BMJ Open

Impact of the Covid-19 pandemic on frail elderly: protocol for a SARS-CoV-2 registry

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-071134
Article Type:	Protocol
Date Submitted by the Author:	15-Dec-2022
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	Dreischulte, Tobias; LMU Klinikum, Institute of General Practice and Family Medicine BaCoM Study Group, The ; LMU Klinikum
Keywords:	COVID-19, MENTAL HEALTH, QUALITATIVE RESEARCH, REGISTRIES, PRIMARY CARE, Public health < INFECTIOUS DISEASES

Note from the Editors: Instructions for reviewers of study protocols

Since launching in 2011, BMJ Open has published study protocols for planned or ongoing research studies. If data collection is complete, we will not consider the manuscript.

Publishing study protocols enables researchers and funding bodies to stay up to date in their fields by providing exposure to research activity that may not otherwise be widely publicised. This can help prevent unnecessary duplication of work and will hopefully enable collaboration. Publishing protocols in full also makes available more information than is currently required by trial registries and increases transparency, making it easier for others (editors, reviewers and readers) to see and understand any deviations from the protocol that occur during the conduct of the study.

The scientific integrity and the credibility of the study data depend substantially on the study design and methodology, which is why the study protocol requires a thorough peer-review.

BMJ Open will consider for publication protocols for any study design, including observational studies and systematic reviews.

Some things to keep in mind when reviewing the study protocol:

- Protocol papers should report planned or ongoing studies. The dates of the study should be included in the manuscript.
- Unfortunately we are unable to customize the reviewer report form for study protocols. As such, some of the items (i.e., those pertaining to results) on the form should be scores as Not Applicable (N/A).
- While some baseline data can be presented, there should be no results or conclusions present in the study protocol.
- For studies that are ongoing, it is generally the case that very few changes can be made to the methodology. As such, requests for revisions are generally clarifications for the rationale or details relating to the methods. If there is a major flaw in the study that would prevent a sound interpretation of the data, we would expect the study protocol to be rejected.

Impact of the Covid-19 pandemic on frail elderly: protocol for a SARS-CoV-2 registry

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ABSTRACT

Introduction

Frail elderly persons 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 psycho-social impact of the Covid-19 pandemic on frail elderly in need of care in Southern Germany. To describe the persons' life conditions comprehensively, we assess the perspectives and needs of the respective care teams, too. Results will serve as an evidence-based source to manage the pandemic and long-term prevention strategies.

Methods and analysis

The "Bavarian Outpatient COVID-19 Monitor-BaCoM" is a multicenter registry including a convenience sample of up to 1000 patient participants across three study sites in Bavaria, Germany. The study group consists of 600 people in need of care with a positive SARS-CoV-2 polymerase chain reaction (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, but are not in need of care. We assess the clinical course of infection, psycho-social 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) for their health and needs. Finally, we conduct qualitative interviews with 60 stakeholders (caregivers, general practitioners, politicians) to explore interface problems of actors in health care. Main analyses are stratified by level of care I-V (I=minor/V=most severe impairment of independence/abilities), inpatient/outpatient setting, sex and age. We use descriptive and inferential statistics to analyze cross-sectional data and changes over time.

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.

Trial registration: BaCoM is registered at the German Clinical Trials Register (DRKS); ID: DRKS00026039

ARTICLE SUMMARY

Strengths and limitations of this study

- This large, multicenter registry fills an evidence gap in Covid-19 research by focusing on a vulnerable, underrepresented group of people, who are in need of care in outpatient settings (long-term care facilities, informal/family care etc.) and survived COVID-19 infection.
- A 36 months follow-up provides data on long-term clinical course and sequels.
- A multi-professional research team (i.e. General practice, Nursing, Sociology and Infectology) and a triangulated research approach combining quantitative and qualitative methods provide multiple perspectives and comprehensive analyses.
- Pre-status (before the pandemic) of the study population is not available; patient reported outcomes and interviews are at risk for re-call bias and social desirability.
- Cause of limited life expectancy of the frail participants, we include additional participants over time (open registry).

INTRODUCTION

By February 2022, the World Health Organization (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 group by the Covid-19 pandemic are 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 more than half of the COVID-19 deaths involved frail 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 frail 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 exception among older people and COVID-19 may exacerbate both general frailty and specific co-morbidities 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-/Post-Covid syndrome and increase dependency (10, 11). In addition, long-term care facilities frequently implemented drastic infection control measures, with external and internal contact restrictions aggravating feelings of loneliness and isolation, which may have long-term consequences for mental and physical health (12-15).

