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# BMJ Open

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

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## Note from the Editors: Instructions for reviewers of study protocols

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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 scored 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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## 31 **ABSTRACT**

### 32 **Introduction**

33 Frail elderly persons are severely affected by the Covid-19 pandemic. We lack valid data of long-term  
34 assessments. We present a register-study to detect the physical and psycho-social impact of the Covid-  
35 19 pandemic on frail elderly in need of care in Southern Germany. To describe the persons' life  
36 conditions comprehensively, we assess the perspectives and needs of the respective care teams, too.  
37 Results will serve as an evidence-based source to manage the pandemic and long-term prevention  
38 strategies.

### 39 **Methods and analysis**

40 The "Bavarian Outpatient COVID-19 Monitor-BaCoM" is a multicenter registry including a  
41 convenience sample of up to 1000 patient participants across three study sites in Bavaria, Germany. The  
42 study group consists of 600 people in need of care with a positive SARS-CoV-2 polymerase chain  
43 reaction (PCR) test. Control group 1 comprises 200 people in need of care with a negative SARS-CoV-2  
44 PCR test, while control group 2 comprises 200 people with a positive SARS-CoV-2-PCR, but are not  
45 in need of care. We assess the clinical course of infection, psycho-social aspects and care needs using  
46 validated measures. Follow-up is every 6 months for up to 3 years. Additionally, we assess up to 400  
47 people linked to these patient participants (caregivers, general practitioners) for their health and needs.  
48 Finally, we conduct qualitative interviews with 60 stakeholders (caregivers, general practitioners,  
49 politicians) to explore interface problems of actors in health care. Main analyses are stratified by level  
50 of care I-V (I=minor/V=most severe impairment of independence/abilities), inpatient/outpatient setting,  
51 sex and age. We use descriptive and inferential statistics to analyze cross-sectional data and changes  
52 over time.

### 53 **Ethics and dissemination**

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

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3 58 **Trial registration:** BaCoM is registered at the German Clinical Trials Register (DRKS); ID:  
4  
5 59 DRKS00026039  
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8 60 **ARTICLE SUMMARY**  
9

10 61 **Strengths and limitations of this study**

- 11 62 • This large, multicenter registry fills an evidence gap in Covid-19 research by focusing on a  
12  
13 vulnerable, underrepresented group of people, who are in need of care in outpatient settings (long-  
14 63 term care facilities, informal/family care etc.) and survived COVID-19 infection.  
15  
16 64  
17  
18 65 • A 36 months follow-up provides data on long-term clinical course and sequels.  
19  
20 66 • A multi-professional research team (i.e. General practice, Nursing, Sociology and Infectology) and  
21  
22 67 a triangulated research approach combining quantitative and qualitative methods provide multiple  
23  
24 68 perspectives and comprehensive analyses.  
25  
26 69 • Pre-status (before the pandemic) of the study population is not available; patient reported outcomes  
27  
28 70 and interviews are at risk for re-call bias and social desirability.  
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31 71 • Cause of limited life expectancy of the frail participants, we include additional participants over  
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33 72 time (open registry).  
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## 76 INTRODUCTION

77 By February 2022, the World Health Organization (WHO) noted 433 million cases and almost six  
78 million deaths from COVID-19. Many COVID-19 survivors will be affected by long-lasting and  
79 debilitating sequelae (1). One of the most vulnerable and affected group by the Covid-19 pandemic are  
80 older and frail people (2-6). In Germany, until end of 2022, people aged 60 years and older accounted  
81 for more than two thirds (71.4%) of COVID-19 cases in old people's and nursing homes (7), and more  
82 than half of the COVID-19 deaths involved frail people under care of an outpatient care service or living  
83 in a long term care facility (8).

84 Apart from a higher risk of death from COVID-19 for the frail older, the physical, psychological and  
85 social impact of the Covid-19 pandemic and the subsequent needs of COVID-19 survivors may differ  
86 between younger and frail older survivors of COVID-19 for a number of reasons. Multimorbidity is the  
87 rule rather than exception among older people and COVID-19 may exacerbate both general frailty and  
88 specific co-morbidities that are particularly affected by COVID-19 (such as respiratory and  
89 cardiovascular disease) (2, 9). All of these factors may prolong recovery, increase the likelihood of  
90 Long-/Post-Covid syndrome and increase dependency (10, 11). In addition, long-term care facilities  
91 frequently implemented drastic infection control measures, with external and internal contact  
92 restrictions aggravating feelings of loneliness and isolation, which may have long-term consequences  
93 for mental and physical health (12-15).

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

99 Against this background, it appears likely that the COVID-19 pandemic has and will continue to have  
100 a relevant impact on the physical and psycho-social health of older, frail people dependent on care as  
101 well as on those caring for them, including formal (e.g. nursing staff) and informal (e.g. family  
102 members /relatives) caregivers and GPs.

103



## 104 **AIM AND OBJECTIVES**

105 The aim of the “Bavarian Outpatient Covid-19 Monitor (BaCoM)” is therefore to conduct a systematic  
106 assessment of the physical, psychological and social long-term outcomes and sequels of the COVID-19  
107 pandemic on older people dependent on care, as well as their care needs and the needs of care providers.

108 The findings should support the development and implementation of long-term prevention and aftercare  
109 strategies. The specific study objectives are:

110 (1) To examine clinical parameters, psycho-social burden and care needs in older, frail people dependent  
111 on care or support.

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

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

114

## 115 **METHODS AND ANALYSIS**

### 116 **Study design and setting**

117 BaCoM is a multicenter, open registry study in the State of Bavaria (Southern Germany). For objectives  
118 (1) and (2), we include patient participants in one study group (SG) and two control groups (CG1 and  
119 CG2). The SG comprises people with evidence of a previous SARS-CoV-2 infection, who were frail  
120 and dependent on care or support at the time of infection, and survived COVID-19. In order to examine  
121 the impact of COVID-19 on clinical parameters and psychosocial burden, participants in CG1 comprise  
122 people with frailty and dependent on care or support during the COVID-19 pandemic, but without  
123 evidence of SARS-CoV-2 infection. In order to examine effect modification of the COVID-19 impact  
124 by frailty, participants in CG2 comprise people with evidence of a previous SARS-CoV-2 infection but  
125 without frailty at the time of infection. For objective (3), we also collect information from formal and  
126 informal caregivers of participants included in SG, CG1 and CG2 as well as their general practitioners.

### 127 **Study Population**

#### 128 **Eligibility criteria for patients**

129 The inclusion/exclusion criteria of the study and control groups are provided in Table 1. All adult  
130 residents of in State of Bavaria who are 18 years or older at the time of recruitment and have had at least  
131 one SARS-CoV-2 test are eligible for inclusion in BaCoM. In order to determine COVID-19 status (for

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2  
3 132 assignment to SG and CG2 vs CG1) we consider the results of PCR tests, where people with at least  
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5 133 one previous positive test result (not older than 01 March 2020) are assigned to SG or CG2, respectively,  
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7 134 and otherwise to CG1. In cases, where PCR test results are not available, people with rapid SARS-  
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9 135 CoV-2 antigen test results can be enrolled (not older than 6 month) and the results from antigen tests  
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11 136 will be interpreted in combination with any evidence of nucleocapsid antibodies measured as part of the  
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13 137 study protocol (see data collection below). The assessment of nucleocapsid antibodies serves as a further  
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15 138 means to verify any previous infection with SARS-CoV-2, which is not influenced by exposure to  
16  
17 139 vaccines (since vaccines only trigger antibodies against the spike protein).

#### 21 140 **Eligibility criteria for participating caregivers**

22 141 Formal and informal caregivers are eligible for recruitment, if they are involved in the care or support  
23  
24 142 of a recruited patient.

#### 28 143 **Eligibility criteria for recruiting general practitioners (GPs)**

29 144 GPs are eligible for recruitment, if a) they offer statutory health insurance service, b) they care for  
30  
31 145 COVID-19 patients, c) offer a primary health care service open for all patient groups.

