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EDITED BY: Manuel Trachsel, Cynthia M. A. Geppert and
Rebecca Weintraub Brendel

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ETHICS IN PSYCHIATRY AND PSYCHOTHERAPY

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Editorial: Ethics in Psychiatry and Psychotherapy

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Editorial on the Research Topic

Ethics in Psychiatry and Psychotherapy

The multifaceted and multidisciplinary field of ethics is relevant to any practitioner of psychiatry and psychotherapy. There is hardly another branch of medicine that has, from its very emergence as a specialty, raised such profound and complex ethical questions as the fields of psychiatry and psychotherapy (1, 2). Traditional ethical issues in psychiatry and psychotherapy include the value judgments inherent in the irreducibly subjective aspects of the processes of formulating a diagnosis and setting treatment goals. Other ethical questions in psychiatry and psychotherapy are related to involuntary commitment, coercion, or autonomy in patients whose psychiatric disorders may compromise decisional capacity and hence the ability to provide informed consent, the therapeutic relationship, privacy, confidentiality, therapeutic boundary violations, multiple relationships, and any form of exploitation. In recent years, new ethical questions have arisen related to dramatic changes in treatment modalities, exponential growth in neuroscience, and major shifts in social attitudes toward mental health and its most distinctive and essential values. These novel ethical challenges facing psychiatrists and psychotherapists range from the uses of new techniques, such as deep brain stimulation and the impact of evolving concepts of psychiatric genetics, to the role of online interventions, clinical palliative care for individuals with mental illness, or peer support in treatment. These are just a few examples of ethical issues in psychiatry and psychotherapy, and for the present Special Topic, we welcomed contributions spanning the landscape of this broad field to capture its depth and complexity and also included not only empirical but also conceptual papers. As a result, the Special Topic now captures the diversity of interest and expertise in psychiatric and psychotherapeutic ethics.

Two articles address neuroscience and the Cartesian mind-body problem, transmuting it into mind-brain dualism. Glannon examines the ethical implications for treatment of this current critical tension in psychiatry between seeing mental illnesses alternatively as disorders of the mind or of the brain and the implication of this practice for patients. He argues, instead, that neuroscience research has demonstrated the interdependency of mental and neural processes in maintaining mental health and causing mental illness and, therefore, that as an ethical matter this artificial dualistic thinking can cause harm to patients by limiting therapeutic interventions. The corollary is that dualistic thinking “can limit therapeutic interventions for patients suffering from major psychiatric disorders” and Glannon therefore concludes that “taking the full extent of mind-brain interaction into account is [...] ethically imperative in psychiatric research and practice.” In response to Glannon’s argument, Schleim critiques the persistence of mind-brain dualistic language in philosophical and scientific discourse for its perpetuation of a reductionism.

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Contrary to Glannon's assumption, Schleim contends that patients are quite willing to embrace neuroscientific explanations of psychiatric illness and may instead underestimate the value of psychotherapy. In rejecting dualist in favor of mechanistic and biopsychosocial explanations that take levels of description and understandings into account, Schleim suggests that we can achieve integrative formulations and approaches to advance the treatment of mental illness.

Approaching ethics from the vantagepoint of empirical study and machine learning, Yao et al. report a cross-sectional study in which they used machine learning and an online survey in We Chat to predict negative side effects from psychotherapy as a means of isolating factors that influence the emergence of unwanted events perceived during psychotherapy. In the 370 online questionnaire responses analyzed, negative emotions such as anxiety and anger were the most common side effects experienced in psychotherapy and the patient's perception of the therapists' own emotional state during the therapy was the most accurate predictor that the patient would experience these negative effects. The authors conclude that machine learning may assist therapists in identifying side effects of therapy that are often overlooked so that they may be addressed constructively.

While Yao et al. embrace the promise of neurotechnology, Stanghellini and Leoni in their exploration of digital phenotyping instead highlight the threat it may represent to integrity and authenticity. In this study, they collected and analyzed quantitative data from personal electronic devices such as mobile phones to identify clinical factors that could be utilized to clarify diagnosis and target treatment. The authors caution that this form of digital psychiatry may substantively and adversely alter bodily experience, violate the privacy of psychophysical space, and reformulate conceptions of humanity and the relationality that grounds it without adding explanatory power to psychiatric etiology.

More traditional ethics dilemmas such as the exercise of coercion are also represented in the present Special Topic. The paper by Efke et al. discusses the development and empirical validation of a German version of the Staff Attitude to Coercion Scale (SACS). While the original version included a 3-factor structure consisting of critical, pragmatic, and positive staff attitudes toward coercion, German translation required a change to an instrument with a one-factor structure constituting rejection or approval of coercion, which was achieved and validated. The authors emphasize the importance of this work to advance the use of validated instruments that measure attitudes toward coercion in order to reduce coercive clinical treatment interventions.

Münch et al. examine whether John Stuart Mill's maxim about the harm principle can form the basis of a diagnosis in the case of pedophilia and antisocial personality disorder. They contend that in DSM-5 and ICD-10, the criterion for both disorders is harm to others rather than the harm to self that is the standard for most diseases in psychiatry and medicine. The authors claim that these classifications rely more on moral judgments of what is socially unacceptable or labeled criminal than scientific criteria. They present arguments for and against keeping the current conceptualizations of the disorders in future

classification systems and conclude with a recommendation that harm to others should not constitute a diagnosis unless there is also distress or dysfunction experienced by the acting individual.

