

COVID Anxiety Project (CAP) Cohort Data Analysis Plan

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Study Information

1. **Title;** The trajectory of severe COVID anxiety in UK adults: a time-dependent 18-month prospective cohort study and analysis of maintenance factors.
2. **Authors;** Jacob D King, Verity C Leeson, Mike J Crawford, Paul Bassett
3. **Introduction;** While anxious thoughts and feelings about COVID-19 are appropriate, given the impact of the virus and disruption to daily life, for some people these anxieties become overwhelming. These individuals may also experience poor sleep, somatic symptoms of anxiety misinterpreted as symptoms of COVID-19 itself, and the excessive use of protective behaviours like hand washing or self-isolation, to an unhelpful degree which stops them from getting on in life. Existing longitudinal data suggest that around half of the population of United Kingdom experienced high levels of anxiety during the initial months of the pandemic, but that for most people this reduced quickly in the following months. (1) To date however, little work has considered those people with the most severe and persistent COVID anxiety, whether there is improvement over time as the pandemic subsides, or if demographic and clinical factors are associated with prolonged dysfunctional levels of COVID anxiety. This work comes from Imperial College London's 'COVID Anxiety Project' (CAP) (<https://www.imperial.ac.uk/brain-sciences/research/psychiatry/covid-19-and-mental-health/>).
4. **Hypotheses**
 - A. In a sample of severely COVID anxious individuals, the severity of coronavirus anxiety will reduce over time.
 - B. Baseline mental health, and risk factors for severe COVID-19, will maintain severe COVID anxiety over time.
 - C. In a sample of severely COVID anxious individuals, functional impairment and quality of life will improve over time, in-line with improving coronavirus anxiety.

Design

5. **Study type;** This is a prospective longitudinal study with follow-up at 3, 6 and 18 months after baseline. A full study protocol is presently under peer-review. (2)
6. **Blinding;** Three and six month follow-up interview data will be blinded from researchers involved in analysis until six month data collection is completed. Eighteen-month data will continue to be blinded to researchers involved in analysis until it is collected in full. Researchers will have very little contact with participants included in the cohort aside prompting for follow-up.

Sampling Plan

7. **Data collection procedures;** An initial screening survey was advertised nationally on social media platforms (Facebook, Instagram, Reddit, Twitter), the MQ mental health research (<https://www.mgmentalhealth.org/home/>) and Anxiety UK (<https://www.anxietyuk.org.uk/>) websites, and through *en masse* text messaging from 19 participating general practices in Greater London.

The screening questionnaire assessed for eligibility to the cohort. The eligibility criteria were: aged over 18, being a UK resident, able to complete interviews in English, no history of psychotic illness, and scoring 9 or more on the COVID Anxiety Scale (representing severe COVID anxiety (Lee, 2020)). Those who met eligibility criteria were invited to complete the cohort baseline interview. Those who were not eligible for the study were directed to a webpage which listed sources of mental health support. All interviews are hosted on the Qualtrics secure online platform (www.qualtrics.com). The survey was designed so that it could be completed only once from any one IP address. Respondents also have the option to complete interviews with one of the research team by telephone call.

Those who were eligible, consented to being recruited into the cohort and completed baseline interview, are contacted again by email at 3, 6 and 18 months after their baseline completion. Follow-up interviews are very similar in content to baseline, except that assessments of personality traits are dropped, from 6 months onward include a question about vaccination status, and at 18 months a scale assessing somatic symptoms is introduced (Table 1). Further prompts by email or where available by telephone are sent after follow-up is due. Up to three reminders are being sent. All baseline responses were collected between January and September 2021. The last 18 month follow-up data is due to be collected by the end of March 2023. Participants received 10GBP for completion of baseline interview, and receive a further 20GBP for completion of the 6 month follow-up. At 18 months participants will have the option of being entered into a randomised draw for one of three 50GBP vouchers.

