How to manage quarantine—adherence, psychosocial consequences, coping strategies and lifestyle of patients with COVID-19 and their confirmed contacts: study protocol of the CoCo-Fakt surveillance study, Cologne, Germany

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INTRODUCTION
Since the first SARS-CoV-2 infections were described in Wuhan, China, in December 2019, the virus has rapidly spread worldwide, leading to considerable restrictions on the lives of most of the world’s population. Infected people as well as their confirmed contacts have been particularly affected as they must go into quarantine or domestic isolation. The aim of quarantining is to prevent further spread by people who may already be infectious but are not (yet) symptomatic. This quarantine can only be effective, however, if individuals adhere to it. Webster et al integrated 14 studies into a rapid review and showed that the range of adherence to such measures varied from 0% during the 2003 SARS outbreak in Taiwan to almost 93% during a 2009 swine influenza outbreak in Australia. Adherence disseminated through peer-reviewed journals and social medicine conferences.
In summary, people in quarantine or domestic isolation should receive close and qualified support. However, what such recommendations should contain in concrete terms, or what of them is actually implemented or can be implemented, has so far mostly been based on analogies. This is because, until now, most studies have focused more on the measures and effects of the lockdown, and less on infected individuals and their relevant contacts during the quarantine or isolation period. However, it is still unclear how and especially what people implement during this time and which individual solutions they develop for themselves and possibly also their children.

This surveillance study therefore aims to assess adherence during quarantine and investigate transmission route, postinfection situation, and the possible positive and negative sociodemographic, psychosocial and lifestyle factors that influence overcoming quarantine time in individuals, and their family members including children to generate measures and recommendations for action for the coming months and/or waves of infection.

Therefore, the following questions are addressed:

► What psychosocial, mental and organisational challenges do people face during quarantine as a result of infection and during domestic isolation due to contact with an index person?

► What knowledge is available regarding quarantine recommendations and how are they implemented by affected individuals and their confirmed contacts?

► Which positive or negative factors influence the individual’s handling of the quarantine rules or quarantine period (eg, family factors, such as single-parent households, number of children, single households, shared apartments)?

► What influence does the quarantine period have on the selected lifestyle factors (physical activity, sedentary behaviour, relaxation techniques, and/or nutrition, smoking and drinking behaviour)?

► Which individual and professional support systems are available and how are they used or evaluated? What should ideal guidance provided by the public health system look like to increase adherence or reduce the psychosocial burden of quarantine?

► What recommendations can be derived from this advice for dealing with the pandemic in the future? What additional measures should be developed?

**METHODS AND ANALYSIS**

**Study design**

Since February 2020, all patients with COVID-19 and their confirmed contacts in Cologne have been contacted by the healthcare office and registered in DiKoMa (Digitales Kontaktmanagement; digital contact management—a database developed by the Department of Information Processing by the city of Cologne). In this context, the individual health status has been recorded, the legal background of quarantining/domestic isolation has been explained, and all persons have been informed that they will also be contacted again for study purposes.
In June/July 2020, an online monitoring study was developed based on the COVID-19 Snapshot Monitoring questionnaire from the University of Erfurt\textsuperscript{17} (COSMO; Prof. Betsch) and the WHO\textsuperscript{18} modified according to the targeted questions. All persons will be included who have a positive SARS-CoV-2 test (quantitative real-time PCR) or are a relevant contact to an infected person, are 16 years of age and older and have provided a written declaration of consent. Exclusion criteria are the absence of a declaration of consent, non-compliance, deceased patients and/or patients in medical or nursing facilities.

This survey will be carried out with the online survey software ‘Unipark’ and sent to the registered persons in the DiKoMa system (figure 1). Answering it will take approximately 30 min, and qualitative data will be evaluated using the MAXQDA software.

**Sample**

Study participants meeting the inclusion criteria will be recruited based on the DiKoMa database in Cologne, Germany. They will receive detailed information outlining the purpose of the study, specific details about participation, and how the data will be stored. They will be informed about confidentiality, that participation is voluntary, and they are free to decline to participate at any point without any negative consequences.

**Survey**

Quantitative and qualitative parameters (‘mixed methods’) will be compiled based on the modified questionnaire of the COVID-19 Snapshot Monitoring study\textsuperscript{17} and WHO\textsuperscript{18} (online supplemental file 1-overview). The survey will be distributed in German, Turkish and English (translated by native speakers; online supplemental file

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**Figure 1** Flow chart of the recruitment and the participants’ inclusion (*date 9 December 2020).*
Demographic data: age, sex, education, size of apartment/situation (balcony, garden), number of children, family structure and household size, primarily spoken language, occupational status and possible previous illnesses. We will calculate the socioeconomic status (SES) by the education and vocational training based on the categorisation by the German Health Update 2009. Migration background will be based on language spoken at home.

