

COVID-19 infections in people with Primary Ciliary Dyskinesia

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Dear young person with PCD,

Thank you for considering to take part in this online study which monitors health of **children and adults who have Primary Ciliary Dyskinesia (PCD)** in the coronavirus outbreak period.

What is the study about?

The COVID-19 outbreak is an International Public Health Emergency. The severity of the disease varies between people. Some have a mild disease, comparable to a common cold, but others become severely ill and need artificial ventilation; some people even die. Most at risk are elderly people, but also those with chronic diseases of the lungs or heart. We do not know whether this applies to people who have PCD. Therefore, patient organisations asked for a study that finds out what happens to people with PCD during the outbreak. By obtaining regular updates via online questionnaires from people with PCD from all over the world, we want to find out how the course of COVID-19 disease is in people with PCD, and what the risk factors are. Ultimately the study should help to improve the health of people with PCD.

Who can participate?

Everybody with a confirmed diagnosis of PCD or a clinical suspicion of PCD can take part. Patient support groups from all over the world support the study. Parents of a child with PCD can take part in the study and fill in the study questionnaires with their child.

What data will be collected?

We need an email address to send you a link to access the questionnaires. We also ask for a mobile phone number to be able to contact you again, if your e-mail stops working. The phone number is not compulsory, though. These data are stored separately and will never be given out.

Parents of children aged 0 to 13 years will receive the link to the study questionnaires, but children are encouraged to help their parents completing the questionnaires.

Adolescents aged 14 to 17 years will be invited to fill in the questionnaires themselves. When adolescents register to the study, their parents receive an e-mail with a link to a short form that informs them about the study and asks for their consent. The following e-mails with links to questionnaires will then be sent to the adolescents directly. We encourage parents to help their adolescent children to complete the baseline questionnaire, but the short follow-up questionnaires can be completed by the adolescents on their own. Parents can always contact the study team with questions.

- **At the start we will send you the link to a baseline questionnaire** which asks about your disease, your “normal” symptoms, and your treatments. We will also ask you if you have already had a COVID-19 infection.
- **Then we will send you links to short symptom questionnaires** in regular intervals. Initially every few days, later in longer intervals. If you are healthy, the questions will be few. If you have an infection, the questionnaires will expand. If you have been in a hospital, we ask if you or a family member can get a report from the hospital and upload it in the database. However, this is not compulsory and will not always be possible.
- **Extra questionnaires** will deal with **special topics**. For instance: physical activity while you are locked up in your home; difficulties to obtain medication; experiences with the government’s information policy and how this could be improved. You can also suggest topics to be included in extra questionnaires and thus help to shape the study.

How long does the study last?

The study will go on as long as the COVID-19 disease outbreak lasts, up two years. But you can withdraw any time and tell us that you don’t want to receive more e-mails.

Are there any benefits for me taking part and are there any risks?

There are no direct benefits for you if you take part, but people with PCD may profit in the future. You will get easy access to our study website where we will regularly publish and update our results so that you will be informed first hand. You can also suggest topics to be investigated. There is no risk of taking part in this study.

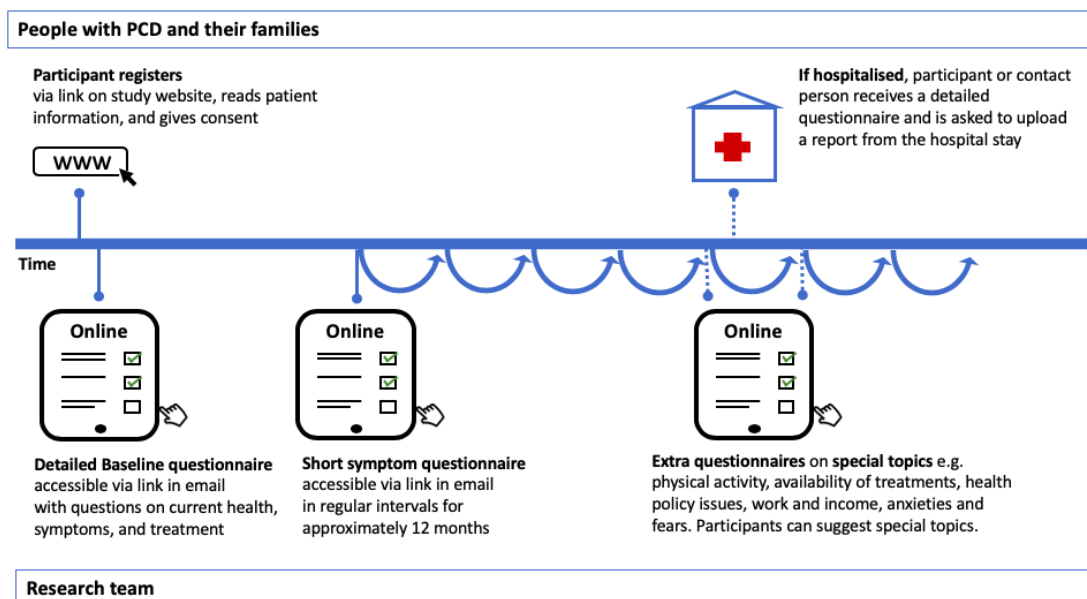
What happens with the data that I provide for this study, and when will I get information about the results?

We will analyse data from the online survey weekly, publish them online on our study website, and make them available to people with PCD, doctors and policy makers. The data will also be published in scientific journals and via the PCD support groups.

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Figure 1 illustrates the steps of the study



Will my data be kept confidential?

With the exception of e-mails (compulsory) and mobile phone number (voluntary) we will not collect any personal or identifying data. Only members of the research team will see your e-mail and phone number, and only to perform tasks related to the project. Your health-related data can be given to other research groups, also abroad, but always encrypted, so that it is not possible to identify you. Encryption means that all data that can identify you (e-mail, mobile phone number) is deleted and replaced with an encryption code. No data in any publication will be traceable to you as an individual. All research personnel who have access to your data as part of this project are subject to confidentiality. The requirements of data protection are complied with and you as a participant have the right to inspect your data at any time.

Do I have to take part in the study and what happens if I change my mind?

It is your free decision whether you want to take part in the study. You can also change your mind and withdraw at any time without giving a reason. To withdraw your consent and step out of the study, you can write an email to covid19pcd@ispm.unibe.ch. We will then stop the automatic e-mails and anonymise your data after analysis.

Who has reviewed this study?

The patient support groups who are supporting the study have contributed to the design of this study and have approved it, and the ethics committee of the canton of Bern, Switzerland has reviewed and approved this study (2020-00830).

Financing

We will submit applications to research organisations to help cover our expenses.

Where can I get more information?

More information and first results are available on the study website www.covid19pcd.ispm.ch. You can also contact the PCD support group in your country, and the research team at the Institute of Social and Preventive Medicine, University of Bern, Switzerland by phone +41 78 912 75 74 or by email to covid19pcd@ispm.unibe.ch. Dr. Eva Pedersen, Ms Eugénie Collaud, and Prof. Claudia Kuehni will answer your questions.