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## STUDY PROTOCOL

# Study Protocol: Prospective, observational, cohort study of COVID-19 in General Practice (North Dublin COVID-19 Cohort ['ANTICIPATE'] Study) [version 1; peer review: 2 approved with reservations]

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## Abstract

**Background:** It is accepted that COVID-19 will have considerable long-term consequences, especially on people's mental and physical health and wellbeing. Although the impacts on local communities have been immense, there remains little data on long term outcomes among patients with COVID-19 who were managed in general practice and primary care. This study seeks to address this knowledge gap by examining how the COVID-19 pandemic has impacted the medium and long-term health and wellbeing of patients attending general practice, especially their mental health and wellbeing.

**Methods:** The study will be conducted at 12 general practices in the catchment area of the Mater Misericordiae University Hospital, i.e. the North Dublin area, an area which has experienced an especially high COVID-19 incidence. Practices will be recruited from the professional networks of the research team. A member of the general practice team will be asked to identify patients of the practice who attended the practice after 16/3/20 with a confirmed or presumptive diagnosis of COVID-19 infection. Potential participants will be provided with

## Open Peer Review

Reviewer Status ? ?

	Invited Reviewers	
	1	2
version 1	?	?
17 Sep 2020	report	report

1. **Thomas Czipionka**<sup>id</sup>, Institute for Advanced Studies, Vienna, Austria  
London School of Economics, London, UK
2. **Catherine Dunlop**, University of Birmingham, Birmingham, UK

Any reports and responses or comments on the article can be found at the end of the article.

information on the study by the clinical team. Data will be collected on those patients who consent to participate by means of an interviewer-administered questionnaire and review of clinical records. Data will be collected on health (especially mental health) and wellbeing, quality of life, health behaviours, health service utilisation, and wider impacts of COVID-19 at recruitment and at two follow up time points (6, 12 months).

**Deliverables:** The project involves collaboration with Ireland's Health Service Executive, Ireland East Hospital Group, and the Mater Misericordiae University Hospital, Dublin. The study is funded by the Health Research Board. Findings will inform health policies that attenuate the adverse impacts of COVID-19 on population mental health and health generally.

### Keywords

COVID-19, Coronavirus, cohort study, follow up study, general practice, primary care



This article is included in the [Coronavirus \(COVID-19\)](#) collection.

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**Competing interests:** No competing interests were disclosed.

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## Introduction

COVID-19 was declared a global pandemic on 11<sup>th</sup> March 2020<sup>1</sup>. As of the 14<sup>th</sup> August 2020, there were over 20 million reported cases of COVID-19 worldwide, and more than 750,000 people are believed to have died with confirmed infection<sup>2</sup>. In Ireland, the total number of confirmed cases is currently 26,929 with 1,774 related deaths. The current median age of people in Ireland infected with COVID-19 is 47, 56.5% of those infected are female, and as is the case globally, infected persons most at risk of suffering severe illness and/or death have been elderly persons and individuals with underlying health conditions<sup>3</sup>. While the pandemic has impacted considerably on healthcare throughout Ireland, this has been especially so in the North Dublin area<sup>4</sup>.

The effects of COVID-19 and the COVID-19 pandemic more generally are many and diverse. Patients with COVID-19 infection present with a range of symptoms including fever, cough, shortness of breath, and fatigue. Severe cases of COVID-19 infection have caused considerable damage to various internal bodily structures and functions, resulting in the onset of multiple issues including acute respiratory stress disorder (ARDS), acute heart, liver, and kidney injury, and septic shock<sup>5-7</sup>. Moreover, it is likely that many discharged COVID-19 patients will have experienced health problems due to intensive care treatment. Prolonged stays in intensive care have been linked to a range of physical and psychological problems including decreased muscle strength, impaired mobility, and cognitive impairment<sup>7</sup>. It is also likely that because of COVID-19 related fears, grievances, and traumas, patients, their families, and the general population will need care for various mental health problems including anxiety, depression, and post-traumatic stress<sup>8-11</sup>.

The medium and long-term effects of the COVID-19 pandemic on health are still unclear. To address the needs of patients experiencing long-term health complications, appropriate long-term care plans are necessary. This study aims to examine the medium and long-term health effects of the COVID-19 pandemic in North Dublin. Using a sample of patients attending general practices in the area, the study will observe the pandemic's effects on general health, mental health, quality of life, substance use behaviour, health service utilisation, and patients' communities. The study can inform health policies that seek to attenuate the adverse impacts of the COVID pandemic on population health in Ireland and internationally.

