

# BMJ Open Loddon Mallee healthcare worker COVID-19 study – protocol for a prospective cohort study examining the health and well-being of rural Australian healthcare workers during the COVID-19 pandemic

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**To cite:** McEvoy M, Parker C, Crombie A, *et al.* Loddon Mallee healthcare worker COVID-19 study—protocol for a prospective cohort study examining the health and well-being of rural Australian healthcare workers during the COVID-19 pandemic. *BMJ Open* 2021;**11**:e050511. doi:10.1136/bmjopen-2021-050511

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online. (<http://dx.doi.org/10.1136/bmjopen-2021-050511>).

Received 22 February 2021  
Accepted 26 July 2021



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## ABSTRACT

**Introduction** The COVID-19 pandemic is creating immense psychosocial disturbance. While global, broad-based research is being conducted, little is known about the effects of the COVID-19 pandemic on health and well-being or how protective and resilience factors influence the human response in Australian rural and regional communities. Rural and regional communities often have less resources to deal with such public health emergencies and face additional environmental adversity. Healthcare workers, including those in rural and regional areas, have felt the immediate impacts of COVID-19 in a multitude of ways and these impacts will continue for years to come. Therefore, this study aims to describe and understand the impacts of the COVID-19 pandemic on the rural and regional healthcare workforce within the Loddon Mallee region, Victoria, Australia.

**Methods and analysis** This prospective cohort of rural and regional healthcare workers will be recruited and followed over 3 years to examine the effects of the COVID-19 pandemic on their health and well-being. Self-administered online questionnaires will be administered every 6 months for a 36-month period. Multiple outcomes will be assessed; however, the primary outcomes are emotional health and well-being and psychological resilience. Emotional health and well-being will be measured using validated instruments that will assess multiple domains of the emotional health and well-being continuum.

Linear and logistic regression and latent growth curve modelling will be used to examine the association between baseline and follow-up participant emotional health, well-being and resilience while adjusting for potentially time-varying confounding variables. Participant characteristics measured at baseline will also be tested for association with incident health, morbidity, mortality and health service utilisation outcomes at follow-up.

**Ethics and dissemination** Ethical approval has been obtained through the Bendigo Health Human Research Ethics Committee. The study findings will be disseminated

## Strengths and limitations of this study

- This large prospective cohort study will examine the impact of the COVID-19 pandemic on the health and well-being of the healthcare workforce in regional and rural Victoria, Australia, which to date has been largely unexplored.
- The longitudinal study design will allow changes in mental health and well-being over time to be measured, defining the temporal sequence of events, and providing stronger evidence for a causal association with risk factors.
- Latent growth curve modelling will allow trajectories of psychological distress and resilience (eg, resilient, chronic distress, recovered and delayed recovery) to be identified; predictors of each class will be examined by incorporating various indicators of resilience into the models.
- Non-English speaking people were excluded from the study, however the prevalence of this is very low in the Loddon Mallee region of Victoria, and even lower in the healthcare workforce.
- The representativeness nature of the sample is limited to the Loddon Mallee region of rural and regional Victoria, Australia.

through international conferences, international peer-reviewed journals and social media.

**Trial registration number** ACTRN12620001269921.

## BACKGROUND

### Context

With the first reports of the global COVID-19 pandemic in December of 2019, and the first case in Australia recorded on 13 January 2020; the situation quickly escalated to declaration of a ‘Public Health Emergency’ by the WHO

on 30 January 2020.<sup>1</sup> Every person has been impacted by COVID-19 in some way. This highly infectious virus exposed healthcare workers to unprecedented situations, enabling the potential for immediate and ongoing negative mental health effects and health-related behaviours. Healthcare workers both endured the severe lockdowns and social restrictions that took place around Australia to reduce transmission, and they also had to cope with the volume of infected cases and the risks to themselves and fear of transmitting the virus to their immediate family.<sup>2</sup>

Within a 20-year span, there has been several viral epidemics of this level.<sup>3</sup> Considering this and the magnitude of similar problems that arose across health services, including exposure concerns, worker fatigue and limited diagnostic tests globally<sup>4</sup> for each of these outbreaks, the scientific community needs to provide factual, clear and timely information to better manage and support healthcare workers.<sup>5</sup> Recent findings suggest that regardless of the volume of cases or deaths, healthcare workers are vulnerable to both physical and psychosocial harm from the COVID-19 pandemic.<sup>6</sup>

