



STUDY PROTOCOL

Assessing and protecting the mental health of the nation: A study protocol [version 1; peer review: awaiting peer review]

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Abstract

Background: Coronavirus disease 2019 (COVID-19) and the public health measures enacted to control its spread may affect the mental health of the general population of Ireland. Funded under the Health Research Board's COVID-19 Pandemic Rapid Response Funding Call, this protocol outlines the aims of a project to assess and protect the mental health of the population of Ireland during this pandemic. We will determine (i) the prevalence of common mental health disorders at various times during the first year of the pandemic, (ii) changes in the prevalence of mental health disorders during the first year of the pandemic, (iii) if there are distinct groups of people experiencing different mental health responses to the pandemic, and (iv) the factors associated with different mental health reactions.

Methods: This quantitative study uses cross-sectional and longitudinal designs. Data have been collected from a nationally representative sample of Irish adults at four assessments: Wave 1 (N = 1,041) occurred during the first week of lockdown in March 2020, Wave 2 in May, Wave 3 in August, and Wave 4 in December. Wave 5 is planned for March 2021. Participants from Wave 1 have been recontacted at each wave to produce a longitudinal dataset. New participants were recruited using quota sampling to ensure the availability of nationally representative samples at each wave. Self-report measures of demographic, economic, psychological, and mental health variables were completed.

Conclusion: This design will allow us to determine whether there has been a change in mental health disorders in the general population during the first year of the pandemic, and if so, what variables are associated with changes in mental health. Results will be used to inform the government's ongoing response to this crisis, to better protect the mental health of the nation during this and any future public health emergency.

Keywords

Mental health, covid-19

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Introduction

The outbreak of coronavirus disease 2019 (COVID-19) was accompanied by several warnings of the consequences that the pandemic would wreak on the mental health of the general population (Adhanom Ghebreyesus, 2020; Campion *et al.*, 2020; Carvalho *et al.*, 2020; Reger *et al.*, 2020). Included among these was a message from the President of the Royal College of Psychiatrists in the United Kingdom (UK), who cautioned that ‘*the prevalence of mental health issues is also expected to grow enormously due to the repercussions of the virus and the lockdown on mental health*’ (Torjesen, 2020).

Trepidation at the possibility of negative mental health consequences during the pandemic is reasonable given the threat posed to billions of people by a novel coronavirus spreading across the globe. The risk of contracting COVID-19 remains a serious risk for billions of people, especially for those aged 65 years or older and those with one or more chronic medical conditions. This prevailing risk, combined with images of mass graves, overrun hospitals, patients being placed on assisted ventilation, as well as stories of people’s loss of family members and livelihoods prevailing in the media, justifies wondering whether the pandemic, and the public health measures imposed to contain the spread of the virus, might have a negative effect on people’s mental health. Moreover, existing data suggests that individuals who had been quarantined within previous pandemics were at risk for negative psychological outcomes (Brooks *et al.*, 2020). Unfortunately, however, many of the early commentaries did not question whether the pandemic *might* affect people’s mental health, but instead were presented in such a way that assumed that mental health problems *would* axiomatically follow from the outbreak of COVID-19. This was done in spite of the now well-established literature in support of resilience as, by far, the modal response to stressful and traumatic life events (Galatzer-Levy *et al.*, 2018).

Initial public declarations of an impending mental health catastrophe were followed by a series of high-profile studies in the initial months after the pandemic claiming to have found a substantial increase in mental health problems in the general population. For example, a study published in JAMA suggested that the rate of clinically relevant psychological distress in the general population of the United States had more than tripled in April 2020, compared to 2018 (McGinty *et al.*, 2020). Another study published in The Lancet Psychiatry using data collected from the United Kingdom Household Longitudinal Study (UKHLS) found that the proportion of people experiencing clinically significant distress rose from 19% in 2014–2016 to 27% in April 2020, and led the authors to conclude that the mental health of the nation had ‘deteriorated compared to pre-pandemic levels’ (Pierce *et al.*, 2020, p. 883). While this conclusion is possible, these studies (among others not mentioned) suffer from significant methodological flaws that preclude any conclusions regarding how the pandemic has affected the mental health of populations.