The additional care needs of 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 psycho-social health of older, frail people dependent on care as well as on those caring for them, including formal (e.g. nursing stuff) and informal (e.g. family members /relatives) caregivers and GPs.

AIM AND OBJECTIVES

The aim of the "Bavarian Outpatient 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 older people dependent on care, 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, psycho-social burden and care needs in older, frail people dependent on care or support.

(2) To examine long-term sequels in older, frail people dependent on care or support

(3) To examine the needs of formal and informal caregivers

METHODS AND ANALYSIS

Study design and setting

BaCoM is a multicenter, 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 frail and dependent on 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 with frailty and dependent on 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 frailty, participants in CG2 comprise people with evidence of a previous SARS-CoV-2 infection but without frailty 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 general practitioners.

Study Population

Eligibility criteria for patients

The inclusion/exclusion criteria of the study and control groups are provided in Table 1. All adult residents of in 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 01 March 2020) are assigned to SG or CG2, respectively, and otherwise to CG1. In cases, where PCR test results are not available, people with rapid SARS-CoV-2 antigen test results can be enrolled (not older than 6 month) and the results from antigen tests will be interpreted in combination with any evidence of nucleocapsid antibodies measured as part of the study protocol (see data collection below). 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).

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.

Eligibility criteria for recruiting general practitioners (GPs)

GPs are eligible for recruitment, if a) they offer statutory health insurance service, b) they care for COVID-19 patients, c) offer a primary health care 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 to be recruited for the project at three study sites in Bavaria (Munich, Erlangen, Wurzburg). In addition, we aim to recruit up to 200 formal caregivers, up to 100 informal caregivers and up to 100 GPs. In order to maximize the geographical spread of study participant resident, 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 (BayFoNet) 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 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 (LGL).

Data collection

Baseline data collection began on 01 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 semi-structured interviews (see tables 2 to 4). Appropriately, trained staff conduct all data collection. It can be assumed that a certain proportion of the study participants will not be able to provide self-disclosure (e.g. in case of cognitive impairment). In these cases, the information collection is to be ensured by relatives or caregivers 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.

Baseline and Follow-Up assessments

The baseline data collection occurs within four weeks after recruitment. For all patient participants, follow-up (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 FU's (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 one-time.

Clinical parameters of patient participants

Table 2 shows that clinical parameters of interest include physical status, laboratory, medication, comorbidities, BMI 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 health care facilities, COVID-19 specific complications and symptoms (Long-/post-Covid) will be 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 will do a brief physical examination with measurement of the vital parameters and take 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 will be carried out. To cover future research questions, serum and whole blood samples will be transferred to quality-controlled long-term storage at -80°C in the Institute of Laboratory Medicine.

Psycho-social 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 psycho-social stress among people in need of care or support at different ages and life situations. To recognise these burdens and identify possible protective factors or risk factors, participant questionnaires with validated measurement instruments will be 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 (Generalized Anxiety Disorder Screener (30) (GAD-7)) and post-traumatic stress disorders (Impact of Event Scale revised(31) (IES-R)). The aim is to identify possible resources (Six-item Self-Efficacy Scale (32) (SES6G)) 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) (HLS-EU-Q16)), individual coping strategies, physical function and frailty, NANDA care diagnoses (North American Nursing Diagnosis Association) (34) and a geriatric assessment (Barthel-Index(35)). From these findings, it is to be derived which offers are 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/domestic and inpatient care as well as GP's (table 4) are collected with regards to coping with the burdens of the pandemic to enable addressing any deficits. Contextual information on socio-demography, 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)) will be collected. In addition, the formaland iformal caregivers will be asked about their own SARS-Cov-2 infection and about their vaccination decision.

Substudy: Constellations of actors in long-term care

The field of long-term care in the context of the Covid-19 pandemic is characterised by a multitude of actors: People in need of care, caregivers, managers, relatives, GPs, administration, etc. Administrative requirements, for example, need to be coordinated with all participating actors. We will assess their interfaces. The aim is to formulate standards to improve the communication between the actors. 60 expert patients, GPs, formal and informal caregivers will be recruited from the main study for semi-standardized, guideline-supported interviews. Additional relevant actors will be selected (greatest possible variance with regard to the characteristics: needs of care, care setting, regions, age, and sex) for

interviews, too. We form conceptual categories (based on the theory of functional differentiation) for the computer-assisted coding and evaluation of the interviews with MAXQDA software, which are adapted and refined in an iterative process.

