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Psychosocial and health behavioural impacts of COVID-19 pandemic on adults in the USA: protocol for a longitudinal cohort study

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ABSTRACT

Introduction Although social distancing may help contain the spread of COVID-19, the social isolation and loneliness it causes can heighten stress, contribute to unhealthy lifestyle behaviours and have deleterious effects on social relationships. This ongoing longitudinal cohort study aims to (1) characterise the psychological, social and health behavioural impacts of the COVID-19 pandemic over a 12-month period in the USA; (2) determine whether these impacts differ for certain subgroups based on sociodemographics and other individual-level factors; and (3) explore whether there are modifiable factors (eg, coping, social support) that moderate the effects of the pandemic over time.

Methods and analysis Adults (aged ≥18 years) who were fluent in either English or Spanish were recruited via social media and invited to complete an online survey during the 8-week period from 13 April to 8 June 2020 (baseline). Follow-up surveys will be conducted 6 and 12 months after baseline. Data transformations, non-parametric tests or other alternative methods will be used when appropriate. Descriptive statistics and cross-sectional analyses will be performed. Longitudinal associations will be analysed using multilevel modelling with time-variant and time-invariant predictors of change in trajectory over the study period.

Ethics and dissemination Research ethics approval was received from the Baylor College of Medicine Institutional Review Board (H-47505). Overall, this study will provide timely information that can be used to inform public health messaging strategies and guide development of assessment tools and interventions to support vulnerable individuals dealing with the long-term impacts of the COVID-19 pandemic.

INTRODUCTION

On 31 December 2019, China reported to the WHO that four cases of pneumonia with an unknown cause had been identified in Wuhan, Hubei Province. The cause was discovered to be a novel coronavirus, SARS-CoV-2, and the ensuing outcome of the infection began to be called COVID-19. Person-to-person transmission was subsequently confirmed, and the virus began to spread. Owing to the absence of a vaccine and the lack of effective pharmacological interventions, social distancing became the primary mitigation strategy. Social distancing is a set of measures intended to prevent the spread of a contagious disease by increasing the space between individuals and decreasing the frequency of contact. It can be implemented in an individual (eg, avoiding physical contact), group (eg, cancelling group activities where individuals will be in close contact) and/or community level (eg, instructing people to stay at home and shutting down non-essential businesses). In response to the unprecedented threat to public health caused by COVID-19, China became the first country to mandate social distancing by instituting a strict quarantine on 23 January 2020 in Hubei and the surrounding provinces. However, by that time, the virus had already spread to other countries around the world. The pandemic continued to evolve, with new variants emerging and spreading rapidly. The public health response to COVID-19 has been complex and multifaceted, with various strategies and guidelines being implemented by different governments and organizations. The pandemic has had significant psychological, social and health impacts on individuals and communities, and understanding these impacts is crucial for effective prevention and intervention strategies. This ongoing longitudinal cohort study aims to characterise the psychological, social and health behavioural impacts of the COVID-19 pandemic over a 12-month period in the USA; determine whether these impacts differ for certain subgroups based on sociodemographics and other individual-level factors; and explore whether there are modifiable factors (eg, coping, social support) that moderate the effects of the pandemic over time.
time, the virus had already spread outside China. French health officials confirmed the first three cases in Europe on 24 January, and the first case of person-to-person transmission was confirmed in the USA on 30 January.7 On 11 March, the number of cases in the USA surpassed 1000,7 and the WHO declared COVID-19 a worldwide pandemic.8 Shortly thereafter, on 13 March, the president of the USA declared COVID-19 to be a national emergency.9

Faced with an exponential rise in cases and deaths and in an effort to avoid overwhelming healthcare systems, countries around the world began to shut down their economies and severely restrict public movement. By 26 March, the USA surpassed China and Italy to become the world’s most infected nation with 83836 cases,7 and by early April, 42 US states had declared state-wide stay-at-home orders.10 US states that did not institute stay-at-home orders were Arkansas, Iowa, Nebraska, North Dakota, Oklahoma, South Dakota, Utah and Wyoming. By the end of the first week in June, rates of infection in the USA had begun to slowly decline, stay-at-home orders in most states had expired and 34 states had either reopened or were in the process of a phased, state-wide reopening.10 In addition, governors in eight hard-hit states had allowed counties or regions that met criteria for slowing the outbreak to open (California, Illinois, Michigan, New York, Oregon, Pennsylvania, Tennessee and Washington).10

