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Recovery and values in psychosis: is there a place for connection?

Dalila Talevi, Alessandro Rossi

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The conclusion of either the pathological process or the disease cycle, both from a clinical and anatomopathological point of view is what medicine means by outcome. Leaving out here the anatomopathological issues, a disease evolution may result in healing, chronicity or death. From a psychopathological perspective, symptoms reduction and social functioning improvement have always been regarded as the two most important outcomes in schizophrenia¹⁻³, although the changes of these domains do not go hand-in-hand⁴. In recent years a “new psychiatry” is emerging, that aims not simply at the achievement of symptoms relief and social abilities, but to a “recovery”⁵⁻⁷. Recovery has received an increasing attention in mental health. However, it is also clear that the term “recovery” has been used in different ways with different meaning.

Two types of recovery

The concept of recovery can be broken down into clinical, or objective, and personal, or subjective, domains. “Personal recovery” stands for “a deeply personal, unique process of changing one’s attitudes, values, feelings, goals, skills and/or roles. It is a way of living a satisfying, hopeful, and contributing life even within the limitations caused by illness. Recovery involves the development of new meaning and purpose in one’s life as one grows beyond the catastrophic effects of mental illness”⁸. In simple terms, the principles of personal recovery are based on the belief that a meaningful life is possible, despite symptoms persistence. This positive approach to mental illness does not focus on full symptoms resolution but promotes resilience and control over problems and life. It endorses the idea that people previously diagnosed with severe mental illness have vocational, educational, and residential needs, beyond symptoms reduction. They have the right to be treated and to have an active part in therapeutic decisions. They are indeed able to establish independent and healthy lives even in the presence of symptoms^{5,6}.

Beyond recovery from schizophrenia

Literature about the long-term course of schizophrenia is uneven. Recent observations suggest that recovery with good outcome in psychoses is a possible achievement^{2,7,9}, occurring in four phases: 1) feeling overwhelmed by the disease; 2) struggling with the disease; 3) living with disability; 4) living beyond the disability.

Subjective and objective elements of recovery reflect different perspectives in schizophrenia outcome, not necessarily concordant with each other and usually representing the consumer’s or the therapist’s point of view⁹.

A number of variables related to personal resources such as resilience, self-esteem, coping styles, internalized stigma and happiness have been associated with a positive outcome in schizophrenia, so that patients with comparable severity of psychopathology may differ in their real-life functioning⁹. These variables have been observed to mediate the impact of symptoms and cognitive impairment on real-life functioning in subjects with schizophrenia and first-degree relatives suggesting that the two domains of recovery are more complementary than incompatible⁹. This finding suggests that specific treat-

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ments aimed to reduce stigma, improve coping strategies and shape recovery styles might be efficacious in producing considerable clinical and functional improvements ^{2,9}.

From recovery to values and back

Personal recovery could be pursued through spiritual, ethical, and human rights/social capital approaches if its conceptual framework is described in a scientific manner ⁷. Kasai and Fukuda ⁷ stated that users, caregivers, and professionals could contribute to the users' personal recovery and subjective well-being if we scientifically redefine a person's "value" or "personalized value". "Values" are motivational constructs guiding behavior, abstract trans-situational goals that reflect what people think and state about themselves and regulate principles in people's lives ¹⁰. In the proposed model, living in the "real-world" impacts on values development, that then influences patterns of actions in life and in turn inducing plasticity in the brain circuit ⁷. These interactions acquire importance especially in adolescence. Schizophrenia research is a promising field for the exploration of the value-based approach, since developmental psychopathology, psychology and neuroscience in adolescence, and functional impairment are core domains of pathological pathways ⁷.

Huguelet and colleagues ¹¹ found that the association between symptoms and meaning was mediated by values. "Meaning" is concerned with one's goal in life. Spirituality, self-esteem and close relationship are determinants of meaning. More significantly, the fulfillment of values allows subjects to achieve a sense of meaning. Hence, depression, hopelessness, self-esteem and the number of relationships influenced values in a heterogeneous clinical sample; the presence and an enactment of values were associated with meaning that, in turn, was associated with some symptoms and social characteristics. Globally, usefulness of values in influencing actions, predicting attitudes, preferences, goals and, sometimes, reflecting personality

traits has been studied by many authors: personal values were found to predict mental health indicators in non-clinical samples ¹² and stigmatization in clinical samples ¹³. Personal values can be directly related to "negative" behaviors such as interpersonal violence ¹⁰. It is reasonable to assume that achievement of this kind of behavior is related to the motivational structure of a given value for a given person. It can be argued that, for some people, motivational structure could deviate from a harmonic development ¹⁰. Moreover, some preliminary findings suggest that subjects with severe mental illness could be prone to report higher "conservation" values in comparison to non-clinical samples. The greater expression of conservation values could reflect an orientation toward conformity underlying fundamental affiliative goals, that, in turn, are strongly activated by stigmatization and threats for self-esteem.

Future developments

All the observations mentioned above open new scenarios in the "recovery" perspective.

Emerging literature supports the relevance of addressing values and meaning in the recovery-oriented care of patients with persistent mental disorders ¹¹. Since recovery is a personal and subjective experience, and values influence the sense of meaning in life by interacting with behavior and mental indicators, tailored intervention targeting personal values and meaning in life should be fulfilled ⁹. Moreover, preliminary findings suggest that tailoring psychological interventions to values assessment and negotiation in clinical populations could help reduce risky behaviors ¹⁰, which in turn, is associated with worse psychopathological pictures and impaired social functioning. In conclusion, the integration of subjective and clinical models would yield a better assessment and overall understanding of recovery and contribute to design individualized and integrated treatment programs aimed to help individuals to live a meaningful and satisfying life ⁹.

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Contagion: society, brain and culture

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The pandemic of the century?

COVID-19 have been described as an infectious disease, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). In the last months, this virus has infected millions of individuals, and killed more than three hundred thousand people around the globe. To date, COVID-19 has been described as the pandemic of the century ¹. Governments around the world have raced to contain and fight the pandemic process, while facing relevant issues on healthcare structures, on the economic system, on the social context. The main threat posed by this new disease lies in its infectiveness. The average infected person spreads the virus to 2-3 others, leading to an exponential curve of increase. Mildly ill or pre-symptomatic subjects are also infective. This situation has led to a serious health threat not only to elderly people with existing health problems, but also to healthy adults. In the last months we have observed how the effect of the pandemic has extended beyond the clinical field, directly affecting our lives. Meanwhile, there is evidence supporting the view on how the COVID-related panic manifestations travel faster and further than the disease itself ^{2,3}. This dramatic phenomenon calls for a broad reflection, a pause and a recollection that might foster specific and accurate scientific works in the immediate future. Today, we are called upon to investigate the contagion.

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The burden of contagion

As Neil Greenberg and colleagues have pointed out ⁴, the COVID-19 pandemic is likely to pose a serious risk to healthcare professionals around the world. Given the novel nature of COVID-19, and its sudden outbreak, many healthcare systems faced the emergency with scant supplies, inadequate testing and limited treatment options. This in many cases led to an increased workload for practitioners. As a matter of fact, the present pandemic process has all the potential to overwhelm a national health care, in the present context ⁵.

There are several problems at stake here. First there is the problem of medical decision, since the actual resources resulted scant in the face of the expected number of patients. At the same time, there are no true and tested protocols for this infection. Even given the increased response from research, an effective clinical management of COVID-19 may have been described too late. Moreover, we should consider the rapidly increasing number of patients, a condition that may lead to exhaustion and/or overworking. Lastly, the lethality of COVID-19, and its infectiveness, may forcefully place the practitioners at risk of death. This stands true in the case of unfavorable treatment outcome and if we consider the risk of infection for healthcare professionals. The practitioner, especially when facing an infectious disease for a prolonged time, may become infected, and may pose a risk to his own family.

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This point alone suggests an increase of risk of relevant psychopathologic injury, in particular of Post-Traumatic Stress Disorder (PTSD) amongst healthcare workers during COVID-19. In this context, several preliminary studies are already available, stressing the insurgence of a new, increased risk related to the pandemic ⁶⁻⁸.

Extending the range of our considerations, one of the primary medical concerns in a population affected by a disaster is actually PTSD ^{9,10}. Whether or not pandemic event fulfills the criteria for trauma required by DSM-5 can be a point for debate; however, given the death rates, such discussion may take a very academic turn, swaying from the simple empiric observation that, to some people, pandemic process has represented exposure to a very menacing risk factor.

Moreover, beyond the stressors inherent to the pandemic process and fear of infection itself, mass home-confinement governmental resolutions (implements of smart working, quarantine, social distancing and domestic confinement) are scantily represented (and understudied) in contemporary western societies, and may be a cause for raised concern and increase in stress level. As a matter of fact, preliminary studies suggest that the contemporary quarantine is likely to have a non-neutral effect on the psychological subject ¹¹.

Thus the last few months has seen the increase of several factors of psychiatric concern, amongst both healthcare workers and the general population. It could very well be that after the COVID-19 pandemic an increase of PTSD cases will be detected.

From culture to brain, and all the way back

Many words related to infective disease have semantic and philological roots in the broad idea of "touching". The word "infection" comes from the latin *inficio*, a verb whose original meaning is "to stain, to dye by immersion". *Inficio* proposes the idea that "something may pass" from one object to another, in certain conditions. Precisely in the way that a tissue, put in a vat containing colourants, changes its colour through contact, so the human being, in certain environments, may be "infected" with something, causing a move towards change. A similar etymology furnishes the now outdated word *miasma*, which has been for a long time a staple for medical etiology. Its origins lie in the greek word *μιαίνω*, another verb related to dying. Unsurprisingly, even the word "contagion" recalls the idea of touch. It comes from latin *contagium*, meaning "contact" and is a derivative of *tangere*, "to touch".

In psychiatry, touch has been described as a relevant dimension in human psychology and psychopathology. Physical contact is not a neutral stimulus, and depending on the context it is an element of comfort or distress ¹². Classical anthropologists have suggested that

"contagion" is one of the main "laws" of primitive/magical thinking, according to the principle "once in contact, always in contact": a number of cultures and societies have "models" that describe or account for "contagious magical effects" ¹³.

In this broader sense, contagion is somewhat of a "total concept", an almost ubiquitous category. As touch is an immediate effect of the division between the Self and the Other, contagion appears as the broad field of experiences and phenomena fostered by the effect of touch. In this sense, contagion may be "good" as well as "bad". Touching (or being "dyeed by") the wrong environment may "magically" transform the healthy individual into a "sick" one. However, the contact with pure persons or things can heal. We all recall how many European kings claimed to possess a holy "healing touch"; and at the same time contact with a sacred relic or place has long been believed to be a powerful cure towards many bodily ailments ¹⁴.

One might wonder why contact is so important in human cultures, how this bodily sensor gateway has long being suspected of being strictly linked to concepts such as "health" and "illness". The principle "contact cause influence" might be learned during the development, a theory already suggested by some classic literature.

From a neurobiological point of view, it is not a surprise. As an example, in preterm infants, massage has shown positive effects on neurodevelopment as detailed by neuroimaging studies ¹⁵.

Inquiring contagion: psychiatric perspectives

Contagion is thus a cultural and a biological fact, a reality of the body and a relational one. As such, we have tried to investigate this dimension in the recent book, *Contagi*, which focuses on the current impact of COVID-19 on our society. Starting from the development of Italian lockdown and proceeding through the psychobiography of painter Edvard Munch, we have tried to describe how the empirical reality of contagion, and its cultural significance and value, translate into psychopathology. Contagion, as a whole, is a historical and anthropological fact, with complex branching effects that range from art to literature. In Munch's life, the effect of illness and death is reflected by the artistic path, a theme that dominated his life and his illness trajectory, in which post-traumatic stress symptoms are the first step. How the remission of psychiatric symptoms changed Munch's artistic expression, from *The Scream* (1893) to *The Sun* (1916) of the Aula of the University of Oslo, is probably not an idle observation ¹⁶.

There are several points of interest in the complex subject of contagion, considered under a psychopathologic light. The first and most obvious one has been

discussed above, and it is represented by the effect of trauma and stress on individuals¹⁷. A disease such as COVID-19 poses a potentially fatal threat, and should be considered as such. High levels of stress may be detected in healthcare professionals, public workers, infected individuals, and families under strict quarantine (or those with one or more members affected by the disease). Moreover, there are collateral stressors to be considered such as complicated grief¹⁸, for instance, in those survivors who lost a beloved one and were also unable to perform proper funerals.

However, stress is not the only relevant stimulus here. Stringent lockdown conditions mark an unusual situation, and one that can cause otherwise stable situations to suddenly worsen. The “pandemic state” of our society may lead to a recurrence of previously remitted clinical pictures for many psychiatric patients, or amplify sub-threshold anxiety symptomatology even precipitate mood symptom onset and psychotic breakdowns. How-

ever, a very productive approach may also be one able to analyze the many factors (genetic, developmental, environmental) related to the trajectory of illness, ranging from subthreshold and atypical symptoms to full-blown, overthreshold disorders. In the population facing pandemic (considered both on a social and on an epidemic level) a continuous distribution of effects could be expected, in the shape of a Gaussian curve. Also, parameters such as suicide rates, self-harm behaviours incidence, and suicidal risk should all be closely monitored, as these variables are likely to fluctuate during and after quarantine measures, both for the immediate stressors and for the long term economic effect of this pandemic.

Concluding, it can hardly be denied that the COVID-19 pandemic will be posing new challenges to contemporary psychiatry. Psychopathologic research, among all other branches and sub-specializations of our field, should be ready to answer this call to action.

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Practical prescribing with COVID-19 medications and psychotropics: a guide to pharmacokinetic interactions

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SUMMARY

Background

The risks of pharmacological interactions increase significantly with the number of drugs a patient is prescribed. Patients with coronavirus (COVID-19) infection and mental disorders often receive several medications, and they may interact.

Methods

We examined the existing literature with the goal to: 1) review the bases of pharmacokinetic interactions between psychotropics and medications that are prescribed to treat COVID-19 infection and its complications; 2) examine the implications for clinical practice.

Results

Pharmacokinetic interactions are possible and may cause adverse effects or decrease the efficacy of one or more of the medications a patient is taking.

Conclusions

A thorough evaluation of the pharmacokinetic interactions is necessary when COVID-19 medications are prescribed to patients with mental disorders that are treated with psychotropic medications. The risk of pharmacokinetic and pharmacodynamic interactions should inform treatment choice and may require dosing adjustments.

Key words: Coronavirus, COVID, interactions, psychotropics, psychiatric, pharmacological, medications, cytochrome, inhibitor, inducer

Introduction

Although COVID-19 pandemic seems to have subsided in some Countries, the illness is continuing its spread across the world. As of June 7, there were about 7 million confirmed cases in 188 countries¹. To date, the time and way in which the pandemic will end is impossible to predict and this is made more complex because of issues such as easy transmissibility, relatively long time (2-10 days in most cases) before the symptoms appear, and inter-individual differences in terms of symptoms that are developed, going from no to deadly symptoms².

Patients with mental illness are at risk of being infected at least as much as everyone else. The infection, or the worry about the risks and consequences of getting infected, may worsen existing mental disorders or contribute to the onset of new diseases.

The risks of pharmacological interactions increase significantly with the number of drugs that a patient receives³. Patients with coronavirus (SARS-CoV2 or COVID-19) and mental disorders often receive more than one medication and therefore the risk of interactions is relatively high. Indeed, COVID-19 causes delirium in a significant proportion of acutely infected

patients and increases the risk for anxiety, depression, or post-traumatic stress disorder. Given that patients with mental disorders may be infected with COVID-19 and patients with COVID-19 may develop a mental disorder, the number of people that are prescribed a psychotropics and COVID-19 has increased. We hereby review the bases of drug-drug interactions and examine the possible interactions between psychotropics and drugs that are most frequently prescribed as a treatment for COVID-19.

Disclaimer

Information presented in this paper is intended only as a partial summary of data available in the public domain. No clinical consultation or advice is implied or given for any specific patient. Clinicians must exercise their own judgement and evaluate the risks and benefits of single and combined medications, which includes but is not limited to the evaluation of pharmacokinetic and pharmacodynamic interactions between two or more medications. The clinician is the only and ultimate responsible for treatment choice and administration, after consulting all the available sources, not limited to this manuscript. The prescriber shall hold the Authors, Editors, Reviewers and Publisher harmless against any consequences arising from the use or application in clinical practice of any information reported in this paper.

Drug-drug interactions

A drug-drug interaction occurs when one drug alters the levels or the pharmacological effects of a second drug. Clinically significant interactions may substantially alter, boost or lessen the activity of one of the drugs, or both. Pharmacological interactions are usually described as either pharmacodynamics or pharmacokinetics. Pharmacodynamic interactions take place at the organ or at the receptor level. Pharmacokinetic interactions, on the other hand, occur when a drug interferes with the absorption, distribution and transport, metabolism or elimination of a second drug. For example, both benzodiazepines and alcohol act on the GABA A receptor, increasing the conductance to chlorine, decreasing neuronal activity and determining a series of clinical effects, including sedation, reduction of anxiety, muscle relaxation and amnesia. If benzodiazepines and alcohol are taken together, a pharmacodynamic interaction occurs, resulting in an excess of the effect that these substances individually would produce, or excessive sedation, motor defects and respiratory depression, which can be fatal ⁴.

Pharmacokinetic interactions, on the other hand, occur when a drug interferes with the absorption, distribution and transport, metabolism or elimination of a second drug ⁴. Alterations in absorption occur in the gastrointestinal tract, for example if a drug causes a change in

gastric pH, a mechanical blockage of the mechanisms responsible for absorption or a modification in the bowel flora. The alterations in distribution and transport occur instead when, for example, two drugs bind to the same transport proteins. In this case, the drug that has the greatest tendency to bind will increase the concentration of the free fraction of the second drug, which is pharmacologically active. An example of a therapeutic substance very sensitive to protein-related displacement is warfarin. Metabolic interactions occur instead when a drug reduces or accelerates the enzymatic metabolism by one second. This is the most frequent pharmacokinetic interaction. Finally, an interaction in the elimination happens when a drug reduces the excretion of a second medicament, for instance when the lithium and some diuretics are administered concurrently ⁵⁻⁹.

Biotransformation

The biotransformation of a medication usually goes through two phases: phase 1 and phase 2 ¹⁰. Phase 1 occurs mainly in microsomes and concerns functionalization through oxidative reactions such as O-dealkylation (for example codeine), N-dealkylation (for instance imipramine), aliphatic hydroxylation (which concerns midazolam), aromatic hydroxylation (amphetamines), n-oxidation (for example acetaminophen), S-oxidation (which concerns chlorpromazine), or deamination (for example diazepam) ¹¹. This process makes the substances more manageable for phase 2. phase 2 concerns conjugation, via endogenous cofactors (such as glucuronic acid, sulphate, glycine) that act on the functional groups present in the substance or introduced during phase 1. The enzymes involved are a group of transferases that transfer the cofactor to the substrate ¹¹. The result is an amplification in polarity and the potential for urinary and biliary excretion. While most conjugations hesitate in a biological inactivation or detoxification, in some cases they can give a bioactivation. Most of the enzymes involved in phase 2 are allocated in the cytosol, with the exception of uridine-diphosphoglucuronic-transferase (UDPTG), which are microsomal. Phase 2 reactions are typically faster than phase 1 reactions which act as a stopper in the metabolism path. Some medications are metabolized through phase 1, followed by phase 2, others are metabolized only through phase 1 or only through phase 2 ¹⁰.

Phase 1

The most important enzyme system that presides phase 1 is the cytochrome P 450; in nature there are more than 200 P450 enzymes, of which at least 40 have been categorized in humans. However, six isoenzymes are involved in least 90% of the entire enzyme activity of cytochrome P450: 1A2, 2C9, 2D6, 2C19, 2E1, and 3A4; all

these enzymes are located in the smooth endoplasmic reticulum of the hepatocytes and in the luminal epithelium of the small intestine. There is a genetic variability (polymorphism) of CYP P450 and marked differences may exist between individuals of different races. Each person has two copies of each gene (allele); variations of the common alleles are generally described as “genetic polymorphisms”. Individuals with a genetic polymorphism characterized by a malfunctioning allele or the absence of an allele are defined as “poor metabolisers”, instead subjects who have several copies of the common alleles are described as “ultra-rapid metabolisers”¹². A common drug interaction mechanism occurs through the inhibition or induction of the CYP P450 system. The affinity of a drug for CYP P450 is called inhibitory potential or K_i ; K_i values lower than 2 micromoles are typically indicators of a powerful inhibition. When two drugs are administered simultaneously, the drug with higher affinity (low K_i) competitively inhibits the binding of the drug with less affinity (high K_i)¹²⁻¹³. Some drugs bind to an enzyme and inhibit it, without however needing that enzyme for their own metabolism, while other medications are both substrates and enzyme inhibitors. Inhibition of the P450 system is immediate and when treatment with the inhibitor is stopped the system quickly returns to normal functionality. Certain drugs and substances, such as cigarette smoke, induce the synthesis of P450 proteins and increase the number of sites available for biotransformation, with consequent loss of efficacy for medications that are deactivated by that system or risk of drug toxicity with potentially harmful metabolites¹⁰⁻¹³.

Cytochrome P450 2D6

Cytochrome P450 2D6 (CYP-450-D6) is located in the endoplasmic reticulum and intervenes in the oxidative metabolism of a series of exogenous or endogenous compounds through hydroxylation, dealkylation or demethylation reactions. For example, 2D6 is responsible for activities such as the hydroxylation of tricyclic antidepressant drugs, the N-demethylation of fluoxetine, and the N-dealkylation of metoclopramide, the hydroxylation of progesterone¹⁰⁻¹³. The cytochrome 2D6 gene is located on chromosome 22, with more than 30 polymorphisms that have been reported. Recent studies have indicated the presence of a high percentage (up to 50%) of poor metabolizers (or zero metabolizers) in people of Asian, African, or African-American origin and of the Pacific islands. In the Caucasian race, this percentage is “only” 26%. The metabolism of drugs oxidized through 2D6 is obviously altered in these patients¹⁴⁻¹⁷. For instance, risperidone is normally converted from 2D6 into its 9-hydroxy metabolite. If a person is a poor (or, even more so, null) metabolizer, the medication is

obliged to “choose” as the main metabolizer the 3A4 isoenzyme, for which it has less affinity and the patient will have higher blood levels of risperidone, and more side effects¹⁸.

Genotypic analyzes of cytochrome P450 are possible, especially in cases where a drug with a narrow therapeutic index is prescribed.

Cytochrome P450 3A4

Cytochrome P450 3A4 (CYP-3A4) is certainly the most represented in humans and presides more than 50% of all drug-oxidation reactions in the liver⁸. Like 2D6, 3A4 intervenes in the phase 1 oxidative metabolism of exogenous and endogenous compounds, for example steroid hormones, cholesterol or lipids⁹⁻¹³. Although 3A4 polymorphisms have been described, the clinical significance is still at the center of controversy and debate. What is certain is that 3A4 is part of the 3A sub-family (the other variations are 3A5 and 3A7) and that the enzymatic activity of 3A changes according to the percentage in which the three variations are expressed¹⁹.

CYP-3A4 inhibitors

There are many 3A4 inhibitors, including grapefruit juice, the antifungals itraconazole and ketoconazole, diltiazem, the macrolide antibiotics erythromycin, troleandomycin and clarithromycin, norfluoxetine, nefazodone, ciprofloxacin, la norfluoxacin^{9-13,19}. The latter drug, together with ketoconazole, is an extremely powerful inhibitor, with k_i values in the order of nanomoles instead of micromoles. Cases of death have been reported due to the association of drugs such as pimozide with drugs such as antifungals, probably caused by excessive blood concentration of pimozide, leading to longer duration of cardiac repolarization (Qtc) and a torsades de pointes up to fibrillation ventricular^{9-13, 19}.

For this reason, the association of pimozide with antifungals, macrolides, protease inhibitors, etc. is contraindicated today. Hence, when a 3A4 inhibitor is administered together with a 4A4 substrate, appropriate adjustments of the dose are necessary²⁰. This is particularly important for medications with low therapeutic index, such as calcium channel blockers, for a risk of hypotension and arrhythmias, or inhibitors of hydroxymethylglutaryl coenzyme A (HMG-CoA) reductase for a risk of rhabdomyolysis, or triazolobenzodiazepines such as alprazolam, midazolam, estazolam and triazolam, or hypnotics such as zolpidem and zaleplon, for the risk of excessive sedation^{9-13, 19-20}. It is also important to remember that 3A4 inhibitors can worsen the side effects of oral contraceptives, given the interaction with the metabolism of estradiol¹⁹⁻²⁰.

CYP-450-3A4 inducers

One of the most known is carbamazepine, which is both

a substrate and an inducer of 3A4. In addition, carbamazepine induces conjugation, phase 2 enzymes. Oxcarbamazepine also induces 3A4 and is therefore able to alter the concentrations of other medications that metabolized via this cytochrome, such as oral contraceptives. Inducers include drugs such as nevirapine and efavirenz, rifampin and rifabutin antitubercular, troglitazone, prednisone and dexamethasone, modafinil, hypericum. Ritonavir is a potent 3A4 inhibitor but can become an inducer after a few weeks of therapy^{9-13, 19-20}.

Cytochrome P-450 1A2

Unlike the other cytochromes, CYP P450 1A2 (CYP-1A2) is localized exclusively in the liver. CYP-1A2 presides the oxidative reactions (primarily hydroxylation and demethylation) of medications such as methylxanthines (e.g. caffeine and theophylline) and endogenous compounds such as 17 Beta estradiol and uroporphyrinogen. When a medication is metabolized from both 2D6 and 1A2, 2D6 (high affinity, low capacity) acts when the drug is at low concentration, while 1A2 starts working when the concentration of the drug in question increases and 2D6 is saturated^{9-13, 19-20}.