The article from Bieber et al. explores the key ethical domains of parental autonomy, decision-making capacity, and consent as they arise in the care of children and adolescents with mental disorders. They report on two cases: one a youth with an eating disorder, and the other a young patient with schizoaffective disorder. In each case, the decisional capacity of the parents to understand the young person's diagnosis and based on that understanding to make appropriate treatment choices is questionable. The authors conclude that in cases where the risk of imminent harm may be low yet concern for medical neglect remains, a formal evaluation of parental capacity within the frame of a systematic review of ethical principles can help guide decision making in this challenging area and fulfill clinicians' beneficence-grounded obligations.

This reflection on consent and decision-making capacity reminds us that one of the most significant contributions of bioethics to medicine and psychiatry is the importance of patient autonomy. Three articles in this Special Topic take a closer look at its ethical importance for the psychotherapeutic alliance. Gerger et al. offer a theoretical and ethical analysis of the key characteristics that constitute "Good Psychotherapy" arguing that ethical values call for an expansion of the patient's role in psychotherapy. They conclude that therapists should facilitate this greater participation through a more personalized and activated informed consent process that empowers patient decision making.

Blease et al. explain how sharing "Open Notes" in psychotherapy is yet another means of promoting patient self-determination and enhancing informed consent in psychotherapy. Health care systems and professionals are increasingly utilizing "Open Notes" which are electronic records patients can access usually through specialized patient portals and often in near real-time. The authors contend that "Open Notes" will enhance relational autonomy, foster patient's procedural knowledge of psychotherapy and improve patient recall and engagement while still safeguarding professional autonomy.

Nestoriuc et al. report on their study to modify informed consent in order to reduce nocebo effects. They assessed the effect of providing information on the nocebo effect to patients on patients' desire for knowledge about antidepressant side effects. Of 97 patients recently prescribed antidepressants and randomized to the nocebo information or education about the history of antidepressants. Those patients who received the nocebo information wanted to know less about side effects and more about mechanisms and placebo effects than the history group. The authors suggest that these results could potentially improve treatment participation and reduce side effect experience and reporting.

Two articles highlight the diverse contexts and persons encountered in psychiatric ethics and the many types of psychotherapeutic interventions available. Amado et al. share their retrospective study of 2 to 9 year outcomes following tailored cognitive remediation (CR) provided as

part of a personalized psychosocial rehabilitation program. Acknowledging the low employment rate of those with serious mental illness, they sought to identify effective interventions for this group with historically low employment rates. The study showed that CR was beneficial to employment and subjective well-being, with effects persisting as much as 9 years after therapy.

An international perspective is provided in an article from Kizilhan and Neumann who focus on the principle of justice in psychotherapy for patients who have suffered trauma from war or other humanitarian crises. Their central question was how psychotherapy can contribute to the restoration of justice in individuals who have suffered violence, displacement, and myriad injustices. The authors compellingly argue that “if war has a negative impact on health, then programs that focus on justice, peace, and stability should be able to offset or reduce this negative impact.” They set out ethical standards and principles to inform new approaches to psychotherapy with traumatized populations based on human rights, and thereby contribute to efforts for achieving social and political justice for survivors.

Two final articles in the collection outline practical approaches to translate ethical values and virtues into treatment to improve the health and lives of patients with mental illness. Gerritsen et al. discuss how the clinical ethics support service (CESS) approach of moral case deliberation (MCD) can aid forensic psychiatrists moving toward contact-based care where boundary and safety concerns are paramount. MCD is a structured conversation

method where professionals with the help of a facilitator engage in critical reflection on difficult moral questions in the practice of forensic psychiatry.

Finally, Haltaufderheide et al. examined CESS, which has been relatively underutilized in psychiatry compared to medicine. The results of their 13 semi-structured interviews with members of CESS and the mental health professionals who consult them illustrate the types of problems and expertise involved in psychiatric CESS. They propose an empirical taxonomy of dyadic, triangular, and systemic ethics concerns noting that CESS focuses mostly on the first two types of problems. Further, professionals and CESS members have different understandings of the CESS expertise and responsibility especially for the third type. This suggests the need for CESS members to attune their solutions more closely to the problems for which practitioners request support, and to develop a stable professional identity.

The 14 articles in this Special Topic offer a fascinating tour of the variety of ethical issues encountered in psychiatry and psychotherapy that the editors hope will inspire readers to take further journeys into the field.

AUTHOR CONTRIBUTIONS

CG wrote the first draft of the manuscript, and MT and RB critically revised it. All authors read and approved the final version.

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Mind-Brain Dualism in Psychiatry: Ethical Implications

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Keywords: biological psychiatry, brain-mind interaction, dualism, global burden of disease, major psychiatric disorders, neuromodulation

INTRODUCTION

Psychiatric disorders are often described as disorders of the mind. Major depressive disorder (MDD), generalized anxiety disorder (GAD), obsessive-compulsive disorder (OCD), and posttraumatic stress disorder (PTSD) are categorized by varying degrees of psychomotor, cognitive, affective, and volitional impairment (1). Many explain them in psychological terms without referring to an underlying neural substrate (2). This position may be traced to Freud's failed attempt to link neural mechanisms to psychodynamic concepts in his *Project for a Scientific Psychology*. It led him to abandon neurology in favor of psychoanalysis (3). Karl Jaspers later stated that biological and psychological investigations of the mind are like "the exploration of an unknown continent from opposite directions, where the explorers never meet because of the impenetrable country that intervenes (4)." Jaspers was not endorsing substance dualism, the theory that brain and mind are ontologically distinct material and immaterial substances (5). He was making an epistemological claim, noting that we have an incomplete understanding of the brain and mind and how they interact. Some contemporary psychiatrists seem to interpret the idea of biology and psychology coming from "opposite directions" as suggesting an epistemological and explanatory dualism between neural and mental processes. This appears to be part of an "identity crisis" in psychiatry reflecting disagreement about characterizing psychiatric disorders as disorders of the mind or brain (6). Dualism as such does not preclude mind-brain interaction. But it supports the position that mind and brain can be functionally distinct. I argue that this is not consistent with neuroscience research showing the extent to which mental and neural processes are interdependent and influence each other in maintaining mental health or causing mental illness. Dualistic thinking of the type I have described can limit therapeutic interventions for patients suffering from major psychiatric disorders.

