**Living alone and the risk of mental health problems reported during the COVID-19 pandemic in primary care: a UK population-based cohort using OpenSAFELY platform**

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# Background

The association between loneliness (or lack of social relationships) and poor health outcomes is well established.[(Pantell et al. 2013; Holt-Lunstad, Smith, and Layton 2010)](https://www.zotero.org/google-docs/?CLFIIN) The magnitude of the association between loneliness and poor health is comparable to those of smoking and high blood pressure on cardiovascular disease,[(Pantell et al. 2013)](https://www.zotero.org/google-docs/?a04khn) making loneliness an important public health concern.

Living alone is used as a measure of loneliness and social isolation. Although the link between living alone and health outcomes is weaker than for social isolation and loneliness,[(Holt-Lunstad, Smith, and Layton 2010)](https://www.zotero.org/google-docs/?CIDG7B) several studies have demonstrated important associations.[(Sundström et al. 2009)](https://www.zotero.org/google-docs/?XO1RhI) For example, in the UK, living alone was a risk factor for a number of physical health outcomes including joint disorders and vision loss[(Kharicha et al. 2007)](https://www.zotero.org/google-docs/?v6gnbF) and a recent study showed that living alone was associated with self-harm and suicide among men.[(Shaw et al. 2021)](https://www.zotero.org/google-docs/?im8NPh) Elsewhere, living alone has been associated with psychological distress, common mental disorders, suicidal ideation, and poorer overall mental health.[(Gyasi, Abass, and Adu-Gyamfi 2020; Heisel et al. 2012; Jacob, Haro, and Koyanagi 2019; Tamminen et al. 2019)](https://www.zotero.org/google-docs/?O928Y9)

Evidence from survey data suggests that the COVID pandemic exacerbated feelings of loneliness, social isolation and connectivity, due to national lockdowns, social distancing rules and shielding.[(Morina et al. 2021; Groarke et al. 2020; Varga et al. 2021)](https://www.zotero.org/google-docs/?FLezPO) There is also evidence that the pandemic increased psychological distress including feelings of anxiety and depression,[(Smith et al. 2020; Shevlin et al. 2020; Jia et al. 2020; Fancourt, Steptoe, and Bu 2021)](https://www.zotero.org/google-docs/?UV5Ehn) and perhaps particularly for those living alone.[(Robb et al. 2020)](https://www.zotero.org/google-docs/?XK5CQy)

However, how this impacted NHS services is less clear. As the first lockdown was introduced in March 2020, there was an immediate and drastic reduction in primary healthcare contacts for mental health issues and referrals to secondary care services, with levels steadily recovering towards Summer 2020,[(Mansfield et al. 2021; Chen et al. 2020)](https://www.zotero.org/google-docs/?eF3bz2) as NHS services were restored. However, the subsequent recovery of rates of diagnosis and referrals, plus the impact on NHS hospitalisations due to mental health issues is unknown. It is also unclear whether those living alone have been more likely to seek help for mental health issues compared to those not living alone.

Electronic health records (EHR) present a unique opportunity to investigate the association between living alone and mental health outcomes (e.g. depression, anxiety, severe mental illness, eating disorders) across the NHS, at scale. This study therefore aims to quantify the effect of the pandemic on mental health outcomes among those living alone, compared to those not living alone in the UK. The study will identify characteristics of people who live alone and develop mental illness, which could allow targeted mental health screening and reduce the burden of mental illness and its associated morbidity and mortality.

# Hypothesis

The effect of the pandemic on mental health outcomes will be exacerbated by living alone.

# Aims and Objectives

## Aim

To estimate the effect of living alone on the association between the Coronavirus pandemic and mental health outcomes.

## Objectives

1. To describe the monthly frequency of healthcare contacts in primary and secondary care due to mental health conditions (depression, anxiety, serious mental illness, obsessive compulsive disorder, self harm): (a) among people that live alone, and (b) among people that do not live alone between 2018 and 2022.
2. To make limited causal inference on the (combined) effect of living alone and the pandemic on poor mental health outcomes, through an interrupted time series analysis.

# Methods

## Database Description

We will use data from general practice (GP) records, obtained from the GP software provider TPP, linked to Emergency Care Data Set, Admitted Patient Care, Outpatient data, and ONS mortality records. The data was accessed, linked and analysed through openSAFELY.org  - a new data analytics platform created by our team on behalf of NHS England to address urgent questions relating to the epidemiology and treatment of COVID-19. OpenSAFELY provides a secure software interface allowing the analysis of pseudonymised primary care patient records from England in near real-time within the EHR vendor’s highly secure data centre, avoiding the need for potentially disclosive pseudonymised patient data to be transferred off-site. This, in addition to other technical and organisational controls, minimises any risk of re-identification. Similarly pseudonymised datasets from other data providers are securely provided to the EHR vendor and linked to the primary care data. Descriptions of OpenSAFELY have been previously published (REF), and more information can be found on<https://opensafely.org/>.