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 study group 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 standard deviation (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, it is expected that after four years about 30% of the study participants, across all levels of care, will still be alive. 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 analyzed descriptively. Analyses will be performed for the entire population and stratified by level of care, outpatient/domestic and inpatient care, gender and age groups. For group comparisons between patients with positive SARS-CoV-2 PCR test and controls, the chi-square 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 control groups is shown graphically using Kaplan-Meier curves. Missing data for the study population will be imputated according to multiple imputation.

Non responder Analysis

As in most research in the outpatient 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 of a broad expertise in the field: Science, patient advocacy, health assurances, health authorities, institutional facilities (CEO), etc.. The board commented and approved the protocol and will comment the results (public outcome symposium). In addition we present the protocol and results to primary care related citizen forum ("Bürgerforum") in Wurzburg und Erlangen.

ETHICS AND DISSEMINATION

Informed Consent

All participants provided written informed consent to participate. If a treating GP participates in BaCoM, he/she will inform his/her patient about the study. Otherwise, the enrolment and information is 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 (e.g. dementia, cognitive impairment), consent can be given by the legal guardian. The BaCoM Team will pursue 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. All methods were performed in accordance with the principles of the Declaration of Helsinki.

The responsible Institutional Review Board of the coordinating study center 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.

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 data base. 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 (ABS) offered by the LRZ based on the IBM Spectrum Protect (ISP) 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 optimizing outpatient Covid-19 care in Bavaria, the results of the interdisciplinary Monitor will be presented in regular progress reports and discussed with other (external) experts at symposia. On this basis, in a Delphi process of the participating experts from different disciplines, further developing questions or measurement instruments can be systematically included in the Monitor, or variables that are not very meaningful can be removed.

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

Data sharing

Individual participant data underlying the results of this article is available to researches 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.

Author Contributions

Conceptualization: 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, FA, CE, DH, HK, PK, DL, KM, SM, LR, MR, LS, RS, MS, DW, IZ; All authors have read and agreed to the final version of the manuscript.

Acknowledgements Members of the BaCoM-study group:

Jochen Gensichen (JG), Tobias Dreischulte (TD), Ildikó Gágyor (IG), Anita Hausen (AH), Michael Hoelscher (MH), Christian Janke (CJ), Armin Nassehi (AN), Thomas Kühlein (TK), Daniel Teupser (DT), Florian Arend (FA), Laura Baumgartner (LB), Barbara Daubner (BD), Christine Eidenschink (CE), Dorothea Fichtl (DF) ,Caroline Floto (CF), Johannes Gorkotte (JG), Dagmar Hindenburg (DH), Susann Hueber (SH), Stephanie Kalms (SK), Helena Kosub (HK), Peter Kurotschka (PK), Daniela Lindemann (DN), Katharina Mayr (KM), Irina Michel (IM), Susann Müller (SM), Britta Pauli (BP), Laura Rink (LR), Marietta Rottenkolber (MR), Linda Sanftenberg (LS), Rita Schwaiger (RS), Maria Sebastiao (MS), Constantin Unger (CU), Sabrina Vetter (SV), Domenika Wildgruber (DW), Isabel Zöllinger (IZ)

Funding statement

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

Competing interests statement

The authors declare that they have no competing interests.

Word Count: 3588

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Tables

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 • 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)(21, 22) • ***Positive*** SARS-CoV-2 PCR test (maximum backdated to 01.03.2020)	• 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) • ***Negative*** SARS-CoV-2 PCR test (maximum backdated to 01.03.2020) with respiratory infection	• ***No*** 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)) • ***Positive*** SARS-CoV-2 PCR test (maximum backdated to 01.03.2020)
Exclusion criteria:		
• Refugees / asylum seekers • Life expectancy < 6 months (clinical judgement of the recruiting doctor) • Persons without health insurance		

Table 2: Schedule of enrolment and assessments in BaCoM: Study group and Control groups

