



Supporting Information

Supplementary material

This appendix was part of the submitted manuscript and has been peer reviewed.
It is posted as supplied by the authors.

Appendix to: Seidler AL, Aberoumand M, Williams JG, et al. The landscape of COVID-19 trials in Australia. *Med J Aust* 2021; doi: 10.5694/mja2.51148.

Table 1. Characteristics of included coronavirus disease 2019 (COVID-19) drug trials (n = 34)

Trial ID	Scientific title	Status	Sample size	Population	Comorbidity	Drug type	Trial purpose
NCT04567810	A Phase 1 Study in Healthy Participants to Evaluate the Safety, Tolerability, and Pharmacokinetics of Single -Ascending and Multiple Doses of an Anti-Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Chicken Egg Antibody (IgY)	Recruiting	48	Healthy volunteers	None	Intranasal anti-severe acute respiratory syndrome coronavirus 2 chicken egg antibody	Prevention: other
ACTRN12620001104943	A Phase 1, Placebo-Controlled, Single Dose, Escalating Dose Study to Determine the Safety and Tolerability of Intranasal REVTx-99 in Healthy Adult Volunteers	Not yet recruiting	32	Healthy volunteers	None	Intranasal REVTx-99	Prevention: other
ACTRN12620000816954	A Double-blinded, Randomised, and Placebo-controlled Safety Study of AT-301 Nasal Spray in Healthy Adults	Not yet recruiting	32	Healthy volunteers	None	Intranasal AT-301	Treatment: drug
NCT04532294	A First-in-Human, Randomized, Double-Blind, Placebo Controlled, Single Dose Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Immunogenicity of SARS-CoV-2 Neutralizing Antibody BGB-DXP593 in Healthy Subjects	Recruiting	30	Healthy volunteers	None	Intravenous SARS-CoV-2 neutralizing antibody BGB-DXP593	Other
ACTRN12620000834954	A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Multiple Ascending Doses of GP1681 in Healthy Adult Participants	Not yet recruiting	24	Healthy volunteers	None	Oral GP1681	Treatment: drug
ACTRN12620000501943	Effectiveness of Prophylactic Hydroxychloroquine on incidence of COVID-19 infection in Front-line Health and Allied Health Care Workers: The COVID-SHIELD Trial	Recruiting	2250	Healthcare professionals	None	Oral hydroxychloroquine	Prevention: other
ACTRN12620000473965	Reducing acute severe respiratory events in health care workers during the Covid-19 pandemic with OM85	Recruiting	1000	Healthcare professionals	None	Oral OM85	Prevention: other

Trial ID	Scientific title	Status	Sample size	Population	Comorbidity	Drug type	Trial purpose
ACTRN12620000417987	Multi-Site, Randomized, Open-Label, Parallel-Group, Placebo-Controlled Study to Assess the Chemoprophylactic Efficacy of Chloroquine Against SARS-CoV-2/COVID-19 in Healthcare Workers at High-Risk of Exposure	Recruiting	680	Healthcare professionals	None	Oral chloroquine	Prevention: other
ACTRN12620000843954	COVID-19 Prevention and Treatment in Cancer; a Sequential Multiple Assignment Randomised Trial; C-SMART study. Arm 1: Effect of daily Interferon-alpha on cancer patients without known positive contact with COVID-19	Not yet recruiting	1914	Individuals at high-risk of poor outcomes	Neoplasm	Intranasal interferon-alpha	Prevention: other
ACTRN12620000842965	COVID-19 Prevention and Treatment in Cancer; a Sequential Multiple Assignment Randomised Trial; C-SMART study. Arm 2: Effect of daily Interferon-alpha on cancer patients with known positive contact with COVID-19	Not yet recruiting	170	Exposure to COVID-19	Neoplasm	Intranasal interferon-alpha	Prevention: other
ACTRN12620000588998	The safety and efficacy of STC3141 in patient with COVID-19 ARDS require intensive care	Withdrawn (recruitment difficulties)	160	Suspected/confirmed COVID-19	None	Intravenous STC3141	Treatment: drug
ACTRN12620000445976	Australasian COVID-19 Trial (ASCOT). A multi-centre randomised clinical trial to assess clinical, virological and immunological outcomes in patients with SARS-CoV-2 infection (COVID-19) treated with lopinavir/ritonavir and/or hydroxychloroquine compared with standard of care	Recruiting	2500	Confirmed COVID-19	None	Intravenous convalescent plasma*	Treatment: drug
NCT04483960	An International Multi-Centre Randomised Clinical Trial to Assess the Clinical, Virological and Immunological Outcomes in Patients Diagnosed With SARS-CoV-2 Infection (COVID-19)	Recruiting	2400	Confirmed COVID-19	None	Intravenous convalescent plasma	Treatment: drug
NCT04382924	A Randomized Open Label Phase 2b/3 Study of the Safety and Efficacy of NP-120 (Ifenprodil) for the Treatment of Hospitalized Patient With Confirmed	Recruiting	682	Confirmed COVID-19	None	Oral NP-120 (Ifenprodil)	Treatment: drug

