BMJ Open

Impact of the COVID-19 pandemic on people in need of care or support: protocol for a SARS-CoV-2 registry

Jochen Gensichen,[1] Isabel Zöllinger ,[1] Ildiko Gagyor ,[2] Anita Hausen,[3] Michael Hölscher,[4] Christian Janke,[4] Thomas Kühlein,[5] Armin Nassehi,[6] Daniel Teupser,[7] Florian M Arend,[7] Christine Eidenschink,[2] Dagmar Hindenburg,[2] Helena Kosub,[1] Peter Konstantin Kurotschka,[2] Daniela Lindemann,[1] Katharina Mayr,[6] Susan Müller,[1] Laura Rink ,[5] Marietta Rottenkolber,[1] Linda Sanftenberg ,[1] Rita Schwaiger,[1] Maria Sebastião,[5] Domenika Wildgruber,[3] Tobias Dreischulte,[1] BaCoM Study group

To cite: Gensichen J, Zöllinger I, Gagyor I, *et al*. Impact of the COVID-19 pandemic on people in need of care or support: protocol for a SARS-CoV-2 registry. *BMJ Open* 2023;**13**:e071134. doi:10.1136/bmjopen-2022-071134

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-071134).

JG and IZ contributed equally.

JG and IZ are joint first authors.

Received 15 December 2022
Accepted 28 April 2023

For numbered affiliations see end of article.

Correspondence to
Dr Jochen Gensichen;
Jochen.Gensichen@med.uni-muenchen.de

ABSTRACT

Introduction People in need of care or support are severely affected by the COVID-19 pandemic. We lack valid data of long-term assessments. We present a register study to detect the physical and psychosocial impact of the COVID-19 pandemic on people in need of care or support in Bavaria, Germany. To describe the persons' life conditions comprehensively, we assess the perspectives and needs of the respective care teams too. Results will serve as evidence-based source to manage the pandemic and long-term prevention strategies.

Methods and analysis The 'Bavarian ambulatory COVID-19 Monitor' is a multicentre registry including a purposive sample of up to 1000 patient–participants across three study sites in Bavaria. The study group consists of 600 people in need of care with a positive SARS-CoV-2 PCR test. Control group 1 comprises 200 people in need of care with a negative SARS-CoV-2 PCR test, while control group 2 comprises 200 people with a positive SARS-CoV-2 PCR test but are not in need of care. We assess the clinical course of infection, psychosocial aspects and care needs using validated measures. Follow-up is every 6 months for up to 3 years. Additionally, we assess up to 400 people linked to these patient–participants (caregivers, general practitioners (GPs)) for their health and needs. Main analyses are stratified by level of care I–V (I=minor/V=most severe impairment of independence), inpatient/outpatient care setting, sex and age. We use descriptive and inferential statistics to analyse cross-sectional data and changes over time. In qualitative interviews with 60 stakeholders (people in need of care, caregivers, GPs, politicians), we explore interface problems of different functional logics, of everyday and professional perspectives.

Ethics and dissemination The Institutional Review Board of the University Hospital LMU Munich (#20-860) and the study sites (Universities of Wurzburg and Erlangen) approved the protocol. We disseminate the results by peer-reviewed publications, international conferences, governmental reports, etc.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This large, multicentre registry fills an evidence gap in COVID-19 research by focusing on a vulnerable, under-represented group of people, who are in need of care in ambulatory settings (long-term care facilities, informal/family care, etc) and survived COVID-19 infection.
⇒ A 36-month follow-up provides data on long-term clinical course and sequels.
⇒ A multiprofessional research team (ie, general practice, nursing, sociology and infectology) and a triangulated research approach combining quantitative and qualitative methods provide multiple perspectives and comprehensive analyses.
⇒ Prestatus (before the pandemic) of the study population is not available; patient-reported outcomes and interviews are at risk for recall bias and social desirability.
⇒ Due to limited life expectancy of the predominantly frail participants, we include additional participants over time (open registry).

INTRODUCTION

By February 2022, the WHO noted 433 million cases and almost six million deaths from COVID-19. Many COVID-19 survivors will be affected by long-lasting and debilitating sequelae.[1] One of the most vulnerable and affected groups by the COVID-19 pandemic are people in need of care or support, including older and frail people.[2–6] In Germany, until end of 2022, people aged 60 years and older accounted for more than two-thirds (71.4%) of COVID-19 cases in old people's and nursing homes,[7] and in the first year of the pandemic, the majority of the COVID-19 deaths involved people under care of an outpatient care service or living in a long-term care facility.[8]

Apart from a higher risk of death from COVID-19 for the older, the physical, psychological and social impact of the COVID-19 pandemic and the subsequent needs of COVID-19 survivors may differ between younger and frail older survivors of COVID-19 for a number of reasons. Multimorbidity is the rule rather than an exception among older people and COVID-19 may exacerbate both general frailty and specific comorbidities that are particularly affected by COVID-19 (such as respiratory and cardiovascular disease).[2 9] All of these factors may prolong recovery, increase the likelihood of long-COVID/post-COVID syndrome and increase dependency.[10 11] In addition, long-term care facilities have frequently implemented drastic infection control measures, with external and internal contact restrictions aggravating feelings of loneliness and isolation among their residents (irrespective of age or frailty status), which may have long-term consequences for mental and physical health.[12–15]

The additional care needs of often frail COVID-19 survivors also placed a further burden on formal and on informal caregivers, who had already been physically and psychologically challenged by staff shortages, fear of infection and frequent encounters with death.[11 16 17] Furthermore, the pandemic was also a disruption to the provision of routine primary care—for example, in Germany, general practitioners (GPs) cared for 90% of COVID-19 patients.[18 19]

Against this background, it appears likely that the COVID-19 pandemic has and will continue to have a relevant impact on the physical and psychosocial health of people in need of care or support as well as on those caring for them, including formal (eg, nursing stuff) and informal (eg, family members /relatives) caregivers and GPs.