Although there are data on the impacts of the COVID-19 pandemic on healthcare workers from other countries that include metropolitan, regional and rural populations,<sup>3 7-11</sup> there is a scarcity of data on regional and rural populations in Australia. To the best of the authors' knowledge, at the time of writing, three COVID-19-related healthcare worker studies have been published in Australia<sup>12-14</sup> and only one of these included healthcare workers from rural and regional communities.<sup>13</sup> Although the COVID-19 pandemic has impacted larger metropolitan health services they are often better equipped than the smaller rural and regional health services. They have a larger pool of experienced health professionals and resources with which to meet the short-term and long-term pressures that challenge the healthcare system in times of intensified pressure such as the current COVID-19 crisis.

The lack of understanding of the effects of the COVID-19 pandemic on rural and regional healthcare workers and their communities is detrimental for the public health of these communities. Due to the relatively small population size of rural communities, the health service is often the largest employer and the workforce touch so many of the community directly through their family and personal contacts, thus the impact on healthcare workers has more direct impact on the community generally than is the case in metropolitan areas. As such a significant and vulnerable group of regional and rural healthcare workers, clinical and non-clinical are being neglected, thus calling for urgent targeted clinical and policy strategies for these extraordinary times.

## Rationale

Like other pandemics and emerging disease outbreaks, COVID-19 is creating immense psychosocial disturbance. While global, broad-based research is being conducted, little is known about the effects of the COVID-19 pandemic

on health and well-being or how protective/resilience factors influence the human response in Australian rural and regional communities who often have less resources and face additional adversity in the form of drought and fire disasters.

This study presents a unique opportunity to conduct rigorous longitudinal analyses with an exclusively rural and regional focus. Longitudinal research of this type has rarely been undertaken in a historically under-represented rural and regional population, within the Australian context. Therefore, this study aims to describe and understand the impacts of the COVID-19 pandemic on the healthcare workforce across multiple health services in rural and regional Victoria, Australia.

## STUDY AIMS

### Research aims

This study aims to examine the impacts of the COVID-19 pandemic on the rural and regional healthcare workforce within the Loddon Mallee region, Victoria, Australia.

### Objectives

- ▶ To use a longitudinal study design to explore and describe the health and well-being impacts of the COVID-19 pandemic among a large rural and regional healthcare worker cohort.
- ▶ To identify protective/resilience factors, at the individual, organisation and community level that predict better physical and mental health outcomes for healthcare workers. Evidence-based resilience interventions may then be implemented in the future to improve the workforce response to major disruptions such as the COVID-19 pandemic.
- ▶ Inform policy options to support rural and regional healthcare workers in responding to major disruptions such as the COVID-19 pandemic.