MIND AND BRAIN

Research in clinical neuroscience can be interpreted to imply that there is no impenetrable barrier between mind and brain in psychiatry. Major psychiatric disorders are not just of the mind *or* brain, but of the mind *and* brain. This rejection of dualism has significant ethical implications. A unified model explaining the extent to which mental and neural processes interact could lead to safer and more effective treatments to control and ideally prevent psychiatric disorders. This could maximize benefit and minimize harm to the millions of people suffering from them for the balance of their lives. It could provide a theoretical and clinical basis for psychiatrists to discharge their obligations of beneficence and nonmaleficence in treating patients (7). It could also disabuse many of the idea

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that mental illness is all in the mind and completely within our conscious control to avoid or resolve. This could prevent affected people from feeling responsible for their illness and thus prevent additional psychological harm. We cannot explain mental processes apart from neural processes, or vice versa. There is no mind without brain and no brain without mind (8). They are functionally interdependent. Normal mind-brain interaction enables persons to adapt to the world. In major psychiatric disorders, there is dysfunction at both mental and neural levels. Indeed, an adequate explanatory model for these disorders, as well as for interventions to treat them, requires an account of not just interaction between the mind and brain, but also how genetic, epigenetic, endocrine, immune and environmental factors influence this interaction.

Nonreductive materialism may provide a satisfactory theory of mind-brain interaction in psychiatry (9). The brain necessarily generates and sustains mental events and processes (10). But these are not reducible or identical to neural events and processes. Mental phenomena are partly but not completely explained in terms of their neural correlates (11). As the comments and examples in the next two sections illustrate, this position rejects the view that mental states are epiphenomenal and cannot cause changes in the brain (12, 13). Consistent with nonreductive materialism, neurobiological naturalism explains mind and brain as interdependent components of a human organism. The mind emerges from the brain when it reaches a certain level of organization and complexity (14). Neural and mental functions constrain each other in a nested hierarchy of reentrant loops that maintain homeostasis in the organism and promote adaptability to the environment (15). The subjectivity and intentionality of mental states provide a person with a more accurate representation of the world than the representation provided by the brain alone (16). Mutual neural and mental constraint prevents misrepresentation of the world, as in psychoses, and hyperactive responses to aversive stimuli, as in stress-induced anxiety and depression. Major psychiatric disorders develop when something goes awry in these processes. The idea that mind and brain are functionally interdependent rather than functionally independent systems was accepted by many neurologists in the nineteenth century. They included Paul Broca, who claimed that “the great regions of the mind correspond to the great regions of the brain (17).” He was not making a reductionist claim but emphasizing how mind and brain have complementary roles in maintaining motor and mental functions.

BIOLOGICAL PSYCHIATRY

According to one definition of biological psychiatry, “mental disorders are relatively stable, prototypical dysfunctional patterns of experience and behavior that can be explained by dysfunctional systems at different levels (18–20).” The systems on which this field has focused are dysfunctional neurotransmitters and neural circuits in cortical and subcortical regions of the brain and how they generate different types and degrees of mental impairment. Because of increased knowledge of the function of the excitatory neurotransmitter glutamate, studies have shown that intranasal delivery of the noncompetitive NMDAR antagonist esketamine can have rapid therapeutic effects in some people with treatment-

resistant depression (21). This is significant because the pharmaceutical industry has largely left a therapeutic vacuum in psychiatry by substantially reducing its investment in the development of new psychotropic drugs. Deep brain stimulation (DBS) and other forms of neuromodulation can ameliorate symptoms in some patients with treatment-resistant MDD and OCD (22, 23). Genome-wide association studies can help to identify people at risk of developing these and other psychiatric disorders (24). In addition, the identification of biomarkers with functional neuroimaging has clarified why some individuals with depression respond or fail to respond to antidepressants or psychotherapy (25). The Research Domain Criteria (RDoC) is grounded in biological psychiatry (26). Unlike the symptom-based DSM-5, the aim of the RDoC is to identify abnormal brain mechanisms that can explain the etiology and pathophysiology of psychiatric disorders and provide earlier and more accurate diagnosis to produce optimal responses and outcomes (27–29).

Biological psychiatry does not exclude psychology. As Henrik Walter points out, “many proponents of biological psychiatry now accept an interplay of neurological and psychological (mental) factors” in explaining psychiatric disorders (18). Therapies based on this interplay can relieve or control symptoms of these disorders more effectively than therapies targeting mental or neural processes alone. Broadly construed, biological psychiatry is based on interaction between brain, mind, body and environment. Even with this broad scope, it has not generated a complete understanding of this interaction and can only approximate this goal with continued research.