#### 35 146 **Participant recruitment**

36 147 Up to 1000 patient participants (n=600 in SG, and 200 in each of CG1 and CG2) are to be recruited for  
37  
38 148 the project at three study sites in Bavaria (Munich, Erlangen, Würzburg). In addition, we aim to recruit  
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40 149 up to 200 formal caregivers, up to 100 informal caregivers and up to 100 GPs. In order to maximize the  
41  
42 150 geographical spread of study participant resident, we implement a Bavarian-wide recruitment campaign  
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44 151 with broad publicity. Recruitment of patient participants can take place at any time after a SARS-CoV-  
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46 152 2 PCR test result (subsequently referred to as the 'index test'). The index test is defined as the first  
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48 153 positive SARS-CoV-2 test result (for SG and CG2) or otherwise the latest negative SARS-CoV-2 test  
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50 154 result without any previous infection (for CG 1). Patient participants are identified via their GP, the  
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52 155 long-term care facility they live in, via outpatient care services or informal caregivers, or via self-  
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54 156 referral. Irrespective of how prospective patient participants are identified, they are either recruited by  
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56 157 their GP or (if not available) a study physician.

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3 158 The recruitment of GPs is carried out via in total 240 GCP-qualified practices of the Bavarian Research  
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5 159 Practice Network (BayFoNet) and cooperating teaching practices. Further eligible general practices with  
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7 160 a past or current focus on managing patients with Covid-19 are identified.

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9 161 The participating GP's receive compensation for their work within the framework of the study  
10  
11 162 (participant inclusion and information, baseline examination, follow-up surveys). For the recruitment  
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13 163 from inpatient and outpatient care facilities, we use a list of about 700 eligible facilities in Bavaria with  
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15 164 documented Covid-19 outbreaks who file their interest in participating in BaCoM via a reporting system  
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17 165 to the Bavarian State Office for Health and Food Safety (Bayerisches Landesamt für Gesundheit und  
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19 166 Lebensmittelsicherheit (LGL).

### 20 167 **Data collection**

21  
22 168 Baseline data collection began on 01 March 2021 and enrolment will continue until the end of 2023.  
23  
24 169 Data collection methods include blood samples, clinical investigations, data abstraction from clinical  
25  
26 170 data sources, surveys as well as semi-structured interviews (see tables 2 to 4). Appropriately, trained  
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28 171 staff conduct all data collection. It can be assumed that a certain proportion of the study participants  
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30 172 will not be able to provide self-disclosure (e.g. in case of cognitive impairment). In these cases, the  
31  
32 173 information collection is to be ensured by relatives or caregivers are asked instead. In order to ensure  
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34 174 that the cognitive status is determined, the "Six Item Screener(20)" - a cognitive short test - is  
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36 175 administered (0-6 points). If the "Six Item Screener" is not successfully completed (< 4 points), the  
37  
38 176 information collection of the self-reports will be ensured according to the substitution principle  
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40 177 mentioned above.

### 41 178 **Baseline and Follow-Up assessments**

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43 179 The baseline data collection occurs within four weeks after recruitment. For all patient participants,  
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45 180 follow-up (FU) assessments are conducted at 6-month intervals after the date of the index test for a  
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47 181 period of up to 3 years in order to be able to observe the development of physical and mental health, as  
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49 182 well as provider and care needs over an extended time period. Depending on the date of enrolment, the  
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51 183 number of FU's will therefore range between one and five FU's (3 years). For formal and informal  
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53 184 caregivers and GPs, FU's intervals are similar. The parameters and constructs of interest as well as their  
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185 corresponding data collection methods are provided in tables 2-5 and their rationale is briefly described  
186 below. The qualitative interviews with stakeholder are one-time.

#### 187 *Clinical parameters of patient participants*

188 Table 2 shows that clinical parameters of interest include physical status, laboratory, medication,  
189 comorbidities, BMI and vaccination status. Tests for frailty (Clinical Frailty scale(21, 22)) and for  
190 cognitive impairment (Moca-Blind(23)) are performed. In addition, the use of health care facilities,  
191 COVID-19 specific complications and symptoms (Long-/post-Covid) will be used to characterise the  
192 course of the disease. Many target variables are collected in accordance with the "German Corona  
193 Consensus Data Set" of the National Research Network of University Medicine on Covid-19 (24). The  
194 attending GP or the study nurse will do a brief physical examination with measurement of the vital  
195 parameters and take a venous blood sample. By this an antibody test for SARS-CoV-2 and thus the  
196 influence of Covid-19 disease on the immune response can be measured. For the remaining part of the  
197 blood samples, an immediate laboratory analysis of a complete blood count, a differential blood count,  
198 and 26 organ specific parameters relevant for Covid-19 disease will be carried out. To cover future  
199 research questions, serum and whole blood samples will be transferred to quality-controlled long-term  
200 storage at -80°C in the Institute of Laboratory Medicine.

#### 201 *Psycho-social parameters of patient participants*

202 Table 2 shows psychological parameters of interest that include the mental health status among others.  
203 The Covid-19 pandemic may cause severe psycho-social stress among people in need of care or support  
204 at different ages and life situations. To recognise these burdens and identify possible protective factors  
205 or risk factors, participant questionnaires with validated measurement instruments will be used. This  
206 includes health-related quality of life (EuroQol (25-27) (Eq-5D-5L)), symptoms of depression (Patient  
207 Health Questionnaire (28, 29) (PHQ-9)), anxiety (Generalized Anxiety Disorder Screener (30) (GAD-  
208 7)) and post-traumatic stress disorders (Impact of Event Scale revised(31) (IES-R)). The aim is to  
209 identify possible resources (Six-item Self-Efficacy Scale (32) (SES6G)) and strategies that can  
210 contribute to convalescence on the one hand and address the specific care needs of people in need of  
211 care or support for sustainable prevention on the other.

#### 212 *Care needs of patient participants*

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3 213 Special medical and care needs among this group of people in the different care settings are largely  
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5 214 unknown so far. Table 2 shows the care parameters of interest, which include factors such as deprivation.  
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7 215 In addition to the mobility and social participation, such an assessment should also include care services  
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9 216 already used, health literacy (European health literacy survey(33) (HLS-EU-Q16)), individual coping  
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11 217 strategies, physical function and frailty, NANDA care diagnoses (North American Nursing Diagnosis  
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13 218 Association) (34) and a geriatric assessment (Barthel-Index(35)). From these findings, it is to be derived  
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15 219 which offers are necessary for sustainable prevention in long-term care in order to be able to contribute  
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17 220 to an improvement of resilience so that an individual, self-determined life and living oriented towards  
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19 221 the principle of normality is still possible.

22 222 Sociodemographic differentiations also play a role in all these dimensions and educational level,  
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24 223 (former) professional background, income class and family situation are collected for the distillation of  
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26 224 at least trend statements.

#### 28 225 *Needs of formal and informal caregivers and GPs*

30 226 Tables 3-5 show that parameters of formal (table 3) and informal caregivers (table 4) from  
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32 227 outpatient/domestic and inpatient care as well as GP's (table 4) are collected with regards to coping with  
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34 228 the burdens of the pandemic to enable addressing any deficits. Contextual information on socio-  
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36 229 demography, structural information on the care facility or the GP practice, as well as data on the  
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38 230 psychosocial health (PHQ-9) and stress situation (Maslach-Burnout-Inventory(36)) will be collected. In  
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40 231 addition, the formal and informal caregivers will be asked about their own SARS-Cov-2 infection and  
41  
42 232 about their vaccination decision.