Route of transmission in the personal environment (‘Yes, namely’; ‘No, I don’t know’) before the onset of symptoms, risk contacts resulting in quarantine, and more detailed questioning about risk contact (type of contact, contact time and distance; tested positive, personal protective equipment, outdoors/indoors, …).

Adherence to quarantine measures: hypothetically relevant influencing factors will be presented to the test subjects as statements (eg, ‘When I quarantine, I protect other members of my household’). These factors will be assessed on a six-point endpoint interval scale ranging from ‘I do not agree at all’ (1) to ‘I fully agree’ (6). The quarantine recommendations of the Robert Koch Institute will be presented to the volunteers (eg, ‘Do not allow visitors into your home’). It should then be stated in each case whether the recommendation was known (yes or no), and an assessment should be made on a six-point endpoint interval scale of how the recommendations were implemented and how difficult this was, ranging from ‘I did not implement it at all/It was very difficult for me’ (1) to ‘I fully implemented it/I did not find it difficult at all’ (6).

Assessment of the COVID-19 specific, postinfection situation: physical and mental performance, state of exhaustion, and so on, scored from ‘Not applicable at all’ (1) to ‘Fully applicable’ (6). Individual concerns such as financial loss, exclusion as a result of quarantine/isolation or infection will also be asked.

Psychological situation: the two-question test will be used to assess mood prior to the pandemic, in addition, distress will be assessed with the following items for the period during quarantine adapted from the COSMO study. In detail, item 1 from the generalised anxiety disorder (GAD-7), items 6, 8 and 14 from the Allgemeine Depressionsskala (ADS) and item 19 from the IES-R (impact of event scale) will be integrated into the questionnaire. Based on the COSMO study, a score will be formed from the five items revealing the total reported psychological distress.

Resilience will be measured using the modified Brief Resilience Scale (eg, ‘I do not need much time to recover from a stressful event’), which ranges from ‘I do not agree at all’ (1) to ‘I fully agree’ (6). In addition, coronavirus-specific items will be used (eg, ‘I know that I will not allow myself to be discouraged’), also scored from ‘I do not agree at all (1)’ to ‘I fully agree’ (6).

Coping and support: use of possible support systems; help from neighbours or from a circle of friends with four items scored from ‘Not applicable at all’ (1) to ‘Fully applicable’ (6) and free questions. These questions will also be adapted based on the COSMO study.

Lifestyle: sedentary behaviour, physical activity and relaxation will be recorded before and during the quarantine period as well as nutrition, including alcohol and nicotine consumption (modified according to Ref. 28). Based on the type of sport and intensity, an average baseline metabolic unit (MET) value for the activities will be derived based on the compendium by Ainsworth et al. An average MET value for each sport activity will then be determined from the frequency and duration data using the following formula

\[ \text{MET minutes per week} = \text{MET baseline value} \times \frac{\text{frequency per week}}{60} \times \text{duration per unit} \]

The MET minutes per week of all specified activities before the pandemic and those during the quarantine period will then be summed. Forms of relaxation will be divided into passive and active relaxation, and weekly minutes will be calculated from the frequency and duration data. Sedentary activities will be queried in minutes per week in both professional and private settings. In addition, hobbies and possible changes during the quarantine or isolation period will be recorded.

Smoking will be asked for duration and frequency and changes during quarantine. From this, pack years will be calculated by multiplying the number of cigarette packs smoked per day by the number of years smoked. Pack size will be calculated as 20 cigarettes/pack.

Subgroup analyses: children

Participants will additionally be asked about their children in the following age groups: under 3 years, 3 to under 6 years, 6 to under 10 years, 10 to under 14 years, 14 to under 16 years. Pre-existing conditions will be recorded as well as how they dealt with the lack of childcare in day care or school, current social contacts and leisure activities as compared with before the lockdown and/or isolation. In terms of children’s well-being, item 1 from the GAD-7, items 6 and 14 from the ADS and item 19 from the IES-R will be integrated into the questionnaire. Based on the COSMO study, a score will be formed from the four items revealing the total reported psychological distress.

Non-responder analysis

The non-responders will be matched as far as possible to the full sample in DiKoMa to assess, which groups of people were under-represented in the responses or to what extent the sample will be representative. We will perform an analysis of the reasons for non-participation
or early cancellation based on the feedback via email or in the open questions. Responses will be clustered by topic area. In addition, an analysis will be made of the questions which the participants predominantly refrained from answering.

**Patient and public involvement**

The research questions and methods were developed based on the literature. In order to optimise the survey and align it according to the research questions, affected persons from the personal environment were first approached and asked to answer and assess the draft. From this collective, 20 additional affected persons were then recruited by snowball sampling and the feasibility and duration were tested. Since the online survey is anonymised, no individual results are given to the patients. However, the results and the recommendations or support systems developed from them will be communicated via the press and the homepage of the city and the health department. Therefore, future quarantined persons will benefit from our study if our recommendations are considered in settings which influence their individual needs, worries and coping strategies.