	Timepoint	**Baseline**	**FU_1-FU_x**
CONSTRUCT	**INSTRUMENT**	*Enrolment*	*6 months after PCR-test*
Sociodemographic information[B,C]	***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[B,C]	***Questionnaire***		
Care level (I-V) / Frailty level (1-9) and onset date of the need for care / frailty	Clinical Frailty Scale(21, 22)	x	x
Diagnosis justifying care			
Capacity for giving consent/legal guardian		x	x
Care setting (outpatient/domestic/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
Home 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)[B,C]	***Questionnaire***		
Stability of respiratory parameters(37)	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, 38)	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, 38)	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
Feeling of powerlessness/helplessness		x	x
Physical health status[C]			
Height, weight, Body-mass-index, smoking status	Questionnaire	x	x
Blood sampling: laboratory parameters, serostatus survey, long-term storage (24, 39)	Measurement	x	x

Vital parameters *(blood pressure, pulse, breath rate, O2-saturation, body temperature)*	Measurement	x	x
Identification of patients at risk from sepsis	Quick sepsis-related organ failure assessment (qSofa)(40, 41)	x	x
Mesurement of pulmonary function *PEF, FEV_1, FVC, $FEV_{0.75}$, $FEV_{0.5}$, FEV_1/FVC, FEF_{75} (MEF_{25}), FEF_{25-75} (MFEF), FEF_{50} (MEF_{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(42)	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)[A,B,C]	***Questionnaire***		
Date of pos./neg. SARS-CoV-2 PCR test / POCT rapid test		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-/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)[A,B,C]	***Questionnaire***		
Inpatient medical care (days / diagnosis): Hospitalisation (with Intensive care unit) / Rehabilitation/ Psychatry Number of general practitioner/ other specialists contacts		x	x
Outpatient medical care (days / diagnosis): Number of general practitioner/ other specialists contacts /Treatment in emergency rooms		x	x
Psychosocial health status[B]	***Questionnaire***		
Health-related generic quality of life	EQ-5D-5L and EQ-VAS(25-27)	x	x
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
Health care 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

A=Patient record / care record, B=Survey of the person in need of care or support, C=Survey by medical /nursing staff, (caring) relatives;
*=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(43, 44).
*** Data is 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

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

	Timepoint	**Baseline**	**FU_1-FU_x**
CONSTRUCT	**INSTRUMENT**	*Enrolment*	*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 pos. 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: elderly/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: elderly/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 (45)	x	x
Psychosocial health status	***Questionnaire***		
Depressiveness	PHQ-9(29)	x	x
Burnout	Maslach Burnout Inventory (MBI) (36)	x	x

Table 4: Schedule of enrolment and assesments in BaCoM: Informal/family caregivers

	Timepoint	**Baseline**	**FU_1-FU_x**
CONSTRUCT	**INSTRUMENT**	*Enrolment*	*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 pos. 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 (45)	x	x
Psychosocial health status	***Questionnaire***		
Depressiveness	PHQ-9(29)	x	x
Burnout	Maslach Burnout Inventory (MBI)(36)	x	x

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

	Timepoint	Baseline	FU_1-FU_x
		Enrolment	*6 months*
CONSTRUCT	**INSTRUMENT**		
Sociodemographic information	***Questionnaire***		
Age, sex, rofessional 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 (45)	x	x

Impact of the Covid-19 pandemic on frail elderly: protocol for a SARS-CoV-2 registry

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-8
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	5,6, 16
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	-
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7-9, 17-21
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7-9, 17-21
Bias	9	Describe any efforts to address potential sources of bias	11
Study size	10	Explain how the study size was arrived at	10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10,11
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10,11
		(*b*) Describe any methods used to examine subgroups and interactions	10,11
		(*c*) Explain how missing data were addressed	11
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	10

		(*e*) Describe any sensitivity analyses	10
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6,7
		(b) Give reasons for non-participation at each stage	11
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	5,6
		(b) Indicate number of participants with missing data for each variable of interest	-
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	7
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	7,8
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	-
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	-
		(*b*) Report category boundaries when continuous variables were categorized	-
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	-
Discussion			
Key results	18	Summarise key results with reference to study objectives	5
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	3
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	-
Generalisability	21	Discuss the generalisability (external validity) of the study results	3
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-071134.R1
Article Type:	Protocol
Date Submitted by the Author:	19-Apr-2023