#### 46 233 **Substudy: Constellations of actors in long-term care**

47 234 The field of long-term care in the context of the Covid-19 pandemic is characterised by a multitude of  
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49 235 actors: People in need of care, caregivers, managers, relatives, GPs, administration, etc. Administrative  
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51 236 requirements, for example, need to be coordinated with all participating actors. We will assess their  
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53 237 interfaces. The aim is to formulate standards to improve the communication between the actors. 60  
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55 238 expert patients, GPs, formal and informal caregivers will be recruited from the main study for semi-  
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57 239 standardized, guideline-supported interviews. Additional relevant actors will be selected (greatest  
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59 240 possible variance with regard to the characteristics: needs of care, care setting, regions, age, and sex) for

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3 241 interviews, too. We form conceptual categories (based on the theory of functional differentiation) for  
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5 242 the computer-assisted coding and evaluation of the interviews with MAXQDA software, which are  
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7 243 adapted and refined in an iterative process.  
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#### 10 244 **Sample size calculation and stratification**

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12 245 Based on 600 (SG) and 200 (each CG) persons recruited for the registry, we simulate minimal detectable  
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14 246 (statistical) difference for major outcomes (age, comorbidities and mortality). Comparing the study  
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16 247 group and the controls using a two-tailed t-test or log-rank test, with the assumptions for the significance  
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18 248 level  $\alpha=0.05$  and the power  $\beta=0.8$  and given standard deviation (SD), the detectable differences for the  
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20 249 following variables are obtained: Age: SD=10.0; detectable difference of -2.29 or 2.29; Comorbidities:  
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22 250 SD=3.1; detectable difference of -7.10 or 7.10; Mortality: median survival time= 4.0; detectable  
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24 251 difference of 2.66 or 6.56; EQ-5D-5L: SD=0.29; detectable difference of -0.07 or 0.07. With respect to  
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26 252 the limited life expectancy of care recipients, it is expected that after four years about 30% of the study  
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28 253 participants, across all levels of care, will still be alive. The registry will therefore be expanded with  
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30 254 additional participants at regular intervals and evaluated separately in subgroups. The aim is to achieve  
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32 255 a relative distribution of the persons in need of care or support in outpatient care (50%) and inpatient  
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34 256 care (50%). In order to account for the differences in medical infrastructures, population density and  
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36 257 regional differences in infection incidence, we are aiming at an equal stratification according to the  
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38 258 seven administrative districts in Bavaria.  
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#### 43 259 **Statistical analysis**

44  
45 260 All collected parameters of the study participants are analyzed descriptively. Analyses will be performed  
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47 261 for the entire population and stratified by level of care, outpatient/domestic and inpatient care, gender  
48  
49 262 and age groups. For group comparisons between patients with positive SARS-CoV-2 PCR test and  
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51 263 controls, the chi-square test or Fisher's exact test are used for categorical variables, the t-test (normally  
52  
53 264 distributed variables) or Mann-Whitney-U test (non-normally distributed variables) for metric variables,  
54  
55 265 and the log-rank test for survival times. All p-values are purely exploratory. Regression models are used  
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57 266 to identify, among other things, risk factors that predict a severe course, occurrence of long-term  
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267 consequences of a Covid-19 infection or a deterioration of the quality of life due to a Covid-19 infection.

268 The survival of the study and control groups is shown graphically using Kaplan-Meier curves.

269 Missing data for the study population will be imputed according to multiple imputation.

### 270 **Non responder Analysis**

271 As in most research in the outpatient care environment, the external validity of our findings is

272 vulnerable to participation bias. For example, it is conceivable that non-responding institutions are

273 particularly burdened by the pandemic. To understand better who does and does not participate, we

274 will conduct an analysis of a subsample of the non-responding care facilities or practices via telephone

275 or postal surveys scheduled 6 and 12 months after first contact, in order to elicit structural and

276 contextual information about the facilities.

### 277 **Patient and public involvement**

278 Members of the BaCoM advisory board (listed [twwww.bacomstudie.de](http://www.bacomstudie.de)) represent of a broad expertise in

279 the field: Science, patient advocacy, health assurances, health authorities, institutional facilities (CEO),

280 etc.. The board commented and approved the protocol and will comment the results (public outcome

281 symposium). In addition we present the protocol and results to primary care related citizen forum

282 (“Bürgerforum”) in Wurzburg und Erlangen.

## 283 **ETHICS AND DISSEMINATION**

### 284 **Informed Consent**

285 All participants provided written informed consent to participate. If a treating GP participates in BaCoM,

286 he/she will inform his/her patient about the study. Otherwise, the enrolment and information is provided

287 by the doctor of the study team. If the person in need of care or support is not capable of giving consent

288 him or herself (e.g. dementia, cognitive impairment), consent can be given by the legal guardian. The

289 BaCoM Team will pursue all measures to protect the interests of participants who are unable to consent.

### 290 **Study registration and ethics**

291 BaCoM is registered at the German Clinical Trials Register (DRKS) ID: DRKS00026039. All methods

292 were performed in accordance with the principles of the Declaration of Helsinki.

1  
2  
3 293 The responsible Institutional Review Board of the coordinating study center of BaCoM (Ethics  
4  
5 294 Committee of the Medical Faculty of the University Hospital of LMU Munich; ethical vote number:  
6  
7 295 #20-860) and of all participating study sites (Ethical Committees at the Medical Faculties of the  
8  
9 296 University of Würzburg and Friedrich-Alexander-University of Erlangen-Nuremberg) approved  
10  
11 297 BaCoM.

### 14 298 **Data access and protection**

15 299 All data are collected with pseudonyms (ID) first on paper based case report forms and then  
16  
17 300 transferred in electronic case report forms (double data entry). Data entry takes place on the servers of  
18  
19 301 University Hospital of the LMU with 'LibreClinica<sup>®</sup>', an open source validated study management  
20  
21 302 software. To ensure a pseudonymised analysis of data, each participant data set is given a unique  
22  
23 303 participant identification number (ID) when being entered into the study data base. The anonymity of  
24  
25 304 the data in the context of evaluations is ensured. The allocation between study participant and  
26  
27 305 participant ID takes place in the study centre through the password-protected allocation lists of the  
28  
29 306 study participants. This information is stored separately and not in the database. By using a  
30  
31 307 hierarchical access concept, unauthorised access to the pseudonymised patient data in the database is  
32  
33 308 impossible.

34  
35 309 Storage resources for the data are available in the personal cloud storage of the Leibnitz  
36  
37 310 Rechenzentrum (LRZ). For long-term archiving, the Archive and Backup Service (ABS) offered by  
38  
39 311 the LRZ based on the IBM Spectrum Protect (ISP) software is used. Copies of all data in the archive  
40  
41 312 are made on separate tapes to increase security. Data quality is checked for errors electronically and  
42  
43 313 on-site by experienced monitors. Data access to the final data set is provided to the BaCoM Study  
44  
45 314 Group along with written use and access rules.

### 48 315 **Dissemination**

49  
50 316 As an instrument for optimizing outpatient Covid-19 care in Bavaria, the results of the interdisciplinary  
51  
52 317 Monitor will be presented in regular progress reports and discussed with other (external) experts at  
53  
54 318 symposia. On this basis, in a Delphi process of the participating experts from different disciplines,  
55  
56 319 further developing questions or measurement instruments can be systematically included in the Monitor,  
57  
58 320 or variables that are not very meaningful can be removed.