Aim and objectives

The aim of the 'Bavarian ambulatory COVID-19 Monitor (BaCoM)' is, therefore, to conduct a systematic assessment of the physical, psychological and social long-term outcomes and sequels of the COVID-19 pandemic on people in need of care or support as well as their care needs and the needs of care providers. The findings should support the development and implementation of long-term prevention and aftercare strategies. The specific study objectives are:

1. To examine clinical parameters, psychosocial burden and care needs in people dependent on care or support.
2. To examine long-term sequels in people in need of care or support.
3. To examine the needs of formal and informal caregivers

METHODS AND ANALYSIS

Study design and setting

BaCoM is a multicentre, open registry study in the State of Bavaria (Southern Germany). For objectives 1 and 2, we include patient-participants in one study group (SG) and two control groups (CG1 and CG2). The SG comprises people with evidence of a previous SARS-CoV-2 infection, who were in need of care or support at the time of infection and survived COVID-19. In order to examine the impact of COVID-19 on clinical parameters and psychosocial burden, participants in CG1 comprise people in need of care or support during the COVID-19 pandemic but without evidence of SARS-CoV-2 infection. In order to examine effect modification of the COVID-19 impact by need of care or support, participants in CG2 comprise people with evidence of a previous SARS-CoV-2 infection who were not in need of care or support at the time of infection. For objective 3 we also collect information from formal and informal caregivers of participants included in SG, CG1 and CG2 as well as their GPs.

Study population

Eligibility criteria for patients

The inclusion/exclusion criteria of the SGs and CGs are provided in table 1. All adult residents of the State of Bavaria who are 18 years or older at the time of recruitment and have had at least one SARS-CoV-2 test are eligible for inclusion in BaCoM. In order to determine COVID-19 status (for assignment to SG and CG2 vs CG1), we consider the results of PCR tests, where people with at least one previous positive test result (not older than 1 March 2020) are assigned to SG or CG2, respectively, and otherwise to CG1. In cases, where PCR test results are not available (which is commonly the case in later stages of the pandemic), people with rapid SARS-CoV-2 antigen test results (not older than 6 months) can be enrolled. Test results from antigen tests are interpreted in combination with any evidence of nucleocapsid antibodies measured as part of the study protocol (see the Data collection section). The assessment of nucleocapsid antibodies serves as a further means to verify any previous infection with SARS-CoV-2, which is not influenced by exposure to vaccines (since vaccines only trigger antibodies against the spike protein). Patients, who have previously been allocated to CG1, but who subsequently test positive for nucleocapsid antibodies, are classified as group-switchers and are reallocated to the SG accordingly.

Eligibility criteria for participating caregivers

Formal and informal caregivers are eligible for recruitment, if they are involved in the care or support of a recruited patient-participant.

Eligibility criteria for recruiting GPs

GPs are eligible for recruitment, if (a) they offer statutory health insurance service, (b) they care for COVID-19 patients, (c) they offer a primary healthcare service open for all patient groups.

Participant recruitment

Up to 1000 patient-participants (n=600 in SG and 200 in each of CG1 and CG2) are recruited at three study sites in Bavaria (Munich, Erlangen and Wurzburg). In addition, we recruit up to 200 formal caregivers, up to 100 informal

Table 1 Inclusion/exclusion criteria of patient-participants

Study group	*Control group 1*	*Control group 2*
Inclusion criteria:		
► Signed informed consent from the participant or a legal guardian ► Age≥18 years ► Sufficient knowledge of German to give consent/answer questionnaires or possibility of translation by an interpreter ► residence in Bavaria		
► Existing need for care (care level I–V*) *or* support (according to the clinical judgement of the recruiting doctor: current need for care or expected need in the near future (Clinical Frailty Scale≥5 and <9)[21 22] ► ***Positive*** SARS-CoV-2 PCR test (maximum backdated to 1 March 2020)	► Existing need for care (care level I–V*) *or* support (according to the clinical judgement of the recruiting doctor: current need for care or expected need in the near future (Clinical Frailty Scale≥5 and <9) ► ***Negative*** SARS-CoV-2 PCR test (maximum backdated to 1 March 2020) with respiratory infection	► ***No*** existing need for care (**no** care level I–V*) *or* support (according to the clinical judgement of the recruiting doctor: **no** current need for care or expected need in the near future (Clinical Frailty Scale<5)) ► ***Positive*** SARS-CoV-2 PCR test (maximum backdated to 1 March 2020)
Exclusion criteria:		
► Refugees/asylum seekers ► Life expectancy<6 months (clinical judgement of the recruiting doctor) ► Persons without health insurance		

The levels of care I–V are:
Care level I: minor impairment of independence.
Care level II: significant impairment of independence.
Care level III: severe impairment of independence.
Care level IV: most severe impairment of independence.
Care level V: most severe impairment of independence with special requirements for nursing care.
*The degree of independence of the person in need of care is decisive for classification into the care levels.

caregivers and up to 100 GPs. Patient-participants can be recruited in inpatient (long-term care facilities) or outpatient care settings (home care provided by informal caregivers and/or outpatient care services). In order to maximise the geographical spread of study participants, we implement a Bavarian-wide recruitment campaign with broad publicity. Recruitment of patient-participants can take place at any time after a SARS-CoV-2 PCR test result (subsequently referred to as the 'index test'). The index test is defined as the first positive SARS-CoV-2 test result (for SG and CG2) or otherwise the latest negative SARS-CoV-2 test result without any previous infection (for CG 1). Patient-participants are identified via their GP, the long-term care facility they live in, via outpatient care services or informal caregivers, or via self-referral. Irrespective of how prospective patient-participants are identified, they are either recruited by their GP or (if not available) a study physician.

The recruitment of GPs is carried out via in total 240 GCP-qualified practices of the Bavarian Research Practice Network and cooperating teaching practices. Further eligible general practices with a past or current focus on managing patients with COVID-19 are identified.