Trial ID	Scientific title	Status	Sample size	Population	Comorbidity	Drug type	Trial purpose
	COVID-19 Disease						
NCT04394117	Controlled evaluation of Angiotensin Receptor Blockers for COVID-19 respiratory Disease	Recruiting	605	Confirmed COVID-19	None	Oral angiotensin II receptor blockers	Treatment: drug
ACTRN12620000982910	A randomized double-blind placebo-controlled trial of oral ivermectin outpatient treatment, to prevent hospitalisation, of those at high risk for hospitalization due to SARS-CoV-2 (COVID-19)	Not yet recruiting	400	Confirmed COVID-19	Circulatory system disease, respiratory system disease and endocrine disease	Oral ivermectin	Treatment: drug
NCT04439071	Evaluation of the Efficacy and Safety of PTC299 in Hospitalized Subjects With COVID-19 (FITE19)	Recruiting	380	Confirmed COVID-19	None	Oral PTC299	Treatment: drug
NCT03808922	A Phase III Randomized Placebo-Controlled Study to Examine the Efficacy and Safety of DAS181 for the Treatment of Lower Respiratory Tract Parainfluenza Infection in Immunocompromised Subjects	Recruiting	250	Confirmed COVID-19	None	Nebulised DAS181	Treatment: drug
ACTRN12620000557932	Therapies to prevent progression of COVID-19, including Hydroxychloroquine, Azithromycin, Zinc, Vitamin D, Vitamin B12 with or without Vitamin C, a multi-centre, international, randomized trial: The International ALLIANCE Study	Recruiting	200	Confirmed COVID-19	None	Intravenous vitamin C (sodium ascorbate)	Treatment: drug
NCT04445467	An Adaptive Randomised Placebo Controlled Phase II Trial of Antivirals for COVID-19 Infection	Recruiting	190	Confirmed COVID-19	None	Oral favipiravir	Treatment: drug
ACTRN12620000731998	Safety and efficacy of a pharmacological strategy using Losartan in hospital patients with COVID-19	Not yet recruiting	36	Confirmed COVID-19	None	Oral losartan	Treatment: drug
ACTRN12620000788976	Safety and efficacy of intranasal delivery of	Not yet	30	Confirmed	None	Intranasal bromelain	Treatment:

Trial ID	Scientific title	Status	Sample size	Population	Comorbidity	Drug type	Trial purpose
	BromAc® (Bromelain & Acetylcysteine) in swab positive SARS-CoV-2 patients – inactivating the COVID-19 virus by cleavage of the spike and other glycoproteins	recruiting		COVID-19		and acetylcysteine	drug
ACTRN12620000470998	Virucidal pilot study of Nasodine® Antiseptic Nasal Spray (povidone-iodine 0.5%) in people with COVID-19 and confirmed nasal shedding of SARS-CoV-2 virus	Not yet recruiting	20	Confirmed COVID-19	None	Intranasal Nasodine Antiseptic Spray (povidone-iodine 0.5%)	Prevention: other
NCT04323761	Expanded Access Treatment Protocol: Remdesivir (RDV; GS-5734) for the Treatment of SARS-CoV2 (CoV) Infection	Completed	N/A	Confirmed COVID-19	None	Intravenous remdesivir	Not available
ACTRN12620000517976	A randomised controlled trial of Nebulised Heparin in critically ill mechanically ventilated patients with COVID-19 to assess the effect on the duration of mechanical ventilation.	Recruiting	206	Severe COVID-19	None	Nebulised heparin	Treatment: drug
ACTRN12620000447954	Use of therapeutic drug monitoring (TDM) to optimise oral/enteral hydroxychloroquine dosing in critically ill patients with COVID-19	Recruiting	150	Severe COVID-19	None	Oral/enteral hydroxychloroquine	Treatment: drug
ACTRN12620000454976	High-dose intravenous zinc (HDIVZn) as adjunctive therapy in COVID-19 positive critically ill patients: A pilot randomized controlled trial	Recruiting	160	Severe COVID-19	None	Intravenous high dose zinc	Treatment: drug
ACTRN12620000841976	COVID-19 Prevention and Treatment in Cancer; a Sequential Multiple Assignment Randomised Trial; C-SMART study. Arm 3: Effect of selinexor in cancer patients with moderate COVID-19 infection	Not yet recruiting	126	Moderate COVID-19	Neoplasm	Oral selinexor	Treatment: drug
ACTRN12620000478910	Cord Blood Therapy to prevent progression of COVID-19 related pneumonia	Not yet recruiting	24	Moderate COVID-19	None	Intravenous cord blood therapy	Treatment: drug
ACTRN12620000840987	Phase I trial on safety and tolerability of bone-marrow derived mesenchymal stromal cells (MSC)	Recruiting	10	Moderate COVID-19	None	Intravenous bone-marrow derived	Treatment: drug