8. **Existing data;** Baseline data of this cohort have been analysed by analytic cross-sectional methodology and are under peer-review (3). As of the date of submission of this research data analysis plan, some of the data from the 6-month interviews and all of the 18 month follow-up interviews have not yet been collected. Some of these collected data have been observed by researchers who will not be involved with the data analysis.
9. **Sample size;** We had initially arrived at a target figure of recruiting 280 people to the cohort as we estimated this would have enabled us to recruit 40 individuals to a nested feasibility trial. We stopped recruitment to the cohort when recruitment to this nested trial was complete. This resulted in 335 participants providing some baseline data. Of these, 302 provided at least minimum baseline data; age, and sex or gender, along with Coronavirus Anxiety Scale score from the initial screening survey, and who were then recruited to the cohort. We will not include those in the treatment arm of our nested trial in the cohort, leaving 282 participants. At baseline the mean Coronavirus Anxiety Scale score of the cohort was 12.37, with standard deviation of 3.0 (3). It is assumed that the standard deviation of the change in scores from baseline to 18-months is equivalent to the SD at baseline. In anticipation of a follow-up rate of 75% at 18 months, our cohort of 282 study participants will generate data on 212 people. This will provide greater than 99% power to detect a 10% reduction in population Coronavirus Anxiety Scale scores based on a paired t-test , using a significance level of 0.05.

Variables

10. **Measured variables;** Data will be collected from participants at baseline, 3 months, 6 months and finally 18 months. The study assessment measures schedule is displayed in Table 1. The concepts of interest in our study are assessed in the following ways:

COVID anxiety is measured with the Covid Anxiety Scale (CAS), a brief, validated 5-item assessment relating to physical symptoms, sleep and worry in response to distressing perceptions of the coronavirus within the last two weeks. The increasing frequency of symptoms are graded on a 0 - 4 point Likert scale. (4) A score of 9 or more has been able to optimally discriminate dysfunctional from non-dysfunctional covid-related anxiety with 90% sensitivity, and 85% specificity. Individuals with scores below 9 at screening were not invited to complete the baseline assessment.

Generalised anxiety is measured with the General Anxiety Disorder 7-item (GAD-7) instrument, a widely used self-report abbreviated assessment of factors associated with dysfunction associated with anxiety over the preceding 2 weeks. (5) Participants assess the frequency of a symptom's impact on their life from 0, 'not at all' to 3, 'nearly every day'. A score of 10 or more has good diagnostic accuracy for generalised anxiety disorder.

Health anxiety will be assessed with the 14-item main section of the short-form Health Anxiety Inventory (sHAI), assessing responses to 14 Likert items which covers three related domains of perceived likelihood of becoming ill, severity of anticipated illness, and bodily vigilance. (6) A score of 20 or more is used as a cut off for health anxiety.

Depression is assessed with the widely-used Patient Health Questionnaire 9-item tool. (7) Respondents self-report over the past 2 weeks what proportion of days they have experienced each symptom-based item on a 4 point Likert scale. A score of more than 10 has good diagnostic accuracy for a diagnosis of major depression.

Obsessive-compulsive symptoms are measured with the Obsessive Compulsive Inventory – Revised (OCI-R), an abbreviated instrument which assesses participants distress over the preceding month related to 18 obsessive and compulsive symptoms representing 3 items from each of 6 groups; washing, checking, ordering, obsessing, hoarding, and neutralising. (8) A score of 21 or more is has adequate diagnostic accuracy for obsessive-compulsive disorder.

Drug and alcohol use. The Alcohol Use Disorders Identification Test of Consumption (AUDIT-C) is a widely used three item screening instrument to detect hazardous drinking

which requires participants to self-assess the frequency of hazardous alcohol use behaviours on a 0-4 scale of increasing frequency. A single item enquires into the number of instances of illicit drug-use or the inappropriate use of prescription medication within the past year. (9)

Disordered personality traits were assessed using the Standardised Assessment of Personality – Abbreviated Scale (SAPAS) (10), and the Dependent Personality Questionnaire (DPQ) (11) at baseline. Both scales demonstrate good construct validity. The SAPAS offers respondents to agree or disagree with 8 statements about their general temperament. A score of 4 or more indicates probable personality disorder. It has been extensively validated among populations with mental health disorders. The DPQ asks respondents to self-assess on a 4 point Likert scale the degree to which they identify with 8 personality items. Scores of 3 or more and 12 or more respectively are associated with personality disorder and dependent personality disorder. A 7-item version of the Dependent Personality Questionnaire (DPQ) was erroneously administered to participants. Items were adjusted to the full 8-item inventory by dividing the 7-item score by seven and multiplying by eight, on the advice of the designers of the tool (personal communication).

We assessed social and occupational functioning using the Work and Social Adjustment Scale (WSAS), a 5-item self-administered questionnaire which has been widely used and validated in the general population and clinical samples. (12) Scores greater than 10 on the WSAS indicate moderate psychopathology associated functional impairment, and scores of 21 or greater are categorised as ‘severe functional impairment’.

