care they are receiving or have received since discharge from hospital (eg, pulmonary or physical rehabilitation) and mobility status (including risk for falling, level of physical activity and others).

Clinical Frailty Scale (CFS)

We will administer the CFS for patients aged 60 years and older to determine frailty status.[29] This interview-based scale asks patients about their independence and physical abilities to determine their frailty status from 1 (very fit) to 9 (terminally ill).[30] The CFS is a valid tool to identify frail and ill older adults. While the CFS has not been validated in patients ≤65 years, evidence suggests that frailty reflects biological age, rather than chronological age and therefore warrants evaluation in those younger than 65 years.[31] Specific to COVID-19, evidence shows that disease outcomes in hospitalised patients 18 years and older were better predicted by frailty than by age or comorbidity.[32]

Post-COVID-19 Functional Status Scale (PCFSS)

Developed in early 2020, this five-point scale assesses how individuals have been affected in their everyday life by COVID-19 illness and recovery.[33] Lower grades indicate better functioning, with grade 0 representing the absence of symptoms or functional limitations and grade four reflecting severe limitations and symptom burden.[33] The PCFSS can be patient-reported following a flow diagram series of questions to result in a grade, or it can be administered via structured interview, which is more comprehensive. We will conduct the structured interview over the phone and the patient-reported flow chart during the home visits.

Functional Independence Measure

The FIM assesses patients' functional status based on the level of assistance they require, with grading categories ranging from 'total assistance with helper' to 'complete independence with no helper'.[34 35] Evaluated tasks include bowel and bladder control, transfers, locomotion, communication and social cognition. The FIM has good inter-rater reliability, construct validity and responsiveness to change in adults 45 years and older.[36] We included the FIM at 3-month and 6-month post-hospital discharge, as an established measure by which to compare the responsiveness of the AM-PAC and PCFSS. This measure will be administered by telephone interview, which has shown to be a valid alternative to the traditional multidisciplinary observational method of administration with total score agreements (intraclass correlation coefficients) ranging from 0.65 to 0.92.[37–39]

Impact of Event Scale-Revised

This self-report measure includes 22 items that capture subjective distress caused by traumatic events. Each item is rated on a five-point scale from 0 ('not at all') to 4 ('extremely') with total scores from 0 to 88; lower scores indicate less distress. The three subscales are intrusion, avoidance, and hyperarousal; subscale scores can be calculated separately.[40 41]

Hospital Anxiety and Depression Scale (HADS)

The HADS is a 14-item two-dimension scale that identifies depression and anxiety among physically ill patients. Scores range from 0 to 21, with higher scores indicating higher levels of anxiety. In the general ill population, a cut-off of ≥8 indicates depression.[42]

EuroQoL-5D-5L (EQ-5D-5L)

The EQ-5D-5L is a six-item questionnaire measuring health-related quality of life.[43] It assesses five domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each containing five responses from no problems with a domain to extreme problems or 'unable to' in a domain.[44] There is also an overall question of health state using a visual analogue scale from 0 (poor state of health) to 100 (good state of health). The EQ-5D-5L will be used to evaluate change in health-related quality of life over the course of recovery, and scores will be compared as such.

Fatigue Visual Analogue Scale

This visual scale allows individuals to rate their global fatigue from 0 (worst fatigue) to 10 (normal).[21 45]

Medical Research Council breathlessness scale

This brief questionnaire contains five statements describing a range of breathlessness from only becoming breathless with strenuous exercise (grade 1) to being too breathless to leave the house (grade 5). Higher grades indicate more functional limitations due to breathlessness.[46]

Pulmonary function tests

We will collect physiological measures, such as the need for ongoing supplemental oxygen, along with prebronchodilator spirometry measurements, including forced expiratory volume in 1-second (FEV_1), forced vital capacity (FVC), and FEV_1/FVC ratio following American Thoracic Society (ATS)/European Respiratory Society (ERS) guidelines.[47] Both research physiotherapists completed training with a pulmonologist on conducting these spirometry tests. Spirometry will be conducted with the participant sitting and wearing a nose clip. Up to a maximum of eight forced expiratory manoeuvres will be permitted to obtain three acceptable efforts, which will be recorded and graded at a later date. All recorded tests, including the spirographs, will be independently graded for acceptability and reproducibility by two pulmonologists following ATS/ERS criteria.[48]