Trial ID	Scientific title	Status	Sample size	Population	Comorbidity	Drug type	Trial purpose
	for deteriorating COVID-19 pneumonia					mesenchymal stromal cells	
ACTRN12620000580976	Tocilizumab for the treatment of COVID-19 in intensive care patients: effect on days free of ventilatory support	Not yet recruiting	150	Severe COVID-19	None	Intravenous tocilizumab	Treatment: drug
ACTRN12620000844943	COVID-19 Prevention and Treatment in Cancer; a Sequential Multiple Assignment Randomised Trial; C-SMART study Arm 4: Effect of Lenzilumab in cancer patients with severe COVID-19 infection	Not yet recruiting	72	Severe COVID-19	Neoplasm	Intravenous lenzilumab	Treatment: drug
ACTRN12620000676910	Allogeneic Amniotic Epithelial Cells for the Treatment of COVID-19 related respiratory failure, a pilot feasibility randomised controlled trial	Not yet recruiting	40	Severe COVID-19	None	Intravenous allogeneic amniotic epithelial cells	Treatment: drug
ACTRN12620000612910	A pilot, open-label, randomised controlled clinical trial to investigate early efficacy of CYP-001 in adults admitted to intensive care with COVID-19	Recruiting	24	Severe COVID-19	None	Intravenous allogeneic mesenchymoangioblast-derived mesenchymal stem cells	Treatment: drug

ARDS = acute respiratory distress syndrome; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2. * Trial arms were adapted and changes were not reflected through trial registration as of 16 November 2020.

Table 2. Characteristics of all included coronavirus disease 2019 (COVID-19) vaccine trials (n = 10)

Trial ID	Scientific title	Status	Sample size	Population	Comorbidity	Vaccine type	Trial purpose
NCT04368988	A 2-Part, Phase 1/2, Randomized, Observer-Blinded Study To Evaluate The Safety And Immunogenicity Of A SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With Or Without MATRIX-M™ Adjuvant In Healthy Subjects	Recruiting	1419	Healthy volunteers	None	Intramuscular SARS-CoV-2 recombinant Spike protein nanoparticle vaccine	Prevention: vaccine
ACTRN12620000817943	A randomized, observer-blind, placebo-controlled, Phase I/II study to evaluate the safety, reactogenicity and immunogenicity of Receptor Binding Domain (RBD) SARS-CoV-2 (COVID-19) Hepatitis B surface antigen (HBsAg) virus like particle (VLP) Vaccine in Healthy Adults	Recruiting	280	Healthy volunteers	None	Intramuscular receptor binding domain SARS-CoV-2 Hepatitis B surface antigen virus like particle vaccine	Treatment: other
NCT04495933	A Phase 1, Randomised, Double-Blind, Placebo-Controlled, Dosage-Escalation, Single Centre Study to Evaluate the Safety and Immunogenicity of an Adjuvanted SARS-CoV-2 Sclamp Protein Subunit Vaccine in Healthy Adults Aged 18 to 55 Years Old and Healthy Older Adults, Aged 56 Years and Over	Recruiting	216	Healthy volunteers	None	Intramuscular adjuvanted SARS-CoV-2 Sclamp protein subunit vaccine	Prevention: vaccine
NCT04405908	A Phase 1, Randomized, Double-blind, Placebo-controlled, First-in-human Study to Evaluate the Safety and Immunogenicity of SCB 2019, a Recombinant SARS-CoV-2 Trimeric S Protein Subunit Vaccine for COVID-19 in Healthy Volunteers	Recruiting	150	Healthy volunteers	None	Intramuscular recombinant SARS-CoV-2 trimeric S protein subunit vaccine	Prevention: vaccine
ACTRN12620000674932	A Phase 1 Randomised, Double-Blind, Placebo-Controlled, Dosage-Escalation, Single Centre Study To Evaluate The Safety And Immunogenicity Of An Adjuvanted SARS-CoV-2 Sclamp Protein Subunit Vaccine (COVID-19 vaccine) In Healthy Adults Aged 18 To 55 Years Old	Recruiting	120	Healthy volunteers	None	Intramuscular adjuvanted SARS-CoV-2 Sclamp protein subunit vaccine	Prevention: vaccine