## Protocol

This study will be conducted in line with recommendations outlined by the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist for cohort studies. The STROBE checklist is a widely used and trusted framework for ensuring high scientific standards in the conducting of studies of this nature<sup>12</sup>.

## Setting

The study will be conducted at 12 general practices in North Dublin and will involve the eight-week time period from 16/3/20, the Monday of the first week when national guidelines

recommended that patients with possible symptoms of COVID-19 infection contact their GP and when GPs could refer patients for testing if specific criteria were met. Practices will be recruited from the professional networks of the research team and recruitment will purposefully seek to ensure the sample is representative of practices in the area in terms of practice size.

## Participants

Upon agreeing to participate in the study, practices will be asked to review their practice records for the eight-week time period from 8/3/20 to identify patients with a presumptive diagnosis (i.e. experiencing symptoms consistent with COVID-19 infection) or confirmed cases of COVID-19. In the first instance, they will be asked to provide brief practice reports outlining information on the total number / demographic characteristics of those who attended during this time. Practices will be asked to assign a diagnostic code indicating those patients who were either 'a presumptive diagnosis' or a 'confirmed case' of COVID-19, using relevant diagnostic codes from the International Classification of Disease<sup>13</sup>. All adult (aged 18 years or more) patients who contacted practices during the eight-week time period starting 16/03/2020 who were diagnosed as either a confirmed or presumptive diagnosis of COVID-19 and who have the capacity to provide informed consent will be eligible for the study.

## Sample size and power calculations

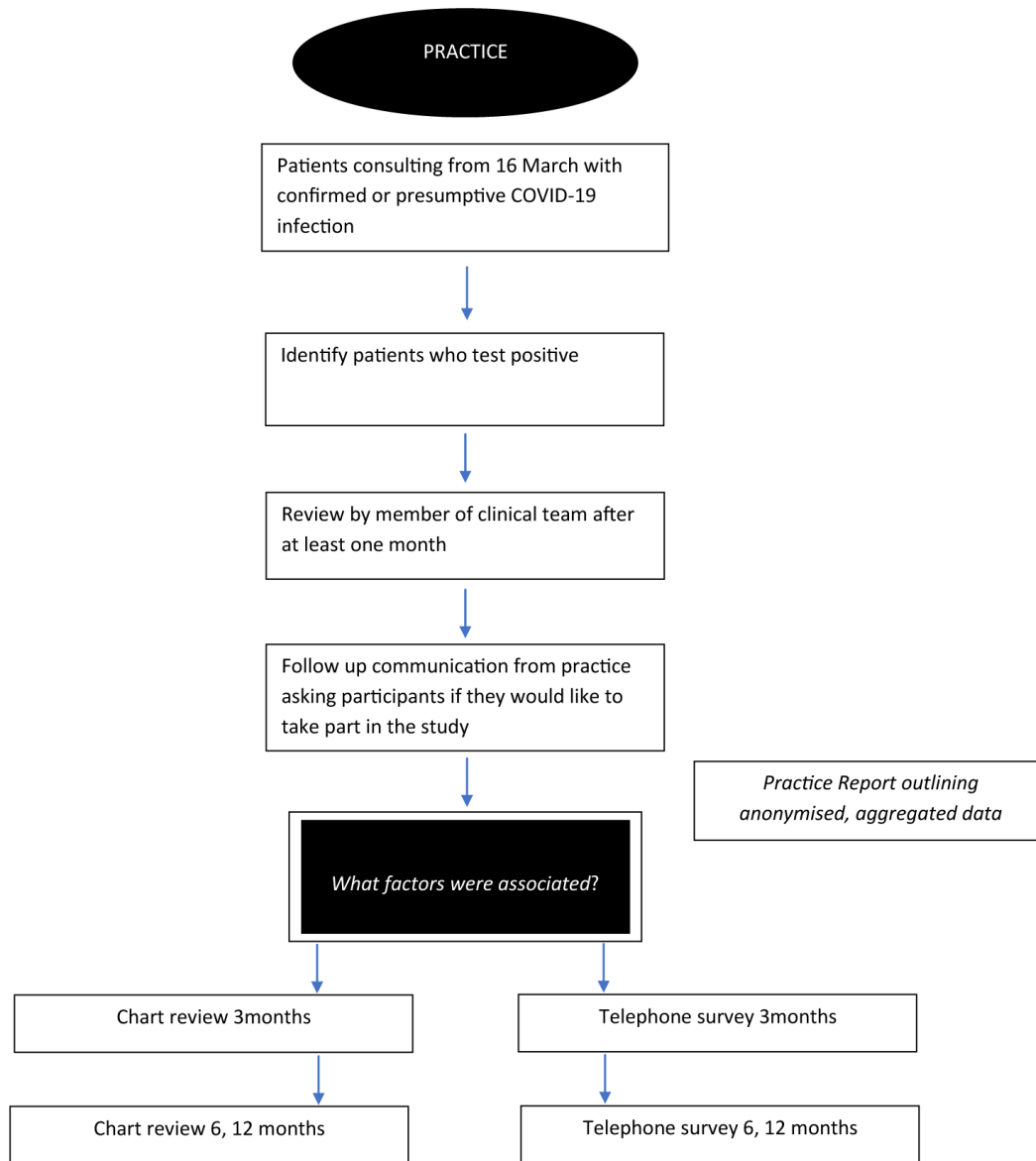
It is estimated that the prevalence of mental health disorders among patients attending general practice in Europe pre-COVID-19 is 29%<sup>14-16</sup>. Based on this estimate of mental health disorders among patients attending general practice, we estimate that a sample size of 360 will detect a 29% prevalence of mental health disorders, with a margin of error of +/-5% at a 95% confidence level. Allowing for attrition during recruitment<sup>17</sup>, to reach a target of 360 patients, we will over-sample. Thus, we expect to achieve a sample of 40 patients per practice (total N=480).