The participating GP's receive compensation for their work within the framework of the study (participant inclusion and information, baseline examination, follow-up (FU) surveys). For the recruitment from inpatient and outpatient care facilities, we use a list of about 700 eligible facilities in Bavaria with documented COVID-19 outbreaks who file their interest in participating in BaCoM via a reporting system to the Bavarian State Office for Health and Food Safety (Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit.

Data collection

Baseline data collection began on 1 March 2021 and enrolment will continue until the end of 2023. Data collection methods include blood samples, clinical investigations, data abstraction from clinical data sources, surveys as well as semistructured interviews (see tables 2–5). Appropriately trained study staff conduct all data collection, so that inter-rater reliability for all assessments (including questionnaires and clinical tests) can be ensured. It can be assumed that a certain proportion of the study participants will not be able to provide self-disclosure (eg, in case of cognitive impairment). In these cases, the information collection is to be ensured by relatives or caregivers who are asked instead. In order to ensure that the cognitive status is determined, the 'six-item screener'[20]—a cognitive short test—is administered (0–6 points). If the 'six-item screener' is not successfully completed (<4 points), the information collection of the self-reports will be ensured according to the substitution principle mentioned above.

Table 2 Schedule of enrolment and assessments in BaCoM: study group and control groups

Construct	Timepoint / Instrument	Baseline / Enrolment	FU_1–FU_x / 6 months after PCR test
Sociodemographic information*†	***Questionnaire***		
Age, sex, migration background, educational level, professional life/activity, income, marital status, health insurance, insurance number		x	
Care-specific parameters with reference to the need for care†*	***Questionnaire***		
Care level (I–V)/frailty level and onset date of the need for care/frailty	Clinical Frailty Scale[21 22]	x	x
Diagnosis justifying care		x	x
Capacity for giving consent/legal guardian		x	x
Care setting (outpatient/inpatient care)		x	x
Change of care level/frailty level and care setting since start of the pandemic		x	x
Provision of aids/therapies (Which are needed? Which ones are not supplied/prescribed due to the pandemic, etc? Which individual solution is used?)		x	x
Measures involving deprivation of freedom (before pandemic/during pandemic)		x	x
Pressure ulcer (before pandemic/during pandemic)		x	x
respiration		x	x
Self-rated pain levels	Rating scale[1–10]	x	x
Activities of daily living (ADL)	Barthel Index[35]	x	x
Nursing diagnoses in terms of NANDA-I (Definitions and Classification 2018–2020)[34] *†	***Questionnaire***		
Stability of respiratory parameters[38]	Likert Scale		
Impaired gas exchange		x	x
Impaired spontaneous breathing		x	x
Ineffective airway clearance		x	x
Sense of smell and taste	Likert Scale		
Smells all primary odours		x	x
Tasting all substance spectra		x	x
Social interaction[34 39]	Likert Scale		
Mobility, ability to walk		x	x
Communication verbal/via electronics (impaired/reports needs)		x	x
Family processes (*before and since the beginning of the pandemic*)	Likert Scale		
Continuous family processes (before and since the beginning of the pandemic)		x	x
Interrupted family processes (before and since the beginning of the pandemic)		x	x
Social isolation[34 39]	Likert Scale		
Feeling of being alone (during the COVID-19 pandemic, as imposed by others)		x	x
Feeling of being alone (before and since the beginning of the pandemic)		x	x
Can explain current situation of the pandemic		x	x
Can place current challenges in the context of the pandemic		x	x
Can get help to cope with current life situation		x	x
Can cope with tasks and challenges themselves		x	x

Continued

Table 2 Continued

Construct	Timepoint Instrument	Baseline *Enrolment*	FU_1–FU_x *6 months after PCR test*
Feeling of powerlessness/helplessness		x	x
Physical health status†			
Height, weight, body mass index, smoking status	Questionnaire	x	x
Blood sampling: laboratory parameters, serostatus survey, long-term storage[24 40]	Measurement	x	x
Vital parameters (*blood pressure, pulse, breath rate, O_2-saturation, body temperature*)	Measurement	x	x
Identification of patients at risk from sepsis	Quick sepsis-related organ failure assessment (qSofa)[41 42]	x	x
Measurement of pulmonary function *PEF, FEV_1, FVC, $FEV_{0.75}$, $FEV_{0.5}$, FEV_1/FVC, FEF_{75}, FEF_{25-75}, FEF_{50}, FV-curve*	Spirometry (mySpiroSense, mobile spirometer)	x	x
Cognitive short test	Six-Item-Screener[20]	x	x
Cognitive Impairment	MoCA-BLIND[23]	x	x
Mobility	Timed-Up&Go Test[43]	x	x
Medication	Medication list	x	x
Diagnosis	Diagnosis list	x	x
Vaccination status (COVID-19/influenza/pneumococcus)	Vaccination certificate	x	x
Characteristics of a COVID-19 disease course (Study+Control group 2)/Characteristics of the course of the respiratory infection (control group 1)*†‡	***Questionnaire***		
Date of positive/negative: SARS-CoV-2 PCR test / rapid SARS-CoV-2 antigen test + nucleocapsid antibodies		x	x
Symptomatic/asymptomatic infection		x	x
Time of onset of COVID-19 symptoms/symptoms of the respiratory infection			
COVID-19 symptoms/symptoms of the respiratory infection[24] §		x	x
Duration of symptoms (long-COVID/post-COVID)¶		x	x
COVID-19 specific clinical complications/complications of the respiratory infection (diagnoses)[24]		x	x
New medication since PCR Test		x	x
Mortality (time/cause of death, autopsy findings)			
Use of medical care facilities (since PCR test)*†‡	***Questionnaire***		
Inpatient medical care (days/diagnosis): Hospitalisation (with intensive care unit)/rehabilitation/ psychatry Number of general practitioner/other specialists contacts		x	x
Ambulatory medical care (days/diagnosis): Number of general practitioner/ other specialists contacts /treatment in emergency rooms		x	x
Psychosocial health status*	***Questionnaire***		
Health-related generic quality of life	EQ-5D-5L and EQ-VAS[25–27]	x	x