CYP-1A2 inhibitors

One of the most known 1A2 inhibitors is fluvoxamine. Potent inhibitors are also drugs such as fluoroquinolone antibiotics (e.g., ciprofloxacin, enoxacin, lomefloxacin), theophylline, mexiletine and propafenone. Other inhibitors include grapefruit juice and the antiandrogen metabolite flutamide. Important 1A2 substrates include clozapine, cyclobenzaprine, flutamide, flovatriptan, melatonin, mirtazapine and caffeine (which like melatonin and theophylline depends on 1A2 for more than 90% of its oxidative metabolism). Examples of interaction at the level of 1A2 are those of fluvoxamine with haloperidol, imipramine and clozapine, whose blood concentrations can increase up to over 600% when they are co-administered with fluvoxamine. In many cases (for example in that of clozapine and fluvoxamine) the interactions extend other 1A2, since fluvoxamine is also a potent inhibitor of 2C9 and 2C19 and, albeit less powerful, of 3A4 and 2D6, and is therefore, for example, for example in the case of interaction with clozapine, able to influence all the main pathways of metabolism of the drug CYP-1A2 inducer. Tobacco smoke is one of the most known inducers of 1A2. More specifically, smoking increases the metabolism of olanzapine (metabolized by 1A2 and, to a lesser extent, by 2D6) by about 40% and also can increase the clearance of clozapine by even greater percentages⁸. It is therefore appropriate to appropriately adjust the dosage of these medications in patients who smoke. Instead, people who quit smoking, the prescribed dose should usually be reduced after a few weeks, since the induction process (and return to

normal once the inducer is suspended) is not immediate^{9-13, 19-20}. Of interest, there is a polymorphic variation of 1A2 which is not affected by smoking²¹.

Cytochrome P-450 2C9

Cytochrome P-450 2C9 (CYP-2C9) metabolizes a limited number of drugs, some of which, such as non-steroidal anti-inflammatory drugs and oral hypoglycaemic agents, are however in common use. The main activities of 2C9, like that of the other P450 enzymes, includes hydroxylation, demethylation and dealkylation of exogenous and endogenous compounds^{9-13, 19-20}. Also in this case genetic differences exist and therefore again we speak of scarce and rapid metabolizers¹³⁻¹⁹. Cytochrome 2C9 inhibitors include drugs such as ritonavir, sulfafenazole, fluvoxamine, fluconazole, modafinil, desethylamiodarone (metabolite of amiodarone), zafirlukast and, perhaps to a lesser extent, fluoxetine, paroxetine and sertraline. The S isomer of warfarin is an example of a drug with low therapeutic index that is metabolized by 2C9, while its R isomer is instead metabolised mainly by CYP 1A2. Rifampin is instead an example of an inducer of 2C9.

Cytochrome P-450 2C19

Cytochrome P-450 2C1 (CYP-2C19) is similar to CYP 2C9 but not identical. Similarly to the other CYP 450 isoenzymes, CYP-2C19 presides over hydroxylation, demethylation and dealkylation of exogenous and endogenous compounds. Also in this case there are polymorphisms, poor metabolisers and rapid metabolisers. An example of a powerful CP-2C19 inhibitor is fluvoxamine; other inhibitors are ticlopidine, omeprazole, fluoxetine, ritonavir, oral contraceptives and perhaps paroxetine. An example of substrate is diazepam^{9-13, 22}.

Other cytochromes

Several other isoenzymes of cytochrome P450 have been described. Examples include 2E1 (which is induced by alcohol and inhibited by disulfiram), 2A6, 2B6, and 2C8^{9-13, 19-22}.

P-Glycoprotein

P-Glycoprotein (PGY-1) is a glycosylated and phosphorylated membrane protein consisting of two monomers of approximately 600 amino acids each²³⁻²⁴. Each monomer has a hydrophobic and a hydrophilic polarity. It is present in various cellular districts (proximal renal tubules, biliary canaliculi, small and large intestine, pancreatic ducts, adrenal, blood brain barrier astrocytes) where it binds a large variety of mostly hydrophobic substrates by removing them from the cell (the letter "P" stands for "Permeability"), using energy from the hydrolysis of ATP (adenosine triphosphate)²³⁻²⁴. Its discovery and isolation in the 70s are linked to

the study of the phenomenon of drug resistance which prevented the success of chemotherapy, for which cells seemed to become “impervious” to antitubercular drugs 9. Its function would be to expel substances in the excretory pathways and to protect some districts (brain) from an accumulation of toxic substances ²³⁻²⁷.

In the intestinal lumen, p-glycoprotein has the task of rejecting a fraction of the substrates initially absorbed: the meaning would be to modulate the passage of xenobiotics in the blood, allowing in particular to Cyp3A4, also very present in enterocytes, to cope to an excess of substrate for a first biotransformation. The possible negative implication of this regulatory mechanism obviously lies in the possibility of reducing the availability of drugs ²³⁻²⁷. For example, quinidine increases blood levels of dioxin through the inhibition of glycoprotein in the intestine and kidney. Other examples of glycoprotein inhibitors that can increase the dioxin concentration (mainly by initiating renal p-glycoprotein) are nifedipine, nitrendipine, felodipine, atorvastatin, verapamil, clarithromycin, propafenone, cyclosporine, amiodarone and itraconazole. On the contrary, rifampin decreases the concentration of dioxin through the induction of intestinal P-glycoprotein. In this case, a portion of the dioxin initially absorbed is rejected in the intestinal tract. Another example of a P-glycoprotein inducer is hypericum, which can increase the activity of glycoprotein 1.5 times, reducing the blood levels of some drugs such as digoxin ²³⁻²⁸. Since hypericum is also an inducer of CYP-3A4, drugs that are substrates of both CYP-3A4 and P-glycoprotein undergo a double effect (double induction). Examples of double inhibitors instead include ketoconazole and erythromycin. In the brain, P-glycoprotein excretes some of the drugs that manage to pass the blood brain barrier. Most psychotropic drugs are not P-glycoprotein substrates and can therefore reach adequate concentrations. For example, first generation antihistamines are not P-glycoprotein substrates and therefore give sedation; on the contrary, second generation antihistamines are actively expelled from the P-glycoprotein. Another medication that is actively expelled by P-glycoprotein is loperamide, an antidiarrheal. When loperamide is administered with quinidine (a P-glycoprotein inhibitor), there is a risk of respiratory depression and death, because of an increase in its concentration in the brain. As in the case of cytochrome P450, there are also genetic differences for P-glycoprotein which are evident in the ability to absorb / reject certain specific drugs in different individuals ²⁴⁻²⁹.

Interactions between COVID medications and psychotropics

A number of patients affected by coronavirus develop or were already affected by a mental illness. Combina-

tion treatment of COVID medications and psychotropics may cause adverse events or loss of efficacy. For instance, a side effect that is relatively common for COVID-19 medications is prolongation of the EKG repolarization interval QT, which is commonly observed also for many psychotropics. Hence, COVID-19 and psychotropics may synergically increase QT. Baseline and post administration ECG is necessary in these situations ³⁰.

Hydroxychloroquine

Hydroxychloroquine has been associated to adverse effects such as neutropenia, seizures, myocardial toxicity, and arrhythmia. Cardiovascular side-effects may include cardiac failure, cardiomyopathy, and several arrhythmias and electrocardiographic changes such as T wave inversion, flattened T wave, widened QRS complex, bundle branch or atrioventricular block, longer QT interval, ventricular tachycardia, torsade's de pointes, and ventricular fibrillation ³⁰⁻³¹. Therefore, hydroxychloroquine should not be prescribed on top of psychotropic medications that have similar risks, for instance clozapine.

Ritonavir/lopinavir

Ritonavir/lopinavir are contraindicated if patient is on drugs that are metabolized by the cytochrome CYP-450-3A4 because ritonavir is a potent CYP-3A4 inhibitor. Therefore, any psychotropic which is metabolized mainly through CYP3A4 (buspirone, clonazepam, carbamazepine, lurasidone, quetiapine, mirtazapine, pimozide, trazodone and many others) should be stopped or dose adjusted. For instance, when quetiapine is prescribed in combination with ritonavir/lopinavir, the FDA recommends reducing the dosage of quetiapine to 1/6th and to monitor for related adverse effects ³⁴. Of interest, ritonavir/lopinavir are themselves substrates of CYP3A4. Hence, it should not be prescribed in combination with medications that able to inhibit (e.g., fluvoxamine) or induce (e.g., carbamazepine, topiramate) CYP3A4. Finally, ritonavir/lopinavir, may reduce serum levels of medications such as Valproate or Lamotrigine, because of their tendency to induce their glucuronidation (phase 2) in the liver. Hence, dose adjustments are needed ^{32-33, 35-36}.

Azithromycin

Azithromycin, can increase QTc duration and the coadministration of psychotropics with the same ability should be avoided or prescribed with caution. Also, azithromycin can cause acute increases in liver aminotransferase /transaminases so should be used cautiously in patient on drugs that are potentially hepatotoxic, such as valproate or carbamazepine. When the co-administration is necessary, regular monitoring of liver function tests is in order ³⁷⁻³⁸.

Remdesivir

Remdesivir, has been authorized only recently by the United States Food and Drug Administration for emergency use in patients with severe complications from COVID-19 and only limited data is available about its potential interactions with psychotropics. This medication is a prodrug of a nucleotide analog, which inhibits viral RNA-dependant RNA polymerase³⁹. Remdesivir has shown efficacy against Ebola and acute respiratory syndrome induced by coronavirus. To our knowledge, there is no published report of prolonged QTc, torsades de pointes, or arrhythmias due to remdesivir. Nonetheless, it is known that remdesivir may elevate liver enzymes, which suggest caution when it is co-administered with medications such as valproate or carbamazepine³⁸.

Remdesivir is a substrate for CYP450-2C8, 2D6, and 3A4, along with p-glycoprotein and organic anion transporting polypeptides 1B1 (OATP1B1)⁴⁰. When coadministered with medications able to induce CYP-3A4, such as carbamazepine, phenobarbital, phenytoin, and St John's wort, there is a potential decrease in remdesivir concentration. For instance, antipsychotics like thioridazine (in Countries where thioridazine is still available, since many Countries have withdrawn this medication from the market because of the risk of QTc prolongation and arrhythmia) require close monitoring or dose adjustment. Thioridazine is metabolized by CYP2D6 and to a lesser extent by CYP3A4^{38,40}. Therefore, although remdesivir inhibits CYP3A4 it is unlikely to have a significant effect on thioridazine. However, thioridazine is a moderate inducer of CYP3A4 and may reduce remdesivir concentrations. Remdesivir is also an inhibitor of CYP3A4 and should be used with caution in patients treated with medications primarily metabolized by this isoenzyme^{38,40-41}.

Tocilizumab

Tocilizumab is a recombinant monoclonal antibody, anti-human IL-6 receptor that is primarily used as a treatment for rheumatoid arthritis but is also being studied

as a medication for respiratory failure in patients affected by COVID-19⁴²⁻⁴³. *In vitro* studies showed the ability of tocilizumab to induce multiple CYP enzymes including CYP1A2, CYP2B6, CYP2C9, CYP2C19, CYP2D6 and CYP3A4. In vivo studies with simvastatin, which is metabolized by CYP3A4, showed a 57% decrease in exposure, one week after a single dose of tocilizumab. In vivo studies with omeprazole, which is metabolized by CYP2C19 and CYP3A, showed a 28% decrease in exposure, again one week after a single dose of tocilizumab. The ability of tocilizumab to induce CYP enzymes may be clinically relevant particularly for CYP450 substrates with narrow therapeutic index⁴⁴.

More and updated information

A comprehensive and frequently updated list of interactions with COVID medications is provided in open access by the University of Liverpool Drug Interaction Group⁴⁵⁻⁴⁶.

Conclusions

The combination of COVID and psychotropic drugs is often necessary and, in most cases, the benefits outweigh the risks. Pharmacodynamic and pharmacokinetic interactions are possible and must be taken into consideration to avoid adverse effects or reduced efficacy. This is made more important because of genetic polymorphisms that are responsible for large inter-individual differences in the ability to metabolize medications, with poor and ultra-rapid metabolizers that may achieve very high or very low blood concentration of a given compound. In most cases, COVID medications can be safely prescribed in combination with psychotropic drugs. However, a thorough evaluation of the pharmacodynamic and the pharmacokinetic interactions can inform the most appropriate choice of drugs and doses and help reducing the risks of inefficacy or adverse events.

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Building a resilient hospital in Tor Vergata: the role of emotional defusing for health care workers during COVID-19 pandemic

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SUMMARY

The CORonaVirus Disease 2019 (COVID-19) epidemic crisis caused the re-organization of different hospitals. A key factor in this process of answering mainly for functionality and health security was played by resilience, i.e., the ability to find and apply resources for support, engage in successful coping, or utilize other accessible protective factors. In the process of building a hospital that could show resilience, we adopted the emotional defusing that, by dealing with psychological distress of health care worker in our COVID-19 university hospital, has proven to be a technique at the basis of the growth of individual and group level.

Key words: anxiety, coping, COVID-19, depression, emotional defusing, fear, resilience, stigma

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COVID-19 outbreak: the need of a resilient hospital

The CORonaVirus Disease 2019 (COVID-19) epidemic crisis has constituted a sort of stress test for the national health system and in particular for the so-called COVID hospitals. This highlighted some critical points of the health system such as insufficient hospital availability of beds, lack of emergency services and intensive care, lack of medical and health personnel, inadequacy of intervention paths in continuity of care. In addition, many health care workers (HCWs) have been forced to change their specialist way of working and to endure the great stress of treating COVID-19.

The pandemic situation caused the re-organization of different hospitals in COVID-centres, the rapid and intense change of life and work habits of HCWs and, in an initial phase, “fighting” against a little-known enemy with an increased distress and increased risk of living traumatic incidents. Furthermore, the biggest question is: When, and how, will it end? ¹. This situation appears as “an unexpected war against a difficult enemy” ².

In this demanding situation, resilience plays a key role. Resilience is the ability to find and apply resources for support, engage in successful coping, or utilize other accessible protective factors where there has been exposure to risk or adversity trauma. For resilience, protective factors include internal resources (such as i.e. coping skill, self-efficacy) and external resources (such as social support and access to the service). Feldman ³ has recently emphasized the three tenets of resilience: plasticity, sociality and meaning. The social aspect of resilience is linked directly to the organizational response of a hospital that must not only deal with trauma/problem/stress in its reorganization but must also develop a significant survival advantage. In our case functionality (mainly, organizational, welfare) and social response (mainly, in terms of health security).

It can be assumed that the resilience of an organization is a functional metacapacity, based on the elastic modulation of the different mechanisms of interaction of the units present within the organization ⁴. The resilient hospital is, therefore, the hospital that has the ability 1) to implement proactive actions to anticipate the criticalities of the event, 2) to cope with the management of the emergency when the crisis develops and 3) to change plastically with reactive actions once the event has passed.

In the case of the COVID-19 pandemic, we can identify different dimensions of hospital organizational resilience: reduction of the risk of infections; increase in production-organizational capacity; financial resilience; operational clarity and transparency; staff protection and motivation; development of efficient, economic and sustainable management procedures; cultural resilience, i.e., learning from ongoing experiences and applying the new knowledges to original, more efficient and dynamic organizational models.

Therefore, resilience is essential to building an hospital that strengthen internal and external resources of HCW's against COVID-19. This meant having to develop great resilience on an individual, group, hospital and organizational level.

Emotion defusing as a resilience strategy in COVID-19 hospital

A significant higher risk of adverse mental health outcomes

during the COVID-19 outbreak is present in HCWs ^{5,6}. Consequently, it is important to provide listening and a frontline treatment focused on prevention, like the treatments used in military during the wars. For this reason, we used emotional defusing in HCWs in the moment of re-organization in a COVID-centre, to create a COVID-centre that takes into account the distress and strengthen the internal and external resources of each single HCW. The defusing (from English defuse) is a short intervention organized through group interviews, which is held on subjects who have experienced a highly dramatic or traumatic event ⁷. The goal of this intervention is to try to start briefly and collectively reworking the meaning of the event, and to reduce the emotional impact of a potentially traumatic event. Defusing consists of three phases: introduction, in which the intervention is presented and what its characteristics are, in a non-judgmental climate; exploration, in which we try to bring out facts, thoughts and moods; information, in which the goal is to support, reassure about normal stress reactions and propose the sharing of psychological resources to deal with the stressful event.

We led 19 groups of emotional defusing between the 16th March and the 29th April 2020. The total sample consisted of 189 HCWs from a COVID hospital (Fondazione Policlinico Tor Vergata, the Hospital of University of Rome Tor Vergata) in Rome, Italy. Our sample was primarily composed by women (70.9%) with a mean age of 44.40 (SD = 8.86). Nurses were 102 (44.78%), doctors 48 (25.4%) and others 39 (20.6%). To inves-

TABLE I. Questionnaire on the concern degree in COVID-19 health emergency. Data are frequencies (and percentages).

	Absent	Mild	Moderate	Severe
What is your preoccupation about the situation?	2 (1.06%)	19 (10.05%)	132 (69.84%)	36 (19.05%)
How afraid are you of getting infected?	2 (1.06%)	46 (24.34%)	118 (62.43%)	23 (12.17%)
How worried are you about your family members?	0 (0%)	14 (7.41%)	86 (45.50%)	89 (47.09%)
How often do you experience moments of acute anxiety related to the infection?	47 (24.87%)	77 (40.74%)	51 (26.98%)	14 (7.41%)
How much has your quality of sleep changed?	47 (24.87%)	71 (37.56%)	48 (25.40%)	23 (12.17%)
How much has your life changed?	5 (2.65%)	31 (16.40%)	97 (51.32%)	56 (29.63%)
How satisfied are you of the security measures taken so far?	12 (6.35%)	75 (39.68%)	82 (43.39%)	20 (10.58%)
How much the information disseminated by the media influence your preoccupation?	8 (4.23%)	38 (20.11%)	91 (48.15%)	52 (27.51%)
How worried are you at home?	30 (15.87%)	68 (35.98%)	68 (35.98%)	23 (12.17%)
How worried are you at work?	9 (4.76%)	39 (20.63%)	105 (55.56%)	36 (19.05%)

tigate the concern regarding the ongoing COVID-19 health emergency we created a simple questionnaire comprising 10 questions (1. What is your preoccupation about the situation? 2. How afraid are you of getting infected? 3. How worried are you about your family members? 4. How often do you experience moments of acute anxiety related to the infection? 5. How much has your quality of sleep changed? 6. How much has your life changed? 7. How satisfied are you of the security measures taken so far? 8. How much the information disseminated by the media influence your preoccupation? 9. How worried are you at home? 10. How worried are you at work?). During the emotional defusing, we didn't only evaluate the quantitative answers (see Table I) to the single questions but we listened and discussed the qualitative answers of each individual HCW.

Most of our sample show a moderate preoccupation about the situation (69.84%) and are afraid of getting infected (62.43%), while a moderate to severe preoccupation about family member were found (respectively 45.50% and 47.09%). Furthermore, a moderate to severe change in life of HCW's were found (respectively 51.32% and 29.63%) and the quality of sleep was change in over of 90% of our sample. HCW's are worried more at work than at home (see Table I) and are mild to moderate satisfied of the security measures (see Table I).

In the early defusing sessions, we have highlighted a main fright that was fear of contagion. In fact, being in hospital and treat the pathology COVID-19-related has produced this type of fear. Considering the open answer of these questions, day by day, we observed a better management of this type of fear while another type of fright was found, that is the fear of infecting family members. Consequently, we found a double lockdown: the lockdown of HCWs and the lockdown of their family members.

Towards the end of the defusing sessions, which occurred in the last week (end of April 2020) of phase 1 (the general lockdown for COVID-19 pandemic in Italy), an absolutely new fear appeared, which is the anguish of pandemic recovery and the redesigning life's HCWs

that does not consist only in resuming the activities that were interrupted but above all to imagine the objectives and values of life during with the presence of the COVID-19.

A peculiar issue emerged during the emotional defusing sessions: stigma-generating behaviors against HCWs. Indeed, impact on HCWs' mental health including the question of stigma. Stigma is a powerful social process that is characterized by labelling, stereotyping, and separation, leading to status loss and discrimination. In a pandemic emergency, stigma can be from the non-health worker to the health worker involved in the emergency that is seen as an "infectior". Stigma for HCWs of our COVID-19 hospital generated in HCWs an higher discomfort and frustration with an increase of fear, anxiety and depressive symptoms.

Conclusions

The emotional defusing was generally very appreciated by participants because it has permitted a better management of emotional, individual and group distress (in particular of anxious one) and because in a moment of isolation and solitude, sharing emotions, fear and experiences allowed to increase individual and group resilience.

These results supported emotional defusing as an early, frontline intervention for HCWs' mental health and well-being. Emotional defusing, in fact, acting on sharing fears and concerns can help HCWs to reduce loneliness and fears and to increase resources to deal with the stressful event. Furthermore, during the reorganization of our hospital in a COVID-centre, data, collected during the emotional defusing sessions, have been provided to the risk management unit in order to reduce the fears and anger exposed by its HCWs and to develop appropriate assistances if an HCW needs to a psychological or psychiatric support. In conclusion, emotional defusing proved essential to understand the difficulties of HCWs in the reorganization of a hospital and of their professions, resulting in a COVID-centre that takes into account the distress of each single HCW.

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The impact of the COVID-19 emergency in a community mental health setting of a metropolitan hospital

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SUMMARY

Objectives

To evaluate the relationship between traumatic aspects of the COVID-19 emergency and clinical correlates in a sample of consecutive outpatients in a Community Mental Health setting in Milan, Italy.

Methods

One hundred and forty subjects aged between 18 and 75 years were assessed with the Clinical Global Impression – Severity (CGI-S), Brief Psychiatric Rating Scale (BPRS-18), the 22-item Impact of Event Scale-Revised (IES-R) and the Self Report Questionnaire (SRQ-20). Data analysis were performed using SPSS version 16.0. Basic statistics were used to describe the demographic and clinical characteristics of the participants. The associations between sociodemographic and clinical variables were explored first by performing Pearson's correlation analysis followed by multivariate regression. IES-R total score was used as the dependent variable while sociodemographic variables, SRQ-20, CGI-S and BPRS total score were used as independent variables.

Results

A considerable proportion of participants reported symptoms of distress measured by IES-R: 47 (33.6%) mild, 45 (32.1%) moderate and 37 (26.4%) severe. SRQ-20 total score was positive in 82 (58.6%) patients, particularly in the female population ($p = 0.009$) with an age between 45-65 years ($p = 0.020$). In multiple regression analysis, being actively working ($Beta = 0.15$, $p = 0.03$) and SRQ-20 ($Beta = 0.56$, $p = 0.00$) significantly predicted IES-R total score.

Conclusions

Our data evidenced high level of distress among patients in contact with mental health services during Covid-19 emergency period suggesting the importance of maintaining continuous monitoring for a careful assessment of their condition from both a psychopathological and medical point of view.

Key words: trauma spectrum, quarantine, mental health, coronavirus-2019 disease

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Introduction

In December 2019, the Chinese city of Wuhan reported a novel pneumonia caused by coronavirus disease (COVID-19), which has spread domestically and internationally ^{1,2}. On January 30, 2020, the World Health Organization held an emergency meeting and declared the global COVID-19 outbreak a public health emergency of international concern ³.

According to data released by the Italian National Health Commission, the number of confirmed cases in mainland Italy increased to 212,532 infected, 27,402 deaths as of May 05, 2020⁴. The Italian Government in response, implemented extraordinary measures to limit viral transmission on the 8th March 2020. These included restricting movement of persons with the intent to minimise transmission of the virus from infected individuals to healthy ones.

The psychological response to an event of this magnitude is complex. Different studies show that in an early phase of the severe acute respiratory syndrome (SARS) outbreak, a range of psychiatric morbidities could occur, including persistent depression, anxiety, panic attacks, psychotic symptoms and even suicide⁵. Brooks et al.⁶ reviewed 3166 papers for the psychological impact of quarantine, 24 included studies reported negative psychological effects including post-traumatic stress symptoms, confusion, and anger.

Quarantine is often an unpleasant experience for those who undergo it. The loss of freedom, uncertainty and boredom can, on occasion, have dramatic effects. The potential benefits of mandatory mass quarantine needs to be weighed carefully against the possible psychological consequences⁷. Successful use of quarantine as a public health measure requires us to reduce, as far as possible, the negative effects associated with it.

Two recent online surveys have been conducted to establish psychological distress and identify risk and protective factors among Italian people during the COVID-19 pandemic^{8,9}. In the first one⁸, the sample consisted of 2766 participants. Female gender, negative affect, and detachment were associated with higher levels of depression, anxiety and stress. Having an acquaintance infected was associated with increased levels of both depression and stress, whereas a history of stressful situations and medical problems was associated with higher levels of depression and anxiety. Furthermore, those family members infected and young adults who had to work not from home, presented higher levels of anxiety and stress. In the second one⁹, 62% of the individuals, with a total sample of 500 subjects, reported no psychological distress, whereas 19.4 and 18.6% displayed mild and moderate to severe psychological distress. Moreover, specific affective temperament and attachment features predicted the extent of mental health burden.

Lombardy is the largest and the most affluent Region in Italy with around 10 million inhabitants as well as the most dramatically affected by COVID-19 contagion and related disease. The Regional Health Authority mandates that access to mental health community services is to be guaranteed, in that mental health is a priority for the general population and patients alike. Recommen-

dations for occupational and health safety in community clinical practice was provided to patients and hospital staff, including support for telemedicine activities and remote psychosocial interventions¹⁰. Public Mental Health Services in Lombardy include 27 Departments for Mental Health and Addiction Services and a number of private residential facilities. A single Department consists of a network of psychiatric services covering hospital, community and residential activities in a given area. Public psychiatry services provide all prevention and therapeutic activities, these include emergency response and hospital admissions, community and rehabilitation activities both in outpatient services and inpatient residential facilities, and support for social inclusion¹¹.