Although the disruption of everyday life and social networks may be necessary to contain transmissible diseases such as COVID-19, social distancing challenges the deeply rooted human need to connect with others.11 Social connection helps people regulate negative emotions, cope and remain resilient in times of stress.12 15 By contrast, loneliness and social isolation can worsen the burden of stressful circumstances, contribute to unhealthy lifestyle behaviours (eg, smoking, drinking alcohol)14 15 and have deleterious effects on mental health, romantic relationships and physical health.16–18 Emerging research suggests that the mental health impacts of COVID-19 vary widely,19–21 with sociodemographic factors accounting for some of this variation. For example, studies from the USA22 23 and other countries24–34 have shown that women, younger adults, those with lower levels of education and/or income and those with a pre-existing mental or chronic health condition are more vulnerable to the adverse mental health effects of the pandemic. Informal family caregivers may be especially vulnerable to the effects of reduced access to healthcare, social services and resources that are central to the management of their/their loved one’s condition, but research on the effects of the pandemic on their emotional well-being has been relatively limited.35 Similarly, data from the US Centers for Disease Control and Prevention suggest that racial/ethnic minority communities are disproportionately affected by COVID-19, but few studies have enrolled sufficient numbers of minorities to examine differential mental health or health behavioural impacts. Finally, despite the fact that strict stay-at-home and social distancing measures have resulted in families and romantic partners either being confined together in their homes or sequestered from one another to reduce exposure risk, few studies have been published on the relationship impacts of COVID-19.36 Just as it is possible that the disruptions of daily routines, reduced social outlets and reduced physical contact caused by the pandemic may contribute to decrements in physical, psychological and/or relationship well-being, it is also possible that decrements in one of these domains could adversely affect functioning in other domains, resulting in a cascade effect. Thus, beyond understanding individual risk/protective factors, more research is needed on how different domains of well-being are affected by the pandemic and how they affect each other over time.

To address these knowledge gaps, we are currently conducting a population-based survey to simultaneously examine the psychological, social and health behavioural impacts of the COVID-19 pandemic on individuals living in the USA. Study objectives are to (1) characterise the psychological, social and health behavioural impacts of the COVID-19 pandemic during the mandatory stay-at-home order period in the USA (baseline) and 6 and 12 months later; (2) determine whether psychological, social and behavioural impacts differ for certain subgroups based on sociodemographics (eg, gender, race/ethnicity), geography, health status and caregiving responsibilities; and (3) explore whether there are modifiable factors that moderate effects of the pandemic over time (eg, individual and/or communal coping, social support) that could be targeted to enhance psychosocial and behavioural adjustment.

METHODS AND ANALYSES

Study design

Given the rapidly evolving nature of the COVID-19 pandemic and varied response across different states and municipalities across the USA, baseline surveys were administered during an 8-week recruitment window (13 April 2020 to 8 June 2020), which corresponded to the initial stay-at-home order period in most of the USA.10 Follow-up surveys will be administered 6 and 12 months after baseline to examine overtime effects.

Patient and public involvement

Given the ongoing pandemic, it was not appropriate or possible to involve patients or the public in the design, or conduct, or reporting, or dissemination plans of our research.

Eligibility

Eligible individuals are those aged 18 years, who reside in the USA and are fluent in English or Spanish.
Sampling strategy and recruitment

Our goal was to recruit a minimum of 2000 participants at baseline. As return rates for online health-related surveys are approximately 50%, we hope to obtain 6-month follow-up data from 1000 baseline survey respondents and 12-month follow-up data from 500 baseline survey respondents.