## Procedures

Participating general practices will provide researchers with brief practice reports. These reports will contain anonymous aggregated data pertaining to a sample of patients attending the practice since 16/03/2020 with either a presumptive or confirmed case of COVID-19 infection. After at least one month of their initial attendance at the practice, a member of the practice team will contact those patients who meet the eligibility criteria by text message, to ask if they would like to participate in the study's follow-up procedures. Consenting patients will be contacted by a member of the research team, who will then outline study information and what their participation will involve. At recruitment and at two subsequent time points (6, 12 months) data will be collected using an interviewer administered questionnaire<sup>18</sup>, and by reviewing each patient's clinical record (see [Figure 1](#)).

## Measures

**Anonymous aggregated data:** The anonymous aggregated (i.e. 'brief practice report') data will provide details of patients' demographic profile(s). The data will help us determine what



**Figure 1. Study flow chart.**

factors are associated with COVID-19 related health issues. The reports will contain various types of information including practice location, the number of patients contacting the practice with COVID-19 infection and/or concerns, patient age, gender, General Medical Services (GMS) status, and physical/mental health history. To establish long-term trends, the reports will be collected at recruitment, and at two follow-up time points. Further, to ensure instrument validity, the reports will be prepared using existing tools within practice management systems, one of which has previously reported on the prevalence of mental health disorders among patients attending general practice<sup>19,20</sup>.

Interviewer-administered questionnaires: Patient questionnaire responses, including a chart review instrument<sup>18</sup>, will help us understand whether patients have been experiencing health problems because of the COVID-19 pandemic. Specifically, they will query patients on their age, gender, medical history, general health, mental health, COVID-19 experiences, recent health service experiences, quality of life, substance use behaviour, and their perception of how the COVID-19 pandemic has impacted their community. The questionnaire comprises multiple measures, some of which have been validated and have been frequently used in clinical practice and research settings (i.e. the SF12 Quality of Life Scale<sup>21</sup>; the PRIME-MD instrument

for assessing mental health<sup>22</sup>; the 'Impact of Event Scale-Revised' (IES-R) post-traumatic distress measure<sup>23</sup>; and the AUDIT-C scale for measuring alcohol use<sup>24</sup>. Our questionnaire also contains two measures that are study specific. These instruments relate to patients' experiences of the COVID-19 pandemic, their healthcare experiences during the pandemic, and the pandemic's impact on their community. As these measures are specific to particular contexts and have been developed in response to an unprecedented public health emergency (i.e. the pandemic), they have not been previously validated. Should a health issue be identified during the interview, appropriate follow up with the person's general practitioner will be arranged.