Complete List of Authors:	Gensichen, Jochen; LMU Klinikum, Institute of General Practice and Family Medicine Zöllinger, Isabel; LMU Klinikum, Institute of General Practice and Family Medicine Gagyor, Ildiko; Julius-Maximilians-Universitat Wurzburg, Department of General Practice Hausen, Anita; Katholische Stiftungsfachhochschule Munchen Hölscher, Michael; LMU University Hospitals Munich Department of Infections and Tropical Medicine Janke, Christian; LMU Klinikum, Institute of Laboratory Medicine, University Hospital of LMU Munich, 81377 Munich, Germany Kühlein, Thomas ; University Hospital Erlangen, Institute of General Practice Nassehi, Armin; Ludwig-Maximilians-Universität, Institute of Sociology Teupser, Daniel; University Hospital Munich, Institute of Laboratory Medicine Arend, Florian M.; University Hospital of LMU Munich, Institute of Laboratory Medicine Eidenschink, Christine; Universität Würzburg, Department of General Practice Hindenburg, Dagmar; Universität Würzburg, Department of General Practice Kosub, Helena; Ludwig Maximilians University Munich, Institute of General Practice and Family Medicine Kurotschka, Peter Konstantin; Universitätsklinikum Würzburg, Department of General Practice Lindemann, Daniela; LMU Klinikum, Institute of General Practice and Family Medicine Mayr, Katharina; Ludwig-Maximilians-Universität, Institute of Sociology Müller, Susan; University Hospital of LMU Munich, Institute of General Practice and Family Medicine Rink, Laura; Friedrich-Alexander-University of Erlangen-Nuremberg, Institute of General Practice Rottenkolber, Marietta; University Hospital of LMU Munich, Institute of General Practice/Family Medicine Sanftenberg, Linda; University Hospital, Ludwig-Maximilians-Universität, Institute of General Practice and Family Medicine Schwaiger, Rita; University Hospital of LMU Munich, Institute of General Practice and Family Medicine Sebastião, Maria ; Friedrich-Alexander-Universität Erlangen-Nürnberg Wildgruber, Domenika; Katholische Stiftungshochschule München

	Dreischulte, Tobias; LMU Klinikum, Institute of General Practice and Family Medicine BaCoM Study Group, The ; LMU Klinikum
Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Geriatric medicine, Health policy, Infectious diseases, Nursing, Public health
Keywords:	COVID-19, MENTAL HEALTH, QUALITATIVE RESEARCH, REGISTRIES, PRIMARY CARE, Public health < INFECTIOUS DISEASES

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

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ABSTRACT

Introduction

People in need of care 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 psycho-social 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. 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-BaCoM" is a multicenter 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 polymerase chain reaction (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, psycho-social 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, 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 analyze 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.

Trial registration: BaCoM is registered at the German Clinical Trials Register (DRKS); ID: DRKS00026039

ARTICLE SUMMARY

Strengths and limitations of this study

- This large, multicenter registry fills an evidence gap in COVID-19 research by focusing on a vulnerable, underrepresented 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 months follow-up provides data on long-term clinical course and sequels.
- A multi-professional research team (i.e. general practice, nursing, sociology and infectology) and a triangulated research approach combining quantitative and qualitative methods provide multiple perspectives and comprehensive analyses.
- Pre-status (before the pandemic) of the study population is not available; patient reported outcomes and interviews are at risk for re-call 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 World Health Organization (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 group 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 more than half of the COVID-19 deaths involved frail 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 , 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 and COVID-19 may exacerbate both general frailty and specific co-morbidities 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-/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 psycho-social health of people in need of care or support as well as on those caring for them, including formal (e.g. nursing stuff) and informal (e.g. 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, psycho-social 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 multicenter, 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 general practitioners.

Study Population

Eligibility criteria for patients

The inclusion/exclusion criteria of the study and control groups are provided in Table 1. All adult residents of in 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 01 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 month)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 data collection below). 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.

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 01.03.2020)	• 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 01.03.2020) 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 01.03.2020)
Exclusion criteria:		
• Refugees / asylum seekers • Life expectancy < 6 months (clinical judgement of the recruiting doctor) • Persons without health insurance		

* The degree of independence of the person in need of care is decisive for classification into the care levels.
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.

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.