A range of methods were used to target specific groups to increase the representativeness of the sample. Baseline study participants were initially recruited via unpaid social media advertisements. These strategies included a press release, internal Baylor College of Medicine (BCM) communications (eg, electronic newsletters) and posts about the study on the principal investigator’s (HB) lab page and on social media accounts (eg, LinkedIn, Twitter, Reddit). We also made electronic contact with colleagues, established interest groups and community advocates, and requested that they endorse our project by posting the project advertisement so that it was visible to their contacts/group members. To recruit survey respondents from all 50 US states and ensure a more representative sample with respect to gender and ethnic/racial composition, we also pursued targeted online advertising via Facebook sponsored posts and an online survey crowdsourcing platform, Soapbox Sample (https://www.soapboxsample.com/). Crowdsourcing platforms are web-based marketplaces that allow researchers to post research tasks (such as surveys) that interested subjects can complete for payment or other incentives. Crowdsourcing offers an easy way to quickly recruit a large number of respondents, and platforms such as Soapbox Sample draw a broad demographic of workers who can meet even very specific and targeted inclusion criteria, making this an appealing option for recruiting hard-to-reach groups.

Procedures

Baseline survey

Because this was an online survey, we obtained a waiver of written informed consent under Department of Health and Human Services (DHHS) regulations at 45 CFR 46.117(c) and the Common Rule. The advertisements and social media posts used for participant recruitment contained a web hyperlink that directed participants to the survey website. The survey landing page contained a brief cover letter describing the purpose of the research, eligibility criteria and a plain language statement. If, after reading the study description, individuals were interested in participating, they were asked to check a box that confirmed that they had read the Plain Language Statement, that they understood its contents and that they consented to participate in the study.

The survey was administered online in English and Spanish on the Qualtrics survey platform (Provo, Utah, USA). Given that accountability and validity can be more difficult to enforce in online research, we used tactics to help prevent machine responses (eg, Captcha). We also prevented participants from taking the survey more than once by using the Qualtrics ‘Prevent Ballot Box Stuffing’ feature. Once accessed, participants could take up to 2 weeks to complete the survey. On completion of the baseline survey, all participants were assigned a unique subject ID number and asked to provide their email contact information if they would like to be contacted for the follow-up surveys. The subject ID number will be embedded in the follow-up surveys so that we can link these data to respondents’ baseline survey responses.

Follow-up surveys

Participants will be recontacted 6 and 12 months after completion of the baseline survey via email invitation. Regardless of whether a participant completes the 6-month follow-up survey, he/she will receive the invitation to complete the 12-month survey. All emails to participants will contain a link to opt out from survey completion or from the study entirely.

Measures

Table 1 provides an outline of the survey measures. Measures include (1) sociodemographic questions (eg, age, gender, race/ethnicity, marital status, education, household income, zip code and cross streets), (2) medical variables (eg, COVID-19 status, exposures, symptoms, testing, chronic/serious health conditions, psychiatric diagnoses and effects of the pandemic on disease self-management), (3) caregiving status and experiences, (4) mental health impacts, (5) social/relationship impacts, (6) health behavioural impacts with regard to COVID-19 preventive behaviours (eg, adherence to stay-at-home orders, social distancing, hand hygiene and mask wearing), (7) lifestyle behavioural impacts (eg, alcohol drinking, tobacco use, vaping, exercise and diet), (8) other impacts (eg, different aspects of life affected by COVID-19 and sleep) and (9) possible explanatory variables including knowledge, individual and dyadic coping strategies, and social connectedness and social support. Based on zip code and cross street information, we will use the 2010 rural–urban commuting area (RUCA) codes to define urban and rural areas of residence. RUCA codes classify census tracts based on measures of population density, urbanisation and daily commuting flows. To examine regional variation, states of residence will be divided into one of the four major US census regions: Northeast, South, Midwest and West.