Continued

Table 2 Continued

Construct	Timepoint Instrument	Baseline *Enrolment*	FU_1–FU_x *6 months after PCR test*
Depressiveness	PHQ-9(29)	x	x
Post-traumatic stress disorder (PTSD)	Impact of Event Scale (IES-R)[31]	x	x
Anxiety	GAD-7(30)	x	x
Health literacy	HLS-EU-Q16[33]	x	x
Coping/self-management/self-efficacy	SES6G[32]	x	x
Healthcare utilisation	***Claims data*** **		
Medical diagnoses	ICD-10 codes	x	x
Planned and emergency hospital admissions	ICD-10 codes	x	x
Medication dispensed by community pharmacies	ATC codes	x	x
Level of care applications/assessments	Standardised assessment templates	x	x

*Survey of the person in need of care or support.
†Survey by medical/nursing staff, (caring) relatives.
‡Patient record/care record.
§Main symptoms according to the National Research Network of University Medicine on COVID-19: German Corona Consensus Data Set[24]: Disturbance of the sense of smell and/or taste, abdominal pain, disturbance of consciousness/confusion, diarrhoea, vomiting, cough, shortness of breath (dyspnoea), nausea, fever, headache, fatigue, etc.
¶Long-COVID syndrome is defined as health complaints that persist beyond the acute illness phase of a SARS-CoV-2 infection of 4 weeks or are new. Post-COVID syndrome refers to symptoms that persist for more than 12 weeks after the onset of SARS-CoV-2 infection and cannot be explained otherwise.[44 45]
**Data are provided by the statutory health insurance of study participants and linked nursing care assessment services (Medizinischer Dienst). Data linkage is provided by a dedicated trust centre.
BaCoM, Bavarian ambulatory COVID-19 Monitor; EQ-5D-5L, EuroQol; EQ-VAS, EQ visual analogue scale; FEF, Forced expiratory flow; FEV, Forced expiratory volume ; FU, follow-up; FVC, Forced vital capacity; FV-curve, Flow volume-curve; GAD-7, Generalised Anxiety Disorder Screener; HLS-EU-Q16, European Health Literacy Survey; NANDA, North American Nursing Diagnosis Association; PEF, Peak expiratory Flow; PHQ-9, Patient Health Questionnaire; SES6G, Six-item Self-Efficacy Scale.

Baseline and FU assessments

The baseline data collection occurs within 4 weeks after recruitment. For all patient-participants, FU assessments are conducted at 6-month intervals after the date of the index test for a period of up to 3 years in order to be able to observe the development of physical and mental health as well as provider and care needs over an extended time period. Depending on the date of enrolment, the number of FU's will, therefore, range between one and five FUs (3 years). For formal and informal caregivers and GPs, FU's intervals are similar. The parameters and constructs of interest as well as their corresponding data collection methods are provided in tables 2–5 and their rationale is briefly described below. The qualitative interviews with stakeholder are conducted only once per participant.

Clinical parameters of patientparticipants

Table 2 shows that clinical parameters of interest include physical status, laboratory, medication, comorbidities, body mass index and vaccination status. Tests for frailty (Clinical Frailty Scale[21 22]) and for cognitive impairment (MoCA-Blind[23]) are performed. In addition, the use of healthcare facilities, COVID-19-specific complications and symptoms (long-Covid/post-Covid) are used to characterise the course of the disease. Many target variables are collected in accordance with the 'German Corona Consensus Data Set' of the National Research Network of University Medicine on COVID-19.[24] The attending GP or the study nurse performs a brief physical examination with measurement of the vital parameters and takes a venous blood sample. By this, an antibody test for SARS-CoV-2 and, thus, the influence of COVID-19 disease on the immune response can be measured. For the remaining part of the blood samples, an immediate laboratory analysis of a complete blood count, a differential blood count and 26 organ-specific parameters relevant for COVID-19 disease are carried out. To cover future research questions, serum and whole blood samples are transferred to quality-controlled long-term storage at −80°C in the Institute of Laboratory Medicine.

Psychosocial parameters of patient participants

Table 2 shows psychological parameters of interest that include the mental health status among others. The COVID-19 pandemic may cause severe psychosocial stress among people in need of care or support at different

Table 3 Schedule of enrolment and assessments in BaCoM: formal caregivers and care facilities (inpatient/outpatient)

Construct	Timepoint / Instrument	Baseline *Enrolment*	FU_1–FU_x *6 months*
Sociodemographic information	***Questionnaire***		
Age, sex, ethnicity, migration background, educational level, professional life/ activity, income, marital status		x	
SARS-CoV-2 infection	***Questionnaire***		
SARS-CoV-2 infection in the past		x	x
Date of positive SARS-CoV-2 PCR tests		x	x
COVID-19-Infection symptomatic/asymptomatic		x	x
Care facility parameters	***Questionnaire***		
Inpatient care facilities and other forms of housing (provider: non-profit/ private/public; group of persons: older people/disabled/mentally ill/palliative; organisation: long-term/short-term/day/night care; number of beds; nursing ratio; staffing: specialist ratio/qualification/employment ratio/case numbers COVID-19/ vaccination ratio/visit management/workload)		x	x
Outpatient care facilities (provider: non-profit/private/public; group of persons: older people/disabled/psychologically ill/palliative; care performance; care ratio; staffing: skilled worker ratio/qualification/employment ratio/case numbers COVID-19/vaccination rate/visit management/workload)		x	x
SARS-CoV-2 vaccination	***Questionnaire***		
Psychological factors influencing the decision to vaccinate against SARS-CoV-2	5 C[46]	x	x
Psychosocial health status	***Questionnaire***		
Depressiveness	PHQ-9[29]	x	x
Burnout	Maslach Burnout Inventory (MBI)[36]	x	x

BaCoM, Bavarian ambulatory COVID-19 Monitor; FU, follow-up; PHQ-9, Patient Health Questionnaire.

ages and life situations. To recognise these burdens and identify possible protective factors or risk factors, participant questionnaires with validated measurement instruments are used. This includes health-related quality of life (EuroQol[25–27] (Eq-5D-5L)), symptoms of depression (Patient Health Questionnaire[28 29] (PHQ-9)), anxiety (Generalised Anxiety Disorder Screener[30]) and post-traumatic stress disorders (Impact of Event Scale revised[31]). The aim is to identify possible resources (Six-item Self-Efficacy Scale[32]) and strategies that can contribute to convalescence on the one hand and address the specific care needs of people in need of care or support for sustainable prevention on the other.

