The quality of research on mental health effects of the COVID-19 pandemic:

A note of caution after a systematic review

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Study pre-registration: <https://osf.io/bk3gw/>

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Summary (max. 250 words)

Background: SARS-CoV-2 pandemic has spurred scientific production in diverse fields of knowledge, including mental health. Yet, the quality of current research may be challenged by the urgent need to provide immediate results to understand and alleviate the consequences of the pandemic. This systematic review aims to examine compliance with basic methodological quality criteria and open science practices on the mental health effects of the COVID-19 pandemic.

Methods: A systematic search was performed using PubMed and Scopus databases on the 13th of May. Empirical studies, published in peer-reviewed journals in English, between February and May 2020, were included. The dependent variable(s) required to be quantitative and related to mental health. Exclusion criteria included clinical pharmacological trials, and studies using psychophysiological or biological recordings. The study protocol was previously pre-registered in <https://osf.io/bk3gw/>.

Findings: Twenty-eight studies were identified. More than 75% met the requirements related to reporting key methodological and statistical information. However, 89.3% used convenience samples and 92.86% lacked of a priori power analysis. There was low compliance with open science recommendations, such as pre-registration of studies (0%) and availability of databases (3.57%), which raise concerns about the validity, generalisability, and reproducibility of the findings.

Interpretation: While the importance of offering rapid evidence-based responses to mitigate mental health problems stemming from the COVID-19 pandemic is undeniable, it should not be done at the expense of sacrificing scientific rigor. The results of this study may stimulate researchers and funding agencies to try to orchestrate efforts and resources and follow standard codes of good science.

Keywords: COVID-19, Mental health, Research quality, Systematic review

Introduction

The SARS-CoV-2 pandemic has had profound consequences in many areas of daily life including research activities. The academic world has launched, admirably fast, many initiatives to try to understand both the biological mechanisms of the virus and the associated psychological and social responses in humans ¹. However, this rapid proliferation of studies, and fast-track publication practices, can also be a source of unexpected problems related to the quality of the ongoing studies ² which, ultimately, are leading to enormous ethical and practical problems ³.

The SARS-CoV-2 crisis is likely challenging some of the standard codes of scientific conduct. A gigantic incentive system has been built up to immediately offer results, which might be stimulating a race for social and academic reputation as well as potential economic advantages ⁴. However, even during these difficult times, or perhaps due to it, high-quality research should be inexcusably guided by a series of principles that Zarin et al. (2019; p.813) summarised as: “(1) the study hypothesis must address an important and unresolved scientific, medical, or policy question; (2) the study must be designed to provide meaningful evidence related to this question; (3) the study must be demonstrably feasible (e.g., it must have a realistic plan for recruiting sufficient participants); (4) the study must be conducted and analysed in a scientifically valid manner; and (5) the study must report methods and results accurately, completely, and promptly”. Lack of adherence to these principles may contribute to the crisis replicability and reproducibility in science ⁶ and may favor the creation of a worthless corpus of knowledge based on significant but spurious findings.

It is possible that the urgency of situations may bring some problems, like running studies only for the sake of exploratory purposes with no clear hypotheses and flawed designs or analyses of results, which may harm the credibility of science and, worst of

all, mislead important decisions on prevention and intervention measures ⁷. With the hope of contributing to the improvement of quality future research, the aim of this study was to provide a descriptive perspective on the practices of research and publication related to the mental health consequences of the current COVID-19 crisis. To analyse the quality of quantitative studies, given that there are no clear universal standards of scientific practices in the field of mental health ⁸, we focused on general principles of ethical standards, methodological soundness, adequate reporting, open science practices as described in quality checklists ⁹ and indicators of reproducibility and transparency ⁶.

Methods

Search strategy and selection criteria

This systematic review was based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses-P statement for systematic review and meta-analysis protocols ¹⁰. The study protocol was previously pre-registered: <https://osf.io/bk3gw/>.

The literature search was performed using PubMed and Scopus databases on the 13th of May. Studies were included if they were empirical studies, published in English, between February and May 2020, and in peer-reviewed journals. The dependent variable(s) required to be quantitative, self-reported behavioural, cognitive or emotional measures related to mental health. Exclusion criteria included clinical pharmacological trials, studies using psychophysiological or biological recordings, and opinion articles, letters to the Editor, reviews and the like. The terms used in the search were coronavirus OR COVID (limited to title/abstract) AND mental OR psych* OR depression OR anxiety OR stress OR trauma OR alcohol OR drugs OR substance use.

Two researchers (IN and JFN) independently evaluated search results for inclusion. First, duplicates were removed. Then, studies whose title and abstracts

suggested that they did not meet the inclusion criteria were eliminated. Finally, researchers examined in detail the full text of the remaining studies. Discrepancies were resolved by consensus and, when needed, by referral to a senior researcher (CV).

Data extraction

A list of quality indicators was developed by agreement between the authors, after examining some of the most widely used existing guidelines of quality in social and health research: Checklist for Measuring Quality⁹, the Effective Public Health Practice Project Quality Assessment Tool (EPHPP)¹¹, The Newcastle-Ottawa Scale (NOS) (Wells, Shea, and O'Connell, 2009), The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement¹³ and Critical Appraisal Skills Programme¹⁴ checklists. For the selection, we included indicators that were common to all types of quantitative research, regardless of their design (e.g. clinical trials vs. cross-sectional studies). Since there is a great overlap between checklists, the criteria were mainly based on the Checklist for Measuring Quality⁹. Indicators which required a subjective judgment were avoided (e.g., *Were the statistical tests used appropriately?*). Broadly, these indicators encompassed aspects of the design (e.g. recruitment process, use of validated instruments), the analytical strategy (e.g. control of potential confounders), and the way in which key components of the study are reported (e.g. internal reliability of the instruments used, exact *p*-values).