Short Performance Physical Battery (SPPB)

The SPPB combines the results of three tests of physical function (gait speed over 4 m, five-repetition chair stand, progressive balance test) to assess lower extremity function. Tests are scored on a five-point scale from 0 (patient unable to perform) to four based on the time the patient takes to complete the walk, chair stands and balance tests

with a sum score from 0 (worst performance) to 12 (best performance).[49 50] The SPPB has good to excellent test–retest reliability in older adults (intraclass correlation coefficient 0.81 to 0.91).[51–53] Cut-off scores of ≤10 indicate increased odds of mobility disability[54] and scores of ≤7 indicate increased odds of rehospitalisation or death.[55]

Oxygen saturation (SpO_2)

SpO_2 will be measured using a fingertip pulse oximeter to detect hypoxia and to evaluate any persistent hypoxia post-COVID-19 illness. We will measure SpO_2 before and after the spirometry and physical function assessments based on the findings of a recent systematic review highlighting the importance of assessing exertional desaturation in patients with COVID-19.[56] Based on existing evidence, authors recommend that a drop of 3% in SpO_2 measurements from rest to exertion should be cause for further assessment.[56]

Sample size

We will enrol consecutive patients until a minimum sample of 211 is recruited or until the end of our operational funding window. We calculated sample size based on detecting a minimal clinically important change of 3.3 points (SD 7.3) from premorbid scores in the AM-PAC mobility score over 12 months,[27] which corresponds to an effect size of 0.23, assumes a power of 80% with alpha set to 0.05 and accounts for 30% loss to follow-up.[57] To date, 130 patients have been enrolled and recruitment is ongoing.

Proposed statistical methods

Descriptive analyses for continuous variables using measures of central tendency and dispersion will be conducted. McNemar's test will be used to evaluate within-subject change in categorical variables across follow-up, and paired t-tests will be used to examine changes in continuous variables. If paired differences in continuous variables are not normally distributed, then the Wilcoxon signed-rank test will be used. We will conduct linear mixed effect regression analyses to determine how sociodemographic and clinical factors are associated with long-term functional recovery. Significance will be set at $p<0.05$. We will conduct a priori subgroup analyses based on age (≤65 vs >65) and frailty status (CFS ≤4 vs CFS >5) and VOC as permitted by sample size. If missing data is minimal (<5%) we will conduct a complete case analysis, otherwise we will use multiple imputation.

We will perform interim analyses as data become available to provide as real-time information as possible to inform pandemic care. While this data platform is being developed to answer the core questions outlined previously, the data will be made available to researchers who wish to conduct additional analyses related to COVID-19 recovery.

Data management and confidentiality

We will keep all collected data confidential with only the research team having access to completed questionnaires. At the beginning of the study, each participant will be assigned a unique identifier, and all data sources will be deidentified and coded. Records will only be electronic and will be stored on REDCap through the McMaster University network servers. REDCap is a secure web application that is protected by usernames and passwords that are assigned to individuals responsible for collecting data. Per Hamilton Integrated Research Ethics Board (HiREB) requirements, we will store all data for 5 years after data collection is completed.

ETHICS AND DISSEMINATION

Ethics and informed consent

This study has been approved by the HiREB for all Hamilton study sites, and by the Tri-Hospital Research Ethics Board for Kitchener-Waterloo sites. Participation in this study is voluntary, and participants provide informed consent.

Dissemination

We will report this study in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology Statement.[58] We will disseminate results at national and international academic conferences, through peer-reviewed publications, through communications with key stakeholders and hospital leadership and through the COREG website (www.coregontario.ca). This study will contribute important data to advance our understanding of the recovery of physical function and rehabilitative care needs of survivors of serious COVID-19 illness.

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Contributors MB, APC, MD, TH and RKr conceived the study. MB, JCR, APC, MD, TH, RKr, PR, RKi, AJ, SC, NR, MM, LEG, CS, BV, MM-R, SH, LM, AP and CG assisted in designing the study. JCR, RKi, HM, SC, CS, MJ, CG and TP are assisting with data collection. JCR led the writing of the manuscript in consultation with MB. All authors read, provided feedback and approved the manuscript for submission.

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Competing interests None declared.

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