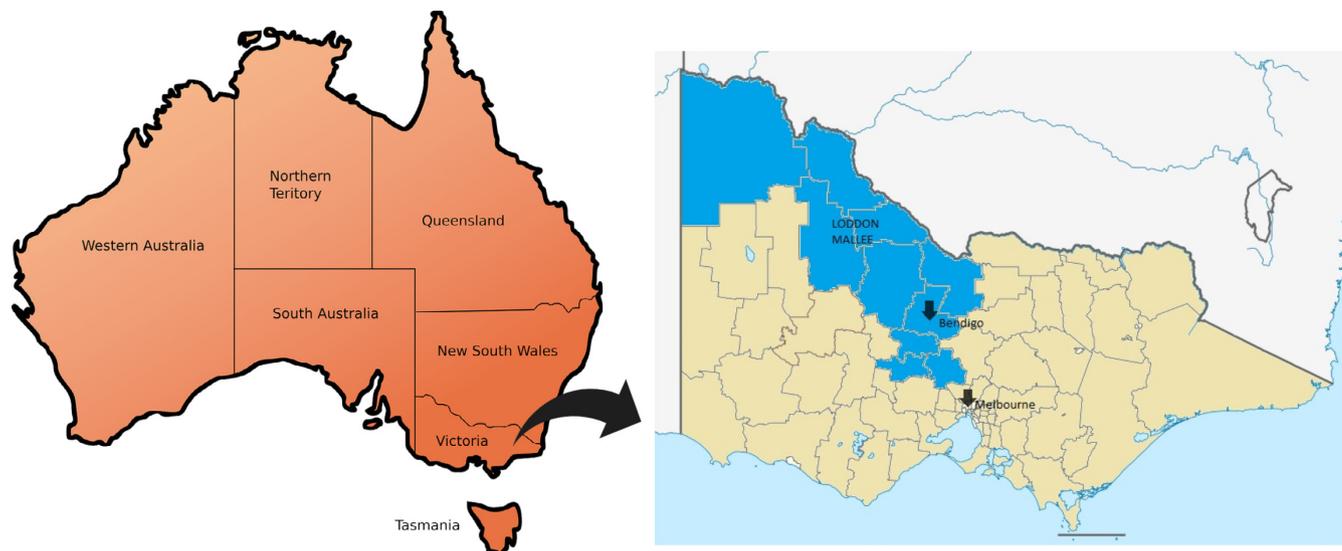
## METHODS AND ANALYSIS

### Study design

A prospective cohort of healthcare workers will be recruited and followed over 3 years to examine the effects of the COVID-19 pandemic on the health and well-being of these workers.

### Setting

The reference population for this study is rural and regional Australian healthcare workers. The source population will be healthcare workers within rural and regional Victoria. The sampling frame is healthcare workers currently working within the Loddon Mallee region. This includes all people who work in healthcare from participating health services within the Loddon Mallee region. The Loddon Mallee region was chosen for this study as it consists of a mix of large regional and smaller rural health services and has a broadly similar demographic profile to the rest of the Victorian rural and regional healthcare workforce in terms of age, gender and profession.<sup>15</sup> The



**Figure 1** Location of the participating healthcare services and Modified Monash geographical classification overview within the Loddon Mallee region, Victoria, Australia.

Loddon Mallee region covers one quarter of the land-mass of north central Victoria<sup>16</sup> and in 2019 had a population of 336 270<sup>17</sup> (figure 1). Of the towns comprising the Loddon Mallee region, 86% of postcodes are designated within the Modified Monash Model (MM),<sup>18</sup> 3–5 classifications with small rural towns (MM5) making up the majority of the region.

All healthcare workers will be invited to participate from 19 rural and regional health services, five community health centres and the Murray Primary Health Network (Murray PHN) with a combined workforce of 14511 people. The Murray PHN, covering an area of almost 100 000 square kilometres in northern Victoria, works directly with primary healthcare providers including general practitioners and other health providers such as hospitals.<sup>17</sup>

#### Eligibility criteria

All eligible healthcare workers at each participating Loddon Mallee health service will be invited to participate in the study. Healthcare worker is defined as a person who is employed or volunteering as a health service provider or health management and support worker.

#### Inclusion

- ▶ Age 18 or over
- ▶ Currently employed or volunteering as a health service provider or health management and support worker in a participating healthcare service in the Loddon Mallee region.

- ▶ Ability to provide informed consent

#### Exclusion

- ▶ Inability to use electronic devices (required to complete the questionnaire)
- ▶ Non-English-speaking people.

#### RECRUITMENT

##### Data collection methods

The study commenced in November 2020 and data collection will continue until December 2023. An online self-administered questionnaire will be conducted at baseline and every 6 months for a 36-month period. At 3, 9 and 15 months, a smaller questionnaire containing selected instruments will also be administered so that short-term changes in important mental health and well-being outcomes are not missed. A summary of the study outcomes, outcome measurement instruments and measurement timepoints is provided in table 1. The baseline questionnaire is available as a online supplemental file.

Potential study participants from the Loddon Mallee healthcare workforce will be identified from organisational staff email lists. One week prior to recruitment a general prenotification email will be sent to all staff members informing them that they will soon receive an invitation to participate in the study. This email will highlight the importance of the study and how the information will be used to help the workforce and to make changes to improve the response to future pandemics and disasters.