In addition, some further criteria that were not considered in the referred guidelines (most of them related to Open science quality criteria) were added: (i) the approval of an ethical committee; (ii) report of the effect sizes; (iii) pre-registration of the study and (iv) open access to data bases (see Table 1, next section, for the list of quality of indicators).

Data analysis

The studies selected were assessed using a dichotomous score (i.e., yes/no) and the main summary measure was the percentage of included studies that met each of the quality indicators mentioned above.

Results

Twenty-eight empirical studies on mental health problems associated with the SARS-CoV-2 were finally included in the analyses (see Figure 1 for a detailed description of search flow and results).

In Table 1 we present the standard ethical, methodological, analytical and open science quality indicators that were selected and the percentage of studies that met each indicator (i.e., our main outcome measure). The studies were coded by two independent judges (IN and JFN). The Kohen's kappa inter-rater reliability score was 0.96. Discrepancies were resolved by discussion between both researchers. Those on which no consensus was reached were referred to the senior researcher (CV) for a final decision. For the sake of transparency, the quality indicator met by each single study is available in Table 1S (Supplementary materials).

All but one study reported some effect size related to their main outcome measures. Two criteria were met by more than 80% of the studies. One related to reporting key information (i.e., estimates of the random variability in the data for the main outcomes) and the other one was the use of validated instruments to measure main

outcomes. Also, a majority of the studies had the approval of an ethics committee and reported information on their inclusion/exclusion criteria for the sample, the period of time in which the sample was recruited and data was collected, and the exact p -values for main results. On the other hand, around sixty percent of studies included analytic strategies to control for the main potential confounders, mostly the half of studies reported the proportion of participants that agreed to participate, but less than forty percent of studies included estimates of the internal reliability of the instruments used. Finally, there was a low compliance with standards of quality regarding the use of random sampling methods to recruit participants, conducting a priori power analysis, making available the database used in a public repository, and pre-registration.

Discussion

The results of the study reveal that some critical components of high-quality research may be lacking in current studies on the mental health consequences of the COVID-19. Whereas most of the studies fulfill basic requirements of standard research (e.g., reporting basic descriptive statistics and inclusion/exclusion criteria), there are some worrying deficits regarding conditions that may pose a threat to the external validity of the studies and the generalisability and replicability of the results. In particular, there are serious flaws in regard to the representativeness of the samples, the quality of internet-collected responses¹⁵, the robustness of the measures used to estimate mental health problems in the studied samples, and the potential control of selective reporting. The low compliance with open science recommendations found in our review is in line with recent findings by Hardwicke et al., (2020), which revealed a reduced adoption of measures to increase replicability in social sciences. This fact, along with the mentioned methodological shortcomings, brings concerns on whether the research examined has potential practical

utility or may instead represent an obstacle to understanding the true impact of the COVID-19 pandemic on mental health.

As London and Kimmelman (2020) have defended, the logistic and practical challenges caused by the pandemic should not be an excuse to loosen up the criteria of quality usually requested in good science practices. Society does not need just data, but sound data. Poor designs and procedures of recruitment and the lack of representativeness of the samples may make findings worthless and being a waste of money and energy. Furthermore, flawed science may reduce trust in science, which is a relevant key for citizens to follow prescriptions during pandemics ¹⁷. Although it is understandable the urgency to conduct studies and publish results, a sound science is typically fed by reflection, research guided by hypotheses, and robust strategic plans. Behind the demand of quality in research in these difficult times, we should remind ourselves that “the moral mission of research remains the same: to reduce uncertainty and enable caregivers, health systems, and policy-makers to better address individual and public health” (London and Kimmelman, 2020; p.476). Otherwise, these efforts may be both as worthless and unproductive as unethical ⁵. We hope that the current study may help to provide information on the current initial orientation of research on mental health difficulties related to COVID-19 and sheds light on some potential obstacles and deficits that are hindering research quality of mental health issues.

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Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram.

Table 1. Percentage of studies meeting quality indicators

Quality indicator		
Ethics		
1	Approval of ethics committee.	71.4%
Reporting		
2	Description of participants' characteristics: inclusion and exclusion criteria for all participants (including control group, if applicable).	75%
3	Report of the period of time in which the sample was recruited.	78.6%
4	Report of estimates of the random variability in the data for the main outcome(s).	85.7%
5	Report of effect size(s) of main outcome(s).	96.4%
6*	Report of exact p-value(s) for the main result(s), except when the probability value is less than 0.001.	79.2%
External validity		
7	Use of random sampling methods to recruit participants.	10.7%
8*	Report of the proportion of participants that agreed to participate.	48.1%
9	Inclusion of a priori power analyses.	7.14%
Internal validity		
10	Use of previously validated instruments to measure main outcomes.	89.3%
11	Report of the internal reliability of measurement instruments within the study.	39.3%
12*	Inclusion of specific analyses to control for potential confounders (e.g. sex, age, health status, etc.).	58.3%
Open science		
13	Pre-registration of the study design, primary outcomes and analysis plan.	0%
14	Open access to databases (i.e. databases available in public repositories).	3.57%

Note: Quality indicators marked with an asterisk were not applicable in some cases. Thus, there were 27 studies that met the eighth indicator, while for the sixth and twelfth indicators there were 24 studies.