Quality of life is assessed using the ‘EuroQuol 5-Domains’ (EQ-5D-3L) instrument, developed for use among a wide range of health populations, where a single item for each domain - mobility, self-care, usual activities, pain/discomfort and anxiety/depression – assesses on three ordinal ‘levels’ of increasing severity of impact. (13) For example, 1 represents ‘no mobility difficulties’ and 3 ‘severe difficulties with mobility’. We calculated EQ-5D-3L index scores to create a continuous variable using the time trade-off valuation technique from UK population standardised scores using a value calculator (<https://cran.r-project.org/web/packages/eq5d/vignettes/eq5d.html>). Standardised to nationwide perceptions of health-related quality of life an index score of 1 is interpreted as full health, and 0 as a health state equated to death.

In this study, COVID health behaviours were investigated using novel items co-developed early in the project in collaboration with service-users who identified

behaviour changes associated with fears of COVID infection. These are listed in Table 2 and include, for example, not leaving one's home, frequently washing hands and not sending children to school despite it being possible to do so. Of the 8 items, 6 are constructed as ordinal variables and established on Likert scales. The least severe item is scored as 1. Scores increase incrementally by 1, with the most severe option representing excessive behaviours or those not recommended by UK public health guidance. The item which regards the frequency of leaving one's home is reverse scored.

The demographic details collected are; date of birth, sex, gender identity, British census ethnicity category, employment status (employed, self-employed, furloughed, unemployed, other), whether the respondent lives alone, with family including children or with someone thought to be vulnerable to COVID-19. In addition, we collect data on whether the individual has previously had COVID-19, and if this diagnosis was confirmed by a clinician or PCR testing.

Vaccination status is asked at 6 and 18 month follow-up with binary, yes or no, options, for first and second doses and any boosters, along with free-text options for reporting the months of each vaccination.

Health conditions are self-reported as free-text responses. These were coded using the MedDRA international system (<https://www.meddra.org/>).

11. **How the variables are used;** CAS scores at 6 and 18 months will be our primary outcomes of interest. Our secondary outcomes of interest are social and occupational functioning (WSAS), quality of life (EQ-5D-3L) and health behaviours (novel items). Scores on assessment scales (CAS, HAI, GAD, OCI-R, PHQ-9, SAPAS, DPQ, WSAS, EQ-5D-3L), as well as age and the 6 ordinal health behaviour items, are to be treated as continuous variables.

For the purpose of analysis, we aim to will explore whether to create binary proxy indicators of perceived high-risk for COVID-19. Where numbers in individual categories, this approach will be taken, whereas if the numbers in each category are sufficient, three or more categories could be considered for some factors. It is hypothesised that high risk factors could include male gender, certain ethnic groups, and having an at-risk health condition. Ethnicity data will be considered being grouped into binary categories of lower and higher risks of hospitalisation and mortality associated with COVID-19, based on British Office of National Statistics reports compiling

data from January 2020 – December 2021. (14) In this way people from South Asian (Indian, Bangladeshi, Pakistani), Black (Black African/Caribbean) and ‘Other’ groups were classified as being at higher risk compared to those with White British and Irish, White Other, and Chinese backgrounds.

Comorbidities associated with an increased risk of hospitalisation or mortality from COVID-19 are reported by the QCOVID project (<https://qccovid.org/>), and at-risk health status is constructed as a binary variable of having ‘1 or more at-risk health condition’ or not.

Living alone, with someone thought to be vulnerable to COVID, and previously having been SARs-CoV2 positive will also be treated as binary variables. Employment will be categorised as employed, or as not-employed. The former is constituted by responses ‘employed’ and ‘self-employed’. The latter is constituted by ‘unemployed’, ‘student’, ‘Other’. Responses to ‘Other’ options offer free-text rationalisation which will be considered and allocated by consensus of two researchers. Living arrangements will be categorised as living alone, or not living alone, the latter constituted by: living with partner, living with family, living with housemates.

Time will be measured as nodal: baseline, 3 months, 6 months, 18 months.