Table 1 Continued

Outcome category	Specific outcome	Outcome measuring instruments	Study timepoint (months)								
			0	3	6	9	12	15	18	24	30
Outcome measures related to the psychological aspects of work	Stress	Job Stress Scale (13-items) <sup>78</sup>	■		■		■		■		■
	Satisfaction	Satisfaction with Work Scale (6-item) <sup>79</sup>	■		■		■		■		■
	Well-being (work-related)	Work engagement: Utrecht Work Engagement Scale (3-items) <sup>80</sup>	■		■		■		■		■
	Burnout	Copenhagen Burnout Inventory <sup>81</sup>	■		■		■		■		■
Outcome measures related to the physical aspects of work	Physical capacity	SF-12 Physical Component Summary Score (5-items) <sup>44</sup>	■		■		■		■		■
	Absenteeism, presenteeism and attrition	Job-stress-related presenteeism (6-items) <sup>82</sup> HR record linkage	■		■		■		■		■
	Performance (productivity and quality)	The Conditions for Work Effectiveness Questionnaire (19-items) <sup>83</sup>		■			■		■		■
Outcome measures related to work status and self-efficacy	Occupational self-efficacy	Occupational Self-Efficacy Scale (6-items) <sup>84</sup>	■		■		■		■		■
Organisational culture	Organisational culture	Use organisational aggregate data	■	■	■	■	■	■	■	■	■
Safety climate	Measures attitudes and perceptions towards safety at a specific point in time	The Multilevel Safety Climate Scale (16-items) <sup>85</sup>			■				■		
Workplace psychological safety	Psychological safety	Psychologically safe workplace questionnaire (7-items) <sup>86</sup>	■		■		■		■		■
Health service quality indicators		Use organisational data	■	■	■	■	■	■	■	■	■
Medical and medication errors		Use organisational data	■	■	■	■	■	■	■	■	■
Workplace accidents		Use organisational data	■	■	■	■	■	■	■	■	■
COVID training/infection control and resource prioritisation		Specific questions (26-items)		■			■		■		■
	Social connectedness	Social Connectedness Index <sup>87</sup>	■		■		■		■		■
	Access and use of support services	Specific questions regarding access and use of support services (1-item)	■		■		■		■		■
	Built environment	Environmental Distress Scale (6-items) <sup>88</sup>			■				■		
	Neighbourhood walkability	GIS-derived street connectivity	■	■	■	■	■	■	■	■	■
	Neighbourhood cohesion	3 questions in household, sociodemographic and neighbourhood section			■				■		
	Neighbourhood disadvantage	Socio-Economic Indices for Area	■	■	■	■	■	■	■	■	■
	Geographic remoteness	Modified Monash Model (Rurality) ARIA	■	■	■	■	■	■	■	■	■

ADLs, Activities of Daily Living; ARIA, Accessibility/Remoteness Index of Australia; GIS, Geographic Information System; HR, Human Resources; SF-12, Short Form-12.

### Participant consent

One week after the prenotification email is delivered, all staff will be sent an email inviting them to participate in the study. The email will provide a link to access an online

questionnaire. Potential participants will be automatically directed to the study 'landing and eligibility page'. Those who are eligible will be automatically directed to the participant information and consent form (PICF). All

potential participants will be informed of the purpose of the study, confidentiality, their rights and how the information provided will be used. Potential participants will be asked if they consent (yes or no). If consent is denied, these people will be thanked for their time and be asked to complete a short eight-item questionnaire asking about their reasons for declining and some demographic characteristics. This will allow the characteristics of the questionnaire responders to be compared with the non-responders to determine if non-response bias is likely to be an issue for the study. Those that provide consent will be automatically directed to complete the questionnaire. Potential participants will be given the option of consenting to participate in:

1. The current research study (yes or no).
2. Future research studies that may or may not be related to the current study (yes or no).
3. Linking of their study information with Victorian and National Health databases (yes or no).