Trial ID	Scientific title	Status	Sample size	Population	Comorbidity	Vaccine type	Trial purpose
NCT04453852	A Randomised, Controlled, Phase 1 Study to Evaluate the Safety and Immunogenicity of a Candidate Adjuvanted Recombinant Protein SARS-COV-2 Vaccine in Healthy Adult Subjects	Recruiting	40	Healthy volunteers	None	Intramuscular adjuvanted recombinant protein SARS-COV-2 vaccine	Prevention: vaccine
NCT04334980	A Phase 1, Randomized, Observer-Blind, Placebo-Controlled Trial to Evaluate the Safety, Tolerability and Immunogenicity of the bacTRL-Spike Oral Candidate Vaccine for the Prevention of COVID-19 in Healthy Adults	Not yet recruiting	12	Healthy volunteers	None	Oral bacTRL-Spike vaccine	Prevention: vaccine
ACTRN12620000707965	A Multicenter, Phase III, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy of the recombinant BCG VPM1002 on the Incidence or Disease Severity of SARS-COV-2/COVID-19 Among High-Risk Participants in Australia	Withdrawn (commercial reasons)	3468	Individuals at high-risk of poor outcomes	Circulatory system disease, respiratory system disease and endocrine disease	Intramuscular recombinant Bacillus Calmette–Guérin (BCG) vaccine VPM1002	Treatment: other
NCT04333732	An International, Multi-site, Bayesian Platform Adaptive, Randomized, Placebo-controlled Trial Assessing the Effectiveness of Candidate Agents in Mitigating COVID-19 Disease in Healthcare Workers	Not yet recruiting	30000	Healthcare professionals	None	Adaptive design*	Prevention: vaccine
NCT04327206	BCG Vaccination to Reduce the Impact of COVID-19 in Healthcare Workers Following Coronavirus Exposure (BRACE) Trial	Recruiting	10078	Healthcare professionals	None	Intramuscular BCG vaccine	Prevention: vaccine

SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2. * Trials with adaptive design are subject to change and have been grouped as per information current on the 16 November 2020.

Table 3. Characteristics of all other included coronavirus disease 2019 (COVID-19) trials (n = 12)

Trial ID	Scientific title	Recruitment status	Sample size	Population	Comorbidity	Intervention type	Trial purpose
ACTRN12620000477921	The use of a simplified negative pressure cuirass style ventilator under COVID-19 pandemic conditions in support of critically overwhelmed healthcare systems	Completed	1	Healthy volunteers	None	Simplified negative pressure cuirass style ventilator	Treatment: other
ACTRN12620000688987	Comparing the user seal check and fit test between two types of N95 respirators in anaesthetic staff members - the Halyard N95 Particulate Filter Respirators and the ProShield® N-95 masks	Completed	80	Healthcare professional	None	Halyard N95 Particulate Filter Respirators and the ProShield® N-95 masks	Treatment: other
ACTRN12620000579998	Simulation time taken among consultant anaesthetists to perform spinal anaesthesia or general anaesthesia for COVID-19 patients requiring an emergency category 1 caesarean delivery	Not yet recruiting	10	Healthcare professional	None	Anaesthesia	Other
ACTRN12620000640909	A phase II, open label non-randomised clinical trial of the safety and efficacy of the CovidCare app to support self-monitoring for COVID-19 symptoms in self-isolation and to determine the impacts on mental health	Not yet recruiting	200	Exposure to COVID-19	None	CovidCare app	Treatment: other
ACTRN12620000698976	Does a Health Package of exercise and advice on anxiety management and nutrition improve outcomes and experiences of patients with COVID-19 isolated at home or Special Health Accommodation under the care of Royal Prince Alfred (RPA) Virtual Hospital and those without COVID-19 quarantined in Sydney Local Health District Special Health Accommodation?: a pilot trial	Recruiting	40	Exposure to COVID-19	None	Exercise and advice on anxiety management and nutrition	Prevention: other
ACTRN12620000472976	Adapting the Decathlon Group Easybreathe® snorkelling face mask for the safer administration of oxygen and/or continuous positive airway pressure	Not yet recruiting	100	Suspected/confirmed COVID-19	None	Decathlon Group Easybreathe® snorkelling face	Treatment: other