MENTAL-NEURAL INTERACTION

Trauma or chronic psychosocial stress can disrupt neural mechanisms maintaining normal mental functions. A hyperactive psychological response to aversive stimuli can trigger a cascade of neurophysiological events causing dysregulation of the hypothalamic-pituitary-adrenal (HPA) axis and result in the symptoms of MDD or GAD (30). They do not begin as brain disorders but become brain disorders over time. The deleterious neural and mental effects of high circulating levels of cortisol from the adrenal cortex and norepinephrine from the adrenal medulla through the locus coeruleus to the amygdala show that mind and brain interact not only with the environment but also the endocrine system. In addition, the role of cytokines in depression is an example of how the immune system can affect the central nervous system (31). The mind can have positive effects in the brain as well. Cognitive behavioral therapy (CBT) can rewire cortico-limbic pathways, resulting in improved cognition and mood for some patients with depression (32, 33). Neurofeedback using EEG or fMRI is another example of how psychological responses to brain activity can regulate it. The use of this technique to improve mood and motivation in depressed patients is an example of “a holistic approach that overcomes bio-psychological dualisms” (34).

Some authors cataloguing the history of psychiatry end their analyses by emphasizing the limits of psychopharmacology (35). They fail to consider how neuromodulation and psychological therapies may be part of a comprehensive treatment plan for

moderately severe to severe psychiatric disorders. As noted, major psychiatric disorders involve not only dysfunctional neurotransmitters but also dysfunctional neural circuits (36). DBS can modulate a dysfunctional fronto-striatal circuit in OCD enough to make it amenable to CBT or other behavioral or psychotherapeutic techniques (37). Combining therapies targeting both neural and mental processing may enable patients to unlearn maladaptive thought and behavior. Focusing only on the mind or brain and failing to appreciate how each influences the other could preclude complementary treatment modalities to improve response rates and relieve symptoms. They could modulate hyperactive or hypoactive brain-mind processing to restore homeostasis and flexible action. By applying this knowledge of neural and mental interaction in research and practice, psychiatrists can more effectively discharge their obligations of nonmaleficence and beneficence to research subjects and patients.

Epigenetic factors influencing gene expression in the brain can shape an individual's response to psychosocial stress. "Growing evidence supports the hypothesis that epigenetics is a key mechanism through which environmental exposures interact with an individual's constitution and influence gene expression to determine risk for depression throughout life (38)." Research could identify epigenetic changes caused by environmental stressors that could influence individuals' susceptibility or resilience to depression. Altering the natural and social environment to reduce external stressors could reduce the risk of developing this disorder. In addition, an integrated model explaining how genetic, epigenetic and environmental factors can dysregulate fear conditioning in PTSD might be able to predict which environments would be more likely to cause the disorder and how it might be prevented (39).

In psychoses, the impaired ability of anterior cortical brain regions to inhibit dysregulated posterior cortical and subcortical regions can result in auditory or visual hallucinations, delusions and other abnormal conscious states. Genetic and neurobiological mechanisms alone seem to account for them. Structural imaging showing gray and white matter abnormalities and functional imaging showing dysfunctional cortico-striatal connectivity in the brains of people with the positive subtype of schizophrenia confirm that they are diseases of the brain with symptoms in distorted mental content (40). This does not mean that the mind cannot have a therapeutic role in this or other psychotic disorders. Studies have shown that a combination of antipsychotic medication, psychotherapy, family support and continued work and social activity results in improved cognitive, affective and volitional function and greater independence among adolescents when initiated shortly after a first-episode psychosis (41, 42). This biopsychosocial approach to treating schizophrenia is another example of how rejecting dualistic mind-or-brain models can increase benefit and reduce harm in people with major psychiatric disorders. Biological psychiatry does not imply that ordered and disordered mental states can be explained entirely in terms of ordered and disordered brain processes. But it does imply that psychomotor, cognitive, affective, and volitional dysfunction correlates with dysfunctional neural networks and can be

treated by modulating these networks through neurobiological and psychological interventions.

CONCLUSION

Caleb Gardner and Arthur Kleinman claim that "biological psychiatry has thus far failed to produce a comprehensive theoretical model of any major psychiatric disorder (6)..." While their comment draws attention to the limitations of biological psychiatry, it does not discredit it or indicate that it should be replaced by a psychological or social research model that excludes neurobiology. Instead, it underscores that it is a work in progress and the need for more research to explain the complex interaction between neural and psychological processes in mental health and illness. Gardner and Kleinman add that "In many ways, the unknown continent of the mind looms even larger now than it did in Jaspers' day—a reality that is both humbling and inspiring (6)." The first part of this comment suggests dualistic thinking about the mind as a mysterious domain epistemologically and explanatorily distinct from the brain. It contributes to the idea that we need to choose between characterizing psychiatric disorders as disorders of the brain or mind. This is a false dichotomy given that brain-mind and mind-brain interaction enables or disables thought and behavior. Yet the second part of their comment points to the motivation for research that will provide a better understanding of how brain and mind influence each other.

"What the research of the past decades has shown us most convincingly is that biology and environment work powerfully together on the brain and the mind—and that psychiatry has hit its roadblock because we know too little about how the brain functions (43)." Biological psychiatry is not part of this roadblock. While much more work is needed, it has the potential to yield a better understanding of major psychiatric disorders by generating increased knowledge of neurobiological, psychological and environmental interaction needed to predict, treat, and prevent them. This is significant because psychiatric disorders constitute a higher percentage of the global burden of disease than cancer and other diseases (44). Research that can generate this knowledge may clarify the etiology and pathophysiology of these disorders. This may advance interventions enabling functional independence and improved quality of life for the millions of people affected by them. Taking the full extent of mind-brain interaction into account is thus ethically imperative in psychiatric research and practice.