Table 1: Study Assessment Schedule

Assessments	Screening	Baseline	3 months	6 months	18 months
Coronavirus Anxiety Scale	X		X	X	X
Single item psychosis history	X				
Demographic and clinical data (Age, ethnicity, gender, household composition, occupational status, medical history)		X			
Standardised Assessment of Personality - Abbreviated Scale		X			
Dependent Personality Questionnaire		X		X	
Use of alcohol and drugs (AUDIT-C, and the single item drug-use screening		X	X	X	X
Generalised anxiety disorder 7-item		X	X	X	X
Patient Health Questionnaire-9		X	X	X	X
Patient Health Questionnaire-15 (Somatic symptom severity scale)					X

Obsessive-Compulsive Inventory – Revised scale		X	X	X	X
Short Health Anxiety Inventory		X	X	X	X
Work and Social Adjustment Scale		X	X	X	X
Health related quality of life (EQ-5D)		X	X	X	X
Novel items assessing health behaviours		X	X	X	X
Vaccination status				X	X

Table 2: COVID related health behaviour items

Question	Options
How much of your time have you spent worrying about COVID-19? (Ordinal)	<ul style="list-style-type: none"> • None of the time • Some of the time (less than daily) • Every day • Several times a day • Constantly
How much time have you spent reading/watching news (TV/online/social media) about COVID-19 (Ordinal)	<ul style="list-style-type: none"> • None of the time • Some of the time (less than daily) • Every day • Several times a day • Constantly
How many times did you leave your home? (Ordinal)*	<ul style="list-style-type: none"> • None of the time • Some of the time (less than daily) • Every day • More than once a day
Regarding food shopping;	<ul style="list-style-type: none"> • You buy all your own food in stores • You buy all your food online for convenience • Other people buy all your food for you • You buy all your food online due to concerns going to stores
When food, letters or parcels come in to your house, was there ever an occasion when you washed or discarded items because of possible contamination with COVID-19 virus? (Ordinal)	<ul style="list-style-type: none"> • None of the time • Yes, one or more items • Yes, most items • Yes, all items

On average, how often do you wash your hands? (Ordinal)	<ul style="list-style-type: none"> · Same as prior to the start of COVID-19 · Slightly more often than prior to the start of COVID-19 · A lot more often than prior to the start of COVID-19 · Constantly
On average, how often are you washing your clothes? (Ordinal)	<ul style="list-style-type: none"> · Same as prior to the start of COVID-19 · Slightly more often than prior to the start of COVID-19 · A lot more often than prior to the start of COVID-19 · Each time an item is worn outside
Do you have children living with you? If so;	<ul style="list-style-type: none"> · Yes, children are able to attend and have been attending school · Yes, children are able to attend school but have not attended due to concerns regarding COVID-19 · Yes, but the children are not able to attend school (due to provision or other factors) · No children

* = item is reverse scored

Analysis Plan

12. **Statistical models;** All data will be managed and analysed using Stata/IC v16.1. We will make reference to existing analysis of baseline data. (3) Analysis will be conducted on baseline, 3 and 6-month follow-up data initially, and at a later date, similar analyses will be re-run to include 18-month data.

The primary outcome is CAS score. The first analyses will examine changes in this outcome between timepoints. This will be performed using a multilevel (mixed) regression model. Two-level models will be used with individual patients nested within timepoints. Time will be considered a fixed factor, with the patient as a random factor. The mean change from baseline at each of the 3, 6 and 18-month timepoints will be reported with a corresponding confidence interval.

Longitudinal descriptions of the variable means, mean differences, and standard deviations of the CAS, other psychopathological assessment scales, and the WSAS, EQ-

5D-3L and COVID health behaviours at each time point - baseline, 3, 6 and 18 months - will be accompanied by a series of one-way ANOVA tests of between-group difference. Changes in COVID health behaviours which are not ordinal will be described in prose. We will also specifically describe the proportion of the sample who are no longer classed as having severe COVID anxiety (their scores drop below 9 on the CAS), as well as those who score less than 5 on the CAS representing no/minimal COVID anxiety. (15)

To identify the variables associated with changes in CAS scores at 3, 6 and 18 months separately, we will run a series of linear regression models. CAS scores at each timepoint will be considered in separate analyses. In these models, the following predictor variables will be considered:

- CAS score at baseline
- time-invariant predictors (age, sex, at-risk ethnicity, at-risk health condition, living alone, living with someone vulnerable, previous COVID-19)
- Baseline values of psychopathological scores (GAD, HAI, PHQ-9, OCI, AUDITC, single item drug-use screening score)
- Baseline SAPAS (binary variable – a score of four or more indicating probable personality disorder) and DPQ
- Vaccination status – whether the participant received a vaccine during the six month follow-up period
- Change in psychological scores (GAD, HAI, PHQ-9, OCI, AUDITC) from baseline to the time of the outcome measurement.

For the continuous predictor variables, the shape of the relationship between each factor and CAS will be examined. If required, quadratic and cubic terms for each factor will be included to improve the model fit.

