Plan Overview

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Title: COVID-19 ESTIMATING THE BURDEN OF SYMPTOMATIC DISEASE IN THE COMMUNITY AND THE IMPACT OF PUBLIC HEALTH MEASURES ON PHYSICAL, MENTAL AND SOCIAL WELLBEING

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Project abstract:

Following the emergence of Covid-19 and its pandemic spread, Ireland in common with countries worldwide has implemented unprecedented public health measures to contain the virus and mitigate its impact. There is now a critical need for evidence on the impact and sustainability of these measures to inform the national and global response to the pandemic in the period ahead and specifically to address questions of relevance to the Health Protection Surveillance Centre and the National Public Health Emergency Team. The specific objectives of this project are to: i) estimate population prevalence and trends of self-reported sensitive symptoms of Covid-19 and (via record linkage) the proportions of symptomatic individuals subsequently testing positive for Covid-19 in a series of four short telephone surveys of 950 participants each during the period May-June, 2020; ii) describe acceptance and compliance with physical distancing and related measures in the population and explore the effects of these public health measures on the physical, psychological and social well-being of the Irish population in three longer telephone surveys involving 1000 participants to be conducted between May and September 2020: iii) develop a mathematical network model that incorporates the outputs from the cross-sectional surveys in addition to relevant publicly available data to inform decisions on the optimal levels and duration of physical distancing measures and thereby support the ongoing work of the Irish Covid-19 Epidemiological Modelling Group. The work will be carried out in collaboration with Ipsos, a global market research firm and in collaboration with the National Health Protection Surveillance Centre. The lead applicant, co-applicants and collaborators draw on a wide range of expertise in survey design and implementation, academic and service-oriented public health, epidemiology, statistics, mathematical modelling, psychology and sociology. The research team will be able to commence work on the project in May 2020.

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COVID-19 ESTIMATING THE BURDEN OF SYMPTOMATIC DISEASE IN THE COMMUNITY AND THE IMPACT OF PUBLIC HEALTH MEASURES ON PHYSICAL, MENTAL AND SOCIAL WELLBEING

Data description and collection or re-use of existing data

How will new data be collected or produced and/or how will existing data be re-used?

We conducted four omnibus telephone surveys (study 1) and three short telephone surveys (study 2) to examine the compliance and acceptance of COVID-19 public health measures and the impact of the pandemic and related public health measures on the population mental health. The surveys were conducted between May and September 2020. Each survey consisted of approximately 1000 participants, aged 18 years or older, selected randomly from the general population using random digit-dialling. The marketing company Ipsos MRBI conducted all the telephone interviews in collaboration with the research team at University College Cork (UCC). All data were fully anonymised without any identifiers.

What data (for example the kind, formats, and volumes), will be collected or produced?

Study 1 included data on sociodemographic variables, household composition, smoking and alcohol consumption, details of work and recent journeys outside the home by members of the household. Whether the respondent or other members of the household were unwell or had been unwell during the preceding two weeks with one or more sensitive symptoms for Covid-19 infection was also queried. Furthermore, individuals answering "yes" to the questions on Covid-19 symptoms among members of the household were offered a follow-up call within 24–48 hours from a Public Health Medicine (PHM) physician. The total size of the dataset is around 12MB.

Study 2 included a series of internationally validated measures of physical, mental and social wellbeing and knowledge about Covid-19 and attitudes to and compliance with control measures. Symptoms of depression and anxiety over the past two weeks was verified with the 16-item Patient Health Questionnaire Anxiety-Depression Scale (PHQ-ADS). The 12-item Social Wellbeing Index was used to assess participants' social wellbeing. Questions relating to participants' health (alcohol and tobacco consumption, health-seeking patterns) were also included, in addition to wider sociodemographic questions (age, gender, region, social class, employment status, highest level of education). Lastly, the survey included open-ended questions in relation to any adversity experienced within the last three and 12 months. From Wave 2 of the survey, the eight-item Woman Abuse Screening Tool, was used to identify and assess intimate partner violence. The total size of the dataset is around 4MB.

Data are maintained in csv format.

Documentation and data quality

What metadata and documentation (for example the methodology of data collection and

way of organising data) will accompany data?

The data were collected by Ipsos, the marketing research company using standard and validated questionnaires that were selected by the UCC research team. The original data will be kept in separate files including a read-only version. Each dataset that was used for a specific study/paper will be saved using clear identifying names.

The data from each wave are saved in a separate file and these can be combined for each study, if needed. Each file has a separate name that reflects the study and wave. The datasets are accompanied by the relevant data dictionaries and the questionnaires used to collect the data.

The study protocol has already been published [https://doi.org/10.12688/hrbopenres.13103.2] and will be included in the metadata of all resultant datasets.

What data quality control measures will be used?

Ipsos MRBI's ISO 9001 certified fieldwork management procedures were used to ensure timely and effective completion of interviewing. These procedures include ongoing contact with interviewers and supervisors to monitor progress across individual sampling points and regions; processes to ensure that (i)completed interviews were uploaded by interviewers on a daily basis to ensure that interim data files could be produced to check the quality and integrity of the data and (ii) that interviewers had the support of supervisors and head office

field management staff throughout the project, ensuring a swift resolution to any problems that emerged.