Care needs of patient participants

Special medical and care needs among this group of people in the different care settings are largely unknown so far. Table 2 shows the care parameters of interest, which include factors such as deprivation. In addition to the mobility and social participation, such an assessment should also include care services already used, health literacy (European Health Literacy Survey[33]), individual coping strategies, physical function and frailty, care diagnoses of the North American Nursing Diagnosis Association (NANDA)[34] and a geriatric assessment (Barthel-Index[35]). From these findings, it is to be derived which services may be necessary for sustainable prevention in long-term care in order to be able to contribute to an improvement of resilience, so that an individual, self-determined life and living-oriented towards the principle of normality is still possible.

Sociodemographic differentiations also play a role in all these dimensions and educational level, former, professional background, income class and family situation are collected for the distillation of at least trend statements.

Needs of formal and informal caregivers and GPs

Tables 3–5 show that parameters of formal (table 3) and informal caregivers (table 4) from outpatient and inpatient care as well as GPs (table 5) are collected with regards to coping with the burdens of the pandemic to enable addressing any deficits. Contextual information on sociodemography, structural information on the care facility or the GP practice as well as data on the psychosocial health (PHQ-9) and stress situation (Maslach-Burnout-Inventory[36]) are collected. In addition, the formal and informal caregivers will be asked about their own SARS-CoV-2 infection and about their vaccination decision.

Table 4 Schedule of enrolment and assessments in BaCoM: informal/family caregivers

Construct	Timepoint / Instrument	Baseline / Enrolment	FU_1–FU_x / 6 months
Sociodemographic information	***Questionnaire***		
Age, sex, ethnicity, migration background, educational level, professional life/activity, income, marital status		x	
SARS-CoV-2 infection	***Questionnaire***		
SARS-CoV-2 infection in the past		x	x
Date of positive SARS-CoV-2 PCR tests		x	x
COVID-19-Infection symptomatic/asymptomatic		x	x
Care burden situation	***Questionnaire***		
Duration and onset of informal/family care		x	x
Support through outpatient care service		x	x
Support through care allowance		x	x
Use of other support services		x	x
Burden Scale for Family caregivers Caregivers	Häusliche Pflegeskala (HPS)	x	x
SARS-CoV-2 vaccination	***Questionnaire***		
Psychological factors influencing the decision to vaccinate against SARS-CoV-2	5 C[46]	x	x
Psychosocial health status	***Questionnaire***		
Depressiveness	PHQ-9(29)	x	x
Burnout	Maslach Burnout Inventory (MBI)[36]	x	x

BaCoM, Bavarian ambulatory COVID-19 Monitor; FU, follow-up; PHQ-9, Patient Health Questionnaire.

Qualitative substudy: stakeholder interfaces in long-term care

The field of long-term care in the context of the COVID-19 pandemic is characterised by a multitude of stakeholders: people in need of care, their professional and informal carers, home managers, relatives, GPs and those responsible in politics and administration. The constellation of stakeholders is complex, generates interactions and must be managed accordingly. Administrative requirements, for example, not only have to be integrated into the everyday care of professionals but also coordinated with the habits and expectations of those in need of care and their relatives. Hence, interface problems arise. A total of approximately 60 expert interviews will be conducted in form of semistandardised, guideline-supported interviews, which

Table 5 Schedule of enrolment and assessments in BaCoM: GPs and practices

Construct	Timepoint / Instrument	Baseline / Enrolment	FU_1–FU_x / 6 months
Sociodemographic information	***Questionnaire***		
Age, sex, professional experience		x	
Practice-specific parameters	***Questionnaire***		
Single/joint practice		x	x
Number of GP's, number of medical assistants		x	x
Number of patients per quarter		x	x
Use of other support services		x	x
Number of COVID-19 patients per quarter		x	x
Number of deceased COVID-19 patients per quarter		x	x
SARS-CoV-2 vaccination	***Questionnaire***		
Psychological factors influencing the decision to vaccinate against SARS-CoV-2	5 C[46]	x	x

BaCoM, Bavarian ambulatory COVID-19 Monitor; FU, follow-up; GPs, general practitioners.

are primarily aimed at the perspective view of the interfaces of the different stakeholders. Patients, GPs, formal and informal carers will be recruited primarily from the study participants of the quantitative study. Based on interviews already conducted, further relevant actors will be identified and requested as interview partners. Here, the aim is to achieve the greatest possible variance with regards to the characteristics of the level of care, the place of residence in urban or rural regions and the presence or absence of family connections. The group of caregivers is also differentiated according to the care setting as well as according to the level of education and function. We will form conceptual categories (deductive—based on the theory of functional differentiation) for the computer-assisted coding and evaluation of the interviews with MAXQDA, which will be adapted, refined and supplemented in an iterative process during analyses (inductive). All interviews will be conducted by appropriately trained staff with a background in sociology (KM), who will also conduct or supervise all qualitative analyses.

The aim of the study is to name not only the challenges and needs of the various stakeholders but also their structural conditionality in a highly differentiated field. The qualitative results, thus, not only complement the quantitative research approach on the one hand but also offer an extended interpretive framework for the quantitative results.