**Data assessment and analysis**

The email addresses necessary for contacting participants will be extracted from DiKoMa. For pseudonymisation, they will be separated from the survey data, and the participants will receive an identification number. This means that third parties will not be able to draw any conclusions about individuals.

The datasets used and/or analysed during the current study will be available from the corresponding author on reasonable request.

The statistical evaluation of all variables will include descriptive statistics (percentage, mean values, SD). Associations between participant characteristics (age, gender, SES, household size, family structure, quarantine duration) and outcomes like the adherence to COVID-19 quarantine measures, postinfection situation, the results of the Brief Resilience Scale, psychosocial items/score, and lifestyle factors (METs, weight change during quarantine/isolation) will be examined in univariable analyses using $\chi^2$ tests, independent t-tests or analysis of variance.

To explore variation in outcomes, multivariable linear regression models will be used to estimate marginal means (with 95% CIs) for continuous variables. Multiple logistic regression will be used to predict categorical variables on multiple independent variables (including ORs and their 95% CIs). All multivariable models will be controlled for age, gender, number of chronic health conditions, language spoken at home (migration background), family structure, SES and month and duration of quarantine. The significance level will be set at $\alpha=0.05$; trends ($\alpha<0.1$) will also be considered, provided they occur in a comprehensible context. Analyses will be performed using the SPSS statistical software V.27.0.

**ETHICS AND DISSEMINATION**

**Ethical and safety considerations**

The study will be conducted according to the Declaration of Helsinki and the principles of Good Clinical Practice. Participation in the survey is on a voluntary basis after obtaining written consent. No risks have been identified and no complications are expected. Ethics approval was obtained from the Rheinisch-Westfälische Technische Hochschule Aachen Human Ethics Research Committee (351/20), and the research will be conducted in accordance with the approved protocol.

**Dissemination**

The results of this study will be disseminated through peer-reviewed journals and social medicine conferences.

**DISCUSSION**

So far, little is known about the personal situation in which quarantined people find themselves and what effects these measures have on those affected.\(^{31}\) In order to contain the pandemic and break chains of infection, it is important to know the measures and follow them. One of the most important, but certainly most challenging instructions is to maintain quarantine or domestic isolation. Brooks et al showed in their rapid review the necessity to explain the background of the measures to those affected and to communicate very clearly.\(^{32}\) They suggest that healthcare workers implementing quarantine should be aware of this unique situation. In the context of the COVID-19 pandemic, stressors like the loss of loved ones, financial loss, depressive symptoms, family conflicts and/or domestic violence are described.\(^{33}\)

Therefore, additional to transmission routes, data on psychological stress, possible coping strategies and individual solutions (also in terms of physical activity, relaxation, etc) will also be an important area of knowledge for optimising counselling, getting evidence for lifestyle recommendations for the quarantine/isolation period, supporting mental health and preventing long-term (psychological) damage. Although corresponding recommendations are available on how to stay active or eat healthy during quarantine/domestic isolation,\(^{6, 7, 34}\) there are limited data so far on what of these can actually be implemented. Di Renzo et al examined the lifestyle of 3533 Italian participants, aged between 12 and 86 years (76.1% females) during the first lockdown.\(^{35}\) The results were inconsistent. While the perception of weight gain was observed in 48.6%, 3.3% of smokers decided to quit smoking and a slight increase of physical activity has been reported. Amatori et al examined nutritional choices, physical exercise and mood in 250 college students during the COVID-19 outbreak.\(^{36}\) Exercise influenced nutritional choices, counteracted the impact of psychological distress on the dietary habits, and mediated the effects of mood states. To the best of our knowledge, there are no comparable data on individuals during imposed home isolation.
Hence, it is of utmost interest to identify as early as possible which individuals need closer monitoring and more intensive support during the quarantine/isolation period and how such support systems must be designed. On the other hand, healthcare workers are equally burdened. In their meta-analysis, Kisely et al showed that, compared with lower risk controls, staff in contact with affected patients had increased levels of both acute or post-traumatic stress and psychological distress with similar results for continuous outcomes.37

The planned study will therefore support both people in quarantine and healthcare professionals in their work. Despite our best efforts to include as many participants as possible by tailoring the survey to individuals of different nationalities (German, Turkish and English version), there are limits to this approach. People without an email address will not be contacted, and lower levels of education and/or language barriers might impact the outcomes of the questionnaire. Due to the specific recruitment area, the sample is regionally limited. Based on the DiKoMa database, we will therefore carry out a non-responder analysis to target the people that could not be reached in a possible follow-up examination. The questionnaire’s duration of 30 min in a pretest is still acceptable due to its complexity but may have a deterrent effect. In sum, however, despite these possible limitations, we assume that the size of the database will generate valuable insights into pandemic control and, above all, into the care of those in quarantine to allow for better preparation for future waves.

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