Primary care records retrieved from the TPP SystmOne electronic health record system include diagnoses (SNOMED or Read 3 CTV3), prescriptions (dictionary of medicines and devices), basic sociodemographics and vital signs for 22 million individuals – approximately 40% of the English population. Data extracted by SystmOne have previously been used in medical research, as part of the ResearchOne dataset (REFS).

All data is held in a secure research environment hosted by TPP, which is a Tier 3 data centre, accredited to NHS Digital standards for centrally hosted clinical systems (ISO 27001 standard and IG Toolkit version 2). We received ethics approval to conduct the data linkage and analyses by the London - City & East Research Ethics Committee on the 2nd of April 2020 (REC reference: 20/LO/0651) and LSHTM Ethics Board (ref 21863). No further ethical or research governance approval was required by the University of Oxford but copies of the approval documents were reviewed and held on record.

*[Latest Database Description available here:*

<https://docs.google.com/document/d/1d6fw9sc80_N_UQO7qib_R8yBZGObLEzPS_xcri222rA/edit>]

## Information Governance

**NHS England is the data controller; TPP is the data processor; and the key researchers on OpenSAFELY are acting on behalf of NHS England.** This implementation of OpenSAFELY is hosted within the TPP environment, which is accredited to the ISO 27001 information security standard and is NHS IG Toolkit compliant 52,53; patient data have been pseudonymized for analysis and linkage using industry standard cryptographic hashing techniques; all pseudonymized datasets transmitted for linkage onto OpenSAFELY are encrypted; access to the platform is through a virtual private network (VPN) connection;  the researchers hold contracts with NHS England and only access the platform to initiate database queries and statistical models; all database activity is logged; and only aggregate statistical outputs leave the platform environment following best practice for anonymization of results such as statistical disclosure control for low cell counts54. **The OpenSAFELY research platform adheres to the data protection principles of the UK Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) 2016.** In March 2020, the Secretary of State for Health and Social Care used powers under the UK Health Service (Control of Patient Information) Regulations 2002 (COPI) to require organizations to process confidential patient information for the purposes of protecting public health, providing healthcare services to the public and monitoring and managing the COVID-19 outbreak and incidents of exposure55. Together, these provide the legal bases to link patient datasets on the OpenSAFELY platform. GP practices, from which the primary care data are obtained, are required to share relevant health information to support the public health response to the pandemic, and have been informed of the OpenSAFELY analytics platform.

## Study Design and Population

This will be an interrupted time series analysis of the monthly frequency of recorded symptoms and diagnoses in primary care and A&E attendance caused by mental health issues, stratified by living alone vs not living alone.

Analysis population

A different study population will be extracted each month. Each month, the study population will be adults (males and females 18 years and above) who were registered in a TPP general practice in England on the 1st day of the month and who were also registered on 1st February 2020 (the date at which the number of patients in each household was ascertained). Study populations will be extracted each month between 1st March 2018 and 31st January 2022. Each month, we will follow the population until the earliest of:

1. Death;
2. De-registration from GP practice from TPP;
3. Latest TPP data are available;
4. End of study (last date of month).

We will censor datasets prior to the earliest of the linkages to make the linked datasets comparable.

### Inclusion Criteria

Adults over the age of 18 who are alive and under follow-up at the study start date (1st of each month), who were registered with a primary care practice using TPP software as of 1st February 2020, with at least three months of continuous GP registration and a valid address or postcode allowing household identification.

### Exclusion Criteria

People in households greater than 15 individuals (based on TPP-derived household size), in order to reduce the likelihood that we will be including institutions such as care homes in our analyses. People with missing age, sex, STP region or index of multiple deprivation, since these are likely to indicate poor data quality. We will exclude individuals identified as living in an old age care home (based on TPP’s care home indicator) and any household with at least one person identified as living in an old age care home. The pseudonymised household identifier developed by TPP links people living at the same address on 1 February 2020 [(Forbes et al. 2021; Wing, Kevin, n.d.)](https://www.zotero.org/google-docs/?zg8siO) and old age care home status is derived from addresses matched to publicly available Care Quality Commission data). Patients who joined a TPP practice after 1 February 2020 will not have a household status and cannot be classified in terms of exposure, and therefore will be excluded.