Notably, the McGinty *et al.* study was based on a comparison of data derived from two distinct samples, each recruited using

different methods. Similarly, the Pierce *et al.* study used data collected in 2014–2016 via face-to-face interviews, and compared this to the same information collected via a self-report, internet survey conducted in 2020. The latter is problematic given that using online, self-report assessments are known within mental health research to yield higher rates of distress than interview-based assessments (Hoffman *et al.*, 2011) - likely because respondents are more comfortable disclosing personal and sensitive information in these situations (Pickard *et al.*, 2018). It is therefore possible (or, indeed, probable) that the observed increases in mental health problems in these general populations are due to methodological issues, rather than to the outbreak of the virus itself. Moreover, we are unaware of any findings published from a population-based study that has assessed mental health disorders pre- and post-the outbreak of the COVID-19 pandemic using identical methods. Without such data, it remains difficult to conclude whether the pandemic has had an effect of people’s mental health.

While we remain open to the possibility that the pandemic has led (or could lead) to a deterioration in the mental health of the general population, given what is known about human resiliency to adversity and trauma (Galatzer-Levy *et al.*, 2018), and the importance of scientists remaining sceptical and prudent in the absence of sufficient evidence, we argue in favour of assuming the null hypothesis to be true (i.e., that the onset of the pandemic is not associated with significant changes in mental health outcomes in the general population) until we can confidently refute it. To this end, we are aware of several longitudinal, nationally representative surveys, taking place across different countries, using identical methods, that were convened in the immediate aftermath of the outbreak of COVID-19.

Among these is the project described herein, entitled ‘Assessing and Protecting the Mental Health of the Nation’ (Mental Health ASAP). As one of a number of arms of the COVID-19 Psychological Research Consortium (C19PRC: McBride *et al.*, 2020), Mental Health ASAP makes up part of the Republic of Ireland arm of the C19PRC (C19PRC-ROI). Launched in March 2020, with the intention of tracking a nationally representative sample of Irish adults over at least the first 12 months of the pandemic, the first three waves of data were collected in late March, early May, and late July/early August 2020, through funding made available by internal university support. Studies based on these data have already been published (e.g., Hyland *et al.*, 2020a). Funding from the Health Research Board (HRB) and the Irish Research Council (IRC) was subsequently obtained in October 2020, allowing us to continue the work of tracking the Republic of Ireland cohort through two new waves of data collection, planned for December 2020 and March 2021, respectively.

The primary goal of Mental Health ASAP is therefore to develop a robust understanding of the mental health of the general adult population of Ireland during the first year following the outbreak of COVID-19, as well as what individual

and psychosocial factors are associated with experiencing positive or negative changes in mental health. To achieve this goal, several objectives were formulated as part of Mental Health ASAP.

First, we will determine (i) what proportion people meet criteria for major depressive disorder (MDD), generalized anxiety disorder (GAD), and posttraumatic stress disorder (PTSD), and (ii) what proportion of people meet criteria for any of these disorders at each assessment during the first year of the pandemic. Moreover, we will assess what proportion of people screen positive for loneliness and somatic problems. Second, we will determine if the proportion of people suffering from each, or any, of these disorders significantly changed during the first year of the pandemic. Third, we will determine if there are distinct groups of people who have experienced different patterns of change in their mental health during the first year of the pandemic. Fourth, and assuming that there will be different groups of people with specific patterns of change in their mental health (e.g., 'deteriorating', 'improving', 'stable'), we will determine the individual and psychosocial factors associated with these different changes in mental health during the first year of the pandemic.

Methods

Study design and sample

Mental Health ASAP is a quantitative, longitudinal study of the Irish adult population aged 18 years and older. Participants were recruited from traditional, actively managed, double-opt-in research panels via email, SMS, or in-app notifications by the survey company Qualtrics. Quota sampling methods were used to construct a sample that was nationally representative in terms of sex, age, and geographical distribution, as per data from the 2016 Irish census (Central Statistics Office, 2020). Inclusion criteria required that respondents be aged 18 years or older, residing in the Republic of Ireland, and capable of completing the survey in English. Participants were remunerated for their time by Qualtrics, and written informed consent was obtained from all participants.

