The Psychopathological Impact of the SARS-CoV-2 Epidemic on Subjects Suffering From Mental Disorders: Data From ASST Monza

The Impact of the COVID-19 (SARS-CoV-2 Disease) on Psychopathology

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STUDY PROTOCOL

Study design and participants

This is an observational retrospective study involving subjects evaluated at three time points: T0, corresponding to the outbreak of the pandemic (January-February 2020); T1, that was the lockdown period (the so-called "phase I", in March-April 2020); T2, corresponding to the reopening and restarting (the so-called "phase II", in May-June 2020).

Outpatients (aged 18-65) were recruited at three mental health services of ASST Monza: Cesano Maderno, Monza and Brugherio. Subjects were interviewed during psychiatric visits from November 12th 2020 until January 31st 2020 and information were collected retrospectively for the purposes of the study.

Inclusion criteria for both patients and HC consisted of: (1) being 18-65 years old; (2) ability to comprehend the Italian language; (3) ability to understand and sign the written informed consent. An additional inclusion criterion for patients was having a diagnosis of SKZ, BD, major depressive disorder (MDD), anxiety disorders, OCD or PDs according to the Diagnostic and Statistical Manual of Mental Disorders – 5th edition (DSM 5 – APA, 2013) criteria. An additional inclusion criterion for HC was living in the same geographical area of patients.

Exclusion criteria (for both patients and HC) were: (1) severe mental retardation; (2) pregnancy or post-partum; (3) presence of medical conditions potentially contributing to psychiatric symptoms (e.g. multiple sclerosis or re-exacerbation of inflammatory diseases); (4) treatment with compounds potentially involved in the onset or worsening of psychiatric symptoms (e.g. corticosteroids); (5) being health care workers involved in the sanitary emergency. Moreover, relatives of patients were excluded as HC.

All participants signed informed consent after the nature of the procedures had been fully explained. Study procedures were reviewed and approved by the local accredited Medical Ethics

Review Committee (named "Brianza Ethic Committee"). The research project is conformed to the provisions of the latest version of the Declaration of Helsinki.

Assessment

Data were collected retrospectively from patients' medical records or, in case they were lacking, by interviews to the patients or their relatives and caregivers. HC were asked to compile a questionnaire to collect the same data as patients. Information included demographic variables such as age, sex, educational level, occupational status and marital status, as well as clinical variables, such as family history of psychiatric disorders, lifetime substance misuse, substance poly-abuse 6 months before and 6 months after the pandemic, medical (co)-morbidity, medical poly-comorbidity, the presence of at least 2 COVID symptoms, and, for patients, diagnosis. The rating scales are routinely administered during patients' visits.

Primary outcomes

- Brief Psychiatry Rating Scale (BPRS) at T0, T1, T2;

- Clinical Global Impression (CGI) severity subscale at T0, T1, T2; improvement subscale at T1 and T2;

- Hamilton Anxiety Rating Scale (HAM-A) at T0, T1, T2;

- Impact of Event Scale – Revised (IES-R) at T1 and T2.

These rating scales were administered to all patients. HC were asked to retrospectively fill in the IES-R items referring to T1 and T2.

Secondary outcomes

- Disability Scale (DISS) at T0, T1, T2;

- Positive and Negative Symptoms Scale (PANSS), collected for SKZ patients at T0, T1, T2;

- Hamilton Depression Rating Scale (HAM-D) and Montgomery and Åsberg Depression Rating

Scale (MADRS), collected for MDD and BD patients at T0, T1, T2;

- Young Mania Rating Scale (YMRS), collected for BD patients at T0, T1, T2;

- Yale-Brown Obsessive-Compulsive Scale (Y-BOCS), collected for OCD patients at T0, T1, T2.

STATISTICAL ANALYSIS PLAN

Descriptive analyses of the entire sample were performed. Patients were divided into 5 groups according to diagnosis (SKZ, BD, MDD, anxiety disorders or OCD, PDs); multivariate analyses of variance (MANOVAs) and chi-square tests were used to compare groups on quantitative and qualitative variables respectively.

Linear regression models, adjusted for repeated measures, were applied to examine whether the change over time in psychometric scores differed between diagnostic groups and, for IES-R, between patients and HC. In the models, psychometric scores were treated as dependent variables. The model included fixed effects of time and diagnosis. The Akaike information criterion (AIC) was used to select the appropriate statistical model. The unstructured variance–covariance matrix was used to account for repeated measures within each subject. The significance was set at $p<0.05$.

Statistical Package for Social Sciences (SPSS) for Windows (version 26.0) was used as statistical program.