1  
2  
3 321 Findings will be presented at scientific conferences and through peer-reviewed publications.  
4  
5

6 322 **Data sharing**

7  
8 323 Individual participant data underlying the results of this article is available to researchers who submit a  
9  
10 324 methodologically sound proposal to the BaCoM steering committee (correspondence:  
11  
12 325 Jochen.Gensichen@med.uni-muenchen.de) for use of data in the approved proposal.  
13  
14

15 326 **Author Contributions**

16 327 Conceptualization: JG, TD, IG, AH, MH, CJ, TK, AN, DT, IZ; Data analysis: MR, DL; Funding  
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18 328 acquisition: JG, TD, IG, AH, MH, CJ, TK, AN, DT, IZ; Supervision: JG, TD, IG, AH, MH, CJ, TK,  
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20 329 AN, DT, IZ; Writing the original draft: JG, TD, IG, AH, MH, CJ, TK, AN, DT, IZ; Review and  
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56 346 The authors declare that they have no competing interests.  
57  
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## 466 Tables

467 **Table 1:** Inclusion/exclusion criteria of patient participants

<i>Study group</i>	<i>Control group 1</i>	<i>Control group 2</i>
<b>Inclusion criteria:</b>		
<ul style="list-style-type: none"> <li>Signed informed consent from the participant or a legal guardian</li> <li>Age <math>\geq 18</math></li> <li>Sufficient knowledge of German to give consent / answer questionnaires or possibility of translation by an interpreter</li> <li>residence in Bavaria</li> </ul>		
<ul style="list-style-type: none"> <li>Existing need for care (care level I-V) <i>or</i> support (according to the clinical judgement of the recruiting doctor: current need for care or expected need in the near future (Clinical Frailty Scale <math>\geq 5</math>))(21, 22)</li> <li><b>Positive</b> SARS-CoV-2 PCR test (maximum backdated to 01.03.2020)</li> </ul>	<ul style="list-style-type: none"> <li>Existing need for care (care level I-V) <i>or</i> support (according to the clinical judgement of the recruiting doctor: current need for care or expected need in the near future (Clinical Frailty Scale <math>\geq 5</math>))</li> <li><b>Negative</b> SARS-CoV-2 PCR test (maximum backdated to 01.03.2020) with respiratory infection</li> </ul>	<ul style="list-style-type: none"> <li><b>No</b> existing need for care (care level I-V) <i>or</i> support (according to the clinical judgement of the recruiting doctor: current need for care or expected need in the near future (Clinical Frailty Scale <math>\geq 5</math>))</li> <li><b>Positive</b> SARS-CoV-2 PCR test (maximum backdated to 01.03.2020)</li> </ul>
<b>Exclusion criteria:</b>		
<ul style="list-style-type: none"> <li>Refugees / asylum seekers</li> <li>Life expectancy &lt; 6 months (clinical judgement of the recruiting doctor)</li> <li>Persons without health insurance</li> </ul>		

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

	Timepoint	Baseline	FU <sub>1</sub> -FU <sub>x</sub>
		Enrolment	6 months after PCR-test
CONSTRUCT	INSTRUMENT		
<b>Sociodemographic information<sup>B,C</sup></b>	<b>Questionnaire</b>		
Age, sex, migration background, educational level, professional life/activity, income, marital status, health insurance, insurance number		x	
<b>Care-specific parameters with reference to the need for care<sup>B,C</sup></b>	<b>Questionnaire</b>		
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
<b>Nursing diagnoses in terms of NANDA-I (Definitions and Classification 2018-2020) (34)<sup>B,C</sup></b>	<b>Questionnaire</b>		
<b>Stability of respiratory parameters(37)</b>	Likert-Scale		
Impaired gas exchange		x	x
Impaired spontaneous breathing		x	x
Ineffective airway clearance		x	x
<b>Sense of smell and taste</b>	Likert-Scale		
Smells all primary odours		x	x
Tasting all substance spectra		x	x
<b>Social interaction (34, 38)</b>	Likert-Scale		
Mobility, ability to walk		x	x
Communication verbal/via electronics (impaired/reports needs)		x	x
<b>Family processes (before and since the beginning of the pandemic)</b>	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
<b>Social isolation (34, 38)</b>	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
<b>Physical health status<sup>C</sup></b>			
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 <i>PEF, FEV<sub>1</sub>, FVC, FEV<sub>0.75</sub>, FEV<sub>0.5</sub>, FEV<sub>1</sub>/FVC, FEF<sub>75</sub> (MEF<sub>25</sub>), FEF<sub>25-75</sub> (MFEF), FEF<sub>50</sub> (MEF<sub>50</sub>), FV-curve</i>	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
<b>Characteristics of a Covid-19 disease course (Study + Control group 2) / Characteristics of the course of the respiratory infection (Control group 1)<sup>A,B,C</sup></b>	<b>Questionnaire</b>		
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)			
<b>Use of medical care facilities (since PCR-test)<sup>A,B,C</sup></b>	<b>Questionnaire</b>		
Inpatient medical care (days / diagnosis): Hospitalisation (with Intensive care unit) / Rehabilitation/ Psychiatry 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
<b>Psychosocial health status<sup>B</sup></b>	<b>Questionnaire</b>		
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
<b>Health care utilisation</b>	<b>Claims data***</b>		
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

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

	Timepoint	Baseline	FU <sub>1</sub> -FU <sub>x</sub>
		Enrolment	6 months
<b>CONSTRUCT</b>	<b>INSTRUMENT</b>		
<b>Sociodemographic information</b>	<b>Questionnaire</b>		
Age, sex, ethnicity, migration background, educational level, professional life/activity, income, marital status		x	
<b>SARS-CoV-2 infection</b>	<b>Questionnaire</b>		
<b>SARS-CoV-2 infection in the past</b>		x	x
Date of pos. SARS-CoV-2 PCR tests		x	x
Covid-19-Infection symptomatic/asymptomatic		x	x
<b>Care facility parameters</b>	<b>Questionnaire</b>		
<b>Inpatient care facilities and other forms of housing</b> (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
<b>Outpatient care facilities</b> (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
<b>Sars-CoV-2 vaccination</b>	<b>Questionnaire</b>		
Psychological factors influencing the decision to vaccinate against Sars-CoV-2	5 C (45)	x	x
<b>Psychosocial health status</b>	<b>Questionnaire</b>		
Depressiveness	PHQ-9(29)	x	x
Burnout	Maslach Burnout Inventory (MBI) (36)	x	x

475

476

477 **Table 4:** Schedule of enrolment and assessments in BaCoM: Informal/family caregivers

	Timepoint	Baseline	FU <sub>1</sub> -FU <sub>x</sub>
		Enrolment	6 months
<b>CONSTRUCT</b>	<b>INSTRUMENT</b>		
<b>Sociodemographic information</b>	<b>Questionnaire</b>		
Age, sex, ethnicity, migration background, educational level, professional life/activity, income, marital status		x	
<b>SARS-CoV-2 infection</b>	<b>Questionnaire</b>		
<b>SARS-CoV-2 infection in the past</b>		x	x
Date of pos. SARS-CoV-2 PCR tests		x	x
Covid-19-Infection symptomatic/asymptomatic		x	x
<b>Care burden situation</b>	<b>Questionnaire</b>		
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
<b>Sars-CoV-2 vaccination</b>	<b>Questionnaire</b>		
Psychological factors influencing the decision to vaccinate against Sars-CoV-2	5 C (45)	x	x
<b>Psychosocial health status</b>	<b>Questionnaire</b>		
Depressiveness	PHQ-9(29)	x	x
Burnout	Maslach Burnout Inventory (MBI)(36)	x	x

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

CONSTRUCT	Timepoint	Baseline	FU <sub>1</sub> -FU <sub>x</sub>
		Enrolment	6 months
<b>Sociodemographic information</b>		<b>Questionnaire</b>	
Age, sex, professional experience		x	
<b>Practice-specific parameters</b>		<b>Questionnaire</b>	
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
<b>Sars-CoV-2 vaccination</b>		<b>Questionnaire</b>	
Psychological factors influencing the decision to vaccinate against Sars-CoV-2	5 C (45)	x	x

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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
<b>Title and abstract</b>	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
<b>Introduction</b>			
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
<b>Methods</b>			
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) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —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 <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	5,6, 16
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —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) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	10

## (e) Describe any sensitivity analyses

10

<b>Results</b>			
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) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	7
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	7,8
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	-
		<i>Cross-sectional study</i> —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	-
<b>Discussion</b>			
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
<b>Other information</b>			
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](http://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

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4 **1 Impact of the Covid-19 pandemic on people in need of care or support: protocol for a**  
5 **2 SARS-CoV-2 registry**  
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**31 ABSTRACT****32 Introduction**

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

**39 Methods and analysis**

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

**53 Ethics and dissemination**

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

57 **Trial registration:** BaCoM is registered at the German Clinical Trials Register (DRKS); ID:  
58 DRKS00026039  
59  
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3 59 **ARTICLE SUMMARY**  
4