Trial ID	Scientific title	Recruitment status	Sample size	Population	Comorbidity	Intervention type	Trial purpose
	and in the intra/interhospital transportation of patients with proven or suspected COVID 19 infection					mask ventilator	
ACTRN12620000524998	ReCOVER (Remote COVID-19 Evaluation and Response): a prospective non-randomised controlled trial to evaluate the effect of a novel smartphone application-centric model of care for the remote monitoring of COVID-19 patients in the community, on avoidable hospital presentations	Not yet recruiting	2000	Confirmed COVID-19	None	Remote monitoring smartphone application and care model	Treatment: other
ACTRN12620000566932	BEAT COVID-19: A Bayesian adaptive randomised controlled trial platform to evaluate the efficacy of interventions for high risk older patients with COVID-19 in reducing the risk of hospital admission or death	Not yet recruiting	400	Confirmed COVID-19	Circulatory system disease, respiratory system disease, nervous system disease, immune system disease, endocrine disease and neoplasm	Treatments or interventions*	Treatment: other
ACTRN12620000443998	Home telerehabilitation for people with COVID-19: Implementing telehealth approaches to care and its effect on reintegration into the community	Not yet recruiting	58	Confirmed COVID-19	None	Home tele rehabilitation	Treatment: other
ACTRN 12620000635965	Open label, prospective study for the Biofourmis Everion armband telemonitoring solution for patients during COVID-19 home isolation within South West Sydney to assess the feasibility and suitability of the Everion armband device in the telemonitoring of	Not yet recruiting	50	Confirmed COVID-19	None	Biofourmis Everion armband telemonitoring solution	Prevention: other

Trial ID	Scientific title	Recruitment status	Sample size	Population	Comorbidity	Intervention type	Trial purpose
	COVID-19 high risk patients under home isolation period						
ACTRN12620000500954	A reusable personalised ventilation hood for care of patients with suspected or confirmed COVID-19 in the intensive care, emergency and respiratory healthcare settings: A phase 1 safety study of a new device (McMonty)	Not yet recruiting	20	Confirmed COVID-19	None	Reusable personalised ventilation hood	Prevention: other
ACTRN12620000740998	A Randomised Controlled Trial of Early Prone Positioning to Improve Oxygenation in Non-Intubated Adults Admitted to Intensive Care with COVID-19	Not yet recruiting	20	Confirmed COVID-19	None	Early prone positioning	Treatment: other

* Trials with adaptive design are subject to change and have been grouped as per information current on the 16 November 2020.

Table 4. Characteristics of coronavirus disease 2019 (COVID-19)-related trials (n = 12)

Trial ID*	Scientific title	Status	Sample size [†]	Population	Health area	Health area specifics	Intervention details
ACTRN12620000975998	Feasibility and acceptability of a volunteer-peer telephone support programme for individuals diagnosed with COVID-19	Not yet recruiting	100	Persons diagnosed with COVID or in close contact with COVID who accessed healthcare by Northern Health Victoria	Mental health	Depression, loneliness and social isolation	Weekly phone calls (20-40 min) from volunteers (supported by psychologists) for a 12-week period, social in nature. No control, all participants tracked over time.
ACTRN12620000811909p	Randomised Controlled Trial of Positive Mood Training versus Enhanced Treatment as Usual on Anxiety and Depression in People Distressed by COVID-19	Not yet recruiting	240	Persons suffering anxiety and depression	Mental health	Depression and anxiety	Random allocation to Positive Mood Training (weekly 60 min video-conference sessions for 7 weeks with psychologist) or Enhanced Treatment as Usual (provided a self-guided manual).
ACTRN12620000787987p	Randomised Controlled Trial of Problem Management Plus versus Enhanced Treatment as Usual on Anxiety and Depression in People Distressed by Financial Problems Due to COVID-19	Not yet recruiting	206	Persons suffering psychological distress	Mental health	Depression and anxiety	Random allocation to Problem Management Plus program (weekly 60 min video-conference sessions for 7 weeks with psychologist) or Enhanced Treatment as Usual (access to a self-guided problem management plus manual).
ACTRN12620000779976	A pragmatic study to disseminate low intensity, evidence supported Cognitive behaviour therapy and the effect on anxiety and depression in adults during the COVID-19 pandemic	Recruiting	100	Individuals accessing mental health services	Mental health	Depression and anxiety	Participants are provided a self-help guide on Cognitive Behaviour therapy upon completion of registration (immediate group) or one week after registration and following post-intervention questionnaire completion (waitlist group).
ACTRN12620000636954p	COACHING FOR COVID-19: A Pilot Study Investigating the Effectiveness of Coaching on	Not yet recruiting	35	Senior doctors employed by Liverpool Hospital	Mental health	Depression, anxiety, other mental health and	Doctors are matched with a coach and meet via Zoom (1 x 30 min intro, 1 x 60 min first session, followed by 5 x 30 min

