Psychotherapeutic and psychiatric intervention in COVID-19 patients and their relatives: the DigiCOVID trial protocol

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Abstract

Background: The COVID-19 pandemic is negatively impacting the mental health of both COVID-19 patients and the general population. As current guidelines are limiting in-person contacts to reduce the spread of the virus, the development of a digital approach to implement in psychiatric and psychological consultation is needed. In this paper we present the DigiCOVID protocol, a digital approach to offer remote, personalized psychological and psychiatric support to former or current COVID-19 patients and/or their relatives.

Objective: The main goal of this project is to evaluate the feasibility, acceptability and usability of the DigiCOVID protocol. Furthermore, we also aim to assess the impact of the abovementioned protocol by means of pre-post changes in psychological clinical variables.

Methods: Participants undergo an initial telephonic screening to ensure inclusion criteria are met. Secondly, participants complete a video-assisted neuropsychological IQ test, and complete online self-reports of health and general wellbeing. Participants are then assigned to a psychotherapist who offers 8 tele-therapy sessions. At the end of the therapy cycle, the online questionnaires are administered for a post-treatment evaluation.

Results: As of April 2022, we enrolled a total of 122 subjects, of which 94 have completed neuropsychological tests and online questionnaires.

Conclusions: Our study aims at testing the feasibility and preliminary efficacy of DigiCOVID, a remote tele-medicine protocol for the improvement of psychological and psychiatric health in COVID-19 patients and their relatives. To date, the approach used seems to be feasible and highly customizable to patients' needs, and thus the DigiCOVID protocol might pave the way for future tele-psychiatry-based interventions. Clinical Trial: This study was approved by our local Ethics Committee (IRCCS Ca' Granda Ospedale Maggiore Policlinico) on 28.10.2020. The trial is registered on clinicaltrials.gov with the following ID: NCT05231018.

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ABSTRACT

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Results: As of April 2022, we enrolled a total of 122 subjects, of which 94 have completed neuropsychological tests and online questionnaires.

Conclusions. Our study aims at testing the feasibility and preliminary efficacy of DigiCOVID, a remote tele-medicine protocol for the improvement of psychological and psychiatric health in COVID-19 patients and their relatives. To date, the approach used seems to be feasible and highly customizable to patients' needs, and thus the DigiCOVID protocol might pave the way for future tele-psychiatry-based interventions.

Trial registration. This study was approved by our local Ethics Committee (IRCCS Ca' Granda Ospedale Maggiore Policlinico) on 28.10.2020. The trial is registered on clinicaltrials.gov with the following ID: NCT05231018.

Keywords: telepsychiatry, telemedicine, COVID-19

INTRODUCTION

The pandemic of coronavirus disease 19 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is a severe and unprecedented event both for the general population and healthcare workers.

Northern Italy has rapidly emerged as one of the epicenters of the first COVID-19 outbreak. Indeed, the hospital in which our trial was designed and implemented, the fondazione istituto di ricerca e cura a carattere scientifico (IRCCS) Ca' Granda ospedale maggiore policlinico in Milan, was completely reorganized to face new cases in the Intensive Care Unit (ICU), which was paralleled by a large-scale optimization of the entire healthcare system [1, 2].

Current literature is focusing on the connections between COVID-19 and psychiatry, in particular concerning the development of post-traumatic stress disorder (PTSD) and related conditions in patients who contracted the disease [3]. Furthermore, evidence suggests that the pandemic itself might be a potential trigger for various other mental health diseases in the general population, with higher rates of psychological deterioration [4], a probable impact on the development of first episodes of psychosis [5], obsessive-compulsive disorder [6], depression [7], anxiety [8], phobic behaviors [9], addictions [10] and a general healthcare workers distress [11, 12]

In such a historical moment, it appears of paramount importance to prevent rather than treat psychological distress with every possible means available despite the limitations associated with in-person visits, social distancing and isolation [13, 14]. In fact, current 'shelter-in-place' guidelines and restrictions implemented by the public-health system to limit the diffusion of the virus, are significantly reducing in-person psychological and psychiatric consultations [15]. On the 24th of March 2020, the Ministry for Technological innovation and Digitalization, the Ministry of Health,

the National institute of Health and the World Health Organization together published a formal invitation to use telemedicine technologies more thoroughly in clinical practice [16].

A multitude of digital approaches have been tentatively operationalized worldwide to meet clinical needs, with COVID-19 serving as a catalyst for a change in the way instruments are used daily in healthcare settings [17]. Telepsychiatry, an innovative approach that consists of remote consultations and evaluations for mental health symptoms, has become a reliable alternative to face-to-face assessments, thus adapting rather than succumbing to COVID-19 [18, 19], and assisting those affected by the psychosocial consequences of the pandemic [20].