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Digital Phenotyping: Ethical Issues, Opportunities, and Threats

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This paper explores the potential threats of digital phenotyping and the ways it may redesign our body experience and conceptualization. We argue that technology in digital medicine, and in psychiatry in particular, is not merely an *extrinsic* device to achieve improvements in knowledge, diagnosis, and treatment of diseases; rather, it *intrinsically* and unavoidably implies potential effects on what it is to be a human person, namely the embodiment and relatedness in human affairs, and not only in the clinical setting. Last but not least, digital phenotyping may improve prediction of abnormal behaviour, but not improve its causal explanation or psychological understanding.

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INTRODUCTION

Medicine is a knowledge and a technique of human bodies. Historically, it has been perhaps the most materialistic knowledge that mankind has developed and practiced, returning to us an image of man in its most concrete and terrestrial version. For better or worse, flesh and blood were the elements of medicine's concrete work, and the horizon of its overall vision of the human.

Medicine, and psychiatry as a part of it, have never been just a specialized science confined to diagnosing and treating diseases, but indeed a widespread set of apparatuses that shape our bodies, and decide what we can do with them or not, what we can expect from our lives or should not expect. In this sense, medicine has defined a whole field of possibilities and impossibilities of human existence, has imprinted large sectors of what is the contemporary form of Western life. Medicine has never been just a “local” science, but it has always proposed and sometimes imposed its explicit or implicit anthropology, whose ambitions and consequences have affected the entire scope of human life—even when it did not intend to do so, or when it expressly abstained from doing so.

DEMATERIALIZED MEDICINE

It is not without the bewilderment of doctors as well as patients, that the object of medicine has recently *dematerialized*. Imaging techniques allow a new and increasingly refined approach to diagnosis, allowing areas of research and intervention unthinkable until a few years ago. They operate remotely thanks to a progressively extensive and powerful interface linked to the support of computing and the artificial intelligence resource. Digital phenotyping (1) is the emblematic

example of an opportunity for extending our knowledge about the disorders that affect the human body, their course and outcome, and therefore it is a resource for diagnosis, especially early diagnosis; its version of tele-care is a means for monitoring patients, treating them timely and continuously over time (2).

There are several concerns about this approach, including ethical concerns which mainly focus on the most effective ways to preserve privacy (3). Another ethical issue is about the effects produced by technology on the patient-clinician relationship; this concern is usually counterbalanced by the argument that technology is seen as producing more improvements (e.g. precision diagnosis and treatments) than negative effects—the latter mainly confined to the worry that the interposition of technological devices may generate a quasi-dehumanized although effective practice (4).

DIGITAL MEDICINE REDESIGNS OUR BODIES

A more subtle concern can be encapsulated in the following questions: is technology, like digital phenotyping, simply a “tool” to achieve improvements in medical practice? Is it an *extrinsic* device that has no effect on the way human beings experience and represent their bodies, interpersonal relationships, and the modes in caring about them and about human existence in general? Does technology *intrinsically* and unavoidably imply potential effects on what it is to be a human person, namely embodiment and relatedness in human affairs, and not only in the clinical setting?

Through technology, we have gained unprecedented access to our bodies and their functions, expanded our knowledge of their mechanisms, and the accuracy of our interventions on them. Yet—and here we come to our main concern—this means that through technology we are *redesigning our bodies*, and that through this set of tools and practices there will be new kinds of bodies, and new men and women too.

We must not think that these new techniques are a linear extension of the old techniques. Each new technique is a new trajectory of knowledge and intervention, only vaguely related to previous trajectories. No new technique is a linear extension of the previous ones, since no new technique applies to the same entities that were the object of their ancestors. Each new technique outlines a new field of unprecedented objects. Digital medicine does not operate in a new way on old bodies, rather it does new things on bodies that are also new. But the halo effect inhibits this implicit but powerful extension ranging from technical-specialistic innovation to the design of new forms of embodiment and of a new anthropology.

Let's take a simple and concrete example, that of the *drill*. Various paleoanthropological findings (5, 6) attest that this technology was available to our ancestors, and that sorcerers/doctors practiced interventions to the skull and perhaps to the

brain. The drill-sorcerer/doctor has in front of him an object: solid, spatially discrete, stable over time. This will install an *epistemic polarity* of the type inside/outside, visible/invisible. This polarity implies a set of oppositions: hidden cause/visible effect. In medicine: etiology/semeiotics. For those who have a drill in their hand, diagnosis and treatment will mean first crossing a surface and accessing a profundity. Then, it will mean using what was previously invisible to causally explain the visible, since the inside is supposed to cause the outside. And, finally, it will mean to set forth to modify the inside/profound/invisible/cause/etiological in order to change the outside/surface/visible/effect/semiological. Each object is supposed to have other objects in its inside, and both knowing and intervening will mean handling from time to time the innermost object, the smallest element, the finest matter. Possibly, the ultimate objectivity, the tissue, the cell, the atom.

We are not arguing that the Neolithic surgeon was identical to the Renaissance surgeon or the contemporary surgeon. It may be that the Neolithic surgeon imagined that the object he was accessing was a spirit to be freed, more than a mood to drain, or a neoplasia to be removed. What matters is the structure of the *epistemic field* in front of which the three surgeons are located. The structure of the field does not vary at all with the changing meanings of the inside—be it a spirit, a mood, or a cell. As long as the technical instrument remains the drill, the structure of the field remains unchanged: inside versus outside, cause versus effect. This field-structure is entirely due to the nature of the technical instrument.