Regarding community mental health care services, the activity has been maintained for patients suffering from clinically severe disorders, and/or affected by relevant socio-economic or forensic issues. For these patients, access to services has been maintained focusing on clinical monitoring and drug administration. Home interventions and off-site activities are only provided in urgent situations¹⁰.

Aim of the study

Our aim is to evaluate the relationship between traumatic aspects of the COVID-19 emergency and clinical correlates in a sample of consecutive outpatients in a Community Mental Health setting in Milan, Italy.

Materials and methods

Participants

The present investigation is a non-experimental, exploratory and descriptive study. The sample included 140 consecutive outpatients recruited over a 2-week period, April 6th to April 19th 2020, seeking treatment at the Community Mental Health Service n. 2-9 of the ASST Great Metropolitan Hospital Niguarda, Milan.

Inclusion criteria for patients included, age between 18 and 75 years; ICD-10 diagnosis of neurotic, stress-related, and somatoform syndromes (F40-48); affective syndromes (F30-39) or schizophrenia, schizotypal, and delusional disorders (F20-29); personality disorders (F60-69). Exclusion criteria included severe systemic or neurological illnesses; inability to give consent or to perform self-report scales.

Instruments and assessments

Patient's sociodemographic and clinical data were collected using a structured interview. The patient's clinical condition was assessed with Clinical Global Impression – Severity of illness (CGI-S), a scale that assesses the severity of the disease at the time of the interview

with a score ranging from 0 (normal) to 7 (extremely ill)¹² and the 18-item Brief Psychiatric Rating Scale (BPRS-18)^{13,14}.

The immediate psychological consequences were evaluated with reliable and valid self-reported questionnaires used in community study, including the 20-item Self-Report Questionnaire (SRQ-20)¹⁵ and the Impact of Event Scale-Revised (IES-R)^{16,17}.

The IES-R was developed to assess the prevalence of post-traumatic stress disorder; it has 22 items with a Likert rating scale from 0 to 4; the maximum score is 88. The SRQ-20 was developed to investigate the general state of mental health; it has 20 items with a 'yes' or 'no' response; the maximum score is 20.

The total scores of these measurement tools were interpreted as follows: IES-R, normal (0-8), mild (9-25), moderate (26-43), and severe (44-88); and SRQ-20, normal (0-6), positive (> 7). These categories were based on values established in literature².

Statistical analysis

Data analysis was performed using SPSS (Statistical Package for the Social Science) version 16.0. Basic statistics were used to describe the demographic and clinical characteristics of the participants.

Chi-square test was used to compare the severity of distress symptoms (IES-R) and general state of mental health (SRQ-20) between two or more groups.

The associations between sociodemographic and clinical variables were explored, firstly by performing Pearson's correlation analysis and followed by multivariate regression. IES-R total score was used as the dependent variable while sociodemographic variables, SRQ-20, CGI-S and BPRS-total score were used as independent variables.

Results

Seventy-seven (55%) of the 140 subjects were women and the mean age was 50.35 years (range 24-75; sd 10.9).

Ten participants (7.1%) suffered from a neurotic, stress-related, and somatoform syndromes (F40-48), 58 (41.4%) from affective syndromes (F30-39). Schizophrenia, schizotypal, and delusional disorders (F20-29) were reported in 28.6% (n = 40) and personality disorder in 32 (22.9%).

Sociodemographic characteristics, as well as mean scores in BPRS, IES-R, SRQ-20 and CGI-S, are summarized in Table I.

The proportion of subjects across IES severity categories did not differ by gender ($\chi^2 = 2.74$, $p = 0.43$), marital status ($\chi^2 = 2.25$, $p = 0.521$), living situation ($\chi^2 = 3.09$, $p = 0.377$), occupation ($\chi^2 = 1.20$, $p = 0.75$) or diagnosis ($\chi^2 = 10.13$, $p = 0.34$); a significant re-

lationship was found between age and IES-R severity scores ($\chi^2 = 18.27$, $p = 0.03$) (Tab. II).

About General State of Mental health (SRQ-20), a significant relationship was found between SRQ-20 severity score and gender ($\chi^2 = 7.42$, $p = 0.009$), age ($\chi^2 = 9.85$, $p = 0.020$), diagnosis ($\chi^2 = 8.28$, $df = 3$, $p = 0.042$) (Tab. III).

By Pearson's correlation analysis (Tab. IV), we obtained a positive statistically significant correlation between IES-R total score and age ($p = 0.035$); SRQ-20 ($p < 0.001$) and BPRS total score ($p = 0.02$). Moreover, SRQ-20 total score correlated with age ($p = 0.011$), BPRS total score ($p < 0.001$) and CGI-S ($p < 0.001$).

In multiple regression analysis, being actively working (Beta = 0.15, $p = 0.03$) and SRQ (Beta = 0.56, $p = 0.00$) significantly predicted IES total score (Tab. V).

Discussion

To our knowledge, no study has investigated psychological response to the ongoing COVID-19 outbreak in a community mental health setting so far. In line with Moccia et al.⁹ the time frame was chosen to assess participants' response during an early phase of the COVID-19 outbreak, following the Italian Government declaration of lockdown (March 8th, 2020) and the WHO announcement of the COVID-19 as a pandemic.

The results of our study show that, in the examined sample, a considerable proportion of participants reported symptoms of distress measured by IES-R and SRQ-20 positive screening according to Wang and colleagues¹⁸ where 53.8% of respondents rated the psychological impact of outbreak as moderate and severe; whereas in Moccia and colleagues' study⁹ only 38% of the general Italian population perceived a form of psychological distress.

Furthermore, there was a correlation between age, IES-R severity categories and SRQ-20 where patients between 45 and 65 years presented greater levels of distress and higher prevalence of "positive" in SRQ-20. The literature reports mixed results for this variable, indicating a greater psychological impact for both young adults and elderly^{19,20}. A possible explanation for our results, is that the sample included mainly employed subjects with a mean age of 50.35 years, that have been forced to completely change their lifestyles.

In our sample the female group presented higher scoring of SRQ-20 (64.6 vs 35.4% positive), suggesting differences in coping strategies and response to stress. Gender differences in psychopathology is well known in literature²¹. Females seem more likely than males to suffer from disorders characterized by hyperarousal symptoms, including post-traumatic stress disorder²². Male gender also represented a protective factor for mild psychological distress in the Moccia et al. study⁹. Female

TABLE. I. Sociodemographic characteristics and mean scores in BPRS, IES-R, SRQ-20 and CGI-S.

Characteristic				Group			N (%)	
Gender	Female				77 (55%)			
	Male				63 (45%)			
Marital Status	Single				75 (53.6%)			
	Married				39 (27.9%)			
	Separated/divorced				24 (17.1%)			
	Widowed				2 (1.4%)			
Living situation	Alone				53 (37.9%)			
	Partner and/or children				55 (39.3%)			
	Other relatives				27 (19.3%)			
	Others				5 (3.5%)			
Occupation	Employed				73 (52.1%)			
	Unemployed				51 (36.5%)			
	Retired				7 (5%)			
	Student/housewife				9 (6.4%)			
Education	Primary school diploma				3 (2.1%)			
	Middle school diploma				35 (25%)			
	High school diploma				70 (50%)			
	Graduate/post-graduate				32 (22.9%)			
Mean				Sd				
BPRS								
Total score				38.20		8.85		
IES-R								
Total score				30.80		15.37		
SRQ-20								
Total score				7.89		5.08		
CGI-S	1	2	3	4	5	6	7	
Sample	0	27	37	62	13	1	0	
N = 140		(19.3%)	(26.4%)	(44.3%)	(9.3%)	(0.7%)		

BPRS: Brief Psychiatric Rating Scale; IES-R: The Impact of the Event Scale-Revised; SRQ-20: Self Report Questionnaire; CGI-S: Clinical Global Impression – Severity.

gender predicted higher levels of stress also in the Mazza et al. study⁸. Similarly, a recent survey conducted in China one month after the COVID-19 outbreak reported higher post-traumatic stress symptoms in women²³.

The present study also found an association between higher scores on SRQ-20 and diagnosis of Affective and Personality Disorder. In line with our result, Moccia et al.⁹ have found that depressive temperament was a risk factor for moderate to severe psychological distress, concluding that specific affective temperament and attachment features predict the extent of mental health burden.

BPRS total score correlated with SRQ-20 and IES-R using Pearson's correlation analysis. Several studies have highlighted that mental health patients are particularly vulnerable both to COVID-19 itself and its complications, as well as to the adverse psychological effects of measures such as self-isolation and disruption to their normal care and lifestyle^{6,24}.

Other studies have highlighted that people with a mental disorder and patients in contact with mental health services represent a population at risk for COVID-19 infection²⁵. The low awareness of these patients regarding risk and the transmission of the infection, as well as the

TABLE II. Severity categories of distress measurements in total sample and subgroups.

IES-R, distress symptoms	Normal, N (%)	Mild, N (%)	Moderate, N (%)	Severe, N (%)
	11 (7.9)	47 (33.6)	45 (32.1)	37 (26.4)
Gender				
Male	7 (63.6)	23 (48.9)	19 (42.2)	14 (37.8)
Female	4 (36.4)	24 (51.1)	26 (57.8)	23 (62.2)
<i>P value 0.433</i>				
Age				
18-34	2 (18.2)	8 (17.0)	3 (6.7)	0 (0)
35-44	3 (27.3)	11 (23.4)	11 (24.4)	3 (8.1)
45-65	6 (54.5)	21 (44.7)	28 (62.2)	29 (78.4)
> 65	0 (0)	7 (14.9)	3 (6.7)	5 (13.5)
<i>P value 0.032</i>				
Marital status				
Single	6 (54.5)	36 (76.6)	33 (73.3)	26 (70.3)
Married	5 (45.5)	11 (23.4)	12 (26.7)	11 (29.7)
<i>P value 0.521</i>				
Living situations				
Alone	2 (18.2)	20 (42.6)	15 (33.3)	16 (43.2)
Others	9 (81.8)	27 (57.4)	30 (66.7)	21 (56.8)
<i>P value 0.377</i>				
Occupation				
Employed	6 (54.5)	23 (48.9)	22 (48.9)	22 (59.5)
Unemployed	5 (45.5)	24 (51.1)	23 (51.1)	15 (40.5)
<i>P value 0.752</i>				
Diagnosis				
Affective disorder	8 (72.7)	21 (44.7)	15 (33.3)	14 (37.8)
Anxiety disorder	0 (0)	2 (4.3)	3 (6.7)	5 (13.5)
Personality disorder	1 (9.1)	10 (21.3)	11 (24.4)	10 (27.0)
Psychotic disorder	2 (18.2)	14 (29.8)	16 (35.6)	8 (21.6)
<i>P value 0.340</i>				

low adherence to precautionary measures, including social distancing; frequent hand-washing; circulation restriction; home isolation, may contribute to this risk. In fact, in our sample, the psychotic disorder group, shows low severity scores of SRQ-20 that means a poor awareness of their own disorder but also for the pandemic related problems. Maintaining continuous monitoring of patients in contact with mental health service is essential for a careful assessment of their condition from both a psychopathological and medical point of view ¹⁰. Finally, in multiple regression analysis, being actively working and SRQ-20 score significantly predicted IES-R total score. Unsurprisingly, the general state of mental

health measured by SRQ-20 predicted severity of distress. Accordingly, Wang and colleagues ¹⁸ evidenced that female gender, student status, specific physical symptoms including myalgia; dizziness, and poor self-rated health status were significantly associated with a greater psychological impact of the outbreak and higher levels of stress, anxiety, and depression ($p < 0.05$). Regarding occupational status as predictor of distress, as aforementioned, it seems that the quarantined workers have been forced to completely change their own lifestyle and have been exposed to the risk of losing their employment. In addition, having to go out to work was associated with higher levels of stress also in the Mazza et

TABLE III. General state of mental health according to Self Report Questionnaire in total sample and subgroups.

SRQ-20	Negative, N (%)	Positive, N (%)
	58 (41.4)	82 (58.6)
Gender		
Male	34 (58.6)	29 (35.4)
Female	24 (41.4)	53 (64.6)
<i>**P value 0.009</i>		
Age		
18-34	7 (12.1)	6 (7.3)
35-44	18 (31.0)	10 (12.2)
45-65	27 (46.6)	57 (69.5)
> 65	6 (10.3)	9 (11.0)
<i>P value 0.020</i>		
Marital status		
Single	43 (74.1)	58 (70.7)
Married	15 (25.9)	24 (29.3)
<i>P value 0.705</i>		
Living situations		
Alone	20 (34.5)	33 (40.2)
Others	38 (65.5)	49 (59.8)
<i>P value 0.596</i>		
Occupation		
Employed	31 (53.4)	42 (51.2)
Unemployed	27 (46.6)	40 (48.8)
<i>P value 0.864</i>		
Diagnosis		
Affective disorder	27 (46.6)	31 (37.8)
Anxiety disorder	3 (5.2)	7 (8.5)
Personality disorder	7 (12.1)	25 (30.5)
Psychotic disorder	21 (36.2)	19 (23.2)
<i>P value 0.042</i>		

TABLE V. Associations between sociodemographic/clinical variables and post-traumatic symptoms.

IES total	Model F = 7.24; p = 0.00; R ² = 41.2%				
	B	SE(B)	Beta	t	p
Age	0.17	0.10	0.13	1.68	0.09
Years of treatment	-0.14	0.13	-0.08	-1.09	0.27
CGI-S	-2.65	1.49	-0.16	-1.77	0.07
Sex	1.14	2.11	0.03	0.54	0.58
Marital status (conjugated)	-3.85	2.73	-0.11	-1.40	0.16
Being employed	4.47	2.13	0.15	2.09	0.03
Living with someone	4.14	2.47	0.13	1.68	0.09
BPRS-total	0.26	0.16	0.15	1.59	0.11
SRQ-20	1.67	0.22	0.56	7.38	0.00

al. study⁸ and further studies have highlighted that those who perform essential jobs, including Health-care workers, have been exposed to a greater risk of contagion, and more frequently have developed PTSD symptoms²⁶.

Conclusions

Our data evidenced high levels of distress among patients in contact with mental health services during COVID-19 emergency period, strongly suggesting the importance of maintaining continuous monitoring for a careful assessment of these patients from both a psychopathological and medical point of view.

During this period, it is not only an ethical imperative but also a public health responsibility to keep the network of community psychiatry services operational, particularly for the most vulnerable subjects^{27,28}.

This study has several limitations. Firstly, since the survey was completed during the quarantine period, no conclusion can be drawn regarding the long-term psy-

TABLE IV. Bivariate correlations between the variables.

	Age	Years of treatment	CGI-S	IES total	SRQ-20	BPRS Total
Age	1	0.25**	0.03	0.17*	0.21*	0.14
Years of treatment	0.25**	1**	0.10	-0.01	0.01	0.16
CGI-S	0.03	0.10	1**	0.09	0.27**	0.67**
IES-total	0.17*	-0.01	0.09	1	0.60**	0.26**
SRQ-20	0.21*	0.01	0.27**	0.60**	1	0.39**
BPRS-total	0.14	0.16	0.67**	0.26**	0.39**	1

p* < 0.05; *p* < 0.01

chological effects. Larger, controlled, prospective studies are needed. Secondly, the reliability of self-administered questionnaires may be partially biased.

Authors' contribution

The Authors contributed equally in the preparation and revision of the manuscript.

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Emotional dysregulation, affective status and personality traits in a sample of migraine patients

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SUMMARY

Background

Several studies hypothesize emotional dysregulation in subjects with migraine related to a generalized hyperexcitability both to sensory and emotional stimuli, involving the cortical-limbic system. The aim of the study was to investigate Emotional Reactivity by means of the International Affective Picture System (IAPS), in a sample of migraineurs in order to evaluate differences between the patients and a healthy reference group and the relationships with clinical evaluations: personality traits, psychopathological symptoms, empathy, affective status, coping and resilience strategy and with the severity of the headache disorder.

Methods

Twenty patients with migraine (14 females, 6 males) and fifteen healthy subjects (9 females, 6 males) matched for age and gender were recruited. Emotional Reactivity was tested using International Affective Picture System (IAPS); Clinical Global Impression evaluated behavioral disturbances. Clinical evaluation, by using the Zung Self-Rating Anxiety Scale, the Beck Depression Inventory II, the Empathy Quotient, the brief TEMPS-M temperament questionnaire, the Millon Clinical Multiaxial Inventory III, the Symptom Check List 90, the Brief Cope, the Resilience Scale 14 and the Migraine Disability Assessment, was performed.

Results

The mean arousal ratings of the clinical group were significantly higher than those of the control group for unpleasant and socially unpleasant pictures. The arousal scores of socially unpleasant pictures showed numerous significant correlations with psychometric scores, since higher arousal is associated with higher migraine disability. Valence to unpleasant images was similarly related to migraine disability, while arousal was inversely related to the Brief Cope score.

Conclusions

The association between personality traits and emotional dysregulation in migraine patients is worth of attention because it could represent the cause of an increased susceptibility to many negative stimuli, may worsen the course and prognosis of the headache disorder and may amplify the vulnerability to psychopathology.

Key words: migraine, emotional reactivity, personality, international affective picture system

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Introduction

Migraine (M) is a disorder that is not only characterized by recurrent headache attacks but also showing comorbidity with psychiatric conditions ¹. This association of psychopathological symptoms with M goes beyond the chance overlapping of frequent disorders ²; it regards mainly major depression, bipolar, anxiety and panic disorder ³.

The comorbidity between M and psychiatric disorders is a challenge for the diagnosis and the clinical approach, as well as for treatment. A psychopathological status may be prior, concomitant or subsequent to the course of the headache and can be concurrent to determine the deterioration of the quality of life of the patients.

M and psychiatric disorders can be related being each other's effect or they can share psychological and behavioral aspects. Alternatively, they can represent the phenotypes of common genetic or environmental factors. From an anatomic and functional point of view limbic system could be the substrate of this comorbidity ⁴.

Some hypotheses have been elaborated about the contribution of psychological factors to the M etiology. Some personality traits may work as predisposing factors and several stressful emotional stimuli may be precipitating factors ⁵. Increased anxiety and somatization scores in women with M evaluated with the Minnesota Multiphasic Personality Inventory (MMPI) ⁶, tendency to aggression with increased hostility scores and increased emotionality in M patients without evidence of past or present significant emotional stress has been found ⁷. They suggested an increased reactivity of the autonomic nervous system in M patients as a predisposing factor for headache attacks. Sanchez-Roman et al. ⁸, using the Temperament and Character Inventory (TCI) ⁹ found that personality features of people with M are avoidance, rigidity, reserve and obsessivity, suggesting a profile indicative of an avoidant personality. Avoidant subjects are hypothetically predisposed to "form conditioned signals of punishment and frustrative nonrewarding" associated with increased activity of the anterior paralimbic circuit (right amygdala, insula and orbitofrontal cortex and left medial prefrontal cortex) related to serotonergic projections to the dorsal raphe ¹⁰. Davis et al. ¹¹ focused on the association between migraine and the personality trait of neuroticism although potential moderators of this relationship have yet to be clarified. Harm avoidance is the trait more consistently linked to migraine. Borderline personality disorder emerged from some researches ^{12,13}, related to the increased impact on the quality of life, medication overuse and poor response to both pharmacological and alternative treatments ¹⁴.

On the other hand, there is a strong evidence about the relationship between headache and emotions ¹⁵. Nociceptive information is integrated with the emotional awareness in the homeostatic interoceptive system. An altered affective status could be both the predisposing factor as well as the effect of headache.

The pain experience is made by sensorial and unpleasant emotional processes ¹⁶.

The concept of cortical hyperexcitability could be hypothesized both for sensory ^{16,18} and emotional aversive stimuli. Wilcox et al. ¹⁹, using fMRI findings in response to the International Affective Picture System (IAPS) ²⁰, demonstrated

an increased neural activity to negative emotional stimuli in people with M. The cerebral regions involved were the posterior cingulate, caudate, amygdala and thalamus. No differences were found in response to positive and neutral emotional stimuli. The pathophysiology of M can include widespread hypersensitivity to negative stimuli involving the cortical-limbic system responsible for both sensory and emotional processing.

We studied the emotional dysregulation using the IAPS paradigm, a widely used tool to obtain an emotion-processing evaluation in psychiatric and neurological conditions ²¹⁻²³.

We measured emotional arousal (EA) and emotional valence (EV) in a sample of people with M to evaluate differences between the patients and a healthy reference group, and to estimate the association with psychological features.

Methods

Study population

Twenty outpatients (14 females, 6 males, mean age 35.2, SD 10.6) suffering from M were recruited at Clinical Neurophysiology Unit of the S. Salvatore Hospital of L'Aquila during a four months' period. According to the criteria of the International Classification of Headache Disorders ²⁴ ten patients (7 females, 3 males mean age 36.8 SD 10.7) were affected by M without aura and ten patients (7 females, 3 males, mean age 33.6, SD 8.5) by M with aura. Patients with a history of psychiatric symptoms previous or coexisting with the onset of M and with the inability to provide an informed consent were excluded from the study.

Fifteen healthy subjects (9 females, 6 males, mean age 39.9, SD 15.7) matched for gender and age with the clinical sample were also recruited through word of mouth during a two months' period.

All patients signed a written informed consent to participate after receiving a full explanation of the study procedures and goals. The study protocol has been approved by the Local Institutional Ethic Committee.

Emotional Dysregulation assessment

Emotional Dysregulation (ED) assessment was carried out using the International Affective Picture System (IAPS) paradigm which consists of a set of static images based on a dimensional model of emotions.

Ninety color pictures were chosen from the IAPS depicting events with different kinds of affective valence, i.e., unpleasant, pleasant, and neutral events. Unpleasant and pleasant events were also distinguished in pictures involving or not involving social human conditions: for example, pictures with social involvement include depictions of mother-child or familial interactions (pleasant) and outcomes of violence (unpleasant) while pictures without

social involvement include landscape scenes or flowers (pleasant) and snakes, contamination, or pollution (unpleasant). Neutral images consisted of pictures of furniture or appliances. For each of the five categories, 18 images were shown.

Reactivity to the pictures was rated on the basis of EA and EV. The valence rating instructions were "Rate how unpleasant or pleasant the image makes you feel using a 1-9 Self-Assessment Manikin (SAM) valence scale (1 = very unpleasant, 5 = neutral, 9 = very pleasant)". The arousal rating instructions were "Rate how emotionally intense or arousing the image makes you feel using a 1-9 scale SAM arousal scale (1 = calm, 5 = somewhat aroused, 9 = excited)". The SAM valence scale consisted of a cartoon-type figure in which nine human emotional expressions, ranging from smiling and happy to frowning and unhappy, were presented. The SAM arousal scale consisted of another cartoon-type figure with nine expressions ranging from calm and relaxed to excited and wide-eyed.

Stimuli presentation and response recording were managed using custom software (Super Lab 4.0 for Windows). The subjects were tested individually in a dimly lit room. They were seated in front of a 15-inch computer monitor at a distance of 50 cm. Trials started with a 2-s full screen presentation of one picture. The presentation order of the pictures depicting neutral and pleasant and unpleasant scenes with or without social involvement was randomized for each subject. Then, after a 1-s black screen, a display containing a smaller version of the same picture (located in the upper part) and the SAM valence scale (located in the lower part) was presented. This display remained visible for 3 s or until the participant responded. After the participants' valence rating, another display was presented in which the SAM valence scale was substituted with the SAM arousal scale. Similarly, the display remained visible for 3 s or until the participant responded. If the subjects did not respond within 3 s, an omission was recorded. Those who showed more than 5% of omitted responses were excluded from the two samples and not considered in the analysis. No subjects in our study were excluded for this reason.

Clinical assessment

Clinical Global Impression (CGI) severity was used to evaluate behavioral disturbances²⁵ by a senior psychiatrist (PS) based on more than thirty years of clinical experience. This experience formed the basis of CGI severity of illness rating along a 7-point Likert scale where 1 is "normal, not ill" and 7 is "extremely ill". All the patients with a CGI score equal to or higher than 2 were excluded from the study.

All the patients underwent a psychological assessment comprehensive of the Zung Self-Rating Anxiety Scale (SAS), the Beck Depression Inventory II (BDI-II), the Empathy Quotient (EQ), the brief TEMPS-M temperament

questionnaire (bTEMPS-M), the Millon Clinical Multiaxial Inventory III (MCMI III), the Symptom Check List 90 (SCL 90), the Brief Cope (BC), the Resilience Scale 14 (RS 14). The SAS is a 20-item self-report rating scale built to measure anxiety levels, based on scoring in 4 groups of symptoms: cognitive, autonomic, motor and central nervous system symptoms. Each question is scored on a Likert-type scale of 1-4 (based on these replies: "a few times", "sometimes", "good part of the time," "most of the time"). The total scores ranged between 20 and 80. The standardized cutoffs were: 0-20: very low anxiety level; 21-40: low anxiety level; 41-60: moderate anxiety level; 61-80: high anxiety level²⁶.

The BDI is a psychometric test for measuring the severity of depression. It contains 21 questions; each answer being scored on a scale value of 0 to 3. Higher total scores indicate more severe depressive symptoms. The standardized cutoffs are: 0-13: minimal depression, 14-19: mild depression, 20-28: moderate depression, 29-63: severe depression²⁷.