5 60 **Strengths and limitations of this study**

- 6 61 • This large, multicenter registry fills an evidence gap in COVID-19 research by focusing on a  
7  
8 62 vulnerable, underrepresented group of people, who are in need of care in ambulatory settings  
9  
10 63 (long-term care facilities, informal/family care etc.) and survived COVID-19 infection.  
11  
12  
13 64 • A 36 months follow-up provides data on long-term clinical course and sequels.  
14  
15 65 • A multi-professional research team (i.e. general practice, nursing, sociology and infectology) and a  
16  
17 66 triangulated research approach combining quantitative and qualitative methods provide multiple  
18  
19 67 perspectives and comprehensive analyses.  
20  
21 68 • Pre-status (before the pandemic) of the study population is not available; patient reported outcomes  
22  
23 69 and interviews are at risk for re-call bias and social desirability.  
24  
25 70 • Due to limited life expectancy of the predominantly frail participants, we include additional  
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27 71 participants over time (open registry).  
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## 75 INTRODUCTION

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

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

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

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

102

## 103 **AIM AND OBJECTIVES**

104 The aim of the “Bavarian ambulatory Covid-19 Monitor (BaCoM)” is therefore to conduct a systematic  
105 assessment of the physical, psychological and social long-term outcomes and sequels of the COVID-19  
106 pandemic on people in need of care or support, as well as their care needs and the needs of care providers.

107 The findings should support the development and implementation of long-term prevention and aftercare  
108 strategies. The specific study objectives are:

109 (1) To examine clinical parameters, psycho-social burden and care needs in people dependent on care  
110 or support

111 (2) To examine long-term sequels in people in need of care or support

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

## 113 **METHODS AND ANALYSIS**

### 114 **Study design and setting**

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

### 126 **Study Population**

#### 127 **Eligibility criteria for patients**

128 The inclusion/exclusion criteria of the study and control groups are provided in Table 1. All adult  
129 residents of in State of Bavaria who are 18 years or older at the time of recruitment and have had at least  
130 one SARS-CoV-2 test are eligible for inclusion in BaCoM. In order to determine COVID-19 status (for

1  
2  
3 131 assignment to SG and CG2 vs CG1) we consider the results of PCR tests, where people with at least one  
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5 132 previous positive test result (not older than 01 March 2020) are assigned to SG or CG2, respectively,  
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7 133 and otherwise to CG1. In cases, where PCR test results are not available (which is commonly the case  
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9 134 in later stages of the pandemic), people with rapid SARS-CoV-2 antigen test results (not older than 6  
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11 135 month) can be enrolled. Test results from antigen tests are interpreted in combination with any evidence  
12  
13 136 of nucleocapsid antibodies measured as part of the study protocol (see data collection below). The  
14  
15 137 assessment of nucleocapsid antibodies serves as a further means to verify any previous infection with  
16  
17 138 SARS-CoV-2, which is not influenced by exposure to vaccines (since vaccines only trigger antibodies  
18  
19 139 against the spike protein). Patients, who have previously been allocated to CG1, but who subsequently  
20  
21 140 test positive for nucleocapsid antibodies are classified as group-switchers and are reallocated to the SG  
22  
23 141 accordingly.  
24  
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26

27 **Table 1:** Inclusion/exclusion criteria of patient participants  
28

<i>Study group</i>	<i>Control group 1</i>	<i>Control group 2</i>
<b>Inclusion criteria:</b>		
<ul style="list-style-type: none"> <li>Signed informed consent from the participant or a legal guardian</li> <li>Age <math>\geq</math> 18 years</li> <li>Sufficient knowledge of German to give consent / answer questionnaires or possibility of translation by an interpreter</li> <li>residence in Bavaria</li> </ul>		
<ul style="list-style-type: none"> <li>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 <math>\geq</math>5 and &lt;9)(21, 22)</li> <li><b>Positive</b> SARS-CoV-2 PCR test (maximum backdated to 01.03.2020)</li> </ul>	<ul style="list-style-type: none"> <li>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 <math>\geq</math>5 and &lt;9)</li> <li><b>Negative</b> SARS-CoV-2 PCR test (maximum backdated to 01.03.2020) with respiratory infection</li> </ul>	<ul style="list-style-type: none"> <li><b>No</b> existing need for care (<b>no</b> care level I-V*) or support (according to the clinical judgement of the recruiting doctor: <b>no</b> current need for care or expected need in the near future (Clinical Frailty Scale &lt;5))</li> <li><b>Positive</b> SARS-CoV-2 PCR test (maximum backdated to 01.03.2020)</li> </ul>
<b>Exclusion criteria:</b>		
<ul style="list-style-type: none"> <li>Refugees / asylum seekers</li> <li>Life expectancy &lt; 6 months (clinical judgement of the recruiting doctor)</li> <li>Persons without health insurance</li> </ul>		

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55  
56 143 \* The degree of independence of the person in need of care is decisive for classification into the care levels.  
57 144 The levels of care I-V are:

58 145 Care level I: minor impairment of independence

59 146 Care level II: significant impairment of independence

60 147 Care level III: severe impairment of independence

148 Care level IV: most severe impairment of independence

149 Care level V: most severe impairment of independence with special requirements for nursing care.

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3 **150 Eligibility criteria for participating caregivers**

4  
5 151 Formal and informal caregivers are eligible for recruitment, if they are involved in the care or support  
6  
7 152 of a recruited patient.

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9  
10 **153 Eligibility criteria for recruiting general practitioners**

11 154 GPs are eligible for recruitment, if a) they offer statutory health insurance service, b) they care for  
12  
13 155 COVID-19 patients, c) offer a primary health care service open for all patient groups.

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16 **156 Participant recruitment**

17 157 Up to 1000 patient participants (n=600 in SG, and 200 in each of CG1 and CG2) are recruited at three  
18  
19 158 study sites in Bavaria (Munich, Erlangen, Würzburg). In addition, we recruit up to 200 formal  
20  
21 159 caregivers, up to 100 informal caregivers and up to 100 GPs. Patient participants can be recruited in  
22  
23 160 inpatient (long-term care facilities) or outpatient care settings (home care provided by informal  
24  
25 161 caregivers and/or outpatient care services). In order to maximize the geographical spread of study  
26  
27 162 participants, we implement a Bavarian-wide recruitment campaign with broad publicity. Recruitment of  
28  
29 163 patient participants can take place at any time after a SARS-CoV-2 PCR test result (subsequently  
30  
31 164 referred to as the 'index test'). The index test is defined as the first positive SARS-CoV-2 test result (for  
32  
33 165 SG and CG2) or otherwise the latest negative SARS-CoV-2 test result without any previous infection  
34  
35 166 (for CG 1). Patient participants are identified via their GP, the long-term care facility they live in, via  
36  
37 167 outpatient care services or informal caregivers, or via self-referral. Irrespective of how prospective  
38  
39 168 patient participants are identified, they are either recruited by their GP or (if not available) a study  
40  
41 169 physician.

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43  
44 170 The recruitment of GPs is carried out via in total 240 GCP-qualified practices of the Bavarian Research  
45  
46 171 Practice Network (BayFoNet) and cooperating teaching practices. Further eligible general practices with  
47  
48 172 a past or current focus on managing patients with Covid-19 are identified.

49  
50  
51 173 The participating GP's receive compensation for their work within the framework of the study  
52  
53 174 (participant inclusion and information, baseline examination, follow-up surveys). For the recruitment  
54  
55 175 from inpatient and outpatient care facilities, we use a list of about 700 eligible facilities in Bavaria with  
56  
57 176 documented Covid-19 outbreaks who file their interest in participating in BaCoM via a reporting system  
58  
59 177 to the Bavarian State Office for Health and Food Safety (Bayerisches Landesamt für Gesundheit und  
60

1  
2  
3 178 Lebensmittelsicherheit (LGL). (long-term care facility/home care provided by informal caregivers  
4  
5 179 and/or outpatient care services)  
6

7 180  
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9

### 10 181 **Data collection**

11 182 Baseline data collection began on 01 March 2021 and enrolment will continue until the end of 2023.