In addition to these standard measures, virtual one-hour training workshops and debriefing sessions were provided to the Ipsos interviewers by psychologists from the National Suicide Research Foundation (NSRF) and School of Applied Psychology, UCC to ensure standardisation and best practice when conducting a telephone survey addressing sensitive topics and to ensure that respondents were guided to relevant health and support services when required. These training workshops were conducted up to one week before the start of data collection for each survey.

Study participants were assigned a participant ID number. No identifying information on study participants was obtained in the telephone surveys.

Storage and backup during the research process

How will data and metadata be stored and backed up during the research process?

All of the study data and metadata are securely stored and backed up in a UCC supported online safe storage facility- UCC NAS (Network Attached Storage) Service and on UCC One Drive. The data and metadata will be retained securely for at least 10 years.

How will data security and protection of sensitive data be taken care of during the research?

No identifying information on study participants was obtained in the telephone surveys. Thus, all the available data from this project are fully anonymous without any identifiers. The data are securely stored on UCC cloud storage facilities as detailed above (UCC NAS and UCC One Drive) UCC cloud storage is protected by Multi-Factor Authentication (MFA). Only Research team members who are involved in the data analysis have access to the relevant data. Professor Ivan Perry (PI) and Dr Ali Khashan (Co-applicant) will control the data during active research.

All data are stored and used in accordance with the Irish Data Protection Amendment Act of 2003 and General Data Protection Regulation (GDPR, 2018).

Legal and ethical requirements, codes of conduct

If personal data are processed, how will compliance with legislation on personal data and on security be ensured?

No personal data was collected during this project. Data were collected using informed consent as the legal basis and anonymized at the collection point. All protocols for data collection follow the Irish Data Protection Act and the GDPR). Only anonymised data were collected. Existing protocols which are compliant with GDPR requirements were followed by both UCC and Ipsos MRBI researchers to ensure participant confidentiality is maintained.

How will other legal issues, such as intellectual property rights and ownership, be managed? What legislation is applicable?

The data are owned, held and controlled by the School of Public Health in UCC. The data will be openly accessible on completion of the primary analyses as set out in the study protocol. Every effort is being made to disseminate the findings of the work to policymakers and other scientists as efficiently and expeditiously as possible. No legal issues arise from this research project in relation to intellectual property rights or other matters.

What ethical issues and codes of conduct are there, and how will they be taken into account?

Ethical approval for the study was sought from the Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC) in University College Cork. CREC Review Reference Number: ECM 4 (b) 05/05/2020 & ECM 3 (eee) 05/05/2020. All data has been collected, managed and processed in line with the recommendations of CREC. All research has been conducted in line with the UCC Code of Research Conduct.

Data sharing and long-term preservation

How and when will data be shared? Are there possible restrictions to data sharing or embargo reasons?

As detailed above, the data will be openly accessible on completion of the primary analyses as set out in the study protocol. The dataset will be tagged with a unique digital object identifier (DOI) and shared using **Zenodo**, a general-purpose open-access repository developed under the European OpenAIRE program and operated by CERN. It is anticipated that all of the data will be discoverable and available for sharing by the end of 2021.

All data will be retained securely for ten years after collection.

How will data for preservation be selected, and where data will be preserved long-term (for example a data repository or archive)?

Data and metadata will be deposited in a trusted data repository for long-term preservation and curation. All data which underlies a publication will be shared. Any other data which is of value for future reuse will also be considered for long term preservation. The data could be used in future studies on public mental health. While conducting this project, we realised that there is no population level data on public mental health in Ireland. These data could be used as a reference for future studies. As detailed above, data will be deposited in the Zenodo for long-term preservation. Repository selection is based on the criteria and standards for trustworthy repositories described by Science Europe.

What methods or software tools are needed to access and use data?

No specialized software will be required to access the data. All data and metadata will be shared in open and accessible file formats such as csv or txt.

How will the application of a unique and persistent identifier (such as a Digital Object Identifier (DOI)) to each data set be ensured?

The infrastructure of the Zenodo repository will be leveraged to assign a unique and persistent Digital Object Identifier (DOI) to the dataset. This will be included in the data availability statement of all publications, linking all research outputs from this project. DOI from previously published outputs such as protocols will be included in the metadata of the shared datasets.

The study protocol which has been published in HRB open [https://doi.org/10.12688/hrbopenres.13103.2] will be updated to include the dataset DOI.

Data management responsibilities and resources

Who (for example role, position, and institution) will be responsible for data management (i.e. the data steward)?

Dr Ali Khashan, Senior Lecturer in Epidemiology, School of Public Health, UCC and Co-applicant on the grant application will be responsible for data management alongside the PI, Professor Ivan Perry.

What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?

The School of Public health in UCC is working with the UCC's Library Research Data Service to ensure that the study data will be FAIR. The Research Data Service is a university wide resource which supports and promotes best practice in data management.