Aside from COVID-19 patients, the psychological aftermath of this pandemic interests to a similar degree those who have not contracted the virus, but have clinical conditions to manage, have lost family members or peers, are unable to enjoy the physical presence of their families, and have been living in restricted conditions for months. This phenomenon is likely due to the general psychological impact of the pandemic event per se, and to systemic modifications in family relationships with high amounts of stress also in healthy relatives [21, 22]. Incidence and prevalence of psychological distress have been skyrocketing beyond the possibilities of any mental health system to intervene with in-person services. This segment of the population has profoundly unmet clinical needs and increasingly requests access to psychiatric services.

In this paper, we aim to describe DigiCOVID, a digital mental-health protocol designed to offer remote, personalized support to former or current COVID-19 patients and/or their relatives. DigiCOVID includes psychotherapy sessions and psychiatric consultations depending on participants' needs. An observational longitudinal study in COVID-19 patients and their relatives is being conducted to investigate whether the intervention described above is feasible, usable and acceptable for the target population. Outcome measures include engagement rates with psychotherapy sessions and psychiatric consultations, overall program completion rates, reported adverse effects, usability ratings and clinician burden. The secondary objectives aim to: 1) evaluate if

DigiCOVID induces changes in self-reports of anxiety, depression, insomnia, trauma, and quality of life; 2) determine whether DigiCOVID impacts COVID-19 patients and family members differently.

METHODS

Overall design and timeline

The study is conducted jointly by the units of pneumology, internal medicine, psychiatry, and by the laboratory of brain injury and therapeutic strategies of the istituto di ricerche farmacologiche Mario Negri. Before accessing DigiCOVID, participants are taken through the following steps. First, participants undergo an initial screening to ensure the main inclusion criteria are met. Then, two trained neuropsychologists remotely perform neuropsychological tests on patients via Zoom. The tests are aimed at assessing patients' intelligence quotient (IQ) through the test di intelligenza breve (TIB) [23] and standard progressive Raven matrices (SPM) [24]. Suicidality is assessed via the Columbia-suicide severity rating scale [25]. Finally, participants complete a battery of online self-reports that include: the general health questionnaire (GHQ-12) [26], the impact of event scale–revised (IES-R) [27], the general anxiety disorder-7 (GAD-7) [28], the insomnia severity index (ISI) [29], and the patient health questionnaire (PHQ-9) [30]. After completing these assessments, participants are assigned to a trained psychotherapist who offers eight tele-therapy sessions carried out through Zoom.

This model is designed to be applied to COVID-19 patients during hospitalization, after discharge, during the remission and recovery phases. Similarly, this model is intended to be delivered to people who are dealing with the hospitalization for/discharge after COVID-19 of a family member, or have lost a family member due to COVID-19. Eight, remote, 50-minute, individual psychological sessions are offered weekly using secure video conferencing software. The severity of the clinical conditions of COVID-19 patients has largely influenced the sequencing of the intervention.

During all phases of the clinical work, suffering is contextualized both in the light of the recent

traumatic experience (bereavement, hospitalization in intensive care, fear for one's life or that of a relative), and in the light of historical ways of suffering, so that the patient is able to recognize the meaning of the symptoms experienced.

We considered it appropriate to circumscribe the exploration of the different psychological targets within each session, given the unpredictable nature of the course of illness, and the possible onset of events that radically change the psychological state of patients and family members. What follows is a very schematic summary that refers to the "ideal" situation, where clinical conditions (of the patient, or of the relative of the patient) evolve linearly toward recovery.

Session 1 includes Introductions exploration of the patient's current experience space as well as identification of the areas of suffering and brief recapitulation of the patient's psychological functioning pre-COVID. Session 2 Attempts to define shared goals for the therapeutic process and creates an initial diagnostic framework identify unprocessed or unregulated emotions. Session 3 aims to Validate the intrapsychic and interpersonal resources associated with a greater degree of adaptation to the stressful situation, including: a flexible personality; positive beliefs about the self; identity roles and acceptance and commitment skills; work functioning; solid network of friends; family/loved ones. In Sessions 4 through 6, areas of clinical concern are Addressed and defense mechanisms are investigated. Session 7 aims to integrate the lived experience in the cohesive narrative of the self. In Session 8, internal working models or relational patterns that have emerged during therapy closure are discussed and psychoeducation on relapse prevention is offered. At the end of the abovementioned cycle, participants repeat the battery of online self-reports.

The following paper follows the SPIRIT guidelines for the trial's publication, as suggested by the EQUATOR Network.

The trial is registered on clinicaltrials.gov with the following ID: NCT05231018. To note, the protocol has been registered as it was designed at the beginning of the project – i.e. it did not include relatives, but only patients. Given the high number of requests, and because the intervention is

customizable to each patient's clinical needs, we have decided to extend our intervention to relatives, thus explaining the differences between the registered protocol and the present methodological paper. Regarding the gap between the registration and the trial start, the internal organization of our research unit does not require the registration of trials that do not involve drugs and placebos. Therefore, the trial has been registered on clinicaltrials.gov to improve the recruitment process.