13 183 Data collection methods include blood samples, clinical investigations, data abstraction from clinical  
14  
15 184 data sources, surveys as well as semi-structured interviews (see tables 2 to 5). Appropriately trained  
16  
17 185 study staff conduct all data collection, so that interrater reliability for all assessments (including  
18  
19 186 questionnaires and clinical tests) can be ensured. It can be assumed that a certain proportion of the study  
20  
21 187 participants will not be able to provide self-disclosure (e.g. in case of cognitive impairment). In these  
22  
23 188 cases, the information collection is to be ensured by relatives or caregivers who are asked instead. In  
24  
25 189 order to ensure that the cognitive status is determined, the "Six Item Screener(20)" - a cognitive short  
26  
27 190 test - is administered (0-6 points). If the "Six Item Screener" is not successfully completed (< 4 points),  
28  
29 191 the information collection of the self-reports will be ensured according to the substitution principle  
30  
31 192 mentioned above.  
32  
33  
34

### 35 193 **Baseline and Follow-Up assessments**

36 194 The baseline data collection occurs within four weeks after recruitment. For all patient participants,  
37  
38 195 follow-up (FU) assessments are conducted at 6-month intervals after the date of the index test for a  
39  
40 196 period of up to 3 years in order to be able to observe the development of physical and mental health, as  
41  
42 197 well as provider and care needs over an extended time period. Depending on the date of enrolment, the  
43  
44 198 number of FU's will therefore range between one and five FU's (3 years). For formal and informal  
45  
46 199 caregivers and GPs, FU's intervals are similar. The parameters and constructs of interest as well as their  
47  
48 200 corresponding data collection methods are provided in tables 2-5 and their rationale is briefly described  
49  
50 201 below. The qualitative interviews with stakeholder are conducted only once per participant.  
51  
52

#### 53 202 *Clinical parameters of patient participants*

54 203 Table 2 shows that clinical parameters of interest include physical status, laboratory, medication,  
55  
56 204 comorbidities, BMI and vaccination status. Tests for frailty (Clinical Frailty scale (21, 22)) and for  
57  
58 205 cognitive impairment (MoCA-Blind(23)) are performed. In addition, the use of health care facilities,  
59  
60

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2  
3 206 COVID-19 specific complications and symptoms (Long-/Post-Covid) is used to characterise the course  
4  
5 207 of the disease. Many target variables are collected in accordance with the "German Corona Consensus  
6  
7 208 Data Set" of the National Research Network of University Medicine on Covid-19 (24). The attending  
8  
9 209 GP or the study nurse performs a brief physical examination with measurement of the vital parameters  
10  
11 210 and takes a venous blood sample. By this, an antibody test for SARS-CoV-2 and thus the influence of  
12  
13 211 Covid-19 disease on the immune response can be measured. For the remaining part of the blood samples,  
14  
15 212 an immediate laboratory analysis of a complete blood count, a differential blood count, and 26 organ  
16  
17 213 specific parameters relevant for Covid-19 disease are carried out. To cover future research questions,  
18  
19 214 serum and whole blood samples are transferred to quality-controlled long-term storage at -80°C in the  
20  
21 215 Institute of Laboratory Medicine.

#### 216 *Psycho-social parameters of patient participants*

217 Table 2 shows psychological parameters of interest that include the mental health status among others.  
218 The Covid-19 pandemic may cause severe psycho-social stress among people in need of care or support  
219 at different ages and life situations. To recognise these burdens and identify possible protective factors  
220 or risk factors, participant questionnaires with validated measurement instruments are used. This  
221 includes health-related quality of life (EuroQol (25-27) (Eq-5D-5L)), symptoms of depression (Patient  
222 Health Questionnaire (28, 29) (PHQ-9)), anxiety (Generalized Anxiety Disorder Screener (30) (GAD-  
223 7)) and post-traumatic stress disorders (Impact of Event Scale revised(31) (IES-R)). The aim is to  
224 identify possible resources (Six-item Self-Efficacy Scale (32) (SES6G)) and strategies that can  
225 contribute to convalescence on the one hand and address the specific care needs of people in need of  
226 care or support for sustainable prevention on the other.

#### 227 *Care needs of patient participants*

228 Special medical and care needs among this group of people in the different care settings are largely  
229 unknown so far. Table 2 shows the care parameters of interest, which include factors such as deprivation.  
230 In addition to the mobility and social participation, such an assessment should also include care services  
231 already used, health literacy (European health literacy survey(33) (HLS-EU-Q16)), individual coping  
232 strategies, physical function and frailty, NANDA care diagnoses (North American Nursing Diagnosis  
233 Association) (34) and a geriatric assessment (Barthel-Index(35)). From these findings, it is to be derived

234 which services may be necessary for sustainable prevention in long-term care in order to be able to  
 235 contribute to an improvement of resilience so that an individual, self-determined life and living oriented  
 236 towards the principle of normality is still possible.

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

#### 240 *Needs of formal and informal caregivers and GPs*

241 Tables 3-5 show that parameters of formal (table 3) and informal caregivers (table 4) from  
 242 outpatient/domestic and inpatient care as well as GP's (table 5) are collected with regards to coping with  
 243 the burdens of the pandemic to enable addressing any deficits. Contextual information on socio-  
 244 demography, structural information on the care facility or the GP practice, as well as data on the  
 245 psychosocial health (PHQ-9) and stress situation (Maslach-Burnout-Inventory(36)) are collected. In  
 246 addition, the formal and informal caregivers will be asked about their own SARS-CoV-2 infection and  
 247 about their vaccination decision.

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

	Timepoint	Baseline	FU <sub>1</sub> -FU <sub>x</sub>
		Enrolment	6 months
<b>CONSTRUCT</b>	<b>INSTRUMENT</b>		after PCR-test
<b>Sociodemographic information<sup>B,C</sup></b>	<b>Questionnaire</b>		
Age, sex, migration background, educational level, professional life/activity, income, marital status, health insurance, insurance number		x	
<b>Care-specific parameters with reference to the need for care<sup>B,C</sup></b>	<b>Questionnaire</b>		
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

1	Activities of daily living (ADL)	Barthel-Index(35)	x	x
2				
3	<b>Nursing diagnoses in terms of NANDA-I (Definitions and Classification 2018-2020) (34)<sup>B,C</sup></b>	<b>Questionnaire</b>		
4				
5	<b>Stability of respiratory parameters(37)</b>	Likert-Scale		
6				
7	Impaired gas exchange		x	x
8	Impaired spontaneous breathing		x	x
9	Ineffective airway clearance		x	x
10				
11	<b>Sense of smell and taste</b>	Likert-Scale		
12				
13	Smells all primary odours		x	x
14	Tasting all substance spectra		x	x
15	<b>Social interaction (34, 38)</b>	Likert-Scale		
16				
17	Mobility, ability to walk		x	x
18	Communication verbal/via electronics (impaired/reports needs)		x	x
19				
20	<b>Family processes (before and since the beginning of the pandemic)</b>	Likert-Scale		
21				
22	Continuous family processes (before and since the beginning of the pandemic)		x	x
23				
24	Interrupted family processes (before and since the beginning of the pandemic)		x	x
25				
26	<b>Social isolation (34, 38)</b>	Likert-Scale		
27				
28	Feeling of being alone (during the Covid-19 pandemic, as imposed by others)		x	x
29				
30	Feeling of being alone (before and since the beginning of the pandemic)		x	x
31				
32	Can explain current situation of the pandemic		x	x
33	Can place current challenges in the context of the pandemic		x	x
34				
35	Can get help to cope with current life situation		x	x
36	Can cope with tasks and challenges themselves		x	x
37	Feeling of powerlessness/helplessness		x	x
38				
39	<b>Physical health status<sup>C</sup></b>			
40				
41	Height, weight, Body-mass-index, smoking status	Questionnaire	x	x
42	Blood sampling: laboratory parameters, serostatus survey, long-term storage (24, 39)	Measurement	x	x
43				
44	Vital parameters ( <i>blood pressure, pulse, breath rate, O2-saturation, body temperature</i> )	Measurement	x	x
45				
46	Identification of patients at risk from sepsis	Quick sepsis-related organ failure assessment (qSofa)(40, 41)	x	x
47				
48	Mesurement of pulmonary function	Spirometry	x	x
49	<i>PEF, FEV<sub>1</sub>, FVC, FEV<sub>0.75</sub>, FEV<sub>0.5</sub>, FEV<sub>1</sub>/FVC, FEF<sub>75</sub> (MEF<sub>25</sub>), FEF<sub>25-75</sub> (MFEF), FEF<sub>50</sub> (MEF<sub>50</sub>), FV-curve</i>	(mySpiroSense®, mobile spirometer)		
50				
51	Cognitive short test	Six-Item-Screener(20)	x	x
52				
53	Cognitive Impairment	MoCA-BLIND(23)	x	x
54				
55	Mobility	Timed-up&Go-Test(42)	x	x
56				
57	Medication	Medication list	x	x
58				
59	Diagnosis	Diagnosis list	x	x
60				
	Vaccination status (Covid-19/ Influenza/ Pneumococcus)	Vaccination certificate	x	x
	<b>Characteristics of a Covid-19 disease course (Study + Control group 2) /</b>	<b>Questionnaire</b>		