The Empathy Quotient (EQ) is a 60-item questionnaire to measure empathy in adults²⁸. The test was developed by Simon Baron Cohen²⁹ and is suitable for use as a casual measure of temperamental empathy.

The bTEMPS-M temperament questionnaire³⁰ consists of 35 items to assess affective temperaments underlying the psychobiological aspect of personality (depressive, anxious, hyperthymic, cyclothymic and irritable) using a dimensional approach with a five-point Likert type scale ranging from 1 to 5 (1 = "not at all"; 2 = "a little"; 3 = "moderately"; 4 = "much"; 5 = "very much").

The MCMI is a psychological assessment tool for adults to provide information on personality traits and psychopathology, including specific psychiatric disorders outlined in the DSM-5³¹.

The SCL-90-R is a self-report questionnaire to evaluate a range of psychological problems and symptoms. It consists of 90 items yielding nine scores along primary symptom dimensions and three scores among global distress indices. The primary symptom dimensions that are assessed are somatization, obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation and psychoticism³².

The Brief Cope (BC) is a 28 item self-report questionnaire designed to measure effective and ineffective ways to cope with a stressful life event³³.

The RS-14 aims to evaluate the levels of resilience in the general population and correlates negatively with depression and positively with meaning in life and self-efficacy³⁴. The disability caused by headache was assessed by means of the Migraine Disability Assessment (MIDAS) that measures the impact of headaches on daily life³⁵.

Statistical analysis

Student's t-test was used for between-group comparisons

of IAPS indexes. Pearson's correlation was also used to evaluate association between IAPS indexes found different in the between group comparisons or with effect size at least medium (Cohen's $d > 0.50$), psychometric scores and MIDAS evaluation.

Results

No differences on all variable scores, demographic, IAPS and clinical, were observed among M participants with or without aura. The analyses were then conducted to the entire M sample.

The between-group comparison of IAPS scores showed that mean arousal ratings of the clinical group were significantly higher than those of controls for unpleasant and socially unpleasant pictures (Tab. I). Observation of Cohen's d effect size showed a very high value for arousal to socially unpleasant images between group difference (4.31). Arousal to unpleasant and valence to unpleasant and socially unpleasant images were higher than 0.5, representing a 'medium' effect size. On the contrary, the remaining values were small.

Correlations of these IAPS indexes (arousal and valence to unpleasant and socially unpleasant images) with the clinical evaluations were therefore investigated. The arousal scores of socially unpleasant pictures showed numerous significant correlations with psychometric scores. In Table II are reported the significant correlations, being the remaining trivial ($r < 0.20$): higher arousal is associated with higher migraine disability ($r = 0.52$, $p < 0.25$); valence to unpleasant images was similarly related to migraine disability ($r = 0.051$, $p < 0.025$) while arousal inversely related to Brief Cope score ($r = -0.47$, $p < 0.05$).

Discussion

Our results confirm previous observations of ED in patients with M¹⁹. This study, however, takes one-step forward, adding the observation that arousal in response to unpleasant cues, is the most important issue, especially if social conditions are involved.

As a matter of fact, emotional arousal scores were higher in response to unpleasant and socially unpleasant pictures of IAPS, supporting the hypothesis of an altered cerebral processing of negative stimuli in M patients, according to several data in the literature^{36,37}. The increased arousal to social negative stimuli may be sustained by the sensitization observed in migraine regarding not only the sensory but the emotional dimension too. This could account for the increased comorbidity with emotional disorders in M patients.

In our sample the ED correlates to some personality traits. Possibly, due to the small sample size, the increased arousal to social unpleasant stimuli moderately correlates with less dependent personality pattern and less inter-individual sensitivity and more with anxiety. These observations can suggest management impairment of social cues. The valence for socially unpleasant stimuli, was found to be reduced, although not significantly, in the M sample, but with a medium effect size. This is related positively with narcissistic, histrionic, thought disorders and negatively with antisocial personality patterns and depressive symptom dimension. Moreover, the inverse relationship with coping strategy score, as evaluated by BC, seems to suggest that this pattern is somewhat advantageous regarding social cues. On the other hand, this pattern is disadvantageous in terms of a trend towards depression, and anxiety, as well as grater severity of the headache disorder measured

TABLE I. Mean (\pm SD) picture arousal and valence (socially pleasant, pleasant, neutral, unpleasant and socially unpleasant) ratings, as a function of group (20 individuals with migraine vs 15 gender and age matched healthy controls).

	Neutral	Unpleasant	Pleasant	Socially unpleasant	Socially pleasant
Arousal					
Migraine sample	2.8 \pm 0.2	5.5 \pm 0.4	6.4 \pm 0.5	6.2 \pm 0.4	6.5 \pm 0.4
Control group	2.8 \pm 0.6	4.8 \pm 1.3	6.6 \pm 1.1	3.2 \pm 0.9	6.2 \pm 1.2
Student's t-test	0.30	2.13	0.83	5.67	0.97
P	NS	< 0.05	NS	< 0.0005	NS
Cohen's d effect size	0	0.73	0.23	4.31	0.33
Valence					
Migraine group	3.5 \pm 0.5	3.9 \pm 0.6	6.5 \pm 0.5	2.7 \pm 0.7	6.2 \pm 1.1
Control group	3.4 \pm 0.8	3.5 \pm 0.9	6.6 \pm 1.1	3.2 \pm 0.9	6.2 \pm 1.1
Student's t-test	0.64	1.22	0.17	1.69	0.00
P	NS	NS	NS	NS	NS
Cohen's d effect size	0.15	0.52	0.11	0.62	0

TABLE II. Correlation coefficients (Pearson *r*) among reaction to IAPS socially unpleasant images, psychometric scores and MIDAS evaluation (*n* = 20).

	IAPS socially unpleasant images	
	Arousal	Valence
MCMI III		
<i>Clinical personality patterns</i>		
Dependent	-0.52**	
Histrionic		0.55**
Narcissistic		0.54**
Antisocial		-0.49*
<i>Clinical syndromes</i>		
Anxiety	0.50**	
Thought disorders		0.74§
SCL 90 - R symptom dimensions		
Inter-individual sensitivity	-0.48*	
Depression		-0.69°
Anxiety	0.57***	
Brief Cope		-0.46**
Migraine disability Assessment (MIDAS)	0.52**	

* $p < 0.05$; ** $p < 0.025$; *** $p < 0.01$; ° $p < 0.001$; § $p < 0.0005$

as impact on daily life, and greater headache severity as measured in terms of impact on daily life, being positively related to unpleasant stimuli (non-social and social).

These results do not allow to speculate on the possible subsistence of a cluster of personality traits specific for M or on the role of a cluster of personality traits that could differentiate M patients from controls or subjects suffering from other diseases. Further researches are needed to clarify this issue.

Nevertheless, the personality traits we found to be related to ED are suggestive for the possible link between ED and some account of neuroticism and even psychoticism, independently from the relationship with anxiety, depression, specific affective temperament and empathy patterns.

Although speculatively, our observation of a significant arousal increase in response to socially unpleasant images may be in agreement with recent research data. Fong et al.³⁸ found that the subjects with M could suffer from a condition of hyperexcitability of the visual cortex. If so, our results could imply moreover that this anomaly would be specifically amplified by social cues.

This study has some limitations. The small sample size is the first one. We aim to have a larger sample size that

may improve the statistical power. This limited sample size could have obscured relationships with empathy or resiliency indexes that intuitively could be related to our IAPS results. Secondly, a longitudinal rather than a cross-sectional design can lead to make causal inferences.

Moreover, based on our results, showing only trivial relationship between Emotional Reactivity and psychopathological symptoms, as evaluate by psychiatric rating scales such as SAS and BDI-II, more in-depth investigation of personality traits rather than the search for specific symptomatology may be appropriate.

People with M could more frequently be prone to develop dysfunctional personality patterns, and this association could interfere with the clinical presentation and the course of the headache disorder, as well as affect the prognosis. The association between personality traits and ED in M patients is worth of attention because it could represent the cause of an increased susceptibility to many negative stimuli, and might also worsen the course of the headache disorder and amplify the vulnerability to psychopathology.

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An overview of mental health recovery-oriented practices: potentiality, challenges, prejudices, and misunderstandings

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SUMMARY

Objectives

The implementation of recovery-oriented practices in the daily activities of mental health organizations is nowadays a challenge internationally. However, there is a lack of studies on the methodology of these practices and on the challenges faced by organizations in implementing them. The purpose of this paper is to report the state-of-the-art of recovery-oriented practices in mental health organizations.

Methods

This paper is a narrative literature review of relevant articles and prior works that have been central to the topic including the history of recovery-oriented practices, recovery-oriented interventions, advantages, and obstacles in implementing recovery-oriented practices in mental health organizations.

Results

Procedures for implementing recovery-oriented practices in mental health organizations and several recovery-oriented interventions have been tested. Despite unsolved challenges, recovery-oriented practices have shown the potential to improve mental health care, with a positive impact on the quality of life, the autonomy of service users and health outcomes.

Conclusions

The implementation of recovery-oriented practices requires a change in the paradigm of care in mental health services that may need to modify traditional priorities, and also for the stakeholders who need to review, redefine and re-evaluate their roles and personal identities. Thus, specific strategies might be adopted to reduce the fear of innovations and increase the awareness of advantages.

Key words: mental health services, mental health recovery, recovery-oriented practices, recovery outcome, review

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Conflict of interest

The Authors declare no conflict of interest

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Introduction

The understanding of recovery as a personal and subjective experience¹, and the theoretical foundations supporting the need to provide recovery-oriented practices are clear and widely shared in many countries^{2,3}. The implementation of recovery-oriented practices in daily activities of mental health organizations is nowadays a significant challenge internationally¹. Efforts in the development of effective strategies are under study^{2,3}. Given that the research in recovery-oriented practices is still a field in the

beginning stages, we have limited knowledge of how recovery-oriented practice is effectively implemented in mental health organizations ^{2,4,5}.

The aim of this paper is to provide an overview of current recovery-oriented practices from the beginning to the current state-of-art including recovery implementation issues in mental health organizations, identification of strengths and of obstacles that impede the provision of recovery-oriented practices, and finally caveats to overcome them.

Methods

This narrative review was based on an electronic search that included two databases, PubMed and Google Scholar, and used four search terms: 'mental health recovery', 'recovery-oriented practices', 'recovery implementation in mental health', 'personal recovery', and 'recovery outcome'.

Full text published articles, books, and recovery-oriented practices guidance and procedures for mental health organizations both in English and in Italian from 1980 to 2019 were included. Additional references were identified by a manual search among the cited references.

The chosen eligibility criteria aimed to report and analyze the current knowledge on recovery-oriented practices. Inclusion criteria focused on i) recovery-oriented practices, ii) personal recovery model, iii) recovery-oriented practices guidance and procedures, vi) evidence on recovery-oriented practices.

Exclusion criteria allow to remove texts focused on i) other recovery models (p.e. clinical and/or functional recovery) development, principles, guidelines, procedures and interventions, ii) measures of recovery outcomes, iii) psychiatric rehabilitation.

The selection resulted in 37 references: 20 articles, 6 books, and 9 recovery-oriented practices guidance and procedures for mental health organizations.

Results

The development of the recovery concept

The concept of recovery owes a historical debt to the "moral treatment" pioneered in the 18th century by the Tukes and Pinel at the 'York Retreat' asylum ^{6,7}. The "moral treatment" is characterized by the effort of fighting mental health disorders by arising in the patients of asylums a sense of responsibility aimed to maintain acceptable levels of self-control, of self-help attitude as expression of the wider tendency of the industrialized society of the 18th century to move from imposed external "coercion" of the body to 'internal coercion' of the 'soul'. In other words, the Tukes showed that moral or psychological forms of treatment in a work-oriented,

peaceful and pleasant environment could replace physical restraint ⁸.

Later, the implementation of deinstitutionalization in the 1960s and 1970s, the increasing ascendancy of the community support system concept, and the practice of psychiatric rehabilitation in the 1980s have laid the foundation for a new 1990s vision of service delivery for people who had a mental illness ⁹. The need to define recovery as the main aim of mental health community services was elicited by the awareness of the inadequacy of the deinstitutionalization process, characterized by community services still predominantly focused on the management of the user's crisis ¹⁰. The failures in the implementation of the deinstitutionalization's policies confronted the mental health professionals with the fact that a person with a mental health illness wants and needs more than just symptom relief. People with severe mental illnesses might have multiple residential, vocational, educational, and social needs and desires. These new ideas have promoted the gradual emergence of the recovery vision, which has guided the mental health system from there on ^{9,10}.

Thus, the recovery paradigm has set a positive approach to mental wellbeing suggesting that people previously diagnosed with long-term or enduring mental health problems are able to establish independent and healthy lives even in the presence of symptoms ⁹⁻¹³.

The key principles of the recovery-oriented approach

The recovery-oriented approach is based on the following principles:

- to implement specific and interconnected good practices in a mental health organization;
- to develop person-centered practices aimed to help individuals in living a meaningful life ¹⁴;
- to promote hope, and facilitate self-determination ¹;
- to put efforts to get a proper understanding of the person's strengths, preferences, and aspirations;
- to support personal choices about life ¹⁵;
- to provide a *co-production spirit* between users and professionals, an equal partnership to learn new ways of working together to support users in pursuing their goals ^{2,17} and to achieve both health and social outcomes ^{2,15,17};
- to provide access to well-organized services that deliver evidence-based treatments ^{14,18};
- to assess needs ¹⁻³;
- to predispose comprehensive plans of treatment ^{19,20};
- to benefit of the specialist skills and expertise necessary for the management of multiple and complex problems, in all areas that are likely to have an effect on outcomes such as finances, housing, employment, and social integration ¹⁵.

Finally, the recovery-oriented approach should combine the professional help, and the informal resources from

the community (such as friends, families, employers, education bodies) to enable service users to achieve their goals^{1,15,21,22}.

The key recovery-oriented practices in daily activities of mental health organizations

The implementation of the recovery-oriented approach in the daily activities of mental health organizations is supported by a series of procedures and guidance.

Recovery-oriented organization

First of all, the translation of the recovery concept into clinical practice implies the change of the organizational culture of the mental health services^{1,3,16}.

Recovery values need to be embodied in the vision and mission of the organization, and in every management process, including recruitment, supervision, appraisal, audit, planning and operational policies, and assessment of outcomes. These necessary changes need to be understood by the commissioners of services and commissioned through co-production between the commissioners and the local service providers. This requires leadership engagement as well as the commitment of managers and practitioners at the front line, and involvement of all the stakeholders¹⁷. Thus, professionals and other stakeholders need to review, redefine and re-evaluate their roles and personal identities^{10,18,19}. Mental health organizations should implement specific staff training^{2,16} and give value to the input of service users, and carers, redefining service user involvement to create a more equal partnership^{6,23,24}. Furthermore, job opportunities in the workforce for people who have experienced mental ill-health should be provided¹⁵.

However, the changes of perspective and roles of professionals and service users are not sufficient if they are not supported by attempts to change the organizational culture of mental health services; without this support, the risk is to have an inevitably weak and short term effect^{2,16}.

Finally, recovery-oriented services must have strong strategic relationships with social care agencies, such as housing, employment, and community networks²⁰.

In 2010 Shepherd and collaborators, during the IMROC program, elaborated the “10 organizational challenges” that, shown in the Table I, provides a schema that can be used by stakeholders to evaluate the current progress of services to support recovery and define the objectives of change with sufficient validity to implement the auditing processes in community services^{3,16,17}.

Recovery-oriented professionals' skills

Mental health professionals should have competences to qualify their daily practices as recovery-oriented as resumed in Table II.

In Table III are listed the Sainsbury Centre's 10 top practical tips for Recovery-oriented practice that mental

TABLE I. *Making organizations more recovery-oriented (from Shepherd, et al., 2010, mod.)²³.*

Ten key organisational challenges
1. Changing the nature of day-to-day interactions and the quality of experience
2. Delivering comprehensive, service user-led education and training programs
3. Establishing a 'Recovery Education Centre' to drive the programs forward
4. Ensuring organizational commitment, creating the 'culture'
5. Increasing 'personalization' and choice
6. Changing the way we approach risk assessment and management
7. Redefining service user involvement
8. Transforming the workforce
9. Supporting staff in their recovery journey
10. Increasing opportunities for building a life 'beyond illness'

health professionals should pursue to adopt the recovery approach³.

Recovery-oriented interventions

In synthesis, the main recovery-oriented practices that have proved to be evidence-based are: i) peer support workers, ii) advanced treatment directive, iii) Refocus, iv) the Strengths Model, v) the IPS model, vi) the Recovery Colleges, vii) Supported housing, viii) Mental health dialogue^{1,2,25}.

Peer support workers

Individuals with mental illness who identify themselves as such, and who use their lived experience to support others to recover. Experts by experience, they offer to users and family members their experience, a model of successful care path, emotional closeness, and trust not replacing mental health professionals and with a range of more or less formal approaches within mental health organizations^{1,2,5,10}. Evidence show peer workers have a positive effect on several outcomes²⁵ with a reduction of admission and length of hospital admissions, an increase in service users satisfaction self-efficacy, and empowerment hope and insight, and increase social networks. However, challenges exist in introducing peer workers in mental health organizations and more research is needed²⁶.

Advanced treatment directive

The formulation of a document that specifies a person's future preferences for treatment, should he or she lose the mental ability to make treatment decisions (lose capacity). An increasingly common variant is the “joint cri-

TABLE II. *Necessary competences for mental health professionals in order to favour recovery.*

Necessary competences according to Farkas M, Gagne C, Anthony W et al. (2005) ¹⁴	Necessary competences according to Carozza P (2006) ¹⁰
The capacity to collaborate.	To consider that people with psychiatric disabilities need not be guarded or assisted, but accompanied to regain their role in the community.
Skills related to inspire, teach and coach.	To know the consequences of the psychiatric disorder, its evolution, its impact on the family, the most appropriate psychosocial interventions.
Skills to facilitate the choice according to the Shared-decision-making process	To provide emotional or instrumental support and help the user to identify his/her goals.
Skills and strategies to promote empowerment, hope, and self-acceptance.	

TABLE III. *Ten top tips for recovery-orientated practice (from Shepherd, et al., 2008, mod.)³.*

A. Understand recovery
Help the person identify and prioritize their personal goals for recovery (not the professional's goals)
Demonstrate a belief in the person's existing strengths in relation to the pursuit of these goals
Be able to identify examples from your own lived experience, or that of other service users, which inspires and validates hope
Accept that the future is uncertain and that setbacks will occur, continue to express support for the possibility of achieving these self-defined goals – maintaining hope and positive expectations
B. Know how to collaborate
Encourage self-management of mental health problems (by providing information, reinforcing existing coping strategies, etc.)
Listen to what the person wants in terms of therapeutic interventions, e.g. psychosocial treatments, alternative therapies, joint crisis planning etc. Show that you have listened to
Behave at all times so as to convey an attitude of respect for the person and a desire for an equal partnership in working together
Indicate a willingness to 'go the extra mile' to help the person achieve their goals
C. Have a broad view
Pay particular attention to the importance of goals that take the person out of the traditional sick role and enable them to serve and help others
Identify non-mental health resources – friends, contacts, organizations – relevant to the achievement of these goals

sis planning", which means to produce a plan for use during a future mental health crisis or relapse^{2,27}. Evidence shows the reduction of compulsory admissions in psychotic patients in terms of reduction of costs, of use of services, and greater personal control over the disease^{1,25}.

Refocus

A program of research, funded by the NHS National Institute for Health Research (Programme Grants for Applied Research), from 2009 to 2014 at King's College London. The aim of REFOCUS was to find ways of making community-based adult mental health services in England more recovery-orientated. The staff is trained in three activities and supported with reflection

and supervision sessions: identification of the values and preferences of the user's treatment, evaluation of the strengths, the support offered in the commitment to reach the objectives². The intervention was validated¹ and has a theoretical basis^{22,28}.

The strengths model

Developed in the mid-1980s, it is both a philosophy of clinical practice and a set of tools and methodologies. Its founding assumption is that the identification and strengthening of the strengths of the person and his/her environment, rather than the identification of his/her deficits and attempts to "repair" them, can facilitate the recovery processes. The adoption of a strengths model-based case management in relation to many areas,

including hospitalization, housing placement, employment, training, symptom reduction, leisure time, social support and family work, highlighted its effectiveness in people with psychiatric disabilities ^{2,17}.

The individual placement and support (IPS) model

The IPS is a psychosocial intervention of supported employment, with a considerable body of evidence for effectiveness in helping people with severe mental illness (SMI) to obtain and maintain competitive employment according to their preferences ²⁹. IPS assumes that nearly all people with severe mental disabilities can engage in some type of work and that work is a good treatment. Thus, while some vocational models attempt to separate rehabilitation from other treatments, IPS integrates them closely. Studies across the world, mostly RCT (there are 18), and a Cochrane review, have consistently shown that IPS produces better work and overall health and social outcomes compared to other types of employment programs for patients with SMI ².

Recovery colleges

Recovery colleges or Recovery Education Centre offer educational courses about mental health and recovery which are designed to increase students' knowledge and skills and to help them feel more confident in self-management of their own mental health and well-being. For a person, with lived experience of mental ill-health, this may help them to take control and become an expert in their own well-being and recovery and move on with their life despite their mental health challenges. This will hopefully help them to achieve or work towards whatever is meaningful in their lives ³⁰. They use an educational paradigm to complement traditional treatment approaches ²¹. There is a strong and consistent body of evidence from an increasing number of uncontrolled studies on the positive impact of Recovery Colleges in several areas such as supported self-management education and peer support ³¹.

Supported housing or housing first intervention

The intervention involves rapid re-housing in independent accommodation, considering that safe and secure permanent housing, regarding their preferences, can act as a base from which people with severe mental illness can achieve numerous recovery goals and improve quality of life. This approach has an emerging evidence base showing improved outcomes and reduced costs.

Mental health trialogues

These meetings are community forums where service users, carers, friends, mental health workers, and others with an interest in mental health participate in an open dialogue. Meetings address different topics, e.g. a task

force on stigma-busting, or a workgroup on trauma and psychosis. International interest and experiences are growing but there is not a consistent bulk of evidence on this intervention. A positive effect on more successful collaboration has been found in qualitative research ¹.

Advantages of recovery-oriented practices

Literature shows that recovery-oriented practices are advantageous both for service users and mental health organizations. The main advantages are: 1) *Positive outcomes for people with a long-term severe mental illness*. Longitudinal researches show that a significant number of people with a severe mental illness, if treated early, effectively and continuously has a substantially positive evolution. About 50% of people with schizophrenia will recover fully or improve substantially after the initial acute illness, being able to live independently, while 10% remain chronically institutionalized ^{10,12,13}. Furthermore, the recovery-oriented approach and, particularly the shared decision-making process, has shown evidence in improving self-management, and autonomy ^{6,15}. 2) *Reduction of health costs*. Recovery-oriented practices have been proved to correlate positively with a reduction of the costs for the health systems because recovery-oriented interactions between different stakeholder groups directly improve the cohesion among stakeholders and the quality of care planning ³². More recovery-oriented is the care planning, more the service user will be able to achieve his/her personal goals with the aim of living 'a satisfying and meaningful life beyond illness' ³³, this will imply increasing contacts with natural community supports, and reduction of the contacts with formal mental health organizations resulting in a cost reduction for health systems ¹. Furthermore, evidence shows that coproduction is cost-effective because it allows having access to the resources of the overall public sector and of the community, resources that tend to be underused even if they do not imply additional costs ²⁴. 3) *Greater value on the personal knowledge of the individual*. The assumption of the presence of two experts in the clinical encounter (the professionals with their technical knowledge and the service users with their expertise by experience) provides greater job satisfaction for professionals as well as the improved engagement of service users in the management of their own problems ^{13,15}. 4) *Greater emphasis on the personal priorities of the service user* rather than on the best interests of the service user defined by the professionals. This emphasizes the values underpinning the clinician's work and helps them to understand their role. Furthermore, this may lead the users to better outcomes and enable them to live the lives they want to lead ^{5,6}. 5) *Re-address the historically subordinate interests of people with mental illness in society*. It provides a means of em-

powering service users and reasserting their rights and citizenship with the potential of greater social inclusion and a potential role for clinicians in helping to promote this ^{15,23,34}.

Challenges for implementing recovery-oriented practice in mental health organizations

Mental health organizations are increasingly trying to implement recovery-oriented practices ¹, with relevant progress in the development and implementation of effective strategies.

However, the translation of the recovery concept into practice has to face a series of challenges for the whole organization, and the stakeholders, due to the complexity and variability of the process as services have different historical contexts and organizational structures ^{2,3}.

Obstacles to recovery-oriented practice

Although over the last ten years a growing number of publications have focused on the themes and the possible implications of recovery, mental health organizations and mental health professionals have still considerable uncertainty and criticisms about the precise meaning of these concepts and their effective application in the everyday clinical practices ^{2,3}. This is probably due to anxiety about new approaches, change, and lack of knowledge about the evidence behind the recovery approach ^{4,10,25}, and deficiency of the recovery phenomenon as a subject of study in the training programs of professionals ^{2,3}.