DIGITAL MEDICINE LOOKS FOR COVARIANCE, NOT FOR CAUSAL EXPLANATION AND PSYCHOLOGICAL UNDERSTANDING

The digital-clinician, as opposed to the drill-clinician, monitoring blood flow, oxygen consumption, the greater or lesser activation of certain vessels or brain areas, is in a quite different epistemic field. Where previously there was an *object*, now there is a *process*. The digital clinician is in the direct presence of a process. A process is not an object (spatially localized, discrete, and stable over time), but a set of fluctuations of a certain set of variables spatially diffused. In this new kind of epistemic field, diagnosis involves monitoring these variations of the process. To the digital-clinician, these variations are not exactly a hidden cause, an invisible etiology for the visible symptoms. The digital-clinician is not looking for causes hidden in the interior of a material body, rather he is studying the *covariance* of two sets of variables chosen for observation in a digitalized body. For example, a set of visual stimuli and a set of brain areas that activate to a greater or lesser extent. He will no longer be led to determine causes and effects.

BOX 1 | Risk factors are not causal explanation or understanding.

Case study 1 (smartphone-based empirical assessments of suicidal ideation): The aim of the study is to assess short-term variability in suicidal ideation in order to provide a novel method of improving the short-term prediction of suicidal ideation (7). Each day for 28 days, participants were signaled by a smartphone-based program at four random intervals separated by 4 to 8 hr (i.e., signal-contingent monitoring) to report on severity of suicidal ideation. The results of fine-grained examination of suicidal ideation advance the information of how suicidal ideation changes over short periods. Well-known risk factors for suicidal ideation such as hopelessness, burdensomeness and loneliness vary considerably over just a few hours and are correlated with suicidal ideation, but were limited in predicting short-term change in suicidal ideation.

Case study 2 (fictional): Imagine that digital phenotyping through big data will allow us to predict that there is a covariance between increased suicidal behavior and increased consumption of, say, soy milk in the last 8 hr. Obviously there is no causal correlation between the two, yet psychiatrists may use this covariance as a predictor of suicidal intention without inquiring about causes and reasons of suicidality. It will be enough to determine a constant correlation between those two sets of variables in order to establish a prevention program. It may matter little to the digital-clinician why those sets of variables are varying together and according to which law. The fact that they vary together, and that you can write the formula of that covariance, is what matters.

Covariance aims to identify risk factors, not causes; and to allow prediction, not causal explanation and psychological understanding (see **Box 1**).

The more data one collects (through digital phenotyping and big data), the less the causal paradigm will be important, and the more exhaustive the pure formulation of what might be called a *morphology* will be. Of course, not only explaining causally a given state will be less important, but even more so *understanding* the personal reasons for a given behavior, or how it feels, for a patient, to behave in a given way, will be less significant.

The digital-clinician may be led by his technological apparatus to abandon the idea that there are things in the world which act on other things, and may be tempted to embrace the perspective that in the world there are local fluctuations of a certain overall process. He will move along this epistemological slanted plane, not so much because he believes that reality is made of processes rather than of objects, but because the technique on which he relies upon reveals more about the processes and fluctuations than about the causal relations between objects (8, 9).

We all, doctors, non-doctors, and patients (10), are spellbound by the *screen* instead of the *drill*, and we will focus on dematerialized bodies, images, algorithms, processes, covariance, etc., rather than on physical bodies, words, personal stories, discrete events, causes and reasons, etc.

If this the trend of digital medicine is substituting cause-effect and motivational-psychological relations with relations of covariance, which effects will this trend have on therapeutic interventions? At present, therapeutic interventions are based on cause-effect relations in the sense that they try to target as

much as possible on etio-pathogenic processes in order to eliminate their epiphenomena (namely, symptoms). It's hard to imagine what the interventions of digital medicine will be like. Devised to obtain a more accurate and comprehensive picture, a hypothesis about the outcome of digital medicine is that it will focus on epiphenomena, for instance abnormal behaviors, rather than on their biological or psychological etiology. This is perhaps too somber an outlook for the destiny of medicine—yet it seems to be a logical consequence of the epistemic field of digital phenotyping—focusing on covariance rather than etio-pathogenesis.

A final concern: will digital phenotyping help to distinguish normality from abnormality? This distinction—given the difficulty to differentiate the “normal” from the “abnormal” in a dichotomic way and given that the definition of “normality” is context-dependent and open to change—is at the moment based on constructs like dysfunction or suffering (11). If the trend is looking at a screen showing graphics and digits, the boundary between norm and pathology will be established numerically too. Will this produce arbitrary thresholds, as is the case for instance with borderline hypertension (12)?

Big data may produce a kind of *cyber-hypochondria*, that is the fear of being or getting sick based on an obsessive monitoring of one's own digitized bodily functions rather than on one's feelings of well-being or ill-being—another example of de-corporealization.

CONCLUSIONS

In conclusion: in the face of such a radical transformation of techniques, it would be helpful to learn to do two things at the same time. On the one hand, we should learn how to take advantage of the instruments that contemporary technology provides for us, looking at the phenomena they show us and the possibilities of intervention that they open up. On the other hand, we should also learn to look at the instruments themselves, without being dazzled by the phenomena to which they seem to apply. When we worry that big data involves a privacy issue, it's already too late—even though we should worry about privacy. The real problem is not that we have to properly manage certain data about our bodies. The problem is that this data doesn't simply talk about how our bodies are made. They talk *about how our instruments are made*, and about *what our instruments can make of our bodies*.

An old proverb reads: when the wise man points to the moon, the fool looks at his finger. We could jokingly say that we are firmly convinced of the opposite: when the fool points to the moon, the wise man first looks at his finger.