Sample size calculation and stratification

Based on 600 (SG) and 200 (each CG) persons recruited for the registry, we simulate minimal detectable (statistical) difference for major outcomes (age, comorbidities and mortality). Comparing the SG and the controls using a two-tailed t-test or log-rank test, with the assumptions for the significance level α=0.05 and the power β=0.8 and given SD, the detectable differences for the following variables are obtained: age: SD=10.0; detectable difference of −2.29 or 2.29; comorbidities: SD=3.1; detectable difference of −7.10 or 7.10; mortality: median survival time=4.0; detectable difference of 2.66 or 6.56; EQ-5D-5L: SD=0.29; detectable difference of −0.07 or 0.07. With respect to the limited life expectancy of care recipients, we conservatively estimate that after 4 years about 30% of the study participants, across all levels of care, will still be alive.[37] The registry will, therefore, be expanded with additional participants at regular intervals and evaluated separately in subgroups. The aim is to achieve a relative distribution of the persons in need of care or support in outpatient care (50%) and inpatient care (50%). In order to account for the differences in medical infrastructures, population density and regional differences in infection incidence, we are aiming at an equal stratification according to the seven administrative districts in Bavaria.

Statistical analysis

All collected parameters of the study participants are analysed descriptively. Analyses are performed for the entire population and stratified by level of care, outpatient and inpatient care, gender and age groups. For group comparisons between patients with positive SARS-CoV-2 PCR test and controls, the χ^2 test or Fisher's exact test are used for categorical variables, the t-test (normally distributed variables) or Mann-Whitney-U test (non-normally distributed variables) for metric variables and the log-rank test for survival times. All p values are purely exploratory. Regression models are used to identify, among other things, risk factors that predict a severe course, occurrence of long-term consequences of a COVID-19 infection or a deterioration of the quality of life due to a COVID-19 infection. The survival of the study and CGs is shown graphically using Kaplan-Meier curves. Missing data for the study population are imputed according to multiple imputation where appropriate.

Non-responder analysis

As in most research in the ambulatory care environment, the external validity of our findings is vulnerable to participation bias. For example, it is conceivable that non-responding institutions are particularly burdened by the pandemic. To understand better who does and does not participate, we will conduct an analysis of a subsample of the non-responding care facilities or practices via telephone or postal surveys scheduled 6 and 12 months after first contact, in order to elicit structural and contextual information about the facilities.

Patient and public involvement

Members of the BaCoM advisory board (listed twww.bacomstudie.de) represent a broad expertise in the field: science, patient advocacy, health assurances, health authorities, institutional facilities, etc. The board commented and approved the protocol and comment on the results (public outcome symposium). In addition, we present the protocol and results to a primary care-related citizen forum ('Bürgerforum') in Wurzburg and Erlangen.

Ethics and dissemination

Informed consent

All participants provide written informed consent to participate. If a treating GP participates in BaCoM, he/she informs his/her patient about the study. Otherwise, the enrolment and information are provided by the doctor of the study team. If the person in need of care or support is not capable of giving consent him or herself (eg, dementia, cognitive impairment), consent can be given by the legal guardian. In case a person who initially gives consent subsequently loses capacity at one or more of the data collection time points, we only carry out further surveys if the consent to the study also signed by the legal guardian.

We made a conscious decision in the study design not to exclude people with severe cognitive impairment, as these groups (such as people with dementia), may have suffered particularly from the effects of the pandemic (eg, through isolation rules, etc). In order to mitigate undue

distress to this vulnerable group, the length of the survey is reduced because some questionnaires are not applicable (eg, health literacy) or the information is collected through an external survey of relatives or carers where this has previously been shown to be possible (eg, PHQ-9). Staff responsible for data collection are instructed to interrupt or end interviews with participants if they notice signs of distress.

The BaCoM Team pursues all measures to protect the interests of participants who are unable to consent.

Study registration and ethics

BaCoM is registered at the German Clinical Trials Register (DRKS) ID: DRKS00026039. The conduct of the study is in accordance with the principles of the Declaration of Helsinki.

The responsible Institutional Review Board of the coordinating study centre of BaCoM (Ethics Committee of the Medical Faculty of the University Hospital of LMU Munich; ethical vote number: #20–860) and of all participating study sites (Ethical Committees at the Medical Faculties of the University of Würzburg and Friedrich-Alexander-University of Erlangen-Nuremberg) approved BaCoM study procedures.

Data access and protection

All data are collected with pseudonyms (ID) first on paper-based case report forms and then transferred in electronic case report forms (double data entry). Data entry takes place on the servers of University Hospital of the LMU with 'LibreClinica', an open source validated study management software. To ensure a pseudonymised analysis of data, each participant data set is given a unique participant identification number (ID) when being entered into the study database. The anonymity of the data in the context of evaluations is ensured. The allocation between study participant and participant ID takes place in the study centre through the password-protected allocation lists of the study participants. This information is stored separately and not in the database. By using a hierarchical access concept, unauthorised access to the pseudonymised patient data in the database is impossible.

Storage resources for the data are available in the personal cloud storage of the Leibnitz Rechenzentrum (LRZ). For long-term archiving, the Archive and Backup Service offered by the LRZ based on the IBM Spectrum Protect software is used. Copies of all data in the archive are made on separate tapes to increase security. Data quality is checked for errors electronically and on-site by experienced monitors. Data access to the final data set is provided to the BaCoM Study Group along with written use and access rules.

Dissemination

As an instrument for optimising ambulatory COVID-19 care in Bavaria, the results of the interdisciplinary monitor are presented in regular progress reports and discussed with other (external) experts at symposia. On this basis, further questions or measurement instruments can be systematically included, or less meaningful variables are removed.

Findings are presented at scientific conferences and through peer-reviewed publications.