Eligibility criteria for recruiting general practitioners

GPs are eligible for recruitment, if a) they offer statutory health insurance service, b) they care for COVID-19 patients, c) offer a primary health care 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, Wurzburg). In addition, we recruit up to 200 formal caregivers, up to 100 informal 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 maximize 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 (BayFoNet) 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 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 (LGL). (long-term care facility/home care provided by informal caregivers and/or outpatient care services)

Data collection

Baseline data collection began on 01 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 semi-structured interviews (see tables 2 to 5). Appropriately trained study staff conduct all data collection, so that interrater 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 (e.g. 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.

Baseline and Follow-Up assessments

The baseline data collection occurs within four weeks after recruitment. For all patient participants, follow-up (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 FU's (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 patient participants

Table 2 shows that clinical parameters of interest include physical status, laboratory, medication, comorbidities, BMI 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 health care facilities,

COVID-19 specific complications and symptoms (Long-/Post-Covid) is 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.

Psycho-social 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 psycho-social stress among people in need of care or support at different 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 (Generalized Anxiety Disorder Screener (30) (GAD-7)) and post-traumatic stress disorders (Impact of Event Scale revised(31) (IES-R)). The aim is to identify possible resources (Six-item Self-Efficacy Scale (32) (SES6G)) 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) (HLS-EU-Q16)), individual coping strategies, physical function and frailty, NANDA care diagnoses (North American Nursing Diagnosis Association) (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/domestic and inpatient care as well as GP's (table 5) are collected with regards to coping with the burdens of the pandemic to enable addressing any deficits. Contextual information on socio-demography, 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 2: Schedule of enrolment and assessments in BaCoM: Study group and Control groups

	Timepoint	**Baseline**	**FU_1-FU_x**
		Enrolment	*6 months*
CONSTRUCT	**INSTRUMENT**		*after PCR-test*
Sociodemographic information[B,C]	***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[B,C]	***Questionnaire***		
Care level (I-V) / Frailty level (1-9) and onset date of the need for care / frailty	Clinical Frailty Scale(21, 22)	x	x
Diagnosis justifying care			
Capacity for giving consent/legal guardian		x	x
Care setting (outpatient/domestic/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
Home 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)[B,C]	***Questionnaire***		
Stability of respiratory parameters(37)	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, 38)	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, 38)	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
Feeling of powerlessness/helplessness		x	x
Physical health status[C]			
Height, weight, Body-mass-index, smoking status	Questionnaire	x	x
Blood sampling: laboratory parameters, serostatus survey, long-term storage (24, 39)	Measurement	x	x
Vital parameters *(blood pressure, pulse, breath rate, O2-saturation, body temperature)*	Measurement	x	x
Identification of patients at risk from sepsis	Quick sepsis-related organ failure assessment (qSofa)(40, 41)	x	x
Mesurement of pulmonary function *PEF, FEV_1, FVC, $FEV_{0.75}$, $FEV_{0.5}$, FEV_1/FVC, FEF_{75} (MEF_{25}), FEF_{25-75} (MFEF), FEF_{50} (MEF_{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(42)	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) /	***Questionnaire***		

Characteristics of the course of the respiratory infection (Control group 1)[A,B,C]			
Date of pos./neg. SARS-CoV-2 PCR test / POCT rapid test		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-/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)[A,B,C]	***Questionnaire***		
Inpatient medical care (days / diagnosis): Hospitalisation (with Intensive care unit) / Rehabilitation/ Psychatry		x	x
Number of general practitioner/ other specialists contacts			
Ambulatory medical care (days / diagnosis): Number of general practitioner/ other specialists contacts /Treatment in emergency rooms		x	x
Psychosocial health status[B]	***Questionnaire***		
Health-related generic quality of life	EQ-5D-5L and EQ-VAS(25-27)	x	x
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
Health care 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

A=Patient record / care record, B=Survey of the person in need of care or support, C=Survey by medical /nursing staff, (caring) relatives;
*=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(43, 44).
*** Data is 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

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251 **Table 3:** Schedule of enrolment and assessments in BaCoM: Formal caregivers and care facilities
252 (inpatient/outpatient)

	Timepoint	**Baseline**	**FU_1-FU_x**
CONSTRUCT	**INSTRUMENT**	*Enrolment*	*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 pos. 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 (45)	x	x
Psychosocial health status	***Questionnaire***		
Depressiveness	PHQ-9(29)	x	x
Burnout	Maslach Burnout Inventory (MBI) (36)	x	x

Table 4: Schedule of enrolment and assesments in BaCoM: Informal/family caregivers