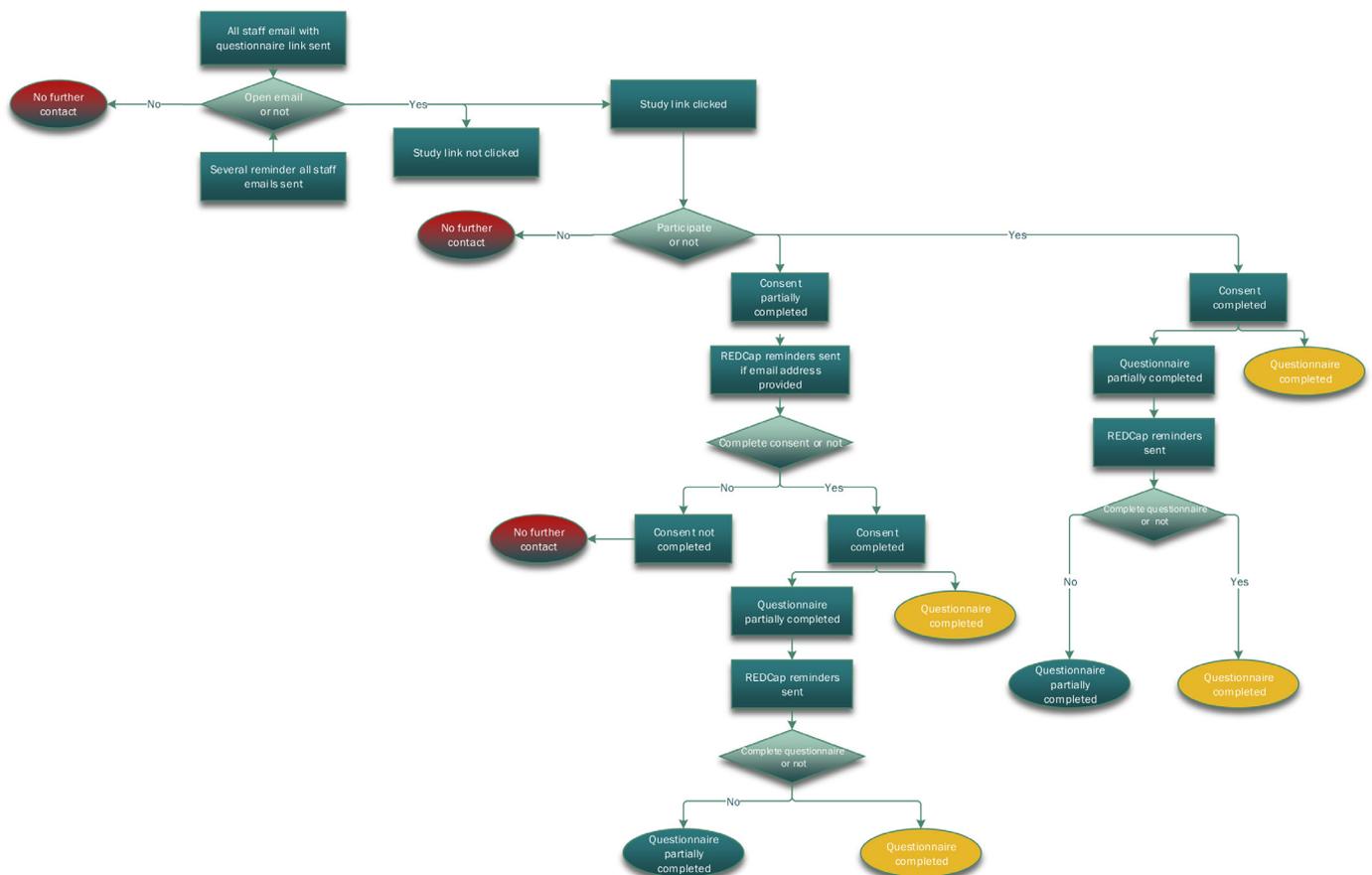
Potential participants who do not respond will be sent several reminder emails. Each reminder email will include a link to the PICF and questionnaire. Those who initially provide consent but do not submit the completed questionnaire will also receive reminder emails as described above. There will be an ability for participants to save their questionnaire if it has not been completed and return to complete it later. Each follow-up questionnaire will be

conducted in the same way as the baseline questionnaire with reminder emails also being sent to those who initially do not reply to the follow-up questionnaire. A summary of this recruitment strategy is outlined in [figure 2](#).

### Follow-up assessments

Follow-up will be conducted two ways—using self-administered online questionnaires and through record linkage to Victorian and National Health administration databases. Except for outcomes that do not usually change over time (eg, personality type), all follow-up questionnaires will readminister the same outcome measuring instruments used at baseline at regular intervals during follow-up so that change in important outcomes can be measured.

To reduce loss to follow-up, study participants will be offered an incentive at each follow-up timepoint in the form of a random draw to win a grocery voucher. A fridge magnet will also be provided to each participant as a reminder that they are a valued study participant. So that we are able to maintain contact with participants, the fridge magnet will also remind participants to contact the study team if they change their contact details. Participants will also be sent a newsletter every 6 months as a way of regularly engaging with participants, and as a means of updating them on important study developments and findings.