<b>Characteristics of the course of the respiratory infection (Control group 1)<sup>A,B,C</sup></b>			
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)			
<b>Use of medical care facilities (since PCR-test)<sup>A,B,C</sup></b>	<b>Questionnaire</b>		
Inpatient medical care (days / diagnosis): Hospitalisation (with Intensive care unit) / Rehabilitation/ Psychiatry		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
<b>Psychosocial health status<sup>B</sup></b>	<b>Questionnaire</b>		
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
<b>Health care utilisation</b>	<b>Claims data***</b>		
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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**Table 3:** Schedule of enrolment and assessments in BaCoM: Formal caregivers and care facilities (inpatient/outpatient)

	Timepoint	Baseline	FU <sub>1</sub> -FU <sub>x</sub>
<b>CONSTRUCT</b>	<b>INSTRUMENT</b>	<i>Enrolment</i>	<i>6 months</i>
<b>Sociodemographic information</b>	<b>Questionnaire</b>		

Age, sex, ethnicity , migration background, educational level, professional life/activity, income, marital status		x	
<b>SARS-CoV-2 infection</b>	<i>Questionnaire</i>		
<b>SARS-CoV-2 infection in the past</b>		x	x
Date of pos. SARS-CoV-2 PCR tests		x	x
Covid-19-Infection symptomatic/asymptomatic		x	x
<b>Care facility parameters</b>	<i>Questionnaire</i>		
<b>Inpatient care facilities and other forms of housing</b> (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
<b>Outpatient care facilities</b> (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
<b>Sars-CoV-2 vaccination</b>	<i>Questionnaire</i>		
Psychological factors influencing the decision to vaccinate against Sars-CoV-2	5 C (45)	x	x
<b>Psychosocial health status</b>	<i>Questionnaire</i>		
Depressiveness	PHQ-9(29)	x	x
Burnout	Maslach Burnout Inventory (MBI) (36)	x	x

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

	Timepoint	Baseline	FU <sub>1</sub> -FU <sub>x</sub>
CONSTRUCT	INSTRUMENT	Enrolment	6 months
<b>Sociodemographic information</b>	<i>Questionnaire</i>		
Age, sex, ethnicity , migration background, educational level, professional life/activity, income, marital status		x	
<b>SARS-CoV-2 infection</b>	<i>Questionnaire</i>		
<b>SARS-CoV-2 infection in the past</b>		x	x
Date of pos. SARS-CoV-2 PCR tests		x	x
Covid-19-Infection symptomatic/asymptomatic		x	x
<b>Care burden situation</b>	<i>Questionnaire</i>		
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
<b>Sars-CoV-2 vaccination</b>	<i>Questionnaire</i>		
Psychological factors influencing the decision to vaccinate against Sars-CoV-2	5 C (45)	x	x
<b>Psychosocial health status</b>	<i>Questionnaire</i>		
Depressiveness	PHQ-9(29)	x	x
Burnout	Maslach Burnout Inventory (MBI)(36)	x	x

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

	Timepoint	Baseline	FU <sub>1</sub> -FU <sub>x</sub>
		Enrolment	6 months

CONSTRUCT	INSTRUMENT		
<b>Sociodemographic information</b>	<b>Questionnaire</b>		
Age, sex, professional experience		x	
<b>Practice-specific parameters</b>	<b>Questionnaire</b>		
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
<b>Sars-CoV-2 vaccination</b>	<b>Questionnaire</b>		
Psychological factors influencing the decision to vaccinate against Sars-CoV-2	5 C (45)	x	x

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260

### 261 **Qualitative sub-study: Stakeholder interfaces in long-term care**

262 The field of long-term care in the context of the COVID-19 pandemic is characterized by a multitude of  
 263 stakeholders: People in need of care, their professional and informal carers, home managers, relatives,  
 264 GPs and those responsible in politics and administration. The constellation of stakeholders is complex,  
 265 generates interactions and must be managed accordingly. Administrative requirements, for example, not  
 266 only have to be integrated into the everyday care of professionals, but also coordinated with the habits  
 267 and expectations of those in need of care and their relatives. Hence interface problems arise. A total of  
 268 approximately 60 expert interviews will be conducted in form of semi-standardized, guideline-supported  
 269 interviews, which are primarily aimed at the perspective view of the interfaces of the different  
 270 stakeholders. Patients, GPs, professional and informal carers will be recruited primarily from the study  
 271 participants of the quantitative study. Based on interviews already conducted, further relevant actors  
 272 will be identified and requested as interview partners. Here, the aim is to achieve the greatest possible  
 273 variance with regard to the characteristics of the level of care, the place of residence in urban or rural  
 274 regions and the presence or absence of family connections. The group of caregivers is also differentiated  
 275 according to the care setting, as well as according to the level of education and function. We will form  
 276 conceptual categories (deductive - based on the theory of functional differentiation) for the computer-  
 277 assisted coding and evaluation of the interviews with MAXQDA which will be adapted, refined and  
 278 supplemented in an iterative process during analyses (inductive). All interviews will be conducted by  
 279 appropriately trained staff with a background in sociology (KM), who will also conduct or supervise all  
 280 qualitative analyses.

1  
2  
3 281 The aim of the study is not only to name the challenges and needs of the various stakeholders, but also  
4  
5 282 their structural conditionality in a highly differentiated field. The qualitative results thus complement  
6  
7 283 the quantitative research approach on the one hand, but also offer an extended interpretive framework  
8  
9 284 for the quantitative results.

### 285 **Sample size calculation and stratification**

286 Based on 600 (SG) and 200 (each CG) persons recruited for the registry, we simulate minimal detectable  
287 (statistical) difference for major outcomes (age, comorbidities and mortality). Comparing the study  
288 group and the controls using a two-tailed t-test or log-rank test, with the assumptions for the significance  
289 level  $\alpha=0.05$  and the power  $\beta=0.8$  and given standard deviation (SD), the detectable differences for the  
290 following variables are obtained: Age: SD=10.0; detectable difference of -2.29 or 2.29; Comorbidities:  
291 SD=3.1; detectable difference of -7.10 or 7.10; Mortality: median survival time= 4.0; detectable  
292 difference of 2.66 or 6.56; EQ-5D-5L: SD=0.29; detectable difference of -0.07 or 0.07. With respect to  
293 the limited life expectancy of care recipients, we conservatively estimate that after four years about  
294 30% of the study participants, across all levels of care, will still be alive (46). The registry will therefore  
295 be expanded with additional participants at regular intervals and evaluated separately in subgroups. The  
296 aim is to achieve a relative distribution of the persons in need of care or support in outpatient care (50%)  
297 and inpatient care (50%). In order to account for the differences in medical infrastructures, population  
298 density and regional differences in infection incidence, we are aiming at an equal stratification according  
299 to the seven administrative districts in Bavaria.