## Study Measures

### Exposure

Our exposure will be the introduction of lockdown in the UK on March 23rd, 2020. Time will be split as follows:

* 1st March 2018 to 22nd March 2020 (pre-pandemic),
* 1st July 2020 to 31st January 2022 (pandemic).

We will also look descriptively at the data, based on the following time periods:

* 1st March 2018 to 22nd March 2020 (pre-pandemic),
* 23rd March 2020 to 30th June 2020 (wave 1, lockdown),
* 1st July 2020 to 31st October 2020 (easing restrictions),
* 1st November 2020 to 31st March 2021 (wave 2),
* 1st April 2021 to 31st November 2021 (easing restrictions)
* 1st December 2021 to 31st January 2022 (Omicron wave).

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### Outcomes

We will separate mental health outcomes into those described in Table 1.

Table 1. Mental health outcomes

| Outcome | Definition | Source |
| --- | --- | --- |
| Depression | Any record of major depressive disorder, dysthymia, mixed anxiety and depression, and adjustment disorders with depressed mood; we will also include codes for depressive symptoms | Primary care |
| Self harm/suicide | Records that indicate explicit or undetermined intention to self-harm, non-suicidal or suicidal self-harm (including overdoses with drugs commonly implicated in suicide, such as paracetamol) | Primary care, hospital admission, emergency care attendance, death records |
| Anxiety | Any record of symptoms or diagnoses of social phobia, agoraphobia, panic, generalised anxiety disorder, and mixed anxiety and depression | Primary care |
| Obsessive compulsive disorder | Codes for hypochondriasis, hoarding disorder, and body focused repetitive behaviour disorders | Primary care |
| Eating disorders | Anorexia nervosa, bulimia nervosa, body dysmorphic disorders, and other specified feeding and eating disorders | Primary care, hospital admission, emergency care attendance, death records |
| Serious mental illness | Diagnoses of schizophrenia and other psychotic disorders, and bipolar disorders | Primary care, hospital admission, emergency care attendance |

We will consider each patient to have an outcome if they have a record from any source during that calendar month.

A maximum of one event per individual per month will be included. However, individuals will be allowed to appear in multiple months if they have repeated records of the outcome. We will then calculate the proportion of individuals who experienced an outcome each month, based on monthly denominators of adult patients in OpenSAFELY.

We will calculate 95% confidence intervals for the monthly proportions.

### Covariates

Our main stratifying variable will be living alone on 1st February 2020. This will be defined according to the number of people living in a household, where household size of 1 is living alone, and 2-15 indicates not living alone (household size >15 will be excluded). The exposure is not time updated.

Household size is calculated based on the number of TPP patients in a household, and complemented by data from the Master Patient Index, which TPP use to calculate the proportion of TPP patients in the household (versus those at practices using other clinical software). Currently, household size is calculated as the number of patients living at the same address as at 1st February 2020. See [https://docs.google.com/document/d/1w\_tETnDhf3mNgbFy0WTfn6TV5qoOAmzZFR3-s8HA2HA/edit#](https://docs.google.com/document/d/1w_tETnDhf3mNgbFy0WTfn6TV5qoOAmzZFR3-s8HA2HA/edit) for variable report on household identifiers.

We will also stratify, in turn, on the following variables:

* Age, categorised in 20 year bands,
* Sex,
* Region (Sustainability Transformation Partnership level (STP, English NHS administrative region)),
* Urban/rural location,
* SES (IMD, in quintiles),
* Ethnicity,
* Eligibility for shielding, and
* History of mental health problems in the five years prior to study start

## Statistical Analysis

Each month (March 2018 to January 2022), the denominator adult population (18+) who meet the inclusion criteria will be extracted (those who died or left their practice before 1 February 2020, or who joined TPP after 1 February 2020 will be excluded as we cannot classify their exposure status). The period prevalence of each mental health outcome (based on the combined frequency of primary care and hospital attendance as defined above) will be calculated across the study population each month. This will assume that a person is eligible in the denominator for the whole month if they are eligible on the 1st of the month. Each mental health outcome will be analysed separately.

Each person will be counted only once each month, but people can appear in multiple months if they have repeated records of the outcome. We will calculate 95% confidence intervals for the total proportions each month.

The monthly prevalences will be stratified, by those living alone and not living alone, and then in turn, by each of the covariates. All models will test for moderation effects between the interruption (i.e., the start of the pandemic in England) and household status or covariate/household status (e.g., the interaction between female lone households and the interruption).