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What are the Key Characteristics of a ‘Good’ Psychotherapy? Calling for Ethical Patient Involvement

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Objective: The evidence-based practice movement clearly defines the relevant components of a good treatment. In the present article, we elaborate on how the active involvement of patients within psychotherapy can and should be increased in order to respect ethical considerations. Our arguments complement the requirements of evidence-based practice, and are independent of the actual psychotherapeutic treatment approach being used.

Method: Theoretical and ethical analysis.

Results: In order to respect patient autonomy, psychotherapy needs to be transparent and honest when it comes to disclosing the relevant factors for promoting therapeutic change. It has been argued that ethical informed consent needs to include empirically supported patient information. In this paper we go one step further: we outline that fully respecting ethical considerations in psychotherapeutic treatment necessarily calls for acknowledging and strengthening the active role of patients in the course of psychotherapy. Accordingly, patients need not only to be informed openly and transparently about the planned treatment, the treatment rationale, and the expected prognosis of improvement in the course of psychotherapy, but they also need to be actively involved in the decision-making process and during the entire process of psychotherapeutic treatment.

Conclusions: Our arguments support the tendency that can be observed in health care in recent years towards more active patient involvement across different health-care domains, but also in clinical research. This article offers an ethical perspective on the question what defines a ‘good psychotherapy’, which, hopefully, will help to leave behind some of the ongoing psychotherapy debates and move the field forward.

Keywords: psychotherapy, patient-centered care, empirically supported treatment, evidence-based practice, patient autonomy

INTRODUCTION

Since Eysenck's provocative conclusion in 1952 that psychotherapy doesn't facilitate recovery from mental disorders (1), it has been a major goal of psychotherapy research to prove the *efficacy* and *effectiveness* of psychotherapy. With the adoption of the criteria of evidence-based medicine (2–4) to psychotherapy outcome research, the proof of efficacy became necessary for a psychotherapeutic treatment to be considered empirically supported and thus to be recommended for clinical practice (5, 6). Within the evidence-based practice framework, however, a broad perspective is taken into account acknowledging that beyond the theory-driven ingredients of the intervention, research evidence points to relevant characteristics of the patient or client, as well as of the treatment provider, and the interactive process of treatment as relevant aspects (e.g., 7, 8). Following previous claims regarding the patient as being a, if not the most important factor contributing to psychotherapy effects (9–11), the present paper will focus on the role of patients within the course of psychotherapeutic treatment.

Calls for more active patient involvement in psychotherapy are not new, and have their origins within humanistic and positive psychology, focusing on each person's potential for growth (12). For instance, Rogers who developed the person-centered psychotherapy approach, stated in 1963 “we could say that in the optimum of therapy the person rightfully experiences the most complete and absolute freedom” (13, p.25). In 1994, Bergin and Garfield wrote that “clients are not inert objects upon which techniques are administered...”, and further, “as therapists have depended more upon the client's resources, more change seems to occur” (14, p.825–826, as cited in 15 p.84). In addition, literature on resilience points out the potential of client- and patient-associated factors to be related with self-directed change and self-healing, and to contribute to health-improvements (16, 17). Interestingly, Maslow's theory of human motivation (18) seems to have anticipated these developments by highlighting the importance of self-fulfillment and self-actualization as forming the basis for personal functioning and resilience. As a practical example of how the patient can be given the lead in psychotherapy, a patient-led approach has been suggested and evaluated, which gives the patient responsibility for the planning and structuring of psychotherapy (19, 20).

Our paper will build on previous literature pointing out the relevance of patient or client involvement in psychotherapy. We will complement this line of research by adding an ethical perspective and deducing that if transferring ethical considerations to psychotherapy practice, actively involving patients in the entire psychotherapeutic process is not only possible but also necessary from an ethical point of view, although doing so, might be a challenge in certain cases. From a practical point of view, providing a clear and evidence-based guideline on how to realize the goal of ethical patient involvement within practice is beyond the scope of this article which rather aims at raising awareness on the relevance of ethical considerations in psychotherapy. However, in some instances we will provide examples on how the suggested goal of ethical patient involvement may be translated or has been translated to clinical practice.

ETHICS IN PSYCHOTHERAPY

In medical ethics, the applied ethics approach of *principlism* forms the basis for many ethical guidelines, and postulates four ethical principles (21): first, *respect for autonomy* (self-determination); second, *beneficence* (do good); third, *non-maleficence* (do no harm); and fourth, *justice* (social distribution of benefits and burdens). In dealing with ethical questions, conflicts, and/or dilemmas, each of the four principles needs to be specified and balanced, recognizing that there is no hierarchical order of the four principles from the outset (21).

Not only in medicine in general but also in psychotherapy, the applied ethics approach of principlism may be an attractive framework for moral decision-making because it is undogmatic, open with regard to any theory of normative ethics, liberal, transparent, and rational. In recent years, an increased emphasis on ethics in psychotherapy can be observed, which may complement the available ethical codes of conduct in several countries (e.g., 22, 23). Over the last five years, the publication of textbooks for practitioners (e.g., 24, 25), of scientific journal articles (e.g., 26, 27), of article collections and special issues (e.g., 28, 29), and the publication of the “Oxford Handbook of Psychotherapy Ethics” (30) reflect the increase in interest and knowledge in this field.