**Review of clinical records:** Using a study specific instrument<sup>18</sup>, data will be collected on demographic characteristics, the presence of any long-term medical conditions, any recent medical conditions, medicines prescribed.

### Data analysis

This study aims to provide an overview of how the COVID-19 pandemic has impacted the physical health, mental health, and wellbeing of patients attending general practices in the North Dublin area. The COVID-19 pandemic has been an unprecedented public health emergency, and so it is not clear how the pandemic will have affected this population. Exploratory statistical analyses will therefore be used to ascertain macro-level practice and patient trends, and to identify unanticipated or noteworthy differences and/or relationships between study variables (e.g. differences between follow-up points and genders in terms of study outcomes, association between health outcomes and COVID-19 diagnostic status). These analyses will likely include a combination of descriptive and inferential statistical methods including frequency, correlation, regression, and between group analysis methods. Statistical tests will be run using IBM SPSS statistical software version 26.

### Ethical considerations

With regards to *informed consent*, potential participants will be approached by a member of the clinical team and will be provided with information on the study. Potential participants will be contacted initially via text message and if interested, they will be provided with a study information sheet and consent form by post. Those who wish to participate in the study will be asked to indicate their informed consent to participate by signing and returning this consent form<sup>18</sup> via prepaid post to the research team. Thus, the researchers will only have access to participants' contact details when participants themselves agree to provide them via their GPs. We will ensure that this agreement is recorded in written form. Lastly, no individual will be identifiable during dissemination. Only grouped results will be published, and we will ensure that details which may render a study participant identifiable are amended in any publications / presentations that arise. All participants (practices and patients) can withdraw their participation at any time up until the point where their data has been anonymised. At this point it will not be possible to identify and delete their information.

With respect to *confidentiality*, anonymised, aggregated practice reports will be collected from participating practices. Furthermore, when collecting data on study participants, an alphanumeric code will be assigned to individual participants (i.e., pseudonymised data). Data will be stored on a password protected computer in the researchers' offices in the Catherine McAuley Research & Education Centre, Nelson St. Dublin 7.

With respect to *data protection*, no third party (i.e. persons external to named investigators) will have access to study participants' information. All electronic data will be stored as pseudonymised data on a secure, password protected server computer hard drive at the UCD School of Medicine Education & Research Centre (i.e. the Catherine McAuley Centre). Further, all hard copy data will be stored in a secure cabinet in a locked room at the same location. All data will be destroyed by the principal investigator after a retention period of three years after study completion. This is to allow dissemination of findings and secondary data analysis by the members of the research team named on this application.

With regards to *vulnerable groups*, the study aims to examine the impact of COVID-19 on a sample of patients attending general practice in North Dublin. Thus, the study involves interacting with and collecting information on vulnerable participants. However, we expect that participants will be exposed to minimal risk because the study involves gathering information using secondary data collection methods and a telephone-administered questionnaire. Also, with regards to contacting patients for the study's follow-up procedures, we will only contact patients that: a) are clinically well enough to be contacted, and b) have consented to participate in the study or to be contacted by the research team. All the researchers have educational and/or professional experience in the field of mental health service delivery, have basic skills when it comes to managing mental health issues that may arise during telephone interviews. The questionnaire will also be accompanied by a statement telling patients that if they have further concerns, they should contact their doctor. Should a health issue be identified during the interview, appropriate follow up with the person's general practitioner will be arranged.

The study has been approved by the UCD Life Sciences Human Research Ethics Committee (reference: LS-20-27-Broughan-Cullen; original approval granted 27/04/20; amendment and extension granted 17/07/20 until 30/06/21).

### Dissemination

The project will involve collaboration with the Irish Health Service (HSE) Clinical Programmes, Ireland East Hospital Group, and the Mater Misericordiae University Hospital Dublin. The study is funded by the Health Research Board (HRB). The study will inform health service policies to attenuate the adverse impacts of the COVID-19 pandemic on population health. Outputs such as technical reports for stakeholders will be delivered accordingly. Study reports will also be submitted for publication in scientific journals, and study datasets, as well



as related material (e.g. study instruments, recruitment forms) will be made publicly available on the [Zenodo](#) open-access repository website.

## Study status

We are currently recruiting general practices to participate in the study. Once recruited, practices will initiate the collection of service level data, and recruitment of patients on our behalf. The first stage of data collection is expected to occur in October 2020.