Author affiliations
[1]Institute of General Practice and Family Medicine, University Hospital, LMU Munich, Munich, Germany
[2]Institute of General Practice, University Hospital of Julius-Maximilians-Universität Würzburg, Würzburg, Germany
[3]Katholische Stiftungshochschule München/University of Applied Sciences, Munich, Germany
[4]Division of Infectious Diseases and Tropical Medicine, Medical Center of the University of LMU Munich, Munich, Germany
[5]Institute of General Practice, Friedrich-Alexander-University of Erlangen-Nuremberg, Erlangen, Germany
[6]Institute of Sociology, Ludwig-Maximilians-Universität, Munich, Germany
[7]Institute of Laboratory Medicine, University Hospital, LMU Munich, Munich, Germany

Acknowledgements Thanks to BayFoNet (Bayerisches Forschungsnetz in der Allgemeinmedizin/ grant number

Contributors Conceptualisation: JG, TD, IG, AH, MH, CJ, TK, AN, DT, IZ. Data analysis: MR, DL. Funding acquisition: JG, TD, IG, AH, MH, CJ, TK, AN, DT, IZ. Supervision: JG, TD, IG, AH, MH, CJ, TK, AN, DT, IZ. Writing the original draft: JG, TD, IG, AH, MH, CJ, TK, AN, DT, IZ. Review and editing: JG, TD, IG, AH, MH, CJ, TK, AN, DT, FMA, CE, DH, HK, PKK, DL, KM, SM, LR, MR, LS, RS, MS, DW, IZ. All authors have read and agreed to the final version of the manuscript.

Funding This work is supported by Bavarian State Ministry for Health and Care grant number G45a-G8300-2021/257-2.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Individual participant data underlying the results of this article are available to researchers who submit a methodologically sound proposal to the BaCoM steering committee (correspondence: Jochen.Gensichen@med.uni-muenchen.de) for use of data in the approved proposal.

ORCID iDs
Isabel Zöllinger http://orcid.org/0000-0002-1235-475X
Ildiko Gagyor http://orcid.org/0000-0002-7974-7603
Laura Rink http://orcid.org/0000-0003-0493-3628
Linda Sanftenberg http://orcid.org/0000-0002-3174-5297

REFERENCES

1 World Health Organization (WHO). Strategic preparedness, readiness and response plan to end the global COVID-19 emergency in 2022. Available: https://www.who.int/publications/i/item/WHO-WHE-SPP-2022.1 [Accessed 10 Nov 2022].
2 Thompson D-C, Barbu M-G, Beiu C, *et al*. The impact of COVID-19 pandemic on long-term care facilities worldwide: an overview on international issues. *Biomed Res Int* 2020;2020:8870249.
3 Pijls BG, Jolani S, Atherley A, *et al*. Demographic risk factors for COVID-19 infection, severity, ICU admission and death: a meta-analysis of 59 studies. *BMJ Open* 2021;11:e044640.