The lack of knowledge on the key recovery concepts has ended in a series of implausible *negative assumptions and prejudices*, such as the following. 1) *Recovery means the introduction of new services*. A recovery approach may not need a wide introduction of new services, as there is a certain overlap between recovery-oriented interventions and some already existing and evidence-based therapeutic and rehabilitative practices ^{2,3}. Thus, what is required is only an adjustment of approaches to re-emphasize the priorities of service users ¹⁵. 2) *Recovery increases providers' exposure to risk and liability*. It is true that a recovery-oriented service will require a change in emphasis from risk avoidance to constructive and creative risk-taking. Mental health professionals must seek to differentiate between the risks that must be minimized (self-harm, harm to others) and the risks which people have a right to experience, the risk that may enhance personal recovery ¹⁵. The recovery approach should encourage opportunities for growth and change but, of course, this must be done in a responsible way, being risk-aware but focused on safety planning in an increasingly collaborative approach that promotes people taking responsibility themselves

for ensuring their safety with service supports ^{4,6,15}. 3) *Recovery adds to the burden of the professional*. On the contrary, it has been shown that if recovery principles and values are integrated and not simply added on or exchanged with previous practice, the result is that assessments and interventions would be collaboratively agreed by staff and service users with the capacity to erasing unnecessary tasks and achieving greater job satisfaction ^{10,15}. 4) *Recovery-oriented practices are an anti-medical profession model*. In reality, recovery-oriented interventions incorporate medical approaches into their holistic vision. Thus, rather than in conflict or in competition with one another, these models can be seen as complementary and potentially useful to one another ^{2,3,13}.

Furthermore, a series of common *misunderstandings* towards the meaning of recovery key-concepts has been detected 1) *Recovery services are neither cost-effective nor evidence-based*. On the contrary, evidence supports the introduction of recovery principles, both according to first-person accounts and randomized controlled trials ^{35,36}. Literature proves the effectiveness of recovery models for the communication about schizophrenia, the approaches to the self-management of symptoms, and for gaining and retaining open employment ^{2,3,13}. In addition, both health and social benefits have been found. Feeling more "control" of one's life and finding meaning beyond illness are outcomes with positive health consequences. 2) *Recovery is nothing new as it means that the person is cured*. More precisely, recovery has a clearer focus on the person and his/her life, while the term 'cure' is prevalently focused on the concept of illness ¹⁵. 3) *Clinical, functional and personal recovery cannot be integrated*. This is not true as it has been proved that these concepts are complementary and synergistic even if they cover different domains ⁸.

Conclusions and implications for research and practice

Overall, the results of the review suggest that the shift to a recovery-oriented approach represents a key challenge in the provision of recovery-oriented practices in mental health services ^{2,3} because it requires a transformation of the paradigm within the practices that are delivered.

This transformation is not easy to assume, given that many rehabilitation models are based on the idea that individuals cannot recover from mental illness ¹⁰, while recovery means 'living a life beyond illness' and 'building a meaningful and satisfying life', as defined by the person him/her-self, whether or not there are ongoing or recurring symptoms and problems' ³³. "Building a meaningful and satisfying life" for the service user is not

the result of good intentions, or optimistic ideology neither of the power of positive thinking because recovery does not happen naturally, and is not only a lifestyle of continuous experiences, more hope for the future, and empowerment. The adoption of the recovery approach by a mental health organization means involving all the stakeholders (service users, family members, professionals, and managers) in a common effort to combine the best rehabilitative practices with personal acceptance and positive self-reinforcement of the users to achieve outcomes such as the remission of symptoms, the improvement of social and work functioning, and the increase of social and life skills. The full partnership or synergy of all these figures represent the necessary engine to promote recovery, improving attitudes and initiatives that aim to empowerment, self-responsibility, hope and user satisfaction¹³.

However, despite the spread of procedures and guidance for mental health organizations and professionals about the way of implementing the recovery-oriented practices, and the growing bulk of evidence about the effectiveness of the recovery-oriented approach and interventions in improving overall outcomes, negative assumptions, prejudices, and misunderstandings towards the recovery concept already exists and represents a frequent reason of lack of an adequate adoption of the recovery-oriented approach in the daily mental health activities of the organizations.

To contribute to overcome the underlined challenges and effectively aiming at 'building a meaningful and satisfying life' for service users, some suggestions for re-

searchers might be useful: 1) to identify the substantial changes necessary to address the specific procedures that impede the delivery of recovery-oriented practices⁵; 2) to prove the impact of recovery approach on health costs^{5,24}; 4) to implement both qualitative and quantitative pilot studies in the field to fill the lack of knowledge³⁷; 5) to recast recommendations for EBM and mental health policies, providing standardized procedures for recovery-oriented practices to improve the integration between EBM and recovery approach^{34,37}. For professionals working in mental health organizations, we suggest 1) to improve organizational dynamics, promoting in figures to coordinate and supervise the group of mental health professionals to improve their skills and motivate them, and introduce elements of change into the system; 2) to adopt strategies aimed to reduce the fear of innovations and increase the awareness of advantages in all the stakeholders; 4) to promote the dissemination of recovery-oriented practices as good practices¹⁰; 5) to develop adequate training for the recovery approach^{10,25}; 6) to fight demotivation and disinterest involving the professionals in programmatic decisions oriented to coproduction¹⁰; 7) to contrast the internalization by service users of the concept of disability as a lack of motivation, interest, hope, and life objectives¹¹ that interfere with the individual's autonomy in work, education, family and social relations, recreational, and independent living¹³; 8) to confront both self and social/public stigmas, that are secondary handicaps for people with mental health disability, who are one of the most socially excluded groups in society^{6,13}.

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Atypical antipsychotic medications in the treatment of delirium: a systematic review

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SUMMARY

Objective

Delirium is an acute neuropsychiatric condition with high mortality rate if untreated. Haloperidol has long been the drug of choice when treating patients with delirium, however more recently atypical antipsychotics have increasingly been used in the management of this condition. We conducted a systematic literature review to assess the effectiveness of atypical antipsychotics in the treatment of delirium.

Methods

We devised a search strategy according to the methodology outlined in the Prisma guidelines on systematic literature reviews to identify randomised controlled trials comparing atypical antipsychotic medications with placebo, haloperidol, or other atypical antipsychotics in adult patients with delirium. We excluded studies where validated rating instruments were not employed and where antipsychotic medications were used to prevent delirium. Multiple risks of bias were estimated and taken into account.

Results

Our initial search yielded 238 articles. Following screening and application of inclusion and exclusion criteria, a total of 8 studies were included in the qualitative synthesis. The results of the reviewed studies showed that atypical antipsychotics can be useful interventions for the treatment of delirium: in addition to superiority to placebo, these medications demonstrated similar levels of effectiveness to conventional antipsychotics, with a better tolerability profile.

Conclusions

The available evidence from randomised controlled trials suggests that atypical antipsychotics are both safe and effective in the treatment of adult patients diagnosed with delirium. The findings of comparative studies indicate that these medications could be a valuable alternative to conventional antipsychotics. The limitations of the reviewed literature include the recruitment of clinical samples that are limited in size and heterogeneous in clinical presentation. Further clinical research should be conducted in patients with different aetiologies and clinical presentations of delirium, including hypoactive forms.

Key words: atypical antipsychotics, delirium, haloperidol pharmacotherapy; trials.

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Conflict of interest

The Authors declare no conflict of interest

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Introduction

Delirium is a neuropsychiatric condition characterised by alterations in cognition and consciousness or impairment in perception that develop over a short period of time (usually hours to days) and fluctuates throughout the course of the day¹. Occurring in approximately 10 to 30% of hospitalised medically ill patients and in up to 80% of terminally ill patients, delirium often presents with psychiatric symptoms such as hallucinations, delusions, confusion, and disorientation². Since delirium is essentially a

manifestation of an underlying medical or surgical illness, the management of delirium should primarily involve treating the underlying pathology³. Delirium is associated with increased mortality, morbidity, length of hospital stay, and long-term cognitive impairment^{4,5}. Although the pathophysiological processes underlying delirium are not fully understood, it is thought that cholinergic neurotransmission and brain plasticity play a key role^{6,7}. Treatment protocols combine management of the acute brain syndrome with general and specific procedures to control the underlying condition. Dealing with the symptom-complex involves the principles and practice of sedation, hydration, nutrition, nursing care, and supportive measures. Over the years, haloperidol, albeit not licensed, has been the preferred medication in the pharmacological management of delirium. More recently, in consideration of the adverse effects associated with haloperidol, atypical antipsychotic medications such as olanzapine have increasingly been used. Compared to haloperidol, relatively little is known about the use of atypical antipsychotic agents in patient with delirium. We therefore conducted a systematic literature review to assess the effectiveness of atypical antipsychotics in the treatment of delirium.

Methods

We devised a search strategy according to the methodology outlined in the Prisma guidelines on systematic literature reviews to identify randomised controlled trials comparing atypical antipsychotic medications with placebo, haloperidol, or other atypical antipsychotics in adult patients with delirium⁸. Both PubMed and Cochrane databases were searched using the following strategy: antipsychotic* (OR amisulpride OR aripiprazole OR asenapine OR clozapine OR lurasidone OR olanzapine OR paliperidone OR quetiapine OR risperidone OR ziprasidone) AND delirium AND random*. Only studies on patients aged at least 18 years and published in English language were included in the review. A further criterion for inclusion was the use of validated rating instruments such as the Delirium Rating Scale (DRS) or DRS Revised 98 (DRS-R-98), the Memorial Delirium Assessment Scale (MDAS), or the Delirium Index (DI). Thus, we excluded studies where validated rating instruments were not employed, as well as studies where antipsychotic medications were used to prevent delirium. Multiple risks of bias were estimated using the Cochrane risk-of-bias criteria and taken into account.

Results

The initial search of our systematic literature review yielded 238 articles, out of which 43 were excluded as duplicates. We screened 195 articles: 149 articles

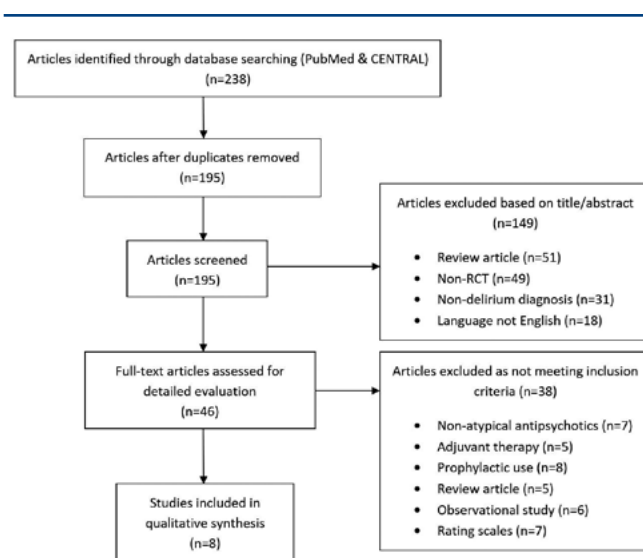


FIGURE 1. PRISMA flowchart illustrating the selection process of the reviewed articles.

were excluded based on the content of their title and abstract. Out of the 149 articles, 51 were review articles, 49 were original studies with a different protocol from randomised controlled trials, 31 had non-delirium diagnosis, and 18 were published in languages other than English. We retrieved 46 full text articles from the remaining number of articles: of these, 38 were excluded as they did not meet the inclusion criteria. Specifically, 7 articles focused on typical antipsychotics, 5 used adjuvant therapy, 8 were prophylactic studies, 5 were review articles, 6 were observational studies, and 7 used less established rating scales that were not part of our inclusion criteria. Therefore, a total of 8 randomised controlled trials were included in our review (Fig. 1).

Table I shows a summary of the main characteristics of the reviewed studies on atypical antipsychotics in the treatment of delirium.

Table II shows a summary of the risk of bias of the reviewed studies based on Cochrane risk-of-bias criteria, whereas Figure 2 shows an overall quantification of such risk.

Discussion

The available evidence from randomised controlled trials suggests that atypical antipsychotics are both safe and effective in the treatment of adult patients diagnosed with delirium. According to the results of our systematic literature review, there was only one placebo-controlled double-blind, randomised trial that compared an atypical antipsychotic medication (quetiapine) with placebo. Only adult patients who met Diagnostic and Statistical

TABLE I. Summary of the main characteristics of the studies on atypical antipsychotics in the treatment of delirium.

Study	Sample size	Type of RCT	Medication	Setting	Rating scale
Placebo controlled randomised studies					
Tahir et al., 2010	42	Double-blind	Quetiapine (n = 21) Placebo (n = 21)	Medical and surgical wards	DRS-R-98
Randomised studies comparing an atypical antipsychotic with haloperidol					
Grover et al., 2016	63	Single-blind	Quetiapine (n = 31) Haloperidol (n = 32)	Liaison psychiatry	DRS-R-98
Maneeton et al., 2013	52	Double-blind	Quetiapine (n = 24) Haloperidol (n = 28)	Liaison psychiatry	DRS-R-98
Grover et al., 2011	64	Single-blind	Risperidone (n = 21) Olanzapine (n = 23) Haloperidol (n = 20)	Liaison psychiatry	DRS-R-98
Han and Kim, 2004	24	Double-blind	Risperidone (n = 12) Haloperidol (n = 12)	Psychiatry	MDAS
Skobrik et al., 2004	73	Single-blind	Olanzapine (n = 28) Haloperidol (n = 45)	Intensive care unit	DI
Randomised studies comparing two or more atypical antipsychotics					
Kim et al., 2010	32	Single-blind	Risperidone (n = 17) Olanzapine (n = 15)	Psychiatry	DRS-R-98
Lee et al., 2005	31	Single-blind	Amisulpride (n = 16) Quetiapine (n = 15)	Liaison psychiatry	DRS-R-98

Abbreviations: RCT: randomised controlled trial; DI: Delirium Index; DRS-R-98: Delirium Rating Scale - Revised 98; MDAS: Memorial Delirium Assessment Scale

TABLE II. Summary of the risk of bias of the reviewed studies.

	Grover et al., 2016	Maneeton et al., 2013	Grover et al., 2011	Han and Kim, 2004	Skobrik et al., 2004	Kim et al., 2010	Lee et al., 2005	Tahir et al., 2010
Random sequence allocation (selection bias)	+	+	+	+	-	+	+	+
Allocation concealment (selection bias)	+	+	+	+	-	+	+	+
Blinding of participants and personnel (performance bias)	-	+	-	+	-	-	-	+
Blinding of outcome assessment (detection bias)	-	+	-	+	?	?	-	+
Incomplete outcome data (attrition bias)	-	+	-	-	-	?	-	+
Selective reporting (reporting bias)	+	+	+	-	-	-	-	+
Other bias	+	+	+	+	?	+	+	+

Note: +: low risk; -: high risk; ?: unknown risk

Manual for Mental Disorders (DSM) criteria for delirium and whose DRS-R-98 total score was 15 or higher were included in the study by Tahir et al.⁹. Patients with major pre-existing cognitive deficits or psychosis, patients

presenting with alcohol withdrawal symptoms, and patients taking medications that were known to interact with quetiapine were excluded. A total of 372 patients were screened and 42 of them were recruited in the

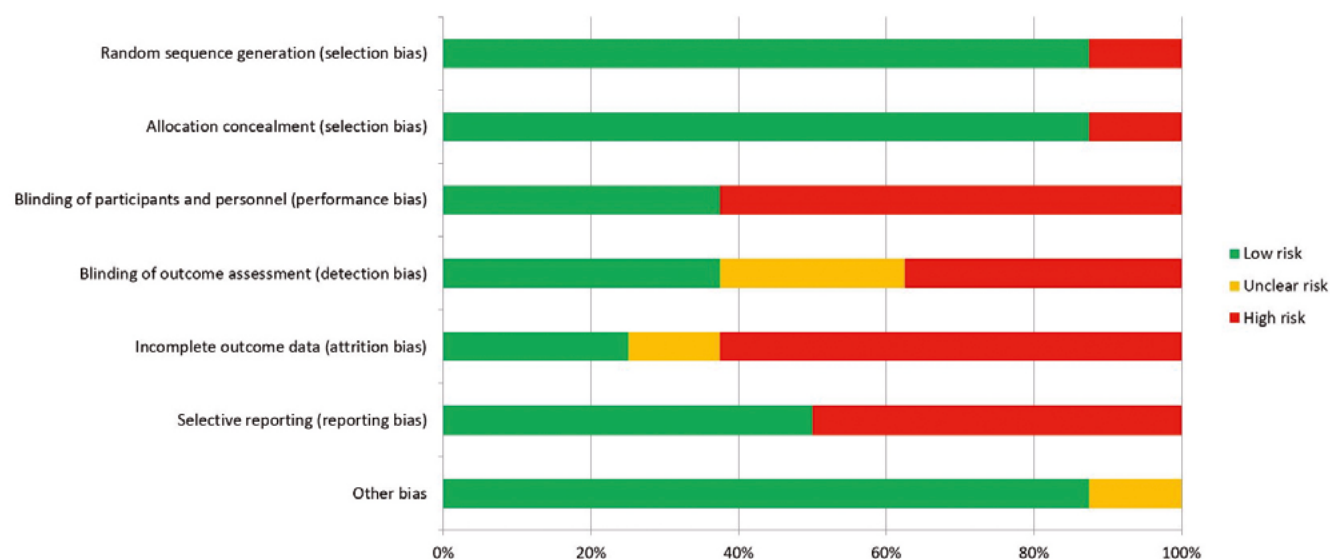


FIGURE 2. *Quantification of the risk of bias in the reviewed studies.*

study. The participants were split into two groups: 21 patients were allocated to the active treatment group and received quetiapine, whereas the remaining 21 patients received a placebo. The mean age of the patients recruited for the trial was 84.2 ± 8.3 years, with ages ranging from 58 to 98 years. The majority of patients (30 out of 42) were female. The trial was completed by 16 patients in the quetiapine group and 13 patients in the placebo group. Participants were assessed on Days 1, 2, 3, 4, 7, and 10 after randomisation, and a follow up assessment was conducted on Day 30. After randomisation, the participants in the active treatment group received a starting dose of quetiapine of 25mg per day. The dose was increased to 175mg per day in divided doses if there was no clinical response or DRS-R-98 score improvement. The authors found a significant difference in severity scores between the quetiapine group and the placebo group. Further analyses on the cognitive and non-cognitive subscales revealed a statistically significant improvement in non-cognitive scores in the quetiapine group. There were a total of 7 deaths within 30 days of the study onset (4 in the quetiapine group and 3 in the placebo group). One patient had to discontinue quetiapine due to sedation as adverse effect. The incidence of involuntary movements was low (4.8% in the quetiapine group and 14.3% in the placebo group). Among the strengths of this study there was the low risk of selection, performance, and attrition bias; its main limitation was the small sample, suggesting that the study could have been underpowered. Importantly, this study was terminated earlier than

originally planned, due to concerns from Food and Drug Administration regarding the use of antipsychotics in the elderly. However, the participants of this study reported a significant improvement in DRS-R-98 scores, as well as non-cognitive symptoms of delirium, with the use of quetiapine.

Out of the eight studies included in our systematic literature review, seven were comparative studies: in five of these, atypical antipsychotics were compared to haloperidol.

The study by Han and Kim ¹⁰ was a double-blind randomised trial to compare the effectiveness of risperidone and haloperidol in the treatment of delirium. Patients referred to the psychiatry team who met DSM-validated criteria for delirium were included in the trial. Patients who had dementia or other psychiatric diagnoses and those who had received injectable antipsychotics during admission were excluded. A total of 28 patients were randomised to receive either risperidone or haloperidol in a flexible dosing manner, as deemed appropriate by clinical judgement. The trial was completed by 12 patients in each group. The mean daily dose of risperidone was 1.02 ± 0.41 mg per day (range 0.5-2.0 mg per day) and that of haloperidol was 1.71 ± 0.84 mg per day (range 1.0-3.0 mg per day). A validated rating scale (MDAS) was used to measure the severity of delirium at baseline and subsequently daily for 7 days. The authors found a significant difference in MDAS scores from baseline to day 7 in both groups, without significant differences between the groups. No clinically significant adverse effects were reported in the study. The

relatively small sample size was one of the main limitations of this study. Based on their findings, the authors concluded that risperidone is as effective as haloperidol in the treatment of delirium, with an overall better tolerability profile.

The study by Skobrik et al.¹¹ was a single-blind, prospective, randomised controlled trial comparing olanzapine and haloperidol in the treatment of delirium. Patients aged between 18 and 75 years following admission to intensive care unit were screened and diagnosed with delirium using DSM-validated criteria. Pregnant patients, patients who had received antipsychotic medication within 10 days prior to admission, or those with Parkinson disease, prolonged QTc interval, liver/renal/oropharyngeal dysfunction were excluded from the study. Randomisation was done on an odd/even day basis to receive olanzapine or haloperidol and the dosing regimen depended on clinical judgement. Out of 80 patients for whom informed consent was obtained, 73 patients provided data that were included in the final analysis. The mean age of patients receiving olanzapine was 67.5 ± 6.0 years and of those receiving haloperidol was 63.3 ± 11.7 years. The daily dose for olanzapine was 4.54mg per day (range 2.5-13.5 mg per day) and for haloperidol was 6.5 mg per day (range 1-28 mg per day). A validated rating scale (DI) was used to measure the severity of delirium, which decreased significantly in both groups with no difference between them. No side effects were reported in the olanzapine group, while 6 patients in the haloperidol group reported extrapyramidal adverse effects. The main limitations of this study included the high risk of bias, with odd/even randomisation leading to selection and performance bias. The results on the treatment of delirium suggested that olanzapine has equal efficacy when compared to haloperidol, with a better tolerability profile.

The first study by Grover et al.¹² was a prospective, single-blind randomised controlled trial assessing the efficacy and safety of olanzapine and risperidone versus haloperidol for the treatment of delirium. Patients referred to liaison psychiatry from medical and surgical wards were considered for enrolment in the study. Eligible participants had a diagnosis of delirium, with quantification of symptoms based on psychometric tools (DRS-R-98 and Confusion Assessment Method). Patients presenting with delirium associated with alcohol/benzodiazepine withdrawal or associated with dementia (based on clinical history), co-morbid psychosis or affective disorders, as well as those suffering from terminal illness, were excluded from the study. Patients with profound hearing or visual loss, aphasia, Parkinson disease, history of neuroleptic malignant syndrome, prolonged QTc interval of more than 500ms and history of sensitivity to drugs involved in the study were

also excluded. A total of 115 patients were assessed, of whom 25 were excluded as they did not meet the inclusion/exclusion criteria. Consent was obtained from 74 participants, who were randomly allocated to one of three groups: 26 to the olanzapine group, 22 to the risperidone group, and 26 to the haloperidol group. Out of these, 64 participants completed the study (23 in the olanzapine group, 20 in the risperidone group, and 21 in the haloperidol group). The doses of these medications were adjusted on a daily basis according to clinical judgement. The mean doses were as follows: olanzapine 3.05 ± 1.44 mg per day (range 1.25-10.0 mg per day), risperidone 0.95 ± 0.28 mg per day (range 0.5-2.0 mg per day), haloperidol 0.88 ± 0.98 mg per day (range 0.25-5.0 mg per day). All participants were assessed on a daily basis for 6 days. There was a statistically significant improvement in DRS-R-98 scores at Day 3 and Day 6 when compared to baseline across the three groups. Clinically significant adverse effects were reported by 2 patients in the olanzapine group, 6 in the risperidone group, and 4 in the haloperidol group. There were no significant differences in the incidence of adverse effects across the groups. The main limitations of this study were the relatively small sample size and the high risk of performance bias and attrition bias. The study showed that olanzapine and risperidone were not only effective, but also better tolerated in terms of adverse effects when compared to haloperidol.

The study by Maneeton et al.¹³ compared quetiapine and haloperidol in a 7-day prospective, double-blind randomised controlled trial in patients with delirium. Patients aged 18-75 years who were referred to liaison psychiatry and met the DSM criteria for delirium were included in the trial. Patients who had substance-induced delirium, had known allergy to quetiapine or haloperidol, were pregnant or breastfeeding at the time of the study, were on any other antipsychotic agent, as well as those who had renal/liver failure, were excluded from the trial. A robust randomisation method that involved a computer-generated randomisation system was employed. The patients were randomised to either quetiapine or haloperidol. Patients, staff, investigators and raters were all blinded. A flexible-dosing regimen based on clinical indications was used. Both medications were concealed in identical capsules. Co-administration of other psychopharmacological agents, including benzodiazepines, was not allowed. A total of 52 patients were recruited: 24 were allocated to the quetiapine group and 28 to the haloperidol group. The mean daily dose of quetiapine and haloperidol was 67.6 ± 9.7 mg and 0.8 ± 0.3 mg, respectively. A total of 13 patients in the quetiapine group and 22 patients in the haloperidol group completed the trial. Data were analysed for all the patients who took part in trial, indicating a low risk

of attrition bias. The DRS-R-98 was used to measure the severity of delirium. Clinically significant responses were defined as reductions in DRS-R-98 scores of at least 50% from baseline and scores of 12 or less without relapse. The rate of clinically significant responses was high with both quetiapine (79.2%) and haloperidol (78.6%), and did not differ significantly between the two. Few adverse effects were observed, with hypersomnia being the most common adverse effect in both groups. The second study by Grover et al.¹⁴ assessed quetiapine and haloperidol in the treatment of delirium. This was a single-blind randomised study in patients referred to liaison psychiatry, aged at least 18 years, who met the DSM criteria for delirium. Patients who had delirium due to alcohol or benzodiazepine withdrawal or delirium associated with dementia were excluded. Patients with prolonged QTc interval, patients unresponsive to verbal or physical stimuli, and patients who had hypersensitivity to quetiapine and haloperidol were excluded. A total of 35 patients were randomised to each group: 31 in the quetiapine group and 32 in the haloperidol group completed the trial. The DRS-R-98 was used to measure the severity of delirium, both at baseline and over the following 6 days. The dose of medication was adjusted according to clinical judgement. The mean dose for quetiapine was 26.63 ± 15.61 mg per day and for haloperidol was 0.67 ± 0.35 mg per day. Out of the 63 patients who completed the trial, 55 patients had the hyperactive type of delirium, 5 had the hypoactive type, and 3 had the mixed type. The DRS-R-98 scores improved significantly in both groups, with no significant differences between the groups. The main limitations of this study included attrition bias and the lack of placebo arm. Moreover, the treating psychiatrist was not blind to randomisation, resulting in high risk of performance and detection bias. The results of this study suggested that quetiapine is as effective as haloperidol in treatment of delirium.