Analytical approach

Quantitative data

Survey data will be exported from Qualtrics to IBM SPSS Statistics for Windows V.26 (IBM) for data cleaning and analysis. We will monitor participant retention to gauge the amount of missing data and take proactive steps to minimise it. If necessary, we will use the restricted maximum likelihood method for estimating the longitudinal statistical models to minimise the impact. This method will allow us to retain cases with partial data with a less restrictive assumption: missing at random (MAR). We will use Little’s missing completely at random (MCAR)
<table>
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<tr>
<th>Construct</th>
<th>Measure</th>
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<tr>
<td><strong>Sociodemographics (20 items)</strong></td>
<td>Age, gender, race/ethnicity, marital status, current living arrangement, number of people living in household, relation, education, employment status, changes in employment due to COVID-19, household income, zip code and cross street</td>
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<tr>
<td><strong>Medical variables</strong></td>
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<tr>
<td>COVID-19 status, exposures, symptoms and testing (10 items)</td>
<td>Adapted from the CoRonavIruS Health Impact Survey V.0.397; Do you think you may have had COVID-19 but did not get tested for any reason? If yes, please specify (open response)</td>
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<td>Health conditions and self-management (11 items)</td>
<td>Diagnosis of cancer (type, stage, treatment) or other chronic/serious medical conditions that require medical management at home; treatment delays due to COVID-19; How has COVID-19 affected daily management of your condition (open-ended)? What are your biggest concerns regarding your health/healthcare since COVID-19?</td>
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<tr>
<td><strong>Caregiving status and experiences (38 items)</strong></td>
<td>Since the beginning of the pandemic, have you provided care for someone in your household who had COVID-19 (1=yes, 2=no), cancer (1=yes, 2=no), a chronic-serious condition that required medical management at home (1=yes (specify), 2=no) or someone with a cognitive, physical or intellectual disability (1=yes (specify), 2=no)? What is their relationship to you? Nature and extent of caregiving activities; change in caregiving responsibilities as a result of COVID-19; How has COVID-19 affected daily management of your loved one’s condition (open response)? Is there someone who shares caregiving responsibilities with you (1=yes (specify), 2=no)? Caregiving challenges experienced as a result of COVID-19 (open response); unmet information, resource and support needs as a result of COVID-19 (open response); concerns about keeping the person you are caring for safe from COVID-19 (open response)</td>
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<tr>
<td><strong>Mental health impacts</strong></td>
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<tr>
<td>COVID-19 Stress (9 items)</td>
<td>Top 5 COVID-19 stressors (open response); Perceived Stress Scale–4-item Short Form58</td>
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<td>General depression (4 items)</td>
<td>PROMIS Depression 4-item Short Form59</td>
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<tr>
<td>General anxiety (4 items)</td>
<td>PROMIS Anxiety 4-item Short Form59</td>
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<tr>
<td>Psychosocial Impact of COVID-19 (9 items)</td>
<td>PROMIS Psychosocial Illness Impact–Negative Scale (instructions reworded to refer to before and after COVID-19 pandemic); positive impacts/silver linings of COVID-19 pandemic (open response)</td>
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<td><strong>Social/relationship impacts</strong></td>
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<tr>
<td>Relationship changes due to COVID-19 (6 items)</td>
<td>Relationship satisfaction, conflict and criticism before and since COVID-19</td>
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<td>Social isolation (5 items)</td>
<td>Social isolation items from the Nottingham Health Profile60</td>
</tr>
<tr>
<td><strong>Health behaviour impacts—COVID-19 preventive measures</strong></td>
<td>Does the area where you live have a stay-at-home order (1=yes, 2=no, 3=I don’t know)? To what extent do you currently follow the stay-at-home order (0=not at all to 10=completely)? How often did you leave your home in the past week, did you leave your home yesterday? Reasons. How many people did you come into contact with when you left your home yesterday?</td>
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<tr>
<td>Social distancing (10 items)</td>
<td>Degree of adherence to social distancing, attitudes and beliefs about the effectiveness of social distancing for stopping spread of COVID-19, perceived barriers and motivations for social distancing</td>
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<td>Hand hygiene (3 items)</td>
<td>Frequency of handwashing and hand sanitiser use, and beliefs about the effectiveness of hand hygiene for stopping spread of COVID-19</td>
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<tr>
<td>Mask use (18 items)</td>
<td>Use of face coverings, perceived barriers and motivations for mask use, and beliefs about the effectiveness of mask use for stopping spread of COVID-19</td>
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<td>Other measures (1 item)</td>
<td>What other steps have you taken to keep yourself and other members of your household safe from COVID-19?</td>
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<td><strong>Health behaviour impacts—lifestyle behaviours</strong></td>
<td>Items from AUDIT-C61; Has your drinking increased/decreased/stayed the same since COVID-19? Since COVID-19, I have had trouble controlling my drinking (1=strongly disagree to 5=strongly agree)</td>
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test to determine the type of missing data. If the test is not significant, data will be treated as MCAR. To address minor amounts of missing data, items will be imputed and used to obtain point estimates. However, as this is a longitudinal study, missing data from attrition are more likely. Outcome missngness due to dropout (yes/no) will be examined using a hierarchical logistic regression model for clustered data using a generalised linear mixed model (LMM) procedure with a logit link function and random intercept. Sociodemographic and medical variables will be examined to identify factors that predict dropout.