4 Morley JE, Vellas B. COVID-19 and older adult. *J Nutr Health Aging* 2020;24:364–5.
5 Li J, Huang DQ, Zou B, *et al*. Epidemiology of COVID-19: a systematic review and meta-analysis of clinical characteristics, risk factors, and outcomes. *J Med Virol* 2021;93:1449–58.
6 Izcovich A, Ragusa MA, Tortosa F, *et al*. Prognostic factors for severity and mortality in patients infected with COVID-19: a systematic review. *PLoS One* 2020;15:e0241955.
7 Robert Koch Institut (RKI). Wöchentlicher Lagebericht des RKI zur Coronavirus-krankheit-2019 (COVID-19) 10.11.2022 – AKTUALISIERTER Stand für DEUTSCHLAND. 2022. Available: https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Situationsberichte/Wochenbericht/Wochenbericht_2022-11-10.pdf?__blob=publicationFile [Accessed 18 Nov 2022].
8 Eggert S, Teubner C. ZQP-analyse: die SARS-CoV-2-Pandemie in der professionellen Pflege: Perspektive stationärer Langzeitpflege und ambulanter Dienste. 2021. Available: https://www.zqp.de/wp-content/uploads/ZQP-Analyse-Corona-Langzeitpflege.pdf [Accessed 4 Nov 2022].
9 European centre for disease prevention and control. increase in fatal cases of COVID-19 among long-term care facility residents in the EU/EEA and the UK. 2020. Available: https://www.ecdc.europa.eu/sites/default/files/documents/Increase-fatal-cases-of-COVID-19-among-long-term-care-facility-residents.pdf [Accessed 28 Nov 2022].
10 Meeting the challenge of long COVID. *Nat Med* 2020;26:1803.
11 Vilches-Moraga A, Price A, Braude P, *et al*. Increased care at discharge from COVID-19: the association between pre-admission frailty and increased care needs after hospital discharge; a multicentre European observational cohort study. *BMC Med* 2020;18:408.
12 Hering C, Gangnus A, Kohl R, *et al*. Projekt COVID-Heim: Lehren aus der Corona-Pandemie für Strukturenentwicklungen im Versorgungssetting Pflegeheim. 2021. Available: https://www.gkv-spitzenverband.de/media/dokumente/pflegeversicherung/forschung/projekte_unterseiten/covid_heim/CovidHeim_ErgebnisReport3_26_05_2021.pdf [Accessed 12 Nov 2022].
13 Gangnus A, Hering C, Kohl R, *et al*. Soziale Teilhabe in Pflegeheimen mit Covid-19-Schutzmaßnahmen in der zweiten Pandemiewelle? Linkage von Verordnungen und Befragung. *Pflege* 2022:1–11.
14 Röhr S, Müller F, Jung F, *et al*. Psychosocial impact of quarantine measures during serious coronavirus outbreaks: a rapid review. *Psychiatr Prax* 2020;47:179–89.
15 Gaertner B, Fuchs J, Möhler R, *et al*. Zur Situation älterer Menschen in der Anfangsphase der COVID-19-Pandemie: ein scoping review. *Journal of Health Monitoring* 2021;6:2–39.
16 Benzinger P, Kuru S, Keilhauer A, *et al*. Psychosocial effects of the pandemic on staff and residents of nursing homes as well as their relatives-A systematic review. *Z Gerontol Geriatr* 2021;54:141–5.
17 Jones K, Schnitzler K, Borgstrom E. The implications of COVID -19 on health and social care personnel in long-term care facilities for older people: an international scoping review . *Health Social Care Comm* 2022;30. 10.1111/hsc.13969 Available: https://onlinelibrary.wiley.com/toc/13652524/30/6
18 Heuer J, Bätzing J, Holstiege J, *et al*. SHI-physicians ambulatory health care for COVID-19 in a nationwide regional comparison (Part 1) – focus on the 1st pandemic wave in Germany. central research Institute for ambulatory health care in the federal Republic of Germany (zi) versorgungsatlas-report; 2022. Available: https://www.versorgungsatlas.de/fileadmin/ziva_docs/128/VA-22-05_Ambul-Versorg-COVID-19-Welle-1_Final.pdf [Accessed 22 Nov 2022].
19 Rawaf S, Allen LN, Stigler FL, *et al*. Lessons on the COVID-19 pandemic, for and by primary care professionals worldwide. *European Journal of General Practice* 2020;26:129–33.
20 Krupp S, Seebens A, Kasper J, *et al*. Validierung der deutschen Fassung des six-item screeners. *Z Gerontol Geriat* 2018;51:275–81.
21 Deutsche Gesellschaft für Geriatrie e.V. 2020. Available: https://www.divi.de/images/Dokumente/200331_DGG_Plakat_A4_Clinical_Frailty_Scale_CFS.pdf [Accessed 29 Oct 2022].
22 Rockwood K, Song X, MacKnight C, *et al*. A global clinical measure of fitness and frailty in elderly people. *CMAJ* 2005;173:489–95.
23 Nasreddine ZS, Phillips NA, Bédirian V, *et al*. The Montreal cognitive assessment, MoCA: a brief screening tool for mild cognitive impairment. *J Am Geriatr Soc* 2005;53:695–9.
24 Sass J, Bartschke A, Lehne M, *et al*. The German corona consensus dataset (GECCO): a standardized dataset for COVID-19 research in University medicine and beyond. *BMC Med Inform Decis Mak* 2020;20:341.
25 EuroQol Group. EuroQol-a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16:199–208.
26 Greiner W, Claes C, Busschbach JJV, *et al*. Validating the EQ-5D with time trade off for the German population. *Eur J Health Econ* 2005;6:124–30.
27 Rabin R, de Charro F. EQ-5D: a measure of health status from the euroqol group. *Ann Med* 2001;33:337–43.
28 Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;16:606–13.
29 Kroenke K, Spitzer RL. The PHQ-9: a new depression diagnostic and severity measure. *Psychiatric Annals* 2002;32:509–15.
30 Löwe B, Decker O, Müller S, *et al*. Validation and standardization of the generalized anxiety disorder screener (GAD-7) in the general population. *Med Care* 2008;46:266–74.
31 Wilson JP, Tang CS. Cross-Cultural assessment of psychological trauma and PTSD. *The Impact of Event Scale: Revised*. Boston, MA: Springer Science + Business Media 2007:219-38, 2007.
32 Freund T, Gensichen J, Goetz K, *et al*. Evaluating self-efficacy for managing chronic disease: psychometric properties of the six-item self-efficacy scale in Germany. *J Eval Clin Pract* 2013;19:39–43.
33 Sørensen K, Pelikan JM, Röthlin F, *et al*. Health literacy in Europe: comparative results of the European health literacy survey (HLS-EU). *Eur J Public Health* 2015;25:1053–8.
34 Herdman TH, Kamitsuru S, Lopes CT. NANDA-I-Pflegediagnosen: Definitionen und Klassifikation 2021-2023. *NANDA International Nursing Diagnoses. Definitions and Classification: 2021-2023*. Kassel: Thieme, 2021.
35 MAHONEY FI, BARTHEL DW. Functional evaluation: the barthel index. *Md State Med J* 1965;14:61–5.
36 Büssing A, Perrar KM. Measuring burnout: a study of a German version of the maslach burnout inventory (MBI-D). *Diagnostica* 1992;38:328–53.
37 Jacobs K, Kuhlmey A, Greß S, *et al*. Pflege-Report 2017: die Versorgung der Pflegebedürftigen; 2017. Available: https://www.wido.de/fileadmin/Dateien/Dokumente/Publikationen_Produkte/Buchreihen/Pflegereport/2017/Kapitel%20mit%20Deckblatt/wido_pr2017_gesamt.pdf [Accessed 10 Apr 2023].
38 Helmbold A, Schäfer A. Covid-19 aus pflegediagnostischer Perspektive; 2020. 60–6.
39 Bensch S. COVID-19 und die Pflegeoutcomes. Pflegewissenschaft, Sonderausgabe: die Corona-pandemie; 2020. 09–13.
40 Greenhalgh T, Knight M, A'Court C, *et al*. Management of post-acute covid-19 in primary care. *BMJ* 2020;370:m3026.
41 Vincent JL, Moreno R, Takala J, *et al*. The sofa (sepsis-related organ failure assessment) score to describe organ dysfunction/failure. on behalf of the Working group on sepsis-related problems of the European Society of intensive care medicine. *Intensive Care Med* 1996;22:707–10.
42 Raith EP, Udy AA, Bailey M, *et al*. Prognostic accuracy of the SOFA score, SIRS criteria, and qsofa score for in-hospital mortality among adults with suspected infection admitted to the intensive care unit. *JAMA* 2017;317:290–300.
43 Mathias S, Nayak US, Isaacs B. Balance in elderly patients: the "get-up and go'' test. *Arch Phys Med Rehabil* 1986;67:387–9.
44 World Health Organization (WHO). A clinical case definition of post COVID-19 condition by a Delphi consensus. 2021. Available: https://www.who.int/publications/i/item/WHO-2019-nCoV-Post_COVID-19_condition-Clinical_case_definition-2021.1 [Accessed 12 Nov 2022].
45 Koczulla AR, Ankermann T, Behrends U, *et al*. S1-leitlinie post-COVID/long-COVID. *Pneumologie* 2021;75:869–900.
46 Betsch C, Schmid P, Heinemeier D, *et al*. Beyond confidence: development of a measure assessing the 5C psychological antecedents of vaccination. *PLoS One* 2018;13:e0208601.