Finally, our systematic literature search identified two randomised controlled trials comparing two or more atypical antipsychotics.

The study by Lee et al.¹⁵ assessed the effectiveness and tolerability of amisulpride and quetiapine in the treatment of delirium. Forty patients who had been referred to a psychiatric consultation service participated in the study. Patients with a history of psychiatric disorders, as well as those who had been taking antipsychotics, were excluded. Patients were randomised to receive either amisulpride or quetiapine with a flexible dosing regimen, according to the clinician's experience and preference. Other antipsychotics or benzodiazepines were not allowed for the duration of the study. The DRS-R-98 was used to measure the response to treatment in terms of delirium severity and effectiveness. Complete

data were obtained from 16 patients in the amisulpride group (mean age 60.8 ± 18.4 years; mean amisulpride dose 156.4 ± 97.5 mg per day; mean treatment duration 6.3 ± 4.4 days) and 15 patients in the quetiapine group (mean age 63.1 ± 14.5 years; mean quetiapine dose 113 ± 85.5 mg per day; mean treatment duration 7.4 ± 4.1 days). DRS-R-98 scores showed a significant decrease in both treatment groups, and there was no significant difference between the groups. No serious adverse effects were reported. The main limitations of the study included its single-blind design (performance bias), the variable dosing regimen, and the relatively small sample size. Overall, the results of this study provided evidence of the efficacy and tolerability of atypical antipsychotics in the clinical management of delirium. The study by Kim et al.¹⁶ was a 7-day trial comparing risperidone and olanzapine in the treatment of delirium. Patients who met DSM-validated criteria of delirium were included in the study, whereas those with dementia, hepatic problems, bone marrow suppression, or those who had previously taken antipsychotics for behavioural problems or patients undergoing intubation were excluded. The DRS-R-98 was used to measure the severity of delirium. A total of 32 patients were enrolled, out of which 17 were randomised to receive risperidone and 15 to receive olanzapine. The trial was completed by 12 patients in the risperidone group and 8 in the olanzapine group. The dosage was adjusted according to clinical judgement over the 7 days and rescue intramuscular injections of haloperidol or benzodiazepine were permitted and recorded. The mean starting doses were 0.6 ± 0.2 mg per day (range 0.25-1 mg per day) for risperidone and 1.8 ± 0.6 mg per day (range 1.25-2.5 mg per day) for olanzapine. The mean doses at last observation were 0.9 ± 0.6 mg per day (range 0.25-2.0 mg per day) for risperidone and 2.4 ± 1.7 mg per day (range 1.25-7.5 mg per day) for olanzapine. Significant improvement was seen in both groups, and no significant differences were found between the groups. Both medications were well tolerated and adverse effects such as extrapyramidal adverse effects were graded as mild-to-moderate and were tolerable in both groups. The main limitations of this study were its relatively small sample size and high dropout rate; moreover, this was a single-blind study in which only the investigators were blinded. Despite its limitations, this study showed that both risperidone and olanzapine were effective in the treatment of delirium and had a good tolerability profile.

Conclusions

The results of our systematic literature review showed that atypical antipsychotics can be useful interventions for the treatment of delirium: in addition to superiority to placebo, these medications demonstrated similar levels

of effectiveness to conventional antipsychotics, with a better tolerability profile. Our findings are in line with the results of previous reviews^{17,18}. Moreover, a Cochrane review found no difference in effectiveness of olanzapine and risperidone when compared with haloperidol; the same review found that higher doses of haloperidol were associated with extrapyramidal adverse effects¹⁹. Out of the eight studies included in our systematic literature review, seven were comparative studies, in which atypical antipsychotics were compared to either haloperidol or to another atypical antipsychotic medication. The reviewed literature has two main limitations: the sample sizes of the reviewed studies were small, and the clinical samples were heterogeneous in terms of several parameters, including the aetiology of delirium.

To reach definitive and firm conclusions, larger sample sizes and well-controlled randomised trials are needed. Our systematic literature review also has intrinsic limitations, which limit the generalizability of its findings: we included only studies published in English language that used established rating scales, such as the DRS-R-98, MDAS, and DI. Moreover, studies on critically ill patients were excluded.

The overall results of our systematic literature review confirm the effectiveness of atypical antipsychotics in the treatment of delirium. Future studies should include pharmacological trials in patients with different subtypes of delirium, including hypoactive presentations that are often undiagnosed due to their clinical features.

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The COVID-19 outbreak: impact on mental health and intervention strategies

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SUMMARY

Although the psychological and psychiatric implications seem to be a central core of health problems during an emergency, they tend to be underestimated and neglected, generating gaps in intervention strategies and increasing the burden of associated diseases. Moreover, pharmacological treatment concerns arise for psychiatrists and the other specialists who deal with psychiatric patients affected by an infectious disease or with patients with an infectious disease that may develop a number of psychiatric symptoms. The mental health consequences of a pandemic may be related to the sequelae of the disease itself or to the preventive measures aimed at containing the spread of infections. In addition, fear of death, drastic changes in family organization and work routines, closings of schools, companies and public places can play a role. Furthermore, stress derived from working activity or economic losses should not be underestimated. In the context of the current COVID-19 pandemic, first studies have shown the presence of stress, anxiety, depression and insomnia in the general population, health-care workers, and people affected by COVID-19. It appears likely that there will be substantial increases in a broad range of other mental disorders, suicide, behavioral disorders, loneliness, domestic violence and child abuse. From these considerations, the evaluation and monitoring of psychological/psychiatric conditions of involved populations, and the provision of focused aid must be part of the care intervention during the initial stage of a pandemic and beyond. The aim of this review is to summarize the current evidence on how mental health outcomes of COVID-19 outbreak have been measured and managed.

Key words: COVID-19, pandemic, mental health, outcomes, psychological impact, measurement, management

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Conflict of interest

The Authors declare no conflict of interest

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Introduction

Since December 2019, the novel coronavirus disease (COVID-19) has spread from Wuhan to other cities in China and around the world. On 11 March 2020, the World Health Organization (WHO) characterized COVID-19 as a pandemic. As of 23 April 2020, there have been 2.475.723 confirmed cases worldwide, 169.151 deaths, and 208 countries involved. These are unprecedented times in the modern world.

It is well-known that health emergencies are associated with detrimental psychosocial consequences ¹, and the COVID-19 outbreak will inevitably cause distress and leave many people vulnerable to mental health problems. Very probably, mental health sequelae will persist for longer and peak later than the actual pandemic. As a matter of fact, during epidemics, the number of people whose mental health is affected tends to be greater than the number of people affected by the infection ².

Although the psychological and psychiatric implications, both on an individual and a collective level, seem to be a central core of health problems during an emergency, they tend to be underestimated and neglected,

generating gaps in intervention strategies and increasing the burden of associated diseases^{3,4}. From these considerations, the evaluation and monitoring of psychological/psychiatric conditions of involved populations, and the provision of focused aid must be part of the care intervention during the initial stage of a pandemic and beyond.

The mental health consequences of a pandemic may be related to the sequelae of the disease itself⁵ or to the preventive measures aimed at containing the spread of infections⁶, such as quarantine or social distancing. In addition, fear of death, drastic changes in family organization and work routines, closings of schools, companies and public places can play a role. Furthermore, stress derived from working activity, as in the case of health professionals⁷, or economic losses⁸ should not be underestimated.

In the context of the current COVID-19 pandemic, first studies have shown the presence of stress^{9-12,14-16,18,21-23}, anxiety^{9,13-16,19,21-23}, depression^{9,13,14,16,17,19,20-23} and insomnia^{10,14,16,21-23} in the general population, health-care workers, and people affected by COVID-19. It appears likely that there will be substantial increases in a broad range of other mental disorders, suicide, behavioral disorders as substance use, loneliness, domestic violence and child abuse, as we learned from previous large-scale disasters^{1,24}.

We have to keep in mind that specific groups are especially vulnerable, for example, older adults, children, pregnant women, persons in detention, people with pre-existing psychiatric or clinical conditions, infected patients and their family members²⁵.

Strategies against stressful factors during a health emergency must be developed and implemented, at the individual and community level²⁶. Mental health-care organizations and public health institutions are now releasing practical guidelines on taking care of mental health and well-being²⁷⁻³¹, but evidence of efficacy is needed for the future.

Last but not least, pharmacological treatment concerns arise for psychiatrists and the other specialists who deal with psychiatric patients infected with COVID-19 or with patients with COVID-19 infection that may develop a number of psychiatric symptoms³². The most pressing question for doctors on the front-line of anti-COVID-19 is how to choose the appropriate psychotropic drug in combination with the recommended or proposed medicines, which include antiviral, antiretrovirals, antimalarials and drugs for the treatment of rheumatoid arthritis³³. The combination of anti-COVID-19 and psychotropic drugs should be considered in the context of potential drug interactions. Most antipsychotic and antiviral drugs utilize cytochrome P450 enzymes for their metabolism. Monoclonal antibodies used for rheu-

matoid arthritis (i.e., tocilizumab) indirectly increase cytochrome P450 (CYP) enzymes levels through the lowering of IL-6 levels³⁴. Special caution should be taken with benzodiazepines as most of them are substrates of various CYP enzymes. In this context, antidepressants, antipsychotic, benzodiazepines and anticonvulsants having minimal P450 interactions should be preferred (i.e., citalopram, escitalopram, olanzapine, lorazepam, valproate)³². Regarding other substances such as tobacco, drugs for treatment of alcoholism, it would be expected that some interactions may occur, as they are metabolized by several CYP enzymes^{32,34}. Furthermore, it must be paid attention to the drug-induced QT prolongation or the lowering of seizure threshold due to chloroquine and hydroxychloroquine³⁴.

As it has been pointed out, challenges to address from a psychiatric perspective are far-reaching. In the following sections we will summarize the current evidence on how mental health outcomes of COVID-19 pandemic have been measured and managed.

How to measure the mental health outcomes of the COVID-19 pandemic

From January until now, dozens of studies have been published on the psychological impact of the COVID-19 outbreak and others are still on-going. Given the measure recommending to minimize face-to-face interaction, the usual conduction of surveys with paper questionnaires has been not possible. Hence, researchers designed online surveys, through which data were electronically collected. These studies⁹⁻²² leveraged online openly accessible platforms to invite people to complete questionnaires or used mobile phone app-based questionnaires or phone interviews. Another study³⁵ used the sampling and analysis of the Weibo (i.e., Chinese social network) posts from active Weibo users, through the approach of Online Ecological Recognition (OER). Convenience and snowball sampling strategy were used. In spite of the inherent limitations of online surveys, the present restrictive measures would have not allowed the enrollment of large samples in specific sampling timeframe as pandemic peaks. The main weaknesses of these studies included information and selection bias. It is possible the surveys did not reach underdeveloped areas due to limited technology availability and omitted people who are not comfortable using technology and the Internet, or who are not on social networks. Anyway, it is likely that these uncommon times will legitimize this research methodology. Preliminary findings call for future research having to overcome multiple methodological obstacles in order to reach useful results.

Most studies focusing on mental health outcomes of COVID-19 pandemic have used self-report question-

naires⁹⁻²². Anxiety, depression, post-traumatic stress symptoms, and insomnia have been the most often explored psychopathological states⁹⁻²². Among questionnaires, some were well-known, standardized and validated instruments, whereas others were Chinese tools or “ad hoc” designed measures, thus limiting the generalizability of results. We report below the more often administered questionnaires in current published researches, and besides, three new assessment tools proposed for psychological outcomes related to COVID-19.

Measure for anxiety: Generalized Anxiety Disorder Questionnaire

The 7-item Generalized Anxiety Disorder Scale (GAD-7) is one of the most widely used instruments for the detection and screening of anxiety disorders. It is a self-report questionnaire rated on a 4-point Likert scale, ranging from 0 to 21. The total score is generally interpreted as follows: normal (0-4), mild anxiety (5-9), moderate anxiety (10-14), and severe anxiety (15-21)³⁶.

Measure for depression: Patient Health Questionnaire

The 9-item Patient Health Questionnaire (PHQ-9) is a self-report measure for the screening, diagnosis, monitoring and measurement of severity of depression. PHQ-9 comprises nine depressive symptoms, rated on a 4-point Likert scale, ranging from 0 to 27. The total score is generally categorized as follows: minimal/no depression (0-4), mild depression (5-9), moderate depression (10-14), or severe depression (15-21)³⁷.

Measure for stress and post-traumatic stress symptoms: Impact of Event Scale – Revised (IES-R)

The Impact of Event Scale – revised is a 22-item self-report questionnaire used to assess the extent of traumatic stress including trauma-related distressing memories and persistent negative emotions resulting from a traumatic event. It is rated on a 5-point Likert scale, ranging from 0 to 88. The total score is categorized as follows: subclinical distress (0-8), mild distress (9-25), moderate distress (26-43), and severe distress (44-88)³⁸.

Measure for insomnia: Insomnia Severity Index

The Insomnia Severity Index (ISI) is a 7-item self-report questionnaire assessing the nature, severity and impact of insomnia, rated on a 5-point Likert scale, ranging from 0 to 28. The total score is categorized as follows: no clinically significant insomnia (0-7); subthreshold insomnia (8-14); moderate clinical insomnia (15-21); severe clinical insomnia (22-28)³⁹.

The Fear of COVID-19 Scale (FCV-19S)

It is a 7-item scale developed to assess the fear of coronavirus. The items were constructed based on extensive review of existing scales on fears, expert evaluations, and participant interviews. The target population

of the validation study was the general Iranian population ($n = 717$). It has shown good psychometric properties. It is rated on a 5-point Likert scale, ranging from 7 to 35. The higher is the score, the greater is the fear of COVID-19. The original authors suggest the FCV-19S as a reliable and valid measure of fear of COVID-19 among the general population⁴⁰.

Coronavirus Anxiety Scale (CAS)

It is a 5-item scale developed to identify cases of dysfunctional anxiety associated with the COVID-19 crisis. A pool of 20 candidate items was created based on the psychology of fear and anxiety literature, then factor analyses identified items related to distressing physical symptoms associated with coronavirus fear and anxiety. The target population of the validation study was of 775 adults with a heterogeneous ethnicity. It has shown good psychometric properties. It is rated on a 5-point time anchored scale, ranging from 0 to 20. The higher is the score, the greater is the level of anxiety⁴¹.

COVID-19 Peritraumatic Distress Index (CPDI)

It is a self-report questionnaire designed *ad hoc* to assess psychological distress during the COVID-19 pandemic. The CPDI measures the frequency of anxiety, depression, specific phobias, cognitive change, avoidance and compulsive behaviour, physical symptoms and loss of social functioning in the past week. Range is from 0 to 100. The total score is categorized as follows: mild to moderate distress (28-51), severe distress (≥ 52). The content validity of the CPDI was verified by psychiatrists from the Shanghai Mental Health Center. The Cronbach's alpha of CPDI is 0.95 ($p < 0.001$) in the original study¹¹.

How to manage the mental outcomes of the COVID-19 pandemic

The world was unprepared for facing a pandemic although health emergencies are part of human history; as a result, there were no universal protocols or guidelines for the most effective psychosocial support practices⁴². During the initial stage of COVID-19 outbreak, the National Health Commission of China has published several guideline documents focusing on notification of principles for emergency psychological crisis intervention and guidelines for psychological assistance hotlines⁴³; subsequently, other reports on local mental health care strategies have been published^{25,44-46}. Since previous evidence refers only to specific situations⁴⁷, more comprehensive emergency guidelines for such scenarios are needed.

Strategies against the negative impacts of this pandemic must include plans for addressing mental health issues for the public²⁶, the health-care professionals⁴⁸

and the other vulnerable sub-populations, such as people with preexisting psychiatric conditions ⁴⁹, patients affected by COVID-19 ⁵, pregnant women ⁵⁰, older adults ⁵¹, children ⁵² and people in detention ⁵³. Public health surveillance during and after this pandemic must include plans for mental health surveillance to allow for an adequate response to the anticipated mental health issues ⁵⁴.

Some general steps can be taken to face the inevitable mental health consequences of this pandemic: designing plans to contrast the loneliness and boredom due to social isolation, giving people as much information as possible and providing adequate supplies ^{6,55}. The institution of multidisciplinary mental health teams and the establishment of secure services for psychological counseling, with improved access for disadvantaged people, are also suggested ²⁵. Further, it is critical having in place mechanisms for surveillance, reporting, and intervention for suicide ⁵⁶, and besides, for domestic violence and child abuse episodes that may increase because of forced cohabitation at home ⁵⁵.

Particular efforts must be directed to vulnerable populations with the provision of targeted interventions. For example, health-care workers ⁴⁸ could benefit from a continuous monitoring of psychological status, from a pre-job training on how to relax properly and on how to deal with uncooperative patients, or from the presence in hospitals of a place for rest where temporarily isolate themselves from their family if they get infected. As regards people affected by COVID-19 ⁵, interventions should be based on a comprehensive assessment of risk factors leading to psychological issues, including poor mental health before a crisis, bereavement, injury to self or family members, life-threatening circumstances, panic, separation from family and low household income. Tele-counseling for pregnancy care and tele-triage should be established for helping pregnant women during pregnancy, childbirth and postpartum ⁵⁰. The combination of online psychological intervention and face-to-face counselling should be widely adopted in psychiatric hospitals; crowded wards with shared dining and bathroom spaces should be reorganized into spaces where social distancing can be respected; the communication, for example through smartphones, between inpatients and their families should be facilitated to alleviate the stress and negative emotions caused by isolation and loneliness ⁴⁹. The use of online counselling tools to preserve continuity in provision of mental health care, the respect of preventive measures and the reorganization of spaces are suggested as well in detention facilities ⁵³. Regarding children, specific response to the mental distress should include pediatric health-care workers formal training and the use of rapid screening tools to facilitate the early identification of children's

mental health problems. In addition, children's access to mental health services has to be improved and evidence-based guidelines to help mental health professionals and parents cope with pandemic-related mental health problems in children are requested ⁵². Special attention should be paid to older adults who are at greater risk for death due to COVID-19. Family, and health policy makers should protect this population from contact with the pathogen, and provide social, emotional and practical support. Further, the elderly need help accessing online mental health services, using smartphones and adhering to clinical and psychiatric medication ⁵¹.

Practical suggestions for the public on how to organize time and manage physical and mental health, provided by mental health-care organizations and public health institutions ²⁷⁻³¹, include: managing media consumption and accessing information which allow us to protect ourselves and our loved ones; doing daily exercise activities; setting up regular phone calls or video conferences with family, friends, and colleagues in order to bridge the gaps brought on by social distancing.

A new psychological crisis intervention model is developing worldwide given the recommendation to minimize face-to-face interaction: digital psychiatry (i.e., online mental health services) and virtualized treatment approaches via telemedicine have been widely adopted in China ⁵⁷ and health-care planners worldwide are drawing from China's experiences ^{44-46,58-60}. Telemedicine is a method of providing health-care services through the use of innovative technologies; it consists of activities involving two-way, real time interactive communication between the patient and the physician or practitioner at distant sites ⁶¹. It leverages video consultations, interactive apps with audio and video capabilities, telephone calls or email allowing for synchronous provider-to-provider encounters. Therefore, at a time when physical meetings are discouraged, online psychological counselling services is a valid option ^{60,62,63}.

Digital psychiatry, that is the delivery of care via technology platforms, is proposed to address the lack of access to psychiatric services and includes artificial intelligence, telepsychiatry and an array of new technologies, like internet-based computer-aided mental health tools and services: for example, mental health education with communication programmes and psychological self-help intervention systems. These tools and means should be utilized as an important part of the whole package of measures to mitigate negative mental health effects of the global coronavirus pandemic ⁶⁴.

Despite there are a number of recommendations and challenges to take into account in developing and implementing a digital health/telemedicine ^{65,66}, there is evidence for the positive impact of digital devices in peoples' lives: younger patients not only are very com-

fortable with this modality, but also sometimes prefer it to in-person interventions⁶⁷⁻⁷⁰; therapeutic alliance is maintained⁶⁷⁻⁷⁰. Nevertheless, drawbacks of digital engagement and communication are reported and disparities in computer and highspeed internet access that must be addressed in the future⁶⁷. Further, we must keep in mind that introducing telemedicine is a complex change that disrupts long established processes and routines. The implementation process is likely to be difficult and resource intensive⁶⁸. For instance, in Italy, lack of the necessary hardware and technical resources in hospitals have limited the capabilities to deliver telemedicine, although all 20 regions had implemented national telemedicine guidelines as of 2018^{59,71}.

Conclusions

Fear, anxiety, depression and post-traumatic stress were common psychological symptoms reported across global disasters, both natural and man-made ones^{1,6,72}. Underlying reasons for these symptoms maybe include disruptions in daily routine due to restrictive measure,

social isolation, job loss and worries for financial security, their loved ones' well-being, the treatment process, and information pertaining to the disease. Health-care workers, people with preexisting psychiatric conditions, pregnant women, older adults, children and people in detention are examples of vulnerable subpopulations at risk of further distress given their specific condition⁴⁸⁻⁵³. Therefore, in addition to efforts at various levels to prevent the spread of the disease, the psychological crisis intervention should be formally integrated into public health preparedness and emergency response plans, as well as part of the Government actions^{25,26}; moreover, evidence-based recommendations for taking care of mental health and well-being should be made accessible and usable for the public. Strategies against psychological distress should consist of actions aimed at helping infected and quarantined patients, as well as interventions targeting the general population and the groups at higher risk of mental health impairment^{25,26,57}. Telemedicine and digital psychiatry are the future of medicine in the context of global disasters and health emergency⁶⁹, but improvements are necessary^{67,68}.

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Italian validation of the Hypersexual Behavior Inventory (HBI): psychometric characteristics of a self-report tool evaluating a psychopathological facet of sexual behavior

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SUMMARY

Introduction

Hypersexuality is characterized by excess of sexual activities, obsession of sex and related consequences. On the other hand, the assessment of problematic sexuality includes several psychometric tools to screen hypersexual behavior. Hypersexual Behavior Inventory is one of these, although its Italian version is not current available.

Objectives

Therefore, we aim to validate the Italian version of the Hypersexual Behavior Inventory (HBI) in a sample of Italian people.

Methods

A study population composed by a convenience sample of 1000 subjects (females: 71.1%) aged 18-60 was recruited from an online platform. Sociodemographic information was collected and a psychometric protocol composed by the Italian version of Hypersexual Behavior Inventory (HBI) to assess hypersexuality, Patient Health Questionnaire (PHQ-9) for depression, General Anxiety Disorder (GAD-7) for anxiety and Relationship Questionnaire for Attachment Styles (RQ) was administered.

Results

The analysis of internal consistency of HBI showed Cronbach's α coefficients in overall and subscales ranged from 0.81 to 0.92. In the confirmatory analysis fit indices were: $\chi^2/df = 5.951$, SRMR = .046, CFI = .92, RMSEA = .070, suggesting a good fit. Positive correlations were found among the three subscales coping factor, control factor and consequences factor, and all these subscales positively correlated with the total score of HBI (Pearson r coefficients ranged from .526 to .883; p -values < .0001). Discriminant validity revealed significant Pearson r correlations ranged from -.086 to .407.

Conclusions

Hypersexuality represents the tip of the iceberg of a more severe condition of psychological suffering. For this reason, the evaluation of hypersexual behavior is fundamental for subjects with a dysfunctional sexuality, and HBI offers a satisfactory evaluation of this phenomenon in all its facets. Moreover, on the basis of psychometric characteristics, HBI can be considered an efficient tool to accurately detect and circumscribe the hypersexual behavior in vulnerable people suffering from psychological and sexological issues, also among Italian population.

Key words: hypersexuality, psychometry, Hypersexual Behavior Inventory (HBI), Italian version

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Conflict of interest

The Authors declare no conflict of interest

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Introduction

The excess of sexual activities, the obsession of sex and the related consequences, is called hypersexuality. This condition includes the excess of compulsive masturbation, pornography, cybersex or telephone sex use, sexual activity with consenting adults, brothel/prostitution and strip/privé club frequentation¹.

In this regards, the hypersexual/addicted subject attempts to antagonize depressive and anxiety states, dysphoric mood or stressful life events through sexual activities, although in a dysregulated way also derived by attachment, relational and emotional difficulties²⁻⁴.

Hence, hypersexuality can be also considered a defensive behavior against other psychological suffering and general psychopathological symptomatology, through unaware behavioral responses^{5,6}. In this regard, the recent scientific debate has been on whether to include hypersexuality within the last version of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), with some proposals based on diagnostic criteria⁷. However, to date the psychiatric nosography does not consider hypersexuality a mental disorder *per se*^{7,8}. On the contrary, the World Health Organization has recently proposed to include the hypersexuality within the last version of the International Classification of Diseases (ICD-11) as a disorder of sexual compulsive behavior (CSBD)⁹. Notably, the CSBD is classified among impulse control disorders together with pathological gambling, intermittent explosive disorder, kleptomania, and pyromania^{10,11}.

The DSM-5 Work Group on Sexual and Gender Identity Disorders proposed possible detailed criteria for hypersexuality, with important considerations about the differential diagnosis^{12,13}. The proposal of DMS-5 can be regrouped as follow: (a) an excessive or disproportionate amount of time consumed by sexual thoughts, urges, and behaviors; (b) using sex in response to unpleasant affective states or to cope with stress; (c) multiple unsuccessful attempts to reduce or control sexual thoughts, fantasies, and behaviors; (d) continued preoccupation with and pursuit of sex despite negative consequences to self or others; and (e) volitional impairment^{12,14,15}.