For each instrument, recommended methods of computation and summarisation of scales and subscales will be followed. The variables will be assessed to determine distributional characteristics and ceiling/floor effects. In secondary analyses, model parameters and preliminary assessments of group differences will be estimated using LMMs. Trend analyses will indicate the shape of group trajectories over time and possible group-by-time interactions. Individual plots of participants' trajectories on major outcomes will be developed.

When predicting study outcomes (eg, mental health, health behaviours), a random-effects LMM will be used. Full information maximum likelihood for parameter estimates does not assume patients are measured at all time points and will thus include participants with missing assessments, and in the case of MAR or MCAR will provide unbiased estimates and accurate SEs. If the MCAR assumption does not hold, we will use multiple imputation by using likelihood methods to estimate pattern mixture and selection models that condition on the baseline characteristics and latent variables to account for non-ignorable missing data.

Data analysis will be conducted in SPSS V.26, SAS V.9.4 or Stata/MP Software V.16. Study variables will be assessed to determine distributional characteristics and ceiling/floor effects. Data transformations, non-parametric tests or other alternative methods will be used when appropriate. We will use descriptive statistics (ie, frequencies, means, SD) to characterise participant responses. We will also use $\chi^2$ tests (for dichotomous variables) or independent-samples t-tests (for continuous variables) to examine differences in the study outcome variables based on sociodemographics, health status and/or caregiving status. Non-parametric equivalents of these tests (ie, Fisher’s exact test or the Wilcoxon Mann-Whitney test) will be used where appropriate.

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<td><strong>Construct</strong></td>
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<td>Tobacco use</td>
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<tr>
<td>Exercise (1 item)</td>
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<td>Diet (2 items)</td>
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<tr>
<td>Other impacts</td>
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<td>Sleep (4 items)</td>
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<tr>
<td><strong>Explanatory variables</strong></td>
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<tr>
<td>COVID-19 knowledge, sources of information and uncertainty (4 items)</td>
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<tr>
<td>Individual coping strategies (20 items)</td>
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<tr>
<td>Dyadic coping strategies (20 items)</td>
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<tr>
<td>Social connectedness and social supports (6 items)</td>
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<tr>
<th>Measure</th>
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<tr>
<td>COPE, Coping Orientation to Problems Experienced; PROMIS, Patient Reported Outcome Measurement Information System.</td>
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Cross-sectional and longitudinal analyses will be performed. For the former, multivariate linear or logistic regressions will be used, depending on the nature of the outcomes. For longitudinal analyses, LMM or logistic mixed model regressions will be used, depending on the nature of the outcomes, to account for repeated measurements. Where relevant, all associations will be investigated in unadjusted analyses and then in adjusted analyses—the latter controlling for the baseline effects of sociodemographic or health-related variables that are significantly associated with the outcome of interest. Decisions about the inclusion of specific covariates in each model will be made using directed acyclic graphs. In these models, we will regress an outcome (eg, anxiety) onto ‘time’, any moderator variables of interest and background covariates. Time will be treated as a continuous predictor in all models (with the baseline time point coded as 0, 6-month time point coded as 1 and 12-month time point coded as 2). The influence of potential moderators on the relationship between these associations will be investigated by including interaction terms.

Power
For available sample sizes of 500 participants, we can detect correlations of 0.05 or higher with 5% significance and 80% power among variables. With a sample size of 500, we will have 80% power (two-tailed alpha=5%) to detect effects of proportional differences among groups of at least 11%, assuming ±20% of the sample falls in one group. We will be able to detect standardised effect differences of at least 0.31 standardised units if ≥20% of the sample falls in a smaller group.