	Timepoint	**Baseline**	**FU_1-FU_x**
CONSTRUCT	**INSTRUMENT**	*Enrolment*	*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 pos. 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 (45)	x	x
Psychosocial health status	***Questionnaire***		
Depressiveness	PHQ-9(29)	x	x
Burnout	Maslach Burnout Inventory (MBI)(36)	x	x

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

	Timepoint	**Baseline**	**FU_1-FU_x**
		Enrolment	*6 months*

CONSTRUCT	INSTRUMENT		
Sociodemographic information	***Questionnaire***		
Age, sex, rofessional 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 (45)	x	x

Qualitative sub-study: Stakeholder interfaces in long-term care

The field of long-term care in the context of the COVID-19 pandemic is characterized 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 semi-standardized, guideline-supported interviews, which are primarily aimed at the perspective view of the interfaces of the different stakeholders. Patients, GPs, professional 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 regard 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 not only to name the challenges and needs of the various stakeholders, but also their structural conditionality in a highly differentiated field. The qualitative results thus 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 study group 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 standard deviation (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 four years about 30% of the study participants, across all levels of care, will still be alive (46). 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 analyzed descriptively. Analyses are performed for the entire population and stratified by level of care, outpatient/domestic and inpatient care, gender and age groups. For group comparisons between patients with positive SARS-CoV-2 PCR test and controls, the chi-square 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 control groups is shown graphically using Kaplan-Meier curves. Missing data for the study population is imputed according to multiple imputation where appropriate.

Non responder Analysis

As in most research in the outpatient 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 (CEO), 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 und 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 is 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 (e.g. 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 (e.g. 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

(e.g. health literacy) or the information is collected through an external survey of relatives or carers where this has previously been shown to be possible (e.g. 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 center 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 data base. 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 (ABS) offered by the LRZ based on the IBM Spectrum Protect (ISP) 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 optimizing 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 removed.

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

Data sharing

Individual participant data underlying the results of this article are available to researches 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.

Author Contributions

Conceptualization: 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, FA, CE, DH, HK, PK, DL, KM, SM, LR, MR, LS, RS, MS, DW, IZ; All authors have read and agreed to the final version of the manuscript.

Acknowledgements Members of the BaCoM-study group:

Jochen Gensichen (JG), Tobias Dreischulte (TD), Ildikó Gágyor (IG), Anita Hausen (AH), Michael Hoelscher (MH), Christian Janke (CJ), Armin Nassehi (AN), Thomas Kühlein (TK), Daniel Teupser (DT), Florian Arend (FA), Laura Baumgartner (LB), Barbara Daubner (BD), Christine Eidenschink (CE), Dorothea Fichtl (DF) ,Caroline Floto (CF), Johannes Gorkotte (JG), Dagmar Hindenburg (DH), Susann Hueber (SH), Stephanie Kalms (SK), Helena Kosub (HK), Peter Kurotschka (PK), Daniela Lindemann (DN), Katharina Mayr (KM), Irina Michel (IM), Susann Müller (SM), Britta Pauli (BP), Laura Rink (LR), Marietta Rottenkolber (MR), Linda Sanftenberg (LS), Rita Schwaiger (RS), Maria Sebastiao (MS), Constantin Unger (CU), Sabrina Vetter (SV), Domenika Wildgruber (DW), Isabel Zöllinger (IZ)

Funding statement

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

Competing interests statement

The authors declare that they have no competing interests.

Word Count: 3846

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Impact of the Covid-19 pandemic on frail elderly: protocol for a SARS-CoV-2 registry

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-8
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	5,6, 16
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	-
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7-9, 17-21
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7-9, 17-21
Bias	9	Describe any efforts to address potential sources of bias	11
Study size	10	Explain how the study size was arrived at	10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10,11
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10,11
		(*b*) Describe any methods used to examine subgroups and interactions	10,11
		(*c*) Explain how missing data were addressed	11
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	10

		(*e*) Describe any sensitivity analyses	10
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6,7
		(b) Give reasons for non-participation at each stage	11
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	5,6
		(b) Indicate number of participants with missing data for each variable of interest	-
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	7
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	7,8
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	-
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	-
		(*b*) Report category boundaries when continuous variables were categorized	-
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	-
Discussion			
Key results	18	Summarise key results with reference to study objectives	5
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	3
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	-
Generalisability	21	Discuss the generalisability (external validity) of the study results	3
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.