A **PROTOCOL** FOR A LIVING SYSTEMATIC REVIEW ON THE EFFECTS OF THE COVID-19 PANDEMIC ON THE GENERAL POPULATION`S MENTAL HEALTH, ALCOHOL/SUBSTANCE ABUSE, VIOLENCE AND AGGRESSION

**IN A NUTSHELL**
- We plan a living, online review of prevalence studies of any mental health condition (such as anxiety, depression, post-traumatic stress syndrome and others), alcohol or substance abuse and violent/aggressive behavior during the COVID19 epidemic/pandemic outbreak.
- We will set up a webpage where information on prevalence will be updated as soon as a new study is published.
- The review is expected to start on the 25th of April.

**REVIEW PROTOCOL**

**REVIEW QUESTION**
We aim to rapidly and continuously provide summaries of a) the prevalence of mental health issues, including alcohol/substance abuse and violent/aggressive behaviour and b) change in mental health symptoms in the general population in relation to the COVID19 epidemic/pandemic outbreak.

**PARTICIPANTS/POPULATION**
Included: the general population irrespective of age (i.e. including children, adolescents and elderly)
Excluded: studies exclusively reporting on health care personnel, SARS-CoV-2 cases (suspected or confirmed) and COVID19 patients. These studies will be excluded from the current review but will be catalogued as such in the course of study selection.

**INTERVENTION(S), EXPOSURE(S)**
Participants should be affected by the COVID19 epidemic/pandemic, hence the study should have taken place after December 2019.

**COMPARATOR(S)/CONTROL**
Not relevant

**TYPES OF STUDY TO BE INCLUDED**
Cohort studies, cross-sectional studies, surveys and prevalence studies.
We will include only studies that used validated questionnaires or interviews about the symptoms the diagnosis of the conditions of interest (listed in section 18).
We will exclude prevalence studies that rely on hospital admissions and diagnoses recorded on medical records as access to the hospitals has been avoided during the epidemic/pandemic.

**Main outcomes**
For each of the identified conditions we will extract, if reported:
1. the mean score of any validated scale used to measure symptoms alongside any measure of uncertainty. They will include but are not limited to; K6, POMS for general distress; PHQ-9, BDI-II, CES-D for depression; GAD-7, BAI, STAI for anxiety; IES-R for post-traumatic stress; PANSS, BPRS for schizophrenia and other psychoses, AUDIT for alcohol use disorder; UCLA Loneliness Scale for loneliness.
2. The number of cases diagnosed with a condition (as defined by crossing a particular threshold specific to each questionnaire or confirmed through diagnostic interviews such as CIDI, SCID or MINI) or exhibiting a certain behavior out of the total number screened.

**Search strategy**
We will search MEDLINE, EMBASE, bioRxiv and medRxiv using the ISPM COVID-19 living evidence database. Key words and terms are:
- **EMBASE** - ncov OR (wuhan AND corona) OR COVID
- **bioRxiv and medRxiv** - ncov OR corona OR wuhan OR COVID

We will retain articles that contain the predefined search terms. A list of these terms can be found at: https://ispmbern.github.io/covid-19/living-review/collectingdata.html.

We will filter these data on (mental) OR (alcoho*) OR (violen*) OR (subst*) OR (abuse) in title or abstract.

**Data extraction**
Two reviewers will independently assess studies for eligibility by screening the titles. Two reviewers will independently extract data using a pre-piloted extraction form in an electronic data capture system REDCap [1]. A third reviewer will resolve any disagreement using the data resolution workflow in REDCap. For articles in languages other than English, French, German, Italian, Korean, Japanese, Chinese, Greek, Spanish we will consult native language speakers or use online translation tools.

The following characteristics will be extracted for each article:

**Study characteristics**
1. Study design
2. Country and/or region
3. Time of study realisation
4. Method of collecting information (telephone interview, posted questionnaires etc)
5. Length of follow-up (if relevant)

**Population characteristics**
1. Specific group within the general population (if yes, description, e.g. students, elderly, pregnant women etc)
2. Age
3. Gender
4. Country
5. Psychiatric comorbidities (mental health)
6. Medical comorbidities (non-related to the mental health)
7. Percentage of SARS-CoV-2 cases (suspected or confirmed)
8. Percentage of COVID19 patients

**Epidemic and Confinement Characteristics**
1. Information about the level of confinement in the area at the time when the study was undertaken
2. Information about the extent of the epidemic (average new cases per day, average deaths per day) in the area at the time when the study was undertaken

**Comparison with Pre-Epidemic Data**
1. Reference to any official data about the prevalence of the measured outcomes in the same or similar population prior to the epidemic

For the EPIDEMIC AND CONFINEMENT CHARACTERISTICS and the PRE-EPIIDEMIC DATA we will use data reported in each study or, if not available, we will identify external sources of information such as data reported by WHO, national health agencies or previous relevant studies.

**Risk of Bias (Quality) Assessment.**
As there is no standard and widely accepted tool for assessing the risk of bias for prevalence studies, we will consider a variety of instruments, tailored to our specific context. Risk of bias will be assessed by one reviewer and verified by a second reviewer. A third reviewer will resolve disagreements if the two reviewers cannot reach consensus.

**Strategy for Data Synthesis.**
Data will be considered according to the condition studied. Mental health conditions include but are not limited to depression, anxiety, psychosis or post-traumatic stress. Two experienced mental health professionals will assess the included studies and define the specific diagnostic categories for all the mental health outcomes reported in the paper. Any disagreement will be discussed and solved with a third member of the review team. When enough data are available for the prevalence of a condition, we will attempt to synthesize them.

We will conduct data synthesis in R (version 3.5.1) using the `metaprop` function from the `meta` package[4]. We will examine forest plots and conduct meta-analysis to estimate a summary of the prevalence, if appropriate. If there are several estimated proportions, we will express their heterogeneity using a prediction interval, which is the interval within which the true proportion is expected to be found in studies conducted in a setting similar to those in the included studies [1].

When enough data is available, we will attempt to tabulate each study’s prevalence(s) for the studied conditions against the EPIDEMIC AND CONFINEMENT CHARACTERISTICS and the PRE-EPIIDEMIC DATA.
The analysis will be conducted on the studies included in the REDCap database as a public notebook (for example R markdown format). We will update the analysis each time the analysis scripts are updated and periodically once per day if new studies have been added. The subsequent report will be compiled semi-automatically and will be published in [https://ispmbern.github.io/covid-19/](https://ispmbern.github.io/covid-19/)

**ANALYSIS OF SUBGROUPS OR SUBSETS**

We will conduct subgroup analyses to investigate possible sources of heterogeneity according to the subpopulation, study region, study design, gender and age. Given the nature of the data and the high anticipated heterogeneity, synthesis within subgroup of patients/studies might be the most reasonable data synthesis approach.

**CONTACT**

**REFERENCES**