**Figure 2** Graphical representation of the Loddon Mallee healthcare COVID-19 study recruitment strategy.



Record linkage will be used to virtually follow the cohort over time to identify outcomes such as mortality, morbidity, hospital admissions, medication use and health service utilisation. With consent, questionnaire data will be linked with health administration databases including: Victorian Emergency Minimum Dataset,<sup>19</sup> Victorian Admitted Episodes Dataset,<sup>20</sup> Victorian Integrated Non-Admitted Health,<sup>21</sup> Mental Health,<sup>22</sup> Mental Health Community Support Services,<sup>23</sup> Victorian Cancer Registry,<sup>24</sup> Victorian Death Index,<sup>25</sup> Elective Surgery Information System,<sup>26</sup> Medical Radiation—Victorian Radiotherapy Minimum Dataset,<sup>27</sup> Cause of Death Unit Record File,<sup>28</sup> Australian Cancer Database,<sup>29</sup> Medicare Benefits Schedule,<sup>30</sup> Pharmaceutical Benefits Schedule<sup>31</sup> and National Death Index.<sup>32</sup>

## Outcomes

This study will serve as a platform for answering a myriad of research questions related to the effects of the COVID-19 pandemic on the health and well-being of the Victorian rural and regional healthcare workforce. Therefore, the study will examine multiple outcomes across the health and well-being continuum. There is no established 'core outcome set' (COS) for examining health and well-being of healthcare workers. COSs are important to ensure that research across populations is standardised to allow valid comparisons of study findings to be made. As such, an outcome taxonomy was created based on the WHO International Classification of Functioning, Disability and Health<sup>33</sup> and Williamson and Clarke taxonomies<sup>34</sup> and constructed according to standards developed by the Core Outcome Measures in Effectiveness Trials initiative.<sup>35</sup> These provide a framework to ensure that all important outcomes across the health and well-being continuum are measured, and informed the decision-making regarding the choice of outcome measurement instruments used in this study.

Study outcomes were categorised at an individual, organisation and community levels. At the individual level, outcomes consist of mortality, morbidity, clinical and physiological function, physical function, emotional health and well-being, cognitive function, social function, health-related quality of life, role function, personal circumstances, lifestyle, family function, and health service utilisation.

At an organisational level, outcomes include those related to the psychological aspects of work, physical aspects of work, work status and self-efficacy, safety climate, workplace psychological safety, health service quality indicators, COVID-19 training/infection control, and resource prioritisation.

At the community level, outcomes consist of access and use of support services, built environment, neighbourhood walkability, neighbourhood cohesion, neighbourhood disadvantage, and geographic remoteness.

The study outcomes and outcome measuring instruments are described in [table 1](#).

## Primary outcomes

Although there are multiple study outcomes, the primary outcomes are emotional health and well-being and psychological resilience. The emotional health and well-being of healthcare workers will be measured at baseline and follow-up using self-administered online questionnaires. Emotional health and well-being will be measured using self-reported validated measures of well-being, generalised anxiety, fear of COVID-19, post-traumatic stress disorder, depressive symptoms, psychological stress, suicide ideation, resilience, mental fatigue, hope, self-efficacy, coping, worry, happiness, purpose, optimism, perceived control over life, childhood trauma, impact of life events, mindfulness, family history of mental disorder, and personality type.

## Secondary outcomes

Secondary outcomes include mortality, morbidity, self-reported clinical and physiological function, physical function, cognitive function, social function, health-related quality of life, role function, personal circumstances, lifestyle, family function, health service utilisation, as well as organisational and community outcomes and these will be measured at baseline and follow-up using self-administered online questionnaires.

## Outcome measurement instruments

The health and well-being outcomes will be measured at baseline and follow-up using validated instruments. The choice of outcome measurement instruments was determined using:

- ▶ Detailed review of existing literature focused on the study population in the context of previous pandemics and disasters.
- ▶ Evidence from published systematic reviews of outcome measuring instruments for each outcome.
- ▶ Consensus-based Standards for the selection of health Measurement Instruments database.<sup>36</sup>
- ▶ Evidence of superior psychometric properties and acceptability within the target population.
- ▶ Consultation with discipline-specific outcome experts.
- ▶ Discussion with lead researchers who have also developed COVID-19 research studies in healthcare workers.
- ▶ Consensus agreement between the study investigator team and the study scientific steering committee.