	Psychological Outcomes in Hospital-Based Senior Doctors					Healthcare professionals	sessions at 3-week intervals) where psychological stress will be monitored throughout.
ACTRN12620000571976	Evaluation of Shift, a smartphone application for New South Wales Junior Medical Officers, on depression and anxiety during the COVID-19 epidemic.	Completed	75	Junior medical officers in NSW	Mental health	Depression, anxiety and healthcare professionals	Participants are all provided with access to the 'Shift' app to address pandemic-related concerns. Participants can use 2-5 activities (of a total 51) per week. Pre- and post-assessment is made.
ACTRN12620000555954	Randomised controlled trial of an app-based intervention, Anchored, to support the mental health of Australians recently unemployed due to COVID-19.	Completed	492	Persons who are unemployed as a result of COVID-19 and experiencing symptomatic depression	Mental health	Anxiety, depression, suicide and unemployment	Random allocation to the 'Anchored' smartphone app (5-10 min completed daily) or given access to a psycho-educational online resources for a 30-day period.
ACTRN12620000468921p	Randomised Controlled Trial of Problem Management Plus versus Enhanced Treatment as Usual on Anxiety and Depression in People Distressed by Covid 19	Not yet recruiting	140	Persons suffering psychological distress	Mental health	Depression and anxiety	Random allocation to Problem Management Plus program (weekly 60 min video-conference sessions for 6 weeks with psychologist) or Enhanced Treatment as Usual (access to a website outlining evidence-based mindfulness strategies).
NCT04602312	Online RCT Comparing the Effects of Mindfulness, Sham Mindfulness and Book Listening Control on Coronavirus-related Catastrophizing in Adults	Recruiting	624	Healthy individuals	Mental health	Anxiety, stress and catastrophizing	Random allocation to mindfulness meditation, specific sham mindfulness meditation, general sham mindfulness meditation or book listening control via 1 x 20 min online audio training.
ACTRN12620000448943	Expressive Writing To Combat Distress Associated With The COVID-19 Pandemic In People With Inflammatory Bowel Disease	Recruiting	154	Person diagnosed with inflammatory bowel disease and suffering mild distress	Mental health and gastrointestinal disease	Depression, anxiety and inflammatory bowel disease	Random allocation to an expressive/gratitude writing program (4 x 30 min sessions in one week writing about their inflammatory bowel disease based on an evidence based writing program) or an active control (4 x 30

							min sessions in one week writing about trivial topics). Both sessions conducted by researcher with psychology degree.
ACTRN12620000492954p	Feasibility of a Facebook delivered physical activity focused group lifestyle intervention for older adults during the COVID-19 pandemic	Not yet recruiting	20	Healthy individuals >60 years living alone	Mental health and physical activity	Depression, physical inactivity and older adults	Participants receive weekly information and contribute to conversations on topics relating to physical activity for a 6-week period through a private Facebook group, delivered by an exercise physiologist and dietitian. Participants can also join 20-30 min Zoom calls organised twice each week.
ACTRN12620000860965	A randomised controlled trial on the effect of a smart device enabled monitoring system on management of heart failure among patients with pre-existing left ventricular dysfunction during COVID-19 isolation	Not yet recruiting	400	Persons with left ventricular dysfunction or heart failure who do not have impaired cognitive function	Cardiovascular disease	Heart failure, and cardiac rehabilitation	Random allocation of access to a smartphone app, in addition to standard care to manage cardiac rehabilitation at home. Daily reporting of blood pressure, medication adherence, task completion, stress, heart rate, goals and patient reported outcomes. Entries are reviewed by patient's clinician.

* Provisional trials are indicated with a 'p', and have been submitted but not yet approved by the ANZCTR. † Sample size represents the target sample size as indicated on the trial record.

Table 5. Definition of coronavirus disease 2019 (COVID-19) core outcomes*

Outcome	Definition
Mortality	Patient mortality; patient death; patient survival
Respiratory failure	Patient respiratory failure; patient need for intubation; patient need for mechanical ventilation; duration of patient intubation/ventilation; P/F ratio (arterial PO ₂ /FIO ₂) indicative of acute respiratory distress syndrome (ARDS) or respiratory failure
Multi-organ failure	Patient organ failure (other than lung); sequential organ failure assessment (SOFA) score; patient sepsis
Shortness of breath	Patient shortness of breath; dyspnoea; breaths/min
Recovery	Patient time to recovery; patient recovery; patient number of sick days; patient time to clinical improvement; duration of hospitalisation