Study population

Our population of interest includes COVID-19 patients previously or currently hospitalized at the Foundation IRCCS Ca' Granda Ospedale Maggiore Policlinico and their relatives, according to inclusion and exclusion criteria.

Inclusion criteria

The inclusion criteria for our study consist of:

1. Age 18-80
2. A positive COVID-19 test at the moment of enrolment for subjects in the 'patients' group
3. Adequate sensory and motor abilities, without impairments in vision, hearing and handling devices
4. Access to Internet wireless technologies.
5. A good level of Italian in terms of speaking, reading and writing.

Exclusion criteria

1. Present of past medical history of schizophrenia, schizoaffective disorder, delusional disorder, bipolar disorder, current substance abuse, all according to the diagnostic and statistical manual fifth edition (DSM-5) [31].
2. With a diagnosis of cognitive impairment and/or dementia (e.g., mild cognitive

impairment, Alzheimer's disease, Parkinson's disease);

3. Intellectual disability defined by a total IQ < 70 as obtained by the TIB [23] or SPM [24]
4. Severe present medical conditions that could interfere with participation.
5. Present or past suicidal ideation or commitment.
6. Significant impairment in the use of digital and technological devices, in questionnaires and test completions, comprehension or with lack of a compliant behavior in the earliest evaluations.
7. Being enrolled in other clinical trials assessing any psychological, or experimental pharmacological treatment.

Recruitment

As of April 2022, 122 subjects have been referred to the study. Participation is voluntary, and an extended informed-consent form is signed before any evaluation, assessment or voice/video call. Consent forms are collected remotely for those who have been discharged and are currently in remission: and in-person for subjects hospitalized in a COVID-19-ward of either pneumology, internal medicine or infectious disease departments.

Primary and secondary outcome measures

Primary outcome measures

Efforts will be made to assess all participants who have completed the minimum required intervention activities: for DigiCOVID, minimum required intervention activities include attending psychotherapy sessions at least 4 times. As the main goal of this project is to evaluate the feasibility, acceptability and usability of DigiCOVID, we will conduct an analysis of the following primary outcome measures in all ITT participants:

1. Assessment completion rate. Based on our previous studies, we expect that ≥80% of participants will complete the battery of online self-reports:
2. Usability ratings obtained post-DigiCOVID via a 7-point Likert-scale questionnaire (mean rating of all responses). This is a brief and embedded post-study questionnaire on program satisfaction, clarity, and perceived benefits. Participants will rate each sentence on the following 7-point Likert scale: 1 = completely agree; 2 = mostly agree; 3 = somewhat agree; 4 = undecided; 5 = somewhat disagree; 6 = mostly disagree; 7 = completely disagree. Based on our previous studies, we hypothesize exit survey ratings of at least ≥4.5 ±1.5 on the 7-point Likert scale items;
3. Reported side effects (raw score). Based on our previous findings, we expect 0 adverse events due to program use;
4. Overall program completion rate. Based on previous findings, we hypothesize full program completion in ≥ 70% study participants.

Secondary outcome measures

The secondary outcome measures will be collected at baseline and immediately after the treatment for all participants. We designed DigiCOVID to improve mental wellbeing. Therefore, we will measure the impact of the intervention by looking at pre-post changes in the following outcome

measures: the GHQ-12 [26] , the IES-R [27], the GAD-7 [28], ISI [29], and the PHQ-9 [30]. We expected to observe a significant improvements across all these secondary outcome measure in both COVID-19 patients and family members. To verify these experimental hypotheses, we will conduct the analysis based on the pre-intervention (baseline) and post-intervention data using parametric and non parametric statistical tests. The criterion for statistical significance is $p < 0.05$. Results with $p < 0.1$ will be described as trends.

Data collection

The sources of the research material will consist of data collected through assessments visits and the DigiCOVID app, strictly for research purposes. Participants will be carefully screened for contraindications prior to participation. All intervention data are coded so as not to identify any given participant and securely stored. Hard copy data from the neuropsychological tests will be stored in a locked file cabinet in a safe location with limited access by authorized personnel or on password protected computers in locked offices. All data from this trial will be recorded on Data a secure, web-based software application designed to support data capture for research studies. To achieve robust and unbiased results, data will undergo a rigorous quality control process to ensure consistency in scoring, coding and accuracy of data entry. Standard data quality procedures will be used, including double scoring and random spot checking of assessments and electronic data capture. Additionally, 20% of all data folders will undergo a random audit every 3 months. The database will be designed to not allow illegal values in entry. Any outliers will be double-checked with the raw data for accuracy.