Given that there are many outcome measurement instruments, what follows is a summary of the instruments used to measure the primary outcomes—emotional health and well-being, and resilience. Emotional health and well-being will be measured using the following validated instruments: Personal Well-being Index-Adult,<sup>37</sup> Generalised Anxiety Disorder-7,<sup>38</sup> Fear of COVID-19 Scale,<sup>39</sup> Impact of Events Scale-6,<sup>40</sup> Patient Health Questionnaire,<sup>41</sup> Perceived Stress Scale,<sup>42</sup> Suicidal Behaviours Questionnaire-Revised,<sup>43</sup> Short Form-12 (SF-12),<sup>44</sup> Adult State (Snyder) Hope Scale,<sup>45</sup> General Self Efficacy Scale,<sup>46</sup> Brief COPE,<sup>47</sup> Penn State Worry Scale,<sup>48</sup> Mental

Health Continuum Short Form,<sup>49</sup> Life Orientation Test-Revised,<sup>50</sup> Perceived Control Scale,<sup>51</sup> Childhood Trauma Questionnaire-Short Form,<sup>52</sup> Mindfulness Attention Awareness Scale<sup>53</sup> and Big 5 Inventory-Short Form.<sup>54</sup>

Resilience will be measured at baseline and follow-up in two ways—the validated Brief Resilience Scale<sup>55</sup> and examining health states/outcomes considered to be markers of resilience (ie, healthy lifestyle behaviours, absence of morbidity, absence of psychological distress, etc.).

### Sociodemographic variables

Sociodemographic variables include age, gender, education, marital status, household income, type of housing, number of people in household, postcode and number of dependents.

### Clinical and physiological variables

Self-reported clinical, anthropometric and physiological variables include height, weight, resting pulse, systolic and diastolic blood pressure, somatic complaints,<sup>56</sup> medical and surgical history, hearing, vision, presymptomatic screening, nutritional supplement use, age at menarche, age at menopause, number of pregnancies, age at each pregnancy, breastfeeding history, use of oral contraceptives and use of hormone replacement therapy.

### Lifestyle and lifestyle change variables

Self-reported lifestyle behaviour variables include dietary consumption, physical activity, smoking tobacco, alcohol consumption, and sleep duration and quality.

Self-reported change in lifestyle behaviours due to the COVID-19 pandemic include change in diet, change in physical activity (time and intensity), change in sitting time, change in the frequency of meals/snacking, and change in sleep duration and quality.

### Employment background and work situation

Occupational variables include employment status, type of healthcare setting and department/service, type of profession, number of years in profession, and absenteeism.

### COVID-19 pandemic-specific variables relating to the workplace

Occupational variables assessing the impacts of the COVID-19 pandemic in the workplace include primary place of work during the pandemic, workplace redeployment, pandemic preparedness, COVID-19 infection control training, access and appropriate use of personal protective equipment (PPE), confidence in PPE training and contact with COVID-19 patients.

### COVID-19 pandemic-specific variables relating to individual health and well-being

Variables assessing the impacts of the COVID-19 on the health and well-being of healthcare workers include impact of the pandemic of everyday life, COVID-19 testing history and status, hospitalisation due to COVID-19, quarantine due to COVID-19, fear of contracting

and transmitting COVID-19, effects of the pandemic on socialisation and travel, effects of the pandemic on relationships, effects of the pandemic on safety behaviours, and self-rated overall health during the pandemic.

### Potential positive experiences encountered during the COVID-19 lockdown

Participants will be asked to reflect on any potential positive experiences that they may have encountered during the COVID-19 pandemic and lockdown. These variables include increased time spent with family, less workplace stress due to working at home, positive changes in relationships, more time to complete household projects, more time for hobbies, learning new skills, saving money and a new-found sense of gratitude for the freedoms that may have previously been taken for granted.

### Confounding variables

As there are several research questions under investigation, the choice of confounding variables will depend on the research question under investigation and the potential causal relationship between the exposure and the outcome. Potential confounding variables include personal characteristics, organisational factors, social and personal lifestyle factors and community factors. Directed Acyclic Graphs<sup>57</sup> will be used to determine potential confounders based on the traditional definition of a confounder.<sup>58</sup> For the primary aim of this study, the following potentially confounding variables will be considered in the analysis: sociodemographic factors (age, sex, marital status, income and education), family history of mental disorders, alcohol intake, tobacco smoking, physical activity, diet quality, sleep duration/quality, adverse life events, comorbidity, social support, and community neighbourhood social and ecological characteristics.

### Patient and public involvement

There are no patients involved in this study. The participants were healthcare workers. Healthcare workers, as members of the study population were involved in the design and management of the study. We received input from healthcare workers who worked in the participating health services and associated organisations in the design of the study materials and management oversight through membership of the scientific steering committee. The burden on the study participants was assessed by administering the baseline questionnaire to a small group of healthcare workers who provided feedback on questionnaire length and impacts of specific questions.

We intend to disseminate the main findings to study participants and will seek their involvement in the development of an appropriate method of dissemination.