### 300 **Statistical analysis**

301 All collected parameters of the study participants are analyzed descriptively. Analyses are performed  
302 for the entire population and stratified by level of care, outpatient/domestic and inpatient care, gender  
303 and age groups. For group comparisons between patients with positive SARS-CoV-2 PCR test and  
304 controls, the chi-square test or Fisher's exact test are used for categorical variables, the t-test (normally  
305 distributed variables) or Mann-Whitney-U test (non-normally distributed variables) for metric variables,  
306 and the log-rank test for survival times. All p-values are purely exploratory. Regression models are used  
307 to identify, among other things, risk factors that predict a severe course, occurrence of long-term  
308 consequences of a Covid-19 infection or a deterioration of the quality of life due to a Covid-19 infection.

1  
2  
3 309 The survival of the study and control groups is shown graphically using Kaplan-Meier curves. Missing  
4  
5 310 data for the study population is imputed according to multiple imputation where appropriate.  
6

### 7 311 **Non responder Analysis**

8  
9 312 As in most research in the outpatient care environment, the external validity of our findings is vulnerable  
10  
11 313 to participation bias. For example, it is conceivable that non-responding institutions are particularly  
12  
13 314 burdened by the pandemic. To understand better who does and does not participate, we will conduct an  
14  
15 315 analysis of a subsample of the non-responding care facilities or practices via telephone or postal surveys  
16  
17 316 scheduled 6 and 12 months after first contact, in order to elicit structural and contextual information  
18  
19 317 about the facilities.  
20  
21  
22

### 23 318 **Patient and public involvement**

24 319 Members of the BaCoM advisory board (listed twww.bacomstudie.de) represent a broad expertise in the  
25  
26 320 field: Science, patient advocacy, health assurances, health authorities, institutional facilities (CEO), etc..  
27  
28 321 The board commented and approved the protocol and comment on the results (public outcome  
29  
30 322 symposium). In addition we present the protocol and results to a primary care related citizen forum  
31  
32 323 (“Bürgerforum”) in Würzburg und Erlangen.  
33  
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## 36 324 **ETHICS AND DISSEMINATION**

### 37 325 **Informed Consent**

38 326 All participants provide written informed consent to participate. If a treating GP participates in BaCoM,  
39  
40 327 he/she informs his/her patient about the study. Otherwise, the enrolment and information is provided by  
41  
42 328 the doctor of the study team. If the person in need of care or support is not capable of giving consent  
43  
44 329 him or herself (e.g. dementia, cognitive impairment), consent can be given by the legal guardian. In case  
45  
46 330 a person who initially gives consent subsequently loses capacity at one or more of the data collection  
47  
48 331 time points, we only carry out further surveys if the consent to the study also signed by the legal  
49  
50 332 guardian.  
51  
52

53  
54 333 We made a conscious decision in the study design not to exclude people with severe cognitive  
55  
56 334 impairment, as these groups (such as people with dementia), may have suffered particularly from the  
57  
58 335 effects of the pandemic (e.g. through isolation rules, etc.). In order to mitigate undue distress to this  
59  
60 336 vulnerable group, the length of the survey is reduced because some questionnaires are not applicable

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2  
3 337 (e.g. health literacy) or the information is collected through an external survey of relatives or carers  
4  
5 338 where this has previously been shown to be possible (e.g. PHQ-9). Staff responsible for data collection  
6  
7 339 are instructed to interrupt or end interviews with participants if they notice signs of distress.

8  
9 340 The BaCoM Team pursues all measures to protect the interests of participants who are unable to consent.

#### 11 12 341 **Study registration and ethics**

13  
14 342 BaCoM is registered at the German Clinical Trials Register (DRKS) ID: DRKS00026039. The conduct  
15  
16 343 of the study is in accordance with the principles of the Declaration of Helsinki.

17  
18 344 The responsible Institutional Review Board of the coordinating study center of BaCoM (Ethics  
19  
20 345 Committee of the Medical Faculty of the University Hospital of LMU Munich; ethical vote number:  
21  
22 346 #20-860) and of all participating study sites (Ethical Committees at the Medical Faculties of the  
23  
24 347 University of Würzburg and Friedrich-Alexander-University of Erlangen-Nuremberg) approved  
25  
26 348 BaCoM study procedures.

#### 27 28 29 30 349 **Data access and protection**

31  
32 350 All data are collected with pseudonyms (ID) first on paper based case report forms and then transferred  
33  
34 351 in electronic case report forms (double data entry). Data entry takes place on the servers of University  
35  
36 352 Hospital of the LMU with 'LibreClinica<sup>®</sup>', an open source validated study management software. To  
37  
38 353 ensure a pseudonymised analysis of data, each participant data set is given a unique participant  
39  
40 354 identification number (ID) when being entered into the study data base. The anonymity of the data in  
41  
42 355 the context of evaluations is ensured. The allocation between study participant and participant ID takes  
43  
44 356 place in the study centre through the password-protected allocation lists of the study participants. This  
45  
46 357 information is stored separately and not in the database. By using a hierarchical access concept,  
47  
48 358 unauthorised access to the pseudonymised patient data in the database is impossible.

49  
50 359 Storage resources for the data are available in the personal cloud storage of the Leibnitz Rechenzentrum  
51  
52 360 (LRZ). For long-term archiving, the Archive and Backup Service (ABS) offered by the LRZ based on  
53  
54 361 the IBM Spectrum Protect (ISP) software is used. Copies of all data in the archive are made on separate  
55  
56 362 tapes to increase security. Data quality is checked for errors electronically and on-site by experienced  
57  
58 363 monitors. Data access to the final data set is provided to the BaCoM Study Group along with written  
59  
60 364 use and access rules.

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3 365 **Dissemination**

4 366 As an instrument for optimizing ambulatory Covid-19 care in Bavaria, the results of the interdisciplinary  
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6  
7 367 Monitor are presented in regular progress reports and discussed with other (external) experts at  
8  
9 368 symposia. On this basis, further questions or measurement instruments can be systematically included,  
10  
11 369 or less meaningful variables removed.

12  
13 370 Findings are presented at scientific conferences and through peer-reviewed publications.

14  
15  
16 371 **Data sharing**

17  
18 372 Individual participant data underlying the results of this article are available to researchers who submit a  
19  
20 373 methodologically sound proposal to the BaCoM steering committee (correspondence:  
21  
22 374 Jochen.Gensichen@med.uni-muenchen.de) for use of data in the approved proposal.

23  
24  
25 375 **Author Contributions**

26 376 Conceptualization: JG, TD, IG, AH, MH, CJ, TK, AN, DT, IZ; Data analysis: MR, DL; Funding  
27  
28 377 acquisition: JG, TD, IG, AH, MH, CJ, TK, AN, DT, IZ; Supervision: JG, TD, IG, AH, MH, CJ, TK,  
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30 378 AN, DT, IZ; Writing the original draft: JG, TD, IG, AH, MH, CJ, TK, AN, DT, IZ; Review and  
31  
32 379 editing: JG, TD, IG, AH, MH, CJ, TK, AN, DT, FA, CE, DH, HK, PK, DL, KM, SM, LR, MR, LS,  
33  
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7

8 394 **Competing interests statement**

9 395 The authors declare that they have no competing interests.  
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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
<b>Title and abstract</b>	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
<b>Introduction</b>			
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
<b>Methods</b>			
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) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —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 <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	5,6, 16
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —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) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	10

## (e) Describe any sensitivity analyses

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<b>Results</b>			
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) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	7
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	7,8
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	-
		<i>Cross-sectional study</i> —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	-
<b>Discussion</b>			
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
<b>Other information</b>			
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](http://www.strobe-statement.org).