On the basis of these criteria, the same authors have also developed a screening tool for hypersexuality named Hypersexual Disorder Screening Inventory (HDSI) composed by seven items along a five-point Likert scale, according to the proposed criteria for the classification of hypersexuality¹³.

On the other hand, other questionnaires and psychometric tools were developed in order to evaluate hypersexual behavior, sexual addiction and sexual compulsivity¹⁶. One of these is the Hypersexual Behavior Inventory (HBI) ideated by Reid et al., an interesting psychometric tool firstly validated on an outpatient sam-

ple of men¹⁷. Also, this tool is based on DSM-5 proposal for hypersexual disorder and its criteria, with also a possible but not definitive cut-off score^{18,19}. HBI is a self-report psychometric test composed by 19 items along a five-points Likert scale. Its items, in the original version, by Reid were developed according to three main characteristics of hypersexuality: the deficit to control sexual urges (fantasies or activities); use of sex to cope with personal stressful states, (b) using sex to cope with unpleasant affective experiences or in response to stress; and (c) negative consequences related to sexual behavior¹⁷.

The validation process was made on a sample of 324 male American patients and the exploratory analysis factor confirmed three main factors named by the authors Control, Coping, and Consequences.

Moreover, the reliability evaluated through the Cronbach's alpha coefficient revealed high internal reliability for the overall scale ($\alpha = .95$) and subscales (Control $\alpha = .94$, Coping $\alpha = .90$, and Consequences $\alpha = .87$)¹⁵. For these reasons, HBI is a suitable tool to assess hypersexuality, and it is largely used in both research field and clinical practice, for the assessment of problematic sexuality and hypersexual behavior^{20,21}. Moreover, another important study investigated and demonstrated the applicability of HBI among non-clinical subjects and into the general population, revealing excellent psychometric proprieties in large non-pathological sample¹⁹.

However, at our knowledge the existing versions are the original ones in the English language, while only recently the Spanish and German language versions have been validated^{17,22,23}. An Italian version of HBI is still not available, and we hypothesize that an Italian adaptation of HBI could be extremely useful to confirm the same psychometric properties of the original version and to properly assess hypersexual behaviors in an Italian context.

Aim

Based on the above considerations, our aim is to validate the HBI in the Italian language and to administer it in a sample of Italian people.

Methods

Sample recruitment

A study population composed by a convenience sample of 1000 subjects aged 18-60 was recruited from an online platform through a snowball recruitment in the main social media. The study protocol was approved by the ethics committee of Department of Dynamic and Clinical Psychology, Sapienza University of Rome, for

investigations involving human subjects, in line with the Declaration of Helsinki. Moreover, all subjects signed an informed consent regarding the handling of personal data.

Assessment

We administered a protocol composed of a sociodemographic questionnaire including information as age, gender, partnership status and education, the Italian translation of the HBI to measure the hypersexual behavior, the main outcome measure of this study.

Moreover, to test discriminant validity referred to hypersexuality, we also administered the Patient Health Questionnaire (PHQ-9) and the Generalized Anxiety Disorder (GAD-7) to test depression and anxiety, respectively, and the Relationship Questionnaire to assess attachment and relational styles.

Hypersexual Behavior Inventory (HBI)

HBI, as previously mentioned, contains 19 items with a 5-point Likert scale (1 = Never; 5 = Very often). HBI calculates a total score about the tendency towards hypersexual behavior (higher scores indicate a major hypersexuality) and three subscales assessing three factors or domains linked to hypersexual behavior: *Coping* (Items 1, 3, 6, 8, 13, 16, and 18), *Control* (Items 2, 4, 7, 10, 11, 12, 15, and 17), *Consequences* (Items 5, 9, 14, and 19). Possible scores range from 19 to 95. Examples of items or sentences of HBI are following: "I use sex to forget about the worries of daily life"; "Even though I promised myself I would not repeat a sexual behavior, I find myself returning to it over and over again"; "I sacrifice things I really want in life in order to be sexual" ¹⁷.

HBI translation

We put the original version of the HBI through a forward and backward translation procedure, having developed a consensus of the authors who developed the scale. The translation and adaptation were carried out from English to Italian by two expert bilingual translators and a team of psychometrists, clinical psychologists and sexologists evaluated each item, according to an accurate understanding of the Italian people.

Patient Health Questionnaire (PHQ-9)

PHQ-9 is a psychometric tool to evaluate depression. It is composed by nine items along a four Likert scale, "0" (not at all) to "3" (nearly every day). It is one of the most used, well validated tools in mental health and can be a powerful tool to assist clinicians with diagnosing depression ^{24,25}.

Generalized Anxiety Disorder 7-item (GAD-7)

GAD-7 is an easy to perform initial screening tool for generalized anxiety disorder. It is composed by seven

items along a four Likert scale from 0 (Not at all) to 3 (Nearly every day). GAD-7 is a very useful tool anxiety symptoms and generalized anxiety and it is very used in clinical field for a primary screening ²⁶.

Relationship Questionnaire (RQ)

RQ is a single item measure made up of four short paragraphs specifically evaluating the relational style according the model of Self and the Other. Each item is referred to a prototypical attachment style (secure, preoccupied, fearful and dismissing) along a 7-point Likert scale, although also a categorical choice is possible. We used the continuous measure of RQ ^{27,28}.

Statistical analysis

The *Statistical Package for Social Science* (SPSS) version 26 for Windows and AMOS were used to run the Confirmatory Factor Analysis (CFA) and the correlation between the variables. Continuous variables were represented statistically as mean and standard deviations. Categorical variables were represented as absolute and percentage frequencies. Internal consistency was assessed by the overall Cronbach α coefficient following the 19 items of the HBI, and also for the three subscales: $\alpha > .90$ are considered excellent indicators, α comprised between .80 and .90 are good indicators, α included between .70 and .80 are evaluated as suitable, coefficient included between .70 and .80 are estimated as sufficient, and $\alpha < .60$ are insufficient indicators ²⁷. A correlation among the factors of HBI was carried out, with Pearson r coefficient. In addition, the relational style and the psychological suffering (anxiety and depression), were tested using Pearson r coefficient in correlation with HBI to establish the discriminant validity of HBI and to avoid eventual construct' overlap ²⁹.

CFA was conducted the Maximum Likelihood as appropriate estimator: a three-factor model with 19 items and scales being allowed to correlate with each other as proposed by Reid and colleagues ¹⁷. Model fit was assessed by means of the following fit indexes (30): the χ^2/df statistic; the *Root Mean Square Error of Approximation* (RMSEA) evaluating the fitting of the model to the general population (the RMSEA value indicates a good adaptation the more its value approaches "0", Browne and Cudek ³¹ suggest that values ranging from .05 and .08 are indicative of an adequate fit); the *Comparative Fit Index* (CFI) display scores between 0 and 1 (a value over .95 is considered excellent and a value between .90 and .95 considerate a good index) and the *(Standardized) Root Mean Square Residual* (SRMR) indicates the difference between the residuals of the sample covariance matrix and the hypothesized model, an acceptable value is considered less than .08.

Results

Sample

The sample recruited was composed by 1000 subjects [females: 711 (71.1%); males: 289 (28.9%)], with a mean age of 29.58 ± 10.94 years. Most subjects were in a relationship ($n = 663$; 66.3%), while the 337 (33.7%) declared themselves as single. Education levels are distributed as follows: secondary education ($n = 29$; 2.9%), high secondary education ($n = 448$; 44.8), bachelor degree (273; 27.3%) master's degree (169; 16.9%), post-graduation degree (81; 8.1%) (Tab. I).

Reliability

The analysis of internal consistency showed an overall Cronbach's α coefficient of .925. In the three subscales, the Cronbach α coefficient was .905 for coping factor, .868 for control factor, and .809 for consequences factor.

Confirmatory analysis

We tested a theory driven model by means of a CFA (Fig. 1): a three-factors model with 19 items and scales being allowed to correlate with each other. Fit indices were: $\chi^2/df = 5.951$, SRMR = .046, CFI = .925, RMSEA = .070. According to these goodness-fit indices, a good adequacy of the model was shown, according to the norms, as suggested by the field literature^{32,33}. Also, these results are similar to those obtained by Bothe and colleagues in a recent reanalysis of HBI in a large non-clinical sample (CFI = .940; RMSEA = .071)¹⁹. Table II shows the factors loading for 19 item and 3 factors, which are adequate.

Correlation among HBI scales

Moreover, we found the positive correlations among the HBI domains. Each of the domains positively correlate

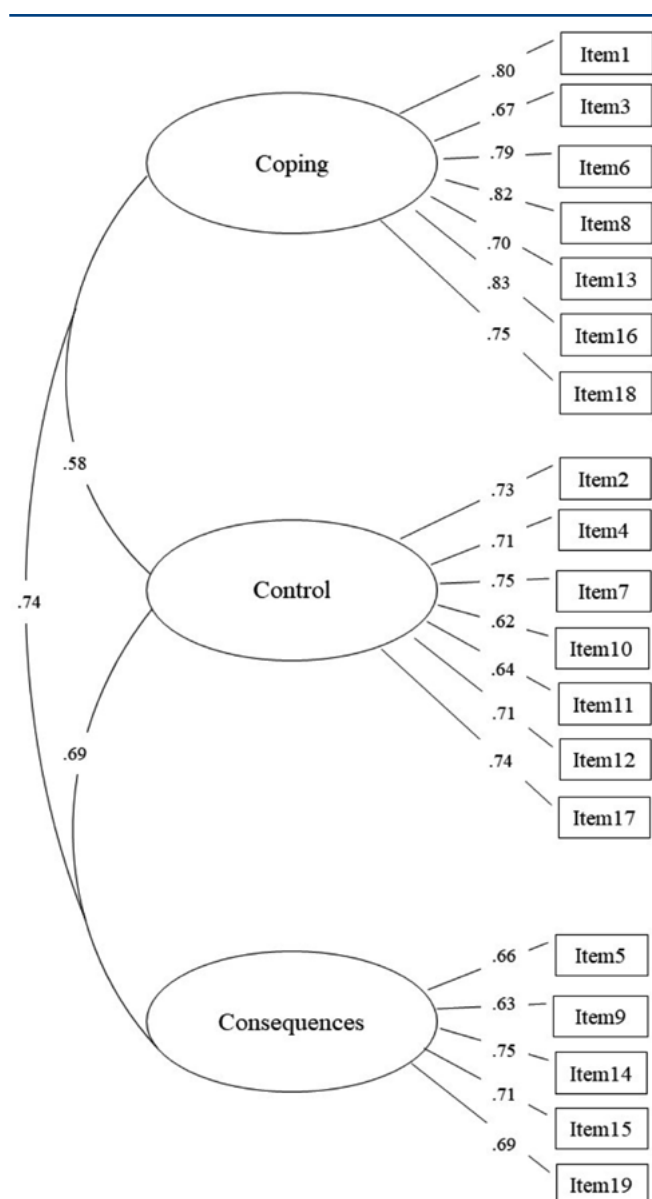


FIGURE 1. Confirmatory factor analysis of HBI. Model shows standardized parameters estimat.

with another subscale of the HBI, e.g., the coping factor has a positive correlation with control factor ($r = .596$; $p < .0001$), with consequences ($r = .639$; $p < .0001$), and with the total score of the HBI ($r = .883$; $p < .0001$). In addition, control factor correlates positively with consequences factor ($r = .590$; $p < .0001$) and with the total score of the HBI ($r = .829$; $p < .0001$), and consequences factor has a positive association with the total score of the HBI ($r = .829$; $p < .0001$).

Discriminant validity

In order to investigate the eventual construct' overlap

TABLE I. Sociodemographic characteristics of sample ($n = 1000$).

	N (%)	M (SD)
Age		29.58; (10.94)
Gender	711; (71.1)	
Female	289; (28.9)	
Male		
Education	29; (2.9)	
Secondary	448; (44.8)	
High Secondary School	273; (27.3)	
Bachelor degree	169; (16.9)	
Master's degree	81; (8.1)	
Post-Graduation degree		
Relationship status	337; (33.7)	
Single	663; (66.3)	
In a relationship		

TABLE II. *Factor loadings of 19-items of HBI.*

	Coping	Control	Consequences
<i>Item</i>			
HBI1	.800		
HBI2		.733	
HBI3	.674		
HBI4		.715	
HBI5			.657
HBI6	.792		
HBI7		.749	
HBI8	.817		
HBI9			.635
HBI10		.623	
HBI11		.644	
HBI12		.709	
HBI13	.696		
HBI14			.753
HBI15			.713
HBI16	.835		
HBI17		.741	
HBI18	.747		
HBI19			.686

among the HBI and its subscales and other related measures, Pearson correlational analyses were computed. We, therefore, have tested different but associated constructs as anxiety-depression symptoms and attachment styles, in the determination of discriminant validity. We found positive associations among HBI total score and PHQ-9 ($r = .404$; $p < .0001$, GAD-7 ($r = .326$; $p < .0001$), RQ-Secure ($r = -.086$; $p < .05$), RQ-Pre-occupied ($r = .250$; $p < .0001$), RQ-Fearful ($r = .236$; $p < .0001$), and RQ-Dismissing ($r = .084$; $p < .05$). Also, the HBI subscales of HBI revealed similar correlation coefficients as shown in Table III.

Discussion

This study has provided the first validation of the HBI in the Italian language and it is proposing its implementation for the assessment of hypersexual behavior in both clinical and research contexts.

The easy and quick administration together with the good psychometric characteristics of this tool are the main qualities emerging after our validation, aspects that should encourage the use of HBI in Italy.

In particular, the internal consistency assessed with Cronbach's α revealed high values for the overall coefficient and in the three subscales, that were similar to the original version¹⁷.

The CFA showed that the first-order model with three factors demonstrated an acceptable fit, and the factor loadings were adequate, as also the correlations between the factors. In comparison with the previous validation studies^{17,34}, the fit indices and the factor loadings were lower in our analysis. These lower values may be due to the diversity of the present large-scale sample, composed by a non-clinical population with a higher percentage of females. Nonetheless, our results overlap the ones obtained by previous validations, and the goodness of the model indices suggests that HBI is a reliable instrument to measure the hypersexual behavior in the general population³⁴. Moreover, the correlation coefficients among the scales demonstrated another good characteristic on the validity of this test. In this regard, the use of the scales of HBI is fundamental to better describe the hypersexuality. The scales of HBI represent a large strong point of this psychometric tool in the assessment of problematic sexuality together with its phenomenology. For instance, the Coping factor is considered a central factor for the hypersexual behavior in response to stress, anxiety or depression¹³. At the same time, the Control factor gives information about the emotional-cognitive aspects related to the hypersexuality and their functional or dysfunctional balance³⁵. Conversely, the Consequences scale gives indication about the insight skill of a possible subject toward the dark side of hypersexual behavior which negatively impacts the quality of life, social and work functioning³⁶.

TABLE III. *Discriminant validity.*

	Depression	Anxiety	RQ Secure	RQ Preoccupied	RQ Fearful	RQ Dismissing
HBI	.404**	.326**	-.086**	.250**	.236**	.084*
Coping	.407**	.354**	-.085**	.246**	.212**	.084**
Control	.293**	.210**	-.096**	.197**	.193**	.073*
Consequences	.308**	.239**	-.018	.177**	.193**	.047

Correlation values in each cell indicate Pearson r ; * $p < .05$; ** $p < .01$

From our analysis it also emerged that the HBI correlates with depression, anxiety and dimensions of insecure attachment, as previous literature demonstrated ^{2,3,37}. However, these correlations with other psychometric measures are in line with the discriminant validity and, therefore we have observed no construct overlap.

This is worth of noting because hypersexual behavior can be considered as a comorbid indicator of other forms of psychopathologies. On the other hand, in different cases, hypersexuality is a consequence of another primary mental or sexual disorder ^{6,37,38}.

Indeed, the diagnosis of hypersexuality is conceptually very difficult, even though we can rely on the ICD-11 criteria for the sexual compulsive disorder. This is due to the low rate of the symptom. In fact, approximately the 1-3% of the population meets the criteria for hypersexual *per se* ^{19,39,40}, although some studies also indicate a percentage up to 6% ^{40,41}. Moreover, according to an ecumenic vision of diagnostic process, the psychometric assessment should be integrated into a more complex psychodiagnostic phase, implementing an evaluation of personality ^{8,34}. Hypersexuality can be considered in fact both a behavioral reactive form to stressful life events, and a comorbidity factor to other psychopathologies ⁶. Therefore, we have taken into consideration the Italian validation of HBI a useful tool for the assessment of a problematic sexuality into a more complex diagnostic process, to care of patients seeking profes-

sional help for dysregulated sexological conducts. At the same time, HBI is an effective tool in research even to set up an experimental protocol focused on a better knowledge of hypersexuality or related disturbances.

This study suffers from some limitations, as the unbalanced gender distribution, although it is similar to most recruitment in convenience samples. Moreover, another limit is the non-clinical population recruited. Future investigations on patients, through case-control studies, will be necessary to establish a reliable cut-off score of HBI in Italian people.

Conclusions

Italian validation of HBI has revealed good psychometric properties for the evaluation of hypersexual behavior. To date, HBI is a useful tool to recognize hypersexuality into the research protocol and the clinical practice. It should be considered the first choice test for evaluating this peculiar area of a problematic sexuality.

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The active and passive use of Facebook: measurement and association with Facebook addiction

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SUMMARY

Objectives

The present study created and validated a questionnaire to measure active and passive Facebook use, and evaluated its association to Facebook addiction.

Methods

Two samples of undergraduate students ($n = 533$, $M \pm SD = 22.73 \pm 2.77$ years old, 51.1% females; and $n = 222$, $M \pm SD = 22.45 \pm 2.83$ years old, 49.5% females, respectively) were recruited. The Active and Passive Use of Facebook Scale (APUF) comprises a list of 17 Facebook activities, covering both active usage (e.g. "commenting on friends' posts") and passive usage (e.g. "viewing posts").

Results

With regard to scale dimensionality, the best-fit measurement model includes four factors: Active use-social connection, Active use-online self-presentation, Passive use-social connection, and Passive use-social comparison ($\chi^2/df = 2.34$; RMSEA [90%CI] = .08[.06-.09]; CFI = .96). With regard to reliability, internal-consistency Cronbach's alpha ranges from .78 to .89. Convergent validity is demonstrated with significant correlations between APUF and time spent online, Generalized Problematic Internet Use Scale 2 score, and Bergen Facebook Addiction Scale score. Passive users who monitor other people lives (i.e. social comparison factor) were more likely to report higher levels of Facebook addiction.

Conclusions

The present findings indicate that the APUF is a useful measure with good psychometric properties for assessing whether people use Facebook actively or passively. Having good measures of this aspect could really provide an important empirical contribution since the way people use social networks has an important role in determining how these sites impact subjective well-being.

Key words: Facebook use, active Facebook use, passive Facebook use, Facebook addiction, Facebook scale

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Conflict of interest

The Authors declare no conflict of interest

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Introduction

Facebook is the world's most popular social network site that enables registered users to connect with friends, family and colleagues. As social network site, Facebook allows individuals to construct a public or semi-public profile within a bounded system, articulate a list of other users with whom they share a connection, and view and traverse their list of connections and those made by others within the system¹.

Activity on Facebook takes essentially the form of content creation (i.e. posting opinions, photos, videos, personal information, and knowledge) and content consumption (i.e. viewing posts, observing others' profiles). In particular, prior research indicates that Facebook activities can be classified into active and passive usage^{2,3}. Active usage refers to activi-

ties that implies an active engagement with the social network site, like posting a content or commenting on posts; passive usage involves consuming information without contributing in the form of posts and comments, like scrolling through news feeds or viewing posts. A further difference between active and passive Facebook use deals with the level of exposure online. Online, passive use is also known as “lurking,” and such behavior allows the user to observe contents of other people while maintaining relatively anonymous. Active use implies showing opinions, interests, and pictures in order to communicate or share something with friends. The distinction between active and passive forms of Facebook usage is important because different outcomes and consequences on psychological well-being have been identified. A recent review on this topic⁴ concluded that passive use was associated with decreases in subjective well-being over time (i.e. negative affect, and a global sense of dissatisfaction with life). Active usage was positively related with psychological well-being (in particular reduced loneliness^{5,6}), although this association received a more tenuous empirical evidence^{4,7,8}. With regard to the mechanisms underlying the effects of social network sites usage on psychological well-being, the above-mentioned review⁴ revealed that, on the one hand, the positive effect of active usage of Facebook on subjective well-being may be partially due to an increase in social capital and associated feelings of social connectedness and social support. On the other hand, passive usage of social network sites seems to elicit social comparison and, in some cases, feelings of envy, that could lead to declines in subjective well-being⁹.

Facebook use has been mainly conceptualized as the time spent on Facebook and the number of Facebook friends. Results from a recent systematic review¹⁰ found these aspects of Facebook use associated with several mental health problems, like Facebook addiction, anxiety, depression, body image and disordered eating, drinking cognitions and alcohol use. Concerning Facebook addiction, time spent on Facebook was found to predict addictive use¹¹⁻¹³. Moreover, Turel¹⁴ found a “vicious cycle” of Facebook addiction: an increase in Facebook use in the past three months drives to higher levels of Facebook addiction, which, in turn, leads to increased logins to Facebook, daily time spent on Facebook, and active Facebook status updates. Across the other psychological problems related to Facebook use, some empirical evidence emerged for a relevant role of passive use, especially in relation to social anxiety¹⁵ and depression¹⁶. As Frost and Rickwood stated¹⁰, Facebook social comparison tendency could mediate the association between Facebook use and psychological problems. De Vries and Kuhne¹⁷ found that Facebook

use was associated with negative social comparison, which would foster to negative perception about a person's social competence.

According to the social skill model of problematic Internet use^{18,19}, the self-perception of social incompetence causes a preference for online social contexts (characterized by anonymity and reduced evaluative non-verbal cues), which, in turn, leads to a compulsive use of Internet social services²⁰. Passive Facebook use, consisting of observing contents produced by others and monitoring other people lives, could elicit negative self-evaluations in relation to others, which could be responsible for Facebook addiction and problematic Internet use. Unfortunately, the association between passive use of Facebook and Facebook addiction has not been investigated so far.

In previous studies Facebook use has been mostly measured through the self-reported amount of time spent on Facebook (per day or week), the number of Facebook friends and the self-estimated frequency of use of some Facebook activities (like posting photos, updating personal information etc.) measured with unidimensional scale. No measure designed to assess the active and passive form of Facebook use has been developed. Therefore, the first aim of the present study is to create and validate a questionnaire to measure active and passive Facebook use. Moreover, since no previous study to the best of our knowledge has evaluated the association between passive use of Facebook and Facebook addiction, the second aim of the current study is to investigate this relationship.

Materials and methods

Participants

533 undergraduate students ($M \pm SD = 22.73 \pm 2.77$ years old; 51.1% females) were recruited in the study rooms of six randomly selected faculties of the University of Florence, Italy. A second sample of 222 undergraduates ($M \pm SD = 22.45 \pm 2.83$ years old; 49.5% females) was recruited in the study rooms of four randomly selected faculties of the Universities of Florence, Salerno and Foggia, in order to perform Confirmative Factor Analysis (CFA). Four research assistants have approached the students at the end of the lectures. Participation was voluntary and anonymous. Informant consent has been obtained for each participant. Study procedures were designed in accordance with the principles of the 1983 Declaration of Helsinki.

Measures

Demographic information as well as self-reports regarding the hours spent online in a typical week (excluding study-related use) were collected.

To create the questionnaire, first we made a list of activities people can do on Facebook and then we divided it into two broad categories: “active” and “passive”, by consulting the literature^{3,21,22} and taking into account the level of personal engagement and online exposure for each activity. The initial version of the Active and Passive Use of Facebook Scale (APUF) comprises a list of 21 Facebook activities, covering both active usage (e.g. “commenting on friends’ posts”) and passive usage (e.g. “viewing posts”). Respondents were asked to rate the frequency of use for each Facebook activity on a 7-point scale (from 1 = “never” to 7 = “several times a day”). After performing the explorative factor analysis (EFA) on the first sample, a 17-item version of the APUF was obtained and then administered to the second sample.

To measure Social Networking addiction, the Italian version²³ of the Generalized Problematic Internet Use Scale 2 (GPIUS2)²⁰ and the Bergen Facebook Addiction Scale (BFAS)²⁴ were administered. The GPIUS2 contains 15 Likert-type items on social networks problematic use rated on an 8-point scale (from “definitely disagree” to “definitely agree”). The Italian version of the GPIUS2 showed good internal consistency (Cronbach’s $\alpha = .78-.89$). The BFAS comprised 18 items, three for each of the six core features of addiction: salience, mood modification, tolerance, withdrawal, conflict, and relapse. Each item is scored on a 5-point scale (from “very rarely” to “very often”). Higher scores indicate greater Facebook addiction. A preliminary Italian version²⁵ showed good psychometric properties.

Statistical analyses

In order to explore the psychometric properties of the Active and Passive Use of Facebook Scale, the EFA was conducted first to identify the underlying factor structure in the original data set ($n = 533$). The CFA was then performed in a new sample ($n = 222$) in order to validate the results of the EFA.

The EFA was conducted using SPSS 25 with principal axis factor analysis employed as an extraction method with promax rotation. The suitability of the data for factor analysis was tested with the Kayser-Meyer-Olkin (KMO) measure of sampling adequacy and Bartlett’s test of sphericity. The number of factors to be extracted was determined by the examination of the scree plot in combination with the conventional cutoff of eigenvalues > 1 . The promax rotation, an oblique rotation, was used because it is reasonable to assume that any extracted factors might be intercorrelated. The internal consistency of each factor was examined by calculating Cronbach’s alpha coefficient.