We will conduct an interrupted time series analysis using a Newey-West model with heteroskedasticity-consistent standard errors, which account for clustering and other iid violations. The interruption will be the onset of the 2020 COVID-19 pandemic in England and we will use a binary pre-pandemic (before 23rd March 2020) vs mid pandemic variable (1st July to January 2022) to measure the step change in behaviour. To estimate the change in contacts as a result of the pandemic (the step change), we will estimate linear marginal effects for the relative difference in contacts with restrictions period compared with the pre-lockdown period.

We will account for seasonal effects by including a seasonal categorical variable (i.e., spring, summer, autumn, winter, with spring as baseline), and autocorrelation by including first-order lagged residuals.

### Sensitivity analyses

1. We will re-run the analysis including missing ethnicity as a category to assess whether performing a complete case analysis using ethnicity generates biased results.
2. We will repeat the analysis and include prescriptions for SSRIs as an additional outcome.
3. We will repeat the analysis and exclude households with less than 100% TPP coverage (i.e. all adults in the household were registered with TPP).

**[Household TPP coverage -**

In England, not all residents of a household are necessarily registered with the same general practice, which means it is possible that not all residents of a household would appear in the same software system. This means that the number of residents attributed to a household in the TPP register is not necessarily equal to the true total number of people in the household.

While all households in our study will have included at least one patient registered at a practice using TPP software, it is possible that some of the other people in some of the households may be registered with other practices that use software other than TPP. For these households, the calculated TPP household size (i.e. the count of records in TPP under the same household ID) will be different from the household size defined in the Master Patient Index (MPI) for the address covered by the TPP household ID. Those people who are registered to non-TPP practices will not have been counted when we created our household composition exposure variable, and this measurement error has the potential to bias results. A “TPP coverage” flag is provided for each household, which compares the TPP household size with the number of records in the Master Patient Index for the same address and is used to indicate the % of occupants of that household who are registered with general practices that use TPP.]

1. We will repeat the analysis and exclude households bigger than 10 people, in order to exclude possible unidentified care homes.
2. Quantitative bias analysis: we will explore the impact of misclassification of living alone on our outcomes.

## Software and Reproducibility

Data management will be performed using Python 3.8 and SQL with analysis carried out using Stata MP 17. Code for data management and analysis as well as codelists archived online <https://github.com/opensafely/school-age-children-and-covid>

## Power

Approximately 11.5% of the UK adult population live alone (7.9 million people in 2020 <https://www.statista.com/statistics/281616/people-living-alone-uk-by-gender/)>.

In previous analysis, the monthly population included in a time series analysis in OpenSaFELY was 17.5 million. This means that approximately 2 million people included in OpenSAFELY live alone.

In a previous analysis of mental health data from English primary care during the pandemic, the incidence of self harm was the lowest of all mental health outcomes, at 920 per 100,000 person months during the first wave of the pandemic.[(Carr et al. 2021)](https://www.zotero.org/google-docs/?1cRhua) Given these numbers, we do not anticipate an issue with power.

# Limitations

* The focus of this analysis is on living alone. We lack information about patients’ subjective experience of loneliness and other factors (employment, community/support groups, close family, friendships, online contacts, social cohesion) that might mediate or exacerbate loneliness and could have an impact on mental health outcomes.
* We only have household size measured on 1st February 2020. Therefore we are unable to account for any changes in household size occurring before or during the pandemic. This includes moving house, death of household members (from any cause), bubble formation, relationship breakdowns, children returning from university etc. This will introduce some misclassification into our household size estimates, which will likely bias our estimates to the null.
* Some people’s household information will be incorrect e.g. those who had moved house prior to 1st Feb 2020 but not updated their GP with their new address by this time. (However, we do exclude those whose house had been sold by this date, on the assumption that their information is incorrect).
* 20% of individuals do not have a household ID and will be dropped from the analysis. The reasons for an individual not having a household ID are not clear. To explore the generalisability of the results, we will compare the proportion of individuals living alone to UK census data.
* Limitations in the granularity of data may mean that we misclassify the number of people living in a household, e.g. for flats within a larger property. This might lead us to underestimate the effect of isolation. Where there are more than 15 individuals living in a household, we will exclude the household, and this will limit the impact of this misclassification.
* We will misclassify the household size of divorced or separated parents whose children spend time in both households but who are only registered at the GP of one parent.
* We anticipate that ethnicity may be strongly associated with living alone, but a large proportion of patients have missing data for this variable. We will include missing ethnicity as a category so that we can stratify for this.

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