Power analyses were conducted to determine the optimal sample size. As this study was primarily concerned with identifying mental health disorders such as MDD, GAD, and PTSD in the general population, sample size calculations were based on existing prevalence estimates for these disorders. In Ireland, the estimated prevalence of PTSD is approximately 5%, and lower than the prevalence estimates of depression and generalized anxiety (Hyland *et al.*, 2020b). To detect a disorder with a prevalence of 5%, with precision of 1%, and 95% confidence level, a sample size of 1824 was required. The survey company could only guarantee a sample size of 1,000 participants. Therefore, the target sample size was set at 1,000 which, holding all other parameters in the sample size calculation equal, resulted in a precision of 1.35%.

Wave 1 ($N = 1,041$) was collected from March 31st to April 5th, 2020 during the first week of Ireland's initial lockdown, and details of this sample are available elsewhere

(Hyland *et al.*, 2020a). Wave 2 ($N = 1,032$) was collected from April 30th to May 19th, 2020 at the end of the lockdown. The Wave 2 sample included 506 participants from Wave 1 (recontact rate = 48.6%) as well as 526 newly recruited participants. New participants were also recruited using the previously described quota sampling method to ensure that the final sample was representative of the general population. Wave 3 ($N = 534$) was collected from July 16th to August 8th, 2020. The goal in this survey was to maximise the number of recontacts and no need participants were recruited. The recontact rate was 51.3%. Wave 4 ($N = 1,100$) took place between December 2nd and 22nd. This sample included 412 participants from Wave 1 (recontact rate = 39.6%), and 688 new participants who recruited using the previously described quota sampling method to ensure that the final sample was representative of the general population. Wave 5 is scheduled to take place in March 2021. This wave will follow the same approach as Wave 4.

Assessments

In line with the overarching goal of the C19PRC study to determine the social and psychological impact of the COVID-19 crisis on the population, a comprehensive battery of tests measuring participants' demographic characteristics, socio-political views, economic status, health problem, mental health status, and psychology are used at each assessment. Table 1 provides a comprehensive overview of the survey content.

Data analysis

Changes in the proportion of people meeting criteria for MDD, GAD, and PTSD will be assessed using a structural equation modelling (SEM). SEM was chosen such that missing data can be handled using full information maximum likelihood estimation, recognised as the most appropriate method for handling missing data (Li & Stuart, 2019; Schafer & Graham, 2002). Models with constrained and unconstrained proportions will be estimated and compared to determine rates of each disorder at each timepoint, and whether any statistically significant change over time has occurred, in fulfilment of the first two research objectives.

Latent class growth analysis (LCGA) will be used to identify whether there are different groups in the sample who have experienced different patterns of change in mental health over time (objective three). An internalizing psychopathology latent variable will be modelled at each time period from the observed scores on depression, anxiety, PTSD, loneliness, and somatic problems. Assuming that qualitatively distinct groups are identified in the Internalizing latent variable, predictor variables will be added to the LCGA model to assess which individual and psychosocial variables predict class membership. Here, a three-step approach will be taken to ensure that the inclusion of the predictors will not influence the formation of the classes. This will be achieved by incorporating the classification uncertainties in the mixture model, as an approach shown to produce more accurate parameter estimates compared to other approaches that do not account for error in classification.

Table 1. Overview of content of C19PRC Study the Republic of Ireland.