The CFA was performed to test the fit of the factor structure identified through EFA. LISREL program was used. The criteria for assessing overall model fit were based

on practical fit measures: the ratio of chi square to its degree of freedom (χ^2/df), the comparative fit index (CFI), and the root mean square error of approximation (RMSEA). For the χ^2/df , values < 3 were considered to reflect fair fit. We considered CFI and TLI values $\geq .90$ to reflect fair fit. For the RMSEA, values $\leq .08$ were considered to reflect adequate fit.

Finally, in order to test the APUF convergent validity, correlations between the APUF subscales scores and sex (point biserial), online-time in a typical week, the GPIUS2, and the BFAS (Pearson’s product moment coefficient) were computed.

Results

EFA

According to the KMO criterion, sampling adequacy was excellent (KMO = .90). Bartlett’s test of sphericity showed that the correlation matrix was suitable for factor analysis ($\chi^2 = 5242.449$, $df = 210$, $p < .001$). Using the conventional criterion for retaining factors with eigenvalues > 1 and the scree plot, a four-factor solution was identified, with the extracted factors explaining 60.38% of the total variance. Since four items had loadings and/or communalities $< .30$ or had high loadings on more than one factor, they were removed from the questionnaire. Accordingly, dimensionality was then explored for the resulting 17-item version of the questionnaire. The results from the KMO’s (coefficient = .89) and the Bartlett’s tests ($\chi^2 = 4452.793$, $df = 136$, $p < .001$) indicated that the data were suitable for factor analysis. Four factors were extracted, accounting for 67.10% of the total variance. All items loaded at .30 or above.

As shown in Table I, the first factor, named “Active use-social connection”, contains five items and relates to commenting on friends’ posts, status updates and photos, and posting or sharing links on friends’ walls. The second factor consists of five items and refers to posting status updates, updating one’s own personal information and photo, and sharing links on one’s own wall/page; we named this factor “Active use-online self-presentation”. Four items related to scrolling through news feed/viewing contents on one’s own wall, reading postings and friends’ links, and clicking “like” compose the third factor; this factor was called “Passive use-social connection”. The fourth factor, named “Passive use-social comparison”, contains three items and refers to looking at one’s own friends’ pages and pictures, and viewing not-friends’ pages.

Internal consistency of the four factors is reported in Table I. All item-corrected total correlations were above .30. There were moderate linear correlations between the four factors, as shown in Table II.

TABLE I. Item descriptive statistics, factor loadings, and internal consistency.

Item	M(SD)	Corrected item-total correlation	F1	F2	F3	F4
Viewing contents on your wall	6.38(1.19)	.46	.01	.23	.68	.06
Viewing friends' profile	4.63(1.55)	.63	.18	.19	.36	.66
Viewing not-friends' profile	3.38(1.63)	.63	.15	-.01	.09	.78
Viewing friends' pictures	3.52(1.48)	.65	.12	.19	.14	.82
Reading friends' links	5.06(1.60)	.61	.26	-.05	.69	.24
Reading posts	5.53(1.57)	.71	.19	.14	.80	.13
Updating your status	2.50(1.49)	.63	.26	.67	.25	.01
Updating your profile picture	2.06(.82)	.63	.18	.79	.01	.10
Updating your profile information	1.58(.78)	.44	.05	.65	-.09	.21
Posting photos	2.81(1.39)	.71	.40	.70	.17	.06
Sharing links and contents on your wall	3.13(1.55)	.69	.47	.61	.28	-.01
Commenting friends' status updates	3.28(1.56)	.75	.78	.20	.23	.14
Sharing links and contents on friends' profile	2.83(1.46)	.69	.76	.23	.09	.11
Clicking "Like"	5.33(1.64)	.56	.39	.15	.63	.10
Posting on friends' profile	2.88(1.48)	.70	.72	.32	.08	.20
Commenting friends' posts	3.74(1.53)	.80	.79	.14	.29	.21
Commenting friends' photos	3.54(1.55)	.77	.76	.20	.22	.21
Explained variance (%)			22.86	16.10	15.53	12.60
Cronbach's Alpha			.89	.81	.78	.79

Note. F1: Active use - social connection; F2: Active use - online self-presentation; F3: Passive use - social connection; F4: Passive use - social comparison

TABLE II. Pearson's correlation coefficients between the four factors.

	(1)	(2)	(3)	(4)
(1) Active use - social connection	—			
(2) Active use - online self-presentation	.63*	—		
(3) Passive use - social connection	.54*	.43*	—	
(4) Passive use - social comparison	.44*	.35*	.44*	—

* $p < .001$

CFA

An acceptable fit for the four-factor solution was obtained ($\chi^2/df = 2.34$; $RMSEA [90\%CI] = .08 [.06 - .09]$; $CFI = .96$). The path diagram and the standardized path coefficients are shown in Figure 1. Standardized factor loadings ranged from .35 to .89, all of which were significant at the .001 level, as well as the estimated correlations among errors.

Convergent validity

Sex was not significantly correlated with APUF subscales'scores. Time spent online in a week, the GPI-

US2 total score and the BFAS score were positively and significantly correlated with APUF scales. The highest correlation was found between Passive use-social comparison score and BFAS total score (Tab. III).

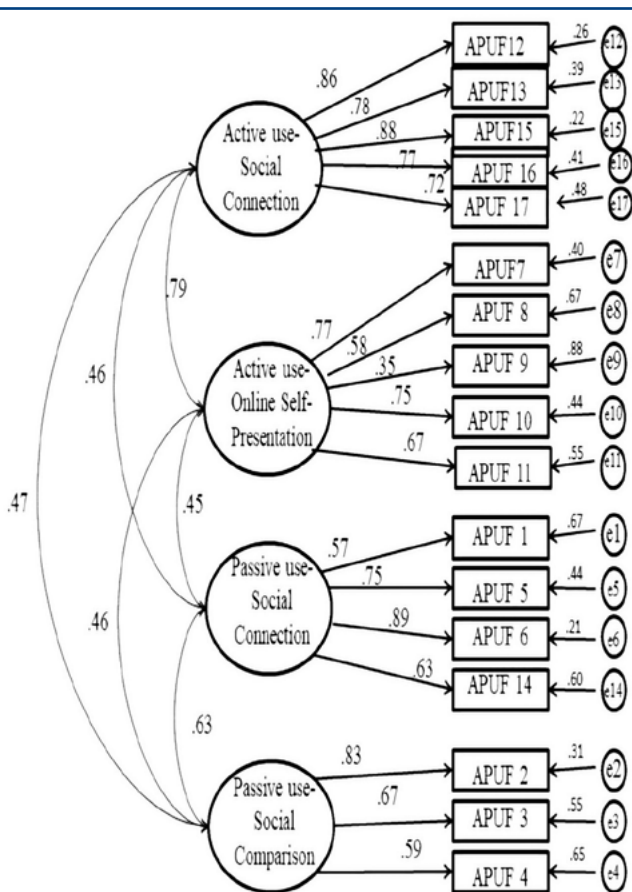
Discussion and conclusions

The primary aim of the present study was to develop a multi-dimensional questionnaire measuring active and passive use of Facebook. The Active and Passive Use of Facebook Scale (APUF) was created and tested for dimensionality and psychometric properties.

TABLE III. Pearson's correlation coefficients between APUF subscales and sex, online time in a typical week, the GPIUS2, and the BFAS.

	Sex	Online time/week	GPIUS2	BFAS
Active use - social connection	-.03	.16*	.22*	.28*
Active use - online self-presentation	-.05	.15*	.24*	.30*
Passive use - social connection	-.08	.14*	.26*	.29*
Passive use - social comparison	-.04	.22*	.26*	.35*

* $p < .001$. Note. GPIUS2: Generalized Problematic Internet Use Scale 2; BFAS: Bergen Facebook Addiction Scale

**FIGURE 1.** Confirmatory factor analysis of the active and passive use of Facebook Scale.

About dimensionality, the results of explorative and confirmative factor analyses revealed that APUF comprises 17 items loading on four factors.

Two factors pertain to active use:

- social connection contains items referring to commenting friends' posts and posting contents on friends' walls;
- online self-presentation contains item focused on updating one's own personal information and posting contents on one's own wall.

Both factors imply online active engagement and exposure although with slightly different purposes. In the first factor, active use is aimed to maintain social bonds by connecting and communicating directly with friends through comments and posts; in the second factor, active use is directed to manage one's own public profile and online self-presentation, which is related to the process of impression management.

The other two extracted factors concern passive usage:

- social connection comprises items related to browsing one's own news feed, reading contents and clicking the "like" button;
- social comparison contains item referring to viewing friends' and not-friends' profiles.

Both factors entail passive content consumption on Facebook. However, whereas the first factor implies a pointless use of Facebook, the items contained in the social comparison factor implies a goal-oriented research of information that is monitoring other people lives. In both cases, the anonymity is maintained. A partial discrepancy could be noted for the "Clicking Like" item, since it describes an activity one would expect to load onto the active use factors. This result could be partially explained by the fact that the "like" activity does not involve a content creation and requires a low level of engagement.

Still concerning APUF dimensionality evaluation, the APUF dimensions are in line with the dual-factor model of Facebook use²⁶. It proposes the existence of two basic needs underlying the use of Facebook: 1) the need to belong, which refers to the intrinsic drive to feel close and accepted by others and gain social acceptance; 2) the need for self-presentation, which is associated with the process of impression management and the desire to create a positive impression of one's self in others. The need for belongingness could be represented by the first active use factor and the two factors of passive use, since they all contain Facebook activities aimed to maintain or create social bonds. The need for self-presentation could be described by the online self-presentation factor, which covers Facebook activities oriented to manage one's own public image (both

in term of opinions, interests and outward appearance). Future studies should assess the relationship between Facebook needs and active/passive usage.

As regards APUF psychometric properties, the factors demonstrated good internal reliability and acceptable convergent validity. Active and passive use of Facebook seems to be not-gender related; however, this association was not previously documented. Time spent online in a typical week was found to be weakly associated with both active and passive use; the highest correlation emerged for passive use social comparison factor; more an individual uses Facebook to view friends' and not-friends' profiles more he/she spends time online.

The second aim of the present study was to assess the relationship between passive use and Facebook addiction. The correlational analyses revealed several relationships. In particular, mild associations were found between both active and passive use and social networking addiction. Facebook addiction displayed moderate relationships with all four APUF factors. However, the highest association was found for passive use social comparison factor. Passive users who monitor other people lives (i.e. social comparison factor) were more likely to report higher levels of Facebook addiction. This finding may be partially explained by the social skill model of problematic Internet use^{18,19}, which identified the self-perception of social incompetence as a risk factor for social networking addiction. Indeed, it is possible to suppose that passive use oriented to social comparison provokes negative self-evaluation, which in turn could lead to prefer online context since it allows great control over self-presentation. According to Caplan^{19,20}, preference for online social interactions is a cognitive

precursor of the tendency to use the web for regulating negative mood states, the compulsive use of the web and the presence of negative outcome in the real life due to Internet use. However, it is also possible that a social self-presentational skill deficit could be responsible of passive Facebook use, which, by promoting social comparison, could in turn exacerbate perceived social incompetence and lead to Facebook addiction. The cross-sectional nature of the present data does not allow us to test the directionality of the emerged relationships. Longitudinal and mediation studies are needed in order to clarify the association between passive use and social networking addiction.

One more limitation of the present study is that the sample is only partially representative of the population and focuses solely on young people. Studies featuring different age samples should be conducted to support the current findings.

Finally, further studies should be performed to strengthen the validity of the scale. For example, the relationship between active and passive Facebook use and well-being indicators needs to be evaluated.

In summary, the present findings indicate that the active and passive use of Facebook scale is a useful measure with good psychometric properties for assessing whether people use Facebook actively or passively. This scale permits researchers to evaluate how users spend time on Facebook and the level of engagement on this site. Having good measures of these aspects could really provide an important empirical contribution since emerging evidence indicates that the way people use social networks has an important role in determining how these sites impact subjective well-being^{3,27}.

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Living in the era of COVID-19: new challenges for psychopathology

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On February 20, 2020, a young man living near Codogno, Lombardy, was admitted to hospital with atypical pneumonia that later was proved to be COVID-19¹. After slightly more than two months from the discovery of the “patient one”, Italy has registered more than 200,000 cases of COVID-19 infections with a number of deaths which is close to 30,000, being the third country in the world for number of deceases (as to May 1st, 2020)². The worldwide pandemic caused by COVID-19 represents a real challenge for clinicians working in every field of medicine. From radiologists to anesthesiologists, all specialists had to change their way of working and to rapidly learn new tasks and procedures. Although “physically” distant from the heart of the emergency, mental health professionals had also to deal with innumerable challenges and changes. In fact, the COVID-19 pandemic has severely impacted on the well-being and mental health of millions of people. Nevertheless, whereas the physical problems caused by COVID-19 infection – if not fatal – are usually circumscribed in time, the psychological consequences of this pandemic will be presumably long-lasting.

Importantly, some groups of individuals appear more vulnerable than others to the development of psychological issues³. First, it is well-known that subjects who live alone are in general more prone to develop mental disorders, such as major depression or anxiety. Nevertheless, the merely forced homestay may lead to emotional responses that do not present a clear and significant clinical dimension, such as loneliness and hopelessness. The management of these emotions is obviously more difficult when social interactions are zeroed. Typical coping strategies, endorsed by the general population and media, are represented by technology-based communication, reading, humor, and entertainment, such as watching TV or listening to music. However, not everyone disposes of the resources to cope with their own emotions using these strategies or may not perceive any real benefit. Thus, the self-isolation and the forced permanence at home may lead to a conspicuous increase of addictive behaviors, such as a pathological use of the internet and video games, as well as online gambling. Surveys have in fact shown that these phenomena have dramatically risen since the beginning of lockdown, with the risk of a huge increase of traditional and novel addictions. The emergence of new forms of psychopathology represents one major challenge that we will need to address in the near future as mental health professionals⁴. A careful look should be given also to older people, who represent a wide portion of the Italian population, and typically dispose of less “technological” tools. Therefore, they may not be fully satisfied by the coping strategies universally acknowledged. Moreover, they are reasonably more worried about the risk of contracting the infection and going through hospitalization with severe medical consequences³. In these groups of people, mental health issues might not fully manifest; on the contrary, they are likely to appear as subthreshold forms, with demoralization, anhedonia, impaired concen-

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Conflict of interest

The Authors declare no conflict of interest

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tration, and sleep difficulties. Insomnia and alterations of sleep patterns are indeed among the main issues reported during the pandemic. This is partially due to the changes in daily routines and habits, but also to anguish and internal tension.

A second category at risk of developing severe mental health sequelae is represented by professionals who are working in the health care systems, particularly those who are directly in contact with COVID-19, such as nurses and physician of the emergency and resuscitation departments. The risk for this population is to develop severe burn-out as well as post-traumatic stress symptoms.

The first Italian report on mental health outcomes and associated risk factors among health workers has indeed confirmed high levels of post-traumatic stress symptoms, depression, anxiety, insomnia, and perceived stress, particularly among young women and first-line operators ⁵.

It is likely that once the pandemic will be finished, we will need to cope with a lack of personnel in our health care system with the necessity to psychologically support all the medical staff that today is working on the front line ³.

Third, individuals with a history of mental illness or substance abuse are more susceptible to the stress and emotional influences produced by the pandemic. Additionally, psychiatric patients regularly follow outpatient visits for drug prescriptions and psychotherapy. Unfortunately, these visits had to be stopped because of the nationwide restrictions ⁶. To overcome this obstacle, mental health services have started to be equipped with appropriate e-health technologies, which can help professionals to manage online consultations and counseling ⁷⁻⁹.

The era of COVID-19 is in fact the era of telepsychiatry: psychiatry and related disciplines are going through a real revolution. The direct, personal, empathic contact that we usually experiment with patients in the clinical setting has now to move virtually. Thus, there is an urgent need to adapt and tailor psychopathology to this new setting. Psychopathology is made of observation and communication, meant not only as the verbal expression of the therapist but also as the reception of feelings, emotions, bodily gestures, behaviors, expressed or manifested by the patient. Adapting the psychopathological principles to the virtual setting might be extremely challenging for clinicians. For instance, therapists may experience significant difficulties in catching non-verbal signals through the screen of a computer or a phone. Moreover, the number of technical issues encountered during a virtual conversation may represent a barrier for a fluid and fruitful therapeutic exchange. However, these challenges should represent an incen-

tive to improve and refine our abilities as psychopathologists rather than actual limitations. We need to acquire the capacity to get in touch with our patients and understand their needs also at a distance, without decreasing the perceived value of the interaction.

This novel therapeutic modality might raise concerns not only for clinicians but also for patients themselves. Patients' major worries seem related to the confidentiality of therapy and to the possibility of video-recording. However, this obstacle may be surpassed by clear communication and agreement through an additional consent. Another important concern is related to the significance of therapeutic alliance: few studies have examined the quality of therapeutic relationship in e-mental health interventions, reporting no differences with face-to-face interactions ¹⁰. However, many of these studies did not take into account the cultural aspects, the educational level, the type of mental health conditions, and the usual routines of patients and therapists. For instance, literature has reported that the presence of serious mental illness, such as schizophrenia, may represent significant barriers to the utilization of telehealth technologies and that the use of telepsychiatry is mostly limited to people with higher educational levels. Of note, building a new virtual therapeutic alliance might be easier than suddenly change a relationship which has been laboriously constructed over months or years. Even if regularly followed-up on the phone or the computer, our patients might feel abandoned, "suspended", looking for the return to the usual therapy routine.

The moment we are living resembles in some way the stagnation that preludes the onset of melancholic depression. As our patients, we have the sensation to live in a "suspended time": we cannot truly live in the present, but we are unable to move to an uncertain future. Analogously, we are experiencing a desynchronization, also typical of melancholic subjects: our internal, subjective time is uncoupled from the external, environmental time. Our chronobiological rhythms are distorted and we are breaking and changing our routines ¹¹. However, in contrast with melancholic depression, we still have the resources for taking advantage of this "suspended time". We have the possibility to enrich ourselves and to cultivate relationships with our family members and friends. Far from the frenzy of the work environment, we can take time for ourselves and for our personal growth. In substance, we really have the opportunity to move from a "social distancing" to a mere "physical distancing".

But what's next? As mentioned above, the consequences of COVID-19 will probably last for a long time. The mental health problems that emerged in the heart of the pandemic are not the only sequelae that we will have to manage. Once the restrictions will be reduced, in fact, there is a high risk to return to live in a "bulimic" way,

with an assault to the pleasures that we could not enjoy over the last few months. Thus, as mental health professionals, we will have to deal with the scarce capacity of control impulses, as a response to the limitations which have been imposed on individual freedom.

In conclusion, the challenges that we are facing and will have to face in the near future should represent a stimulus for a real renovation of psychopathology, but always keeping in mind the solid roots posed by Jaspers more than one century ago.

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Public mental health outpatient service at the time of the COVID-19 pandemic: did we have any other choice?

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As of May 28, 33 072 deaths and 231 139 confirmed cases due to the COVID-19 epidemic make Italy one of the most affected countries in the world. On 7th March 2020, the national authority for welfare ordered a block on all but urgent outpatient services (i.e. dialysis, chemotherapy), while maintaining mental health care activities. This has confirmed that mental health care services are considered as fundamental services to the community ¹. However, Italian Departments of Mental Health (DMHs), agreed by the management of local public health care services, recommended closure of second-level outpatient programs (e.g. for eating disorders, early psychosis, autism spectrum disorders, severe learning disorders), suggesting to implement phone calls and video conference-based visits only for emergencies or specific urgent patient requests ².

Considering how much COVID-19-induced social isolation and unplanned school closure (extended until next September in Italy) may affect mental health of children and adolescents (especially for more vulnerable subgroups, as those with low socioeconomic status and pre-existing severe psychiatric problems or learning difficulties) ^{3,4}, was this the only most appropriate intervention that could be put in place for these young individuals? Were we sure that there were adequate technological supports throughout Italy to set up remote work and home care? Or could this increase the national disparities between users of the most technological areas and users without such possibilities, the latter often living within families with a low socioeconomic status? In this social fragmentation, the area of marginalization/abandonment may be further extended, increasing up the risk of worsening severe mental disorders.

Additionally, several Italian psychiatrists (still in official speeches of prestigious scientific societies) asserted that during the pandemic, "psychiatric patients largely understood the need for social distancing, collaborated on it and did not cause problems". Are we sure this was not a deafening silence, especially for children and adolescents with Severe Mental Illness (SMI)? If access to outpatient services was not facilitated (but was often made difficult by the "material closing" of the doors), in the isolation of their rooms, without dedicated case management and specialized rehabilitative interventions, who could really intercept their suffering? Could emergency phone calls or video conferences be enough? Or perhaps it was another time delay of specific interventions that could not be further delayed (in particular, for young people with severe psychopathology)? And what about families and caregivers? With what support have we decided to sustain them? By depriving them of rehabilitation time and replacing it with the Internet connection? In this perspective, together with unplanned school closure, mental health of adolescents and children

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impacts the risk of loneliness, symptoms' recurrence and academic achievement gaps ⁴, in a prevention total absence.

Italian DMHs also recommended the closure of day services and suggested that general psychiatric outpatient centers should be restricted to urgent visits (maintaining the centrality of the consultation with General Practitioners, especially by a phone triage and dedicated times) and to subjects who require daily administration of drugs or long-acting antipsychotics ². At the same time, they strongly advised home visits, when possible and safely. If the risk of infection had to be managed with caution in outpatient services, with what resourcefulness (and purposeful mood) did mental health professionals go to the patients' home, perhaps with poorly adequate protective devices? And how intense and effective were these interventions? All that was done, was patching up urgent patient requests, forgetting the

crisis prevention. Italian CMHCs have decided to stop/postpone their activities rather than to ask themselves what really could be done for the patient, safely and proactively (especially for those individuals with SMI and the young ones with early severe psychopathology). As in public educational services, it was preferred to block that to seek a possible and feasible proactivity ⁵. It was decided not to play the game. Did we have another choice? As De Gregori ⁶ wrote: "the player: you recognize him for courage, altruism and imagination". Therefore, we strongly suggest that Italian medical, educational and institutional authorities should implement as soon as possible strategic plans for a progressive re-start of mental health outpatient activities and routine therapeutic-rehabilitation interventions, especially for more vulnerable subgroups (as young people with SMI, early severe psychopathology and learning difficulties), so as not to further defer the no longer deferred.

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Contagi

by Liliana Dell'Osso

(ETS, Pisa, 2020; 160 pg.)

For a long while, our lives seemed to revolve around the concept of contagion. The COVID-19 pandemic process changed our lives and our understanding of the western world. It's not far-fetched to consider the spread of the new virus among France, Germany, United Kingdom, Spain, and Italy a historical fact of great relevance in the context of the last 50 years. With more than 5 million cases and three hundreds deaths worldwide, the coronavirus pandemic has changed once and for all our present, and reshaped the future. A new book tries to explore this new horizon, taking into account the most recent psychiatric and psychopathologic research.

Contagi ("Contagions") is three-fold, and presents an interesting internal symmetry, and is available now both in ebook and on Amazon, by Liliana Dell'Osso, Pisa University. The book opens pointing out how safe the Italian society thought to be when receiving the first news of a new illness from Wuhan. The illusion of safety, in her reconstruction of facts, quickly left the population when the contagion curve in Lombardy first, and in the whole country then, began to rise.

The widespread reaction of mass panic is then well described, among the inevitable rise of fake news. The author invite the readers to immunize themselves through knowledge, and explains all the risks of the new COVID-19 pandemic, with several very interesting psychiatric remarks. As a matter of fact, and this is one of this book highlights, a new epidemic process is brewing: and this new wave of illness is likely to be linked to PTSD. Just like COVID-19, it will strike with particular momentum those who fight the battle of public welfare: healthcare workers, who found themselves in a very difficult situation during the epidemic and the lockdown, may present in great numbers and in the foreseen future, stress-related symptomatology.

It's worth noting how the public media, in Italy but also in many western countries, have described the recent efforts of medicine in heroic terms. This is, according to the author, a quick escape made by the political debate in order to avoid many hot topics, since "heroes are not allowed to complain", as the author poignantly notes.

It's not the first (nor the last) time we will face a contagion: and in the second part of the book, written with philosopher and historian of science Dario Muti, Liliana shows how widespread the concept of contagion is in western civilization, and beyond. Rooted in the sense of touch, contagion has been theorized since the classical antiquity, albeit in a very different form than the contemporary one. Contagion deals with illness, as the Plague of Athens shows, but also with "health", as the "healing touch" of royal bloodlines in the Middle Ages shows. Above all, contagion is a metaphor, contend the authors, which has been employed to describe a wide variety of phenomena. As such, it is one of the "total concepts" of our civilization. This point is analyzed in detail during the course of the latter part, where we also find a precious gallery. With psychiatrist Daniela Toschi, professor Dell'Osso realize an interesting psychobiography of Edvard Munch: the eponymous painter of *The Scream* and widely recognized as one of the most iconic author on the concept of trauma. This is no chance, explain the authors, since Edvard was exposed, since early childhood, with contagion and death. Edvard's father, Christian, was a doctor probably affected PTSD. Christian may have "infected" Edvard with more than a strict pietist education: he may have transmitted a very anxious view of the world as a dangerous place, populated by *revenants*. Edvard life had been difficult for a long time, as the painter led a *bohemian* life for quite a long time, with alcohol abuse, unstable relationships and multiple psychopathology. When Edvard undertook a resting period with a psychiatrist, his symptoms withdrew, leading to a new found health a renovating energy in his painting: as the authors puts it, thanks to psychiatry the artist of *The scream* became the author of *the Sun*, a gigantic symbol of hope and rebirth.

Alessandro Rossi