Qualitative analysis
Text responses to open-ended questions will be transcribed and analysed thematically to determine common themes. Thematic analysis is a method of analysing qualitative data that is focused on identifying, examining and recording major patterns or themes in the data. We will follow the six-stage process described by Braun and Clarke for finding patternsed responses or themes. (1) to familiarise ourselves with the data, all open-ended responses will be read by research team members (Dr Badr and two trained analysts) to obtain a sense of the breadth and depth of the data. Team members will meet to discuss initial impressions. (2) We will generate initial codes by extracting all relevant text units that relate to the question of interest and giving them a brief label that captures the essence of the text unit. The team will discuss, refine and verify all the codes and organise them in a data display table. (3) The team will then search for themes by dividing the codes into broad overarching themes based on code similarities. Visual representations will be developed to explore the relationships among codes within each of the themes. (4) Themes will be reviewed and revised by the team and organised into a coherent pattern. A coherent pattern includes internal homogeneity (ie, the codes link together meaningfully in each theme) and external heterogeneity (ie, there are clear distinctions between the themes). The team will then re-examine the narrative data set as a whole to ensure that all relevant data were captured by one of the themes. (5) Next, we will define and name themes and (6) produce a final report that provides a detailed account of each theme prepared. Disagreements will be resolved via mutual discussion, and an audit trail will be maintained to chronicle all methodological and analytical decisions.

Recruitment progress
We have completed baseline survey data collection. Among the 2435 respondents who consented to participate and accessed our survey during that time period, 2222 provided usable data, yielding a 91% overall survey completion rate. Five hundred and nineteen participants (23%) completed less than 50% of the survey, 188 (9%) completed 50%–80% and 1515 (68%) completed 80%–100%. For the 2222 who provided usable data, the median completion time was 24.39 min (mean=1.67 hours; SD=1.39 hours; range=5.08 min to 9.80 days). Follow-up survey data collection is ongoing.

DISCUSSION
Chronic stress and social isolation brought about by the COVID-19 pandemic present significant risks to the physical, psychological and social well-being of US adults. This project seeks to investigate the psychosocial and health behavioural impacts of the pandemic, including the evolving response of COVID-19 preventive behaviours (eg, social distancing, hand hygiene, mask wearing). The novel contribution of this study will be the repeated measures design, which will facilitate the tracking of changes in mental health and behaviours over time.

As with all non-probability samples, there is limited ability to generalise findings to the populations from which participants were drawn. In addition, online recruitment methods can be limited by demographic representation. To overcome this limitation, we used paid social media advertising and crowdsourcing survey platforms to recruit a national study sample that is socio-demographically diverse. These issues notwithstanding, we believe that use of an online convenience sample is appropriate for this study for three reasons. First, a limited budget prevents us from using more costly probability-based sampling methods. Second, the scale of the project (national survey) and the nature of the COVID-19 pandemic and stay-at-home orders render it highly impractical to recruit participants using traditional in-person or community-based approaches. Third, convenience samples are frequently used to recruit members of hard-to-reach populations (eg, socially isolated individuals) because reliable sampling frames are generally not available.

This project was designed to elucidate health disparities and provide timely information to government, researchers and communities on the psychosocial and
behavioural effects of the ongoing COVID-19 pandemic on US adults. Findings can be used in several ways, including (1) to guide development of assessment and screening tools to identify vulnerable individuals who are at greatest risk, (2) to guide researchers in developing targeted interventions to help support vulnerable individuals deal with the long-term impacts of the pandemic on their health and well-being and (3) to help policymakers develop public health messaging strategies and practical information and advice for the public regarding how to cope and protect themselves and others during the pandemic.

ETHICS AND DISSEMINATION

Research ethics approval for this study was received from the BCM Institutional Review Board (H-47505) with a waiver of written consent under DHHS regulations at 45 CFR 46.117(c) and the Common Rule. Findings will be disseminated through peer-reviewed publication and will be presented at conferences related to this field.

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Contributors HB, AO and CA contributed to the conceptualisation of the study, drafting of the study protocol and selection of survey items/measures. HB drafted the manuscript and together with OEM developed all study materials, including the online Qualtrics survey and study advertisements. A0, CA, SAR, XZ, MAF and OEM wrote or revised sections of the manuscript. All authors approved the final version of the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

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