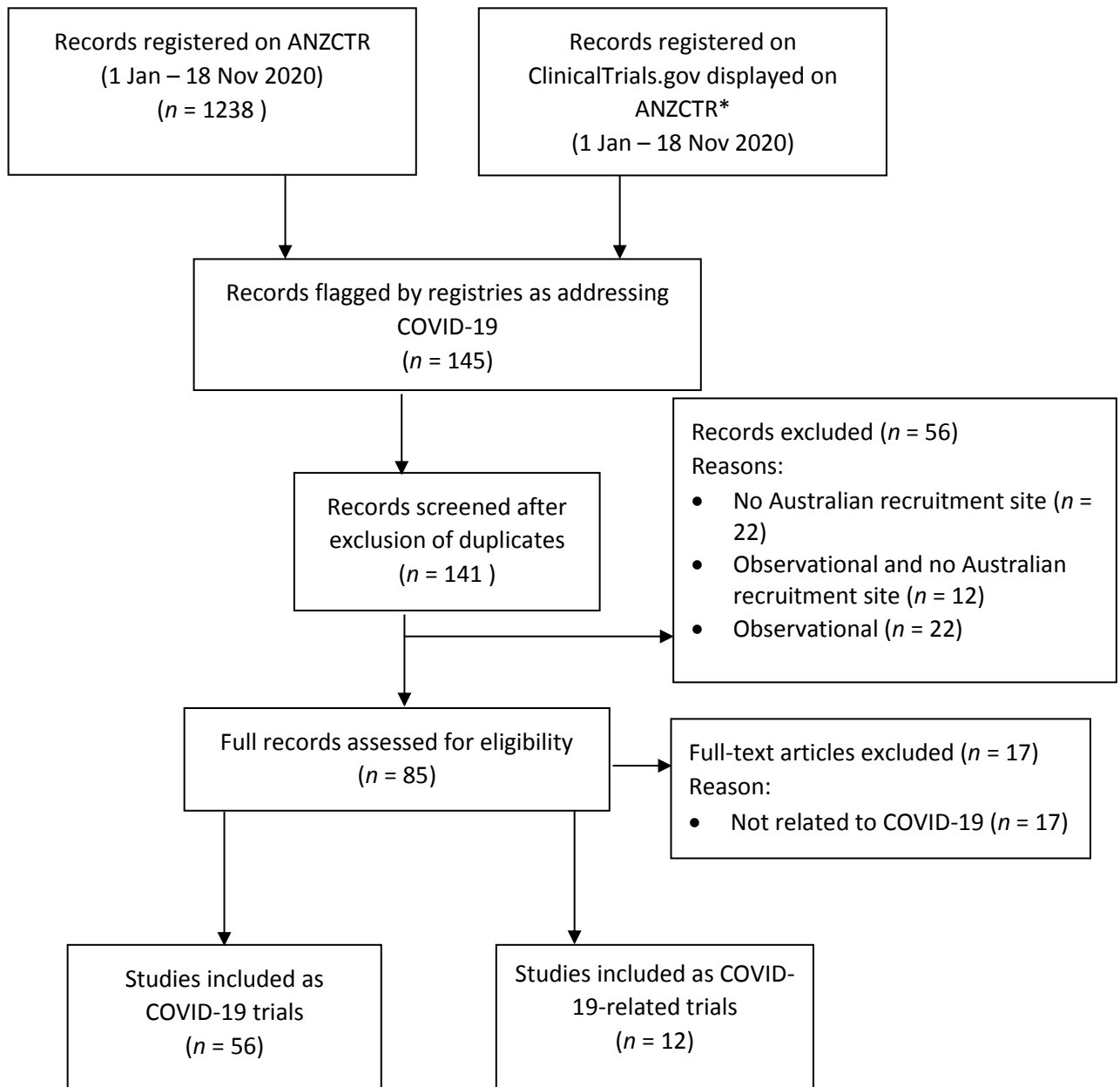
FIO₂ = fraction of inspired oxygen; P/F = arterial partial pressure of oxygen/ fraction of inspired oxygen;
 PO₂ = partial pressure of oxygen. * Core outcomes previously outlined, as defined for our study.