Theme	Indicative content
Demographics	Age, gender, country of residence, marital status, economic activity, key/essential worker status, born in Ireland, grow up in Ireland, urbanicity, level of education, religion
Housing characteristics	Living alone, Number of adults living in household, Number of children living in household, Housing tenure, Residential details (type of property; number of bedrooms; length at property)
Household finances	Estimated annual gross income, change in monthly household income during pandemic, financial spending/saving during pandemic, Perceived future financial security
Health conditions	Existence of any major underlying health conditions – self and family, Currently pregnant – self (partner)
Coronavirus disease 2019 (COVID-19)	Sourcing of information (newspapers, TV, radio, social media, internet, etc.)
	Level of trust in information source
	Engaging in behaviour to reduce risk of contracting COVID-19 (e.g. wearing face mask)
	Engagement with lockdown restrictions
	Anxiety-level relating to COVID-19
	Perceived individual risk contracting COVID-19 over next 6 months
	Experiences of self-isolation
	Experience of being infected with COVID-19 (including testing) - self
	Experience of having COVID-19 (feeling unwell, admitted to hospital)
	Knowing someone close (family member/friend) who has tested positive for COVID-19
	Knowing someone close (family member/friend) who has tested died due to COVID-19
	COVID-19 vaccine acceptability (self)
	COVID-19 vaccine acceptability (child)
	Comfort engaging in activities (e.g. socialising, shopping, going to the gym etc.)
	Preference for pace of easing lockdown restriction
	Predicted course of the pandemic
	Going on holiday/travel abroad
Mental health	Depression: <i>Patient Health Questionnaire-9</i> (Kroenke et al., 2001)
	Anxiety: <i>Generalized Anxiety Disorder Scale-7</i> (Spitzer et al., 2006)
	Traumatic Stress <i>International Trauma Questionnaire</i> (Cloitre et al., 2018)
	Paranoia: <i>Persecution and Deservedness Scale</i> (Melo et al., 2009)
	Somatic symptoms: <i>Patient Health Questionnaire-15</i> (Kroenke et al., 2002)
	Self-harm, suicidal thoughts, and suicide attempts
	Social anxiety: <i>Mini Social Phobia Inventory (Mini-SPIN)</i> (Connor et al., 2001)
Psychological factors	Personality: <i>Big-Five Inventory-10</i> (Rammstedt & John, 2007)
	Loneliness: <i>Loneliness Scale</i> (Hughes et al., 2004)
	Death anxiety: <i>Death Anxiety Inventory</i> (Tomás-Sábado et al., 2005)
	Locus of control: <i>Locus of Control Scale</i> (Sapp & Harrod, 1993)
	Self-esteem: <i>Single-Item Self-esteem Scale</i> (Robins et al., 2001)
	Resilience: <i>Brief Resilience Scale</i> (Smith et al., 2008)
	Attachment style: <i>Relationships Questionnaire</i> (Bartholomew & Horowitz, 1991)
	Happiness: <i>Subjective Happiness Scale</i> (Lyubomirsky & Lepper, 1999)
	Life satisfaction
	Aspects of life better/worse since pandemic
	Social support: <i>Modified Medical Outcome Social Support Survey (mMOS-SS)</i> (Moser et al., 2012)

Theme	Indicative content
Socio-political views/ related behaviours	Voting behaviour last General Election
	Political party identification
	Measure of 'left-wing' or 'right-wing' on social and economic issues
	Satisfaction with how government/institutions handling pandemic
	Child rearing views
	Future voting behaviour
Trust	Institutions

All analyses will be executed using Mplus version 8.2 (Muthén & Muthén, 2017).

Ethics approval

Ethical approval for this study has been granted by the Social Research Ethics Committee at Maynooth University [Ref SRESC-2020-2402202].

Dissemination

Study findings will be submitted as pre-prints to PsychArXiv and submitted for publication in peer-reviewed journals. Findings will also be used to generate policy recommendations enabling the Government of Ireland to understand the level of mental health problems more clearly in the population during the COVID-19 pandemic. In doing so, we hope to contribute towards a health system that is (a) better informed during the current pandemic and (b) better prepared to respond to the mental health needs of the population during any future public health emergency. All research related outputs will be made available through various channels, including the project website: <https://www.mentalhealthsap.com/publications>.

Study status

As described in the methods section, four waves of data have thus far been collected and several studies have been published based on data collected from the earliest waves at this point. Data collection will continue into next March, at which point, the objectives outlined in this protocol will be addressed.

Conclusion

By the conclusion of this project, we will have amassed a longitudinal dataset for a nationally representative sample of Irish adults. Additionally, we will have produced several stand-alone nationally representative datasets. With these data, it will be possible to understand if the COVID-19 pandemic has had any effect – positive or negative – on the mental health of the nation.

Data availability

Underlying data

No data are associated with article.

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