### Sample size

Given that there are multiple study outcomes and no single hypothesis, the sample size for this study was determined based on a range of baseline exposure prevalence and outcome prevalence or incidence. Given a sample size of 4000 participants with statistical power of 80% and

significance of level of 5%, the minimal detectable effects for a range of baseline exposures and outcome prevalence vary between 1.2 and 2.1. With the same sample size and level of statistical significance, the minimal detectable effects for a range of baseline exposure prevalence and outcome incidence vary between 1.2 and 2.5. This is based on a range of outcome incidence over 3 years for those aged 18–65 years.

### Statistical analysis plan

Baseline descriptive characteristics of the sample will be described. Linear and logistic regression will be used to examine the association between participant characteristics measured at baseline with emotional health and well-being and resilience while adjusting for potentially confounding variables.

Participant characteristics measured at baseline will also be tested for association with incident health/disease/mortality/health service utilisation outcomes at follow-up. Cox proportional hazard regression models will be used to investigate the association of baseline measures with each outcome at follow-up while adjusting for potential time-varying confounding variables.<sup>59</sup>

Latent growth curve modelling<sup>60</sup> will be used to identify trajectories of psychological distress and resilience (eg, resilient, chronic distress, recovered and delayed recovery). Predictors and indicators of each class will then be examined by incorporating various indicators of resilience into the models. Missing data will be handled using best practice multiple imputation methodology.<sup>61</sup>

We agree that loss to follow-up can be expected in any cohort study. To reduce loss to follow-up, study participants will be offered an incentive at each follow-up time-point in the form of a random draw to win a grocery voucher. A fridge magnet will also be provided to each participant as a reminder that are a valued study participant. The fridge magnet will also remind participants to contact the study team if they change their contact details. Participants will also be sent a newsletter every 6 months as a way of regularly engaging with participants and as a means of updating them on important study developments and findings.

Depending on the research question, loss to follow-up will be addressed using linear mixed models under the assumption of an immortal cohort with data missing at random. However, this is not appropriate if the data is missing not at random (MNAR). Therefore, a sensitivity analysis will be performed based on the assumption that data could be MNAR. In this case, a linear-increment model or joint modelling of longitudinal outcomes and time to death will be used. Under the assumption of a mortal cohort, inverse probability weighting or multiple imputation will be used.<sup>62</sup>

### Data management, storage and security

An online REDCap database will store collected data.<sup>63 64</sup> This database will be managed by an independent data manager. Study data will be kept securely on password

protected computers at Bendigo Health and only the research team will know the password. Only the data manager will have access to a file with identifiable data. All data will be linked via an ID code. Linked data will be stored in a specific secure unified research environment developed by the Sax Institute<sup>65</sup> as required by the Australian Institute of Health and Welfare and the Department of Health and Human Services.

## ETHICS AND DISSEMINATION

### Ethics approval

Ethics approval has been granted by the Bendigo Health (Review Reference LNR/20/BH/68671), La Trobe University (Reference 68671) and St John of God Healthcare (Reference 1746) Human Research Ethics Committees.

### Dissemination

The study findings will be disseminated through international conferences, international peer-reviewed journals and social media.

### Protocol

This study protocol is registered as a prospective cohort study on the Australian New Zealand Clinical Trials Registry (ANZCTR).

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**Acknowledgements** The authors would like to thank participating Loddon Mallee healthcare workers and volunteers for their support of this study. The authors thank the members of the Study Scientific Steering Committee who provided guidance and support for this study.

**Contributors** AC and MM initially designed the study with input from PF and AM. MM coordinated study set-up and finalisation of study questionnaire with CP, LB and GC. All authors (MM, AC, CP, LB, GC, PF, AM, SB and TS) contributed to questionnaire development and final study design in addition to editing and critiquing the final manuscript for intellectual content.

**Funding** This work was supported by COVID-19 Research grant provided by the Victoria Government Department of Jobs, Precincts and Regions.

**Map disclaimer** The inclusion of any map (including the depiction of any boundaries therein), or of any geographic or locational reference, does not imply the expression of any opinion whatsoever on the part of BMJ concerning the legal status of any country, territory, jurisdiction or area or of its authorities. Any such expression remains solely that of the relevant source and is not endorsed by BMJ. Maps are provided without any warranty of any kind, either express or implied.

**Competing interests** None declared.

**Patient consent for publication** Not required.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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