Table 6. Data sharing plans of coronavirus disease 2019 (COVID-19) trials and COVID-19-related trials

	COVID-19 trials	COVID-19-related trials	Overall
Total number of trials	56	12	68
IPD availability			
Planning on sharing IPD	10 (20%)	4 (36%)	14 (23%)
Not planning on sharing IPD	41 (80%)	7 (64%)	48 (77%)
No data sharing plan provided (excluded from percentage)	5	1	6
Reason for trials not planning on sharing IPD			
No reason	21/41 (51%)	3/7 (43%)	24/48 (50%)
Analyse aggregate data	7/41 (17%)	1/7 (14%)	8/48 (17%)
Undecided	5/41 (12%)	0	5/48 (10%)
Protect participant privacy	3/41 (7%)	1/7 (14%)	4/48 (8%)
Lack ethical approval	2/41 (5%)	1/7 (14%)	3/48 (6%)
No external relevance	2/41 (5%)	0	2/48 (4%)
Not data custodian	0	1/7 (14%)	1/48 (2%)
Mechanism accessibility for trials sharing IPD			
Principal investigator contact	7/10 (70%)	4/4 (100%)	11/14 (79%)
Primary sponsor contact	3/10 (30%)	0	3/14 (21%)
Data repository	0	0	0
Full protocol available	0	0	0

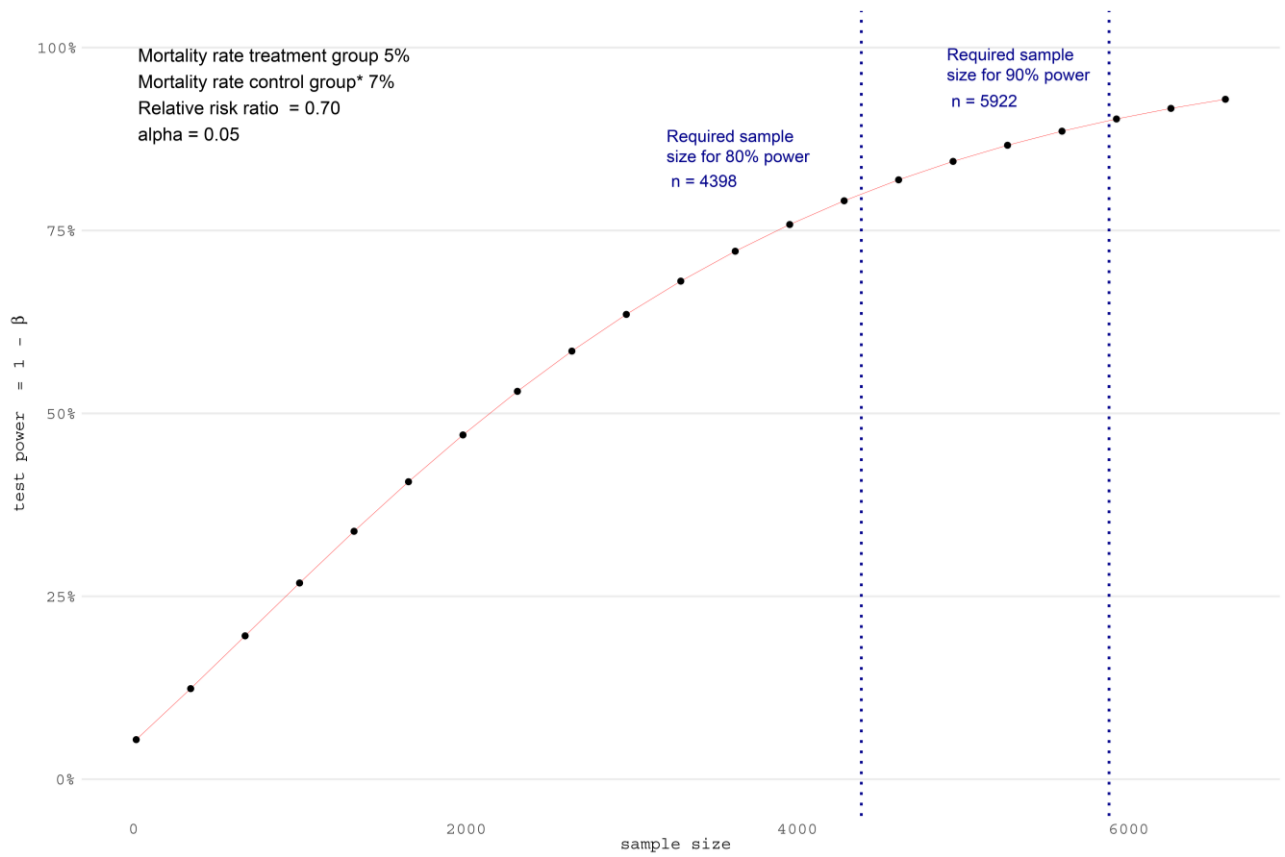
IPD = individual participant data.

Figure 1. Flow chart of study selection



ANZCTR = Australian New Zealand Clinical Trials Registry; COVID-19 = coronavirus disease 2019.

Figure 2. Power calculations to detect mortality for hospitalised coronavirus disease 2019 (COVID-19) patients



* Indicative mortality rates have been extracted. ²

References

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