## Data availability

### Underlying data

No underlying data are associated with this article.

### Extended data

Zenodo: Study Protocol: Prospective, observational, cohort study of COVID-19 in General Practice (North Dublin COVID-19 Cohort ['ANTICIPATE'] Study). <https://doi.org/10.5281/zenodo.4015176><sup>18</sup>

This project contains the following extended data within the file 'ANTICIPATE. GP ARM. Study Instruments, Information Leaflets, and Consent Forms.docx':

- Study instrument to be used collecting data from clinical records (chart) review
- Study instrument to be used collecting anonymised aggregated data from practices
- Study instrument to be used in patient interviews on recent healthcare experiences
- Patient information leaflet
- General Practitioner information leaflet
- Patient consent form
- General Practitioner patient consent form

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](#) (CC-BY 4.0).

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# Open Peer Review

Current Peer Review Status: ? ?

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## Version 1

Reviewer Report 02 February 2021

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### Catherine Dunlop

Institute of Metabolism and Systems Research, University of Birmingham, Birmingham, UK

I think this is a well written protocol and will be a useful and timely study.

I have two broader critiques and one minor query/possible typo in the text.

1. This protocol and the study could be strengthened, in my opinion, by recruiting practices that are representative of the population in North Dublin. The authors talk about taking a range of practices to ensure representation of different practice sizes. However, to ensure the study results are generalisable to the rest of North Dublin, it is important that the included practices are in purposely sampled regions to allow different population groups to be represented, and/or that the population percentage served by these practices is explicitly stated in the text. I.e. if the practices serve 10% of the population of North Dublin then the findings will have directly applicable numbers for policy making and planning. The generalisability would also be improved by selecting practices that serve a range of demographics. If practices have already been selected could their demographics, or population percentage of the city be included in the text?
2. Throughout the text the authors refer to investigating the impact of the COVID-19 pandemic on health and wellbeing in the Dublin area. However, the methods seem to be focussed on the impact of the Covid pandemic, in those who have had covid, on their health and wellbeing. I think this could be emphasised more in the text. If the authors are only interested on the impacts of the pandemic on health and wellbeing, then it isn't necessary to only select patients who have had covid to investigate this. (Both of these would be useful to investigate, I just think the wording could be slightly clearer when this is discussed).

Minor critique:

In your introduction you mention ARDS - it was my understanding that this stands for Acute Respiratory Distress Syndrome, not acute respiratory stress disorder as written.

**Is the rationale for, and objectives of, the study clearly described?**



Yes

**Is the study design appropriate for the research question?**

Yes

**Are sufficient details of the methods provided to allow replication by others?**

Yes

**Are the datasets clearly presented in a useable and accessible format?**

Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** I am a medical doctor in Obstetrics and Gynaecology, currently writing up my PhD entitled improving the prevention of maternal sepsis in global settings. My main area of work is in infection prevention in low resource maternity settings. I have worked on cohort studies previously, including the WHO GLOSS study.

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.**

Reviewer Report 27 October 2020

<https://doi.org/10.21956/hrbopenres.14247.r27974>

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**Thomas Czypionka** 

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The intended study presented has the potential of yielding important insights in the health effects of the pandemic. However, the researchers should make clearer what their research questions or hypotheses are. I find this a bit confusing throughout the text. From the "Participants" section I gather that people with presumptive or actual COVID-19 diagnosis are included, but from the power calculations, it is also about mental health. So do the researchers want to identify patients with COVID-19 AND mental health issues? Then the section on sample size is incomplete, as it only mentions the prevalence of mental health issues, but not of COVID-19 diagnoses in the area! In this vein, the researchers should also make clearer their inclusion criteria at one point in the protocol.

Researchers should also expand on how they want to identify that the pandemic caused possible changes. It should also be made clearer of the hypothesis is that the disease leads to these

changes, the pandemic as such, or measures taken to fight the pandemic.

Researchers should also review their recruitment methods. I am not sure that a text message from a maybe unknown caller is the right form to recruit.

**Is the rationale for, and objectives of, the study clearly described?**

Partly

**Is the study design appropriate for the research question?**

Yes

**Are sufficient details of the methods provided to allow replication by others?**

Yes

**Are the datasets clearly presented in a useable and accessible format?**

Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** health services research, health economics

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.**

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