The analysis will be performed in two stages. Initially the separate association between each factor and CAS at each outcome timepoint will be assessed separately. CAS score at baseline will be included in all these analyses, as the inclusion of this factor will mean that the analyses will reflect factors associated with change in CAS from baseline

The second stage in the analysis will examine the joint association between the factors and CAS score in a multivariable analysis. To restrict the number of variables in this stage of the analysis, only factors showing some association with the outcome ($p < 0.2$) from the first stage of the analysis will be considered in the multivariable analyses. A selection procedure (e.g. backwards selection) will be considered to include only factors significantly associated with the outcome to be included in the final model.

The third hypothesis will be tested by using the WSAS and EQ-5D-3L as the dependent variables in separate mixed-linear effects models to examine changes in these outcomes over time. Additionally, linear regression models will be used to examine factors associated with WSAS scores. Equivalent statistical methods will be used as for those with CAS as the outcome. Predictor variables will be the same, with the addition of CAS

For all regression analyses, the assumptions of the models will be assessed, specifically the normality and homogeneity of residuals, both of which will be assessed graphically. If the assumptions are not met, a data transformation of the outcome (e.g. log transformation) will be considered. Multicollinearity of the model will be assessed with variance inflation factor estimates.

13. **Transformations;** Dependent variables with a skewed distribution may be given an appropriate transformation (e.g. log transformation) before analysis
14. **Inference criteria;** We will use a significance level of 0.05 throughout to assess for meaningful differences. We will use two-tailed tests throughout. Cut-off scores for each psychopathological scale are described above within descriptions of each variable.
15. **Data exclusion;** Participants who do not have a complete Coronavirus Anxiety Scale score at any of the follow-up timepoints, 3, 6 and 18 months, will not be included in analysis. Outlying data points will be included in the analysis.
16. **Handling missing data;** Responses are required by the Qualtrics online survey platform for each item within an assessment scale before the participant can progress, we therefore do not anticipate missing items within variables. We will not impute missing data.

Regarding analysis of loss to follow-up, during analysis of 6 month follow-up data, individuals who complete baseline data but do not complete 6 month data, will be compared to individuals who did complete study data. For 18-month follow-up data the same approach will be taken for the 18-month time-point. A series of χ^2 -tests will examine the key demographic and psychopathological factors at baseline of the

responders at 6 months versus those who did not respond at both 3 and 6 months or 18 month. The unpaired t-test (or Mann-Whitney test) will be used for continuous variables, with the Chi-square test used for categorical variables. Significant differences in groups will be reported and discussed.

17. **Exploratory analysis;** We will have the opportunity with this data set to conduct several exploratory analyses.

This study collects data from January 2021 to March 2022, and also July 2022 until March 2023. There is some evidence from other research to suggest that for some individuals, time, rather than variations in current burden of COVID on populations (including case numbers, hospitalisations and mortality figures) improves mental health impacts of the pandemic. (16, 17) However this has not been explored in severely COVID anxious individuals. This study therefore poses the opportunity to consider whether the severity of COVID anxiety in a COVID anxious population is associated with contemporary COVID case numbers, hospitalisations and mortality figures. In exploratory analysis we would consider linking the date of interviews to daily figures for each of these three variables, using figures collated by gov.uk (<https://coronavirus.data.gov.uk/details/cases>), and examine their relative mediations of coronavirus anxiety over time.

Furthermore, there is an interest in whether vaccination against the coronavirus might offer some relief from COVID anxiety. However, we expect very high uptake of vaccination in our sample, and that the number of unvaccinated respondents (if any) will be negligible for any meaningful core analysis. If the data is suitable, we could explore this question by including the binary time-variant vaccination status factor with fixed-effects in linear mixed models of 43 cohort outcome variables; coronavirus anxiety, functional impairment, and quality of life. A signal might provide reason to explore this question in future work.

Additional items which are not to be included in the core analysis plan include measures of somatic symptoms using the Patient Health Questionnaire 15 (Somatic Symptom Severity Scale). Pre-post self-assessment measures collected at the 18 month follow-up interviews could be analysed in an exploratory fashion to advance a discussion on the role of somatic symptoms in COVID-19 and COVID anxiety.

Other

18. **Ethical approval;** Plans for the study were approved by Leicester Central Research Ethics Committee (reference: 20/EM/0238) in 2020. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.
19. **Data availability;** These data will be made publicly accessible on completion of analysis.

20. References

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