Data analysis

There are three a priori defined analysis populations, including a primary analysis population (i), a secondary analysis population designed to compare effect sizes in populations with no missing data

(ii), a population who completed all study visits (iii).

1. Intent to treat (ITT) population: This is the a priori primary analysis population, defined as including all participants who attended at least four remote psychotherapy sessions.
2. Intent to treat fully-evaluable (ITT-FE) population: This is a secondary analysis population, defined as including all members of the ITT population that complete a post-intervention visit. Note that a participant may complete a specific visit but have missing data for a test in which case the participant is in the overall ITT-FE population but does not contribute data to the ITT-FE population for that visit (e.g., the number of evaluable cases for a specific test on a specific visit may be smaller than the ITT-FE population for that visit, because of missing data).
3. Intent to treat completers (ITT-C) population: This is a secondary analysis population, defined as including all members of the ITT-FE population who complete all intervention sessions. Note that the ITT-C population is a strict subset of the ITT-FE population; a person who completes the treatment but does not complete the post-intervention evaluation visit is not a member of the ITT-C population.

We also plan to perform different analyses in order to better describe the demographics of patients and relatives, and also to test whether there are significant differences in terms of response to our psychotherapy intervention.

Ethics approval

This study was approved by our local Ethics Committee (IRCCS Ca' Granda Ospedale Maggiore Policlinico) on 28.10.2020.

RESULTS

The current project has been funded in June 2020. As of April 2022, we enrolled a total of 122 subjects, of which 94 have completed neuropsychological tests and online questionnaires; data

analyses are currently completed in terms of preliminary results, and we expect results to be published by the end of 2022.

DISCUSSION

This paper describes the methodology adopted to remotely assess and promptly treat psychiatric symptoms in a sample of COVID-19 patients and their first-degree relatives. This digital approach is showing its innovation potential by allowing to manage the psychological suffering caused by the pandemic in COVID-19 patients and/or their relatives.

We expect, as a prediction of our hypotheses, that the DigiCOVID protocol will result in a feasible approach: such a claim is clearly a hopeful statement, yet based on the quick, efficient and technological step-procedure described earlier. In terms of descriptive statistics, we might observe slight differences in terms of symptoms between patients and relatives (i.e. in the post-traumatic scale, which we expect to be higher in patients rather than relatives). In conclusion, we also expect the DigiCOVID protocol to be effective both for patients and for their relatives in diminishing psychological distress. Future directions might involve the standardization of the DigiCOVID protocol in COVID-wards, as part of a complete program for the treatment of COVID-19 patients and subjects who might not have the opportunity to move and to see a professional if not remotely.

To date, we are completing the rectuitment and we are expecting future and conclusive analyses to determine the efficacy and effectiveness of the procool.

Strengths

This project has several lines of innovation. First, the length of the intervention is in line with services routinely offered by the Italian National Health Service (eight-week cycle of psychotherapy sessions) – which makes the implementation of this remote approach feasible and acceptable. Secondly, thanks to the data from the self-reports collected before the intervention starts,

psychotherapists have the opportunity to rapidly customize treatment goals and spare time usually spent collecting past and current psychiatric history. Third, the remote psychological support offered to first-degree relatives

can increase personal resources, positively impact the resources of the family, reinforce familiar bonds, ultimately producing better psychological prognoses for patients. If proven successful and efficacious, this intervention protocol could be standardized and disseminated at a large scale, helping clinicians remotely treat psychological distress, thereby alleviating at large the mental-health consequences of the COVID-19 pandemic.

Limitations

Some limitations have emerged as we operationalized this project. First, we observed a lack of motivation in some patients, likely caused by the remote technology-based approach. Second, even if telepsychiatry has been proven efficacious in assessing patients remotely, psychologists and psychiatrists are asked to adapt their methods of assessment, diagnosis and treatment to new means of communication. The dissemination of this digital approach at a national level may require additional training for mental health professionals to ensure impact and effectiveness of this promising intervention.

ACKNOWLEDGEMENTS

None.

DATA AVAILABILITY

The data sets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

CONFLICTS OF INTERESTS

The authors declare that no conflict of interests is present.

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ABBREVIATIONS

All the abbreviations used in this article are listed as follows in alphabetical order.

COVID-19: coronavirus disease 19; DSM-5: diagnostic and statistical manual fifth edition; GAD-7: general anxiety disorder-7; GHQ-12: general health questionnaire; ICU: intensive care unit; IQ: intelligence quotient; IRCCS; istituto di ricercar e cura a carattere scientifico; ISI: insomnia severity index; ITT-C: intent to treat completers; ITT-FE: intent to treat fully evaluable; ITT: intent to treat; PHQ-9: patient health questionnaire; PTSD: post-traumatic stress disorder; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2; SPM: standard progressive Raven matrices; TIB: test di intelligenza breve (Italian for brief intelligence test);