In this context, ethical arguments have recently been raised to call for adequate patient information in psychotherapy, based on empirical evidence. Ethical patient information is required to provide all the information that is necessary for a patient to make an informed decision concerning a suggested treatment plan (6, 31–33). In a recent systematic review, Lamont-Mills and colleagues summarized the evidence on the role of confidentiality and informed consent in counselling and psychotherapy (34). They concluded that within clinical practice, psychotherapists apply standardized informed consent templates but they also state that we know only little about the actual adequacy of informed consent obtainment in psychotherapy as well as on the patients' own understanding of informed consent and confidentiality. We will argue in the present article that despite the necessity to simply inform patients about the suggested treatment, for instance by using standardized informed consent templates, the patients should be actively involved in the entire therapeutic process in an individualized way. We will elaborate on how this can be done and which aspects are to be considered when doing so.

ETHICAL PATIENT INVOLVEMENT

Providing an Individualized, Plausible, Comprehensive, and Honest Treatment Rationale

From an ethical point of view, transparency in the conduct of psychotherapy is essential and serves to respect and protect patients' autonomy (31–33). To this effect, treatment rationales need to be plausible and clear, but also compelling (35). It is indispensable, however, that honesty is warranted, and that

exaggerations are avoided (26). Therefore, treatment rationales need to be based on evidence-based and empirically supported research findings (5, 31, 36, 37). Moreover, the therapist's language must be adapted with respect to the patient's own language (38), and the patient's individual context needs to be considered. The provision of individualized honest and transparent treatment rationales is key for assuring patient autonomy in that they enable a patient to decide for or against initiating psychotherapeutic treatment in an informed manner (32, 33). In turn, a higher credibility of an initiated treatment, as perceived by patients at an early stage of treatment, as well as patients' outcome expectations have been shown to be significantly associated with treatment outcomes (39, 40). Yet, it is important to note that patient information does not need to include the explanation of complex psychological theories if not warranted. Research on the open and transparent administration of placebo treatment for instance has demonstrated benefits of the provision of rather short, yet compelling treatment rationales even in the absence of an active treatment (41–43). However, the integration of patient's individual views and perspectives within the framework of evidence-based treatment might seem as a contradiction. But recent research proposes to allow for more variability and evidence-based therapist flexibility, for instance, within the context-responsive psychotherapy integration framework. The application of this framework in clinical practice realizes personalization of psychotherapy by therapists' responsiveness to patients' characteristic, for instance their treatment-related beliefs (44). In summary we argue that the process of informing a patient regarding a treatment rationale within psychotherapy should actively consider the patient's own perspectives in order to respect the patient's autonomy.

Defining the Outcome of Psychotherapeutic Treatment Including the Patient Perspective

To take the ethical principles of respect for autonomy and beneficence seriously, patients should also be included in an active manner in the process of defining the domain of outcome of psychotherapeutic treatment. Strupp, Fox (45) were among the first ones to highlight the relevance of the patients' own perspective in outcome assessment in psychotherapy. Besides the core symptoms as defined in diagnostic manuals (e.g. the Diagnostic and Statistical Manual of Mental Disorders DSM-V (46) or the International Statistical Classification of Diseases ICD-10 (47), a range of additional health-related outcomes exist which might be considered relevant as well (e.g., 48, 49). Alternative treatment outcomes might encompass such aspects as quality of life, well-being, self-efficacy, and social relationships, among many more. For instance, meaning of life has been described as being correlated with psychopathological symptoms (50, 51), and as a possible alternative target outcome of psychotherapy (52). In practice, the aim to include patient's perspectives can be realized in diverse ways, including for instance the use of multidimensional routine treatment outcome packages (53), the assessment of personal target complaints (54), but may also include the use of the “miracle

question” or of “scaling questions” (55, 56). It might be argued, that for many patients, particularly those who are ambivalent about change, discussions about treatment goals and desired outcomes of treatments might be challenging if not impossible. De Shazer and Isebaert give an informative overview on how respect for patient autonomy can be realized within inpatient and outpatient psychotherapeutic treatment of alcohol abuse, which has traditionally been described as being difficult to treat, by focusing on “what patients want from therapy” (57, p.51). Thus, in order to meet the ethical principles of respect for patient autonomy and beneficence, the identification of the most relevant health dimension to be improved in the course of a psychotherapeutic treatment needs to actively include and respect the patient's own perspective.

Discussing the Evidence Openly With the Patient

In general, psychotherapy is required to have beneficial effects at least on the core symptoms of a certain diagnosis in order to be considered evidence-based. Unfortunately, due to the scarcity of research on other outcome domains than symptom improvement, we know only little about psychotherapy effects on other outcome domains so-far. In order to respect the ethical principle of respect for the patient autonomy, these lacks of evidence should be discussed with patients. Further, the available evidence on potentially occurring unwanted effects or side effects in the course of psychotherapy is very limited (6, 58). Nevertheless, in accordance with the ethical principles of autonomy and of non-maleficence, the potential risks as well as lacks of available evidence needs to be disclosed to patients openly in order to allow for the patients to make an informed decision.

Likewise, in accordance with the ethical principles of beneficence and of non-maleficence, the influence of therapists, proven to contribute significantly to treatment effects (59), should be taken into account while discussing potential treatment outcomes (60). Research has shown that not all therapists are similarly effective (61–63). Yet, patients wish to obtain information on their therapist's performance level (64). Therefore, it is very important to discuss with a patient the possibility that a mismatch between the patient and the therapist may limit potentially beneficial treatment effects, in order to avoid the patient to conclude that an unsuccessful course of treatment was his or her own fault. Within the therapeutic process, therapists could raise this issue occasionally, and offer the patient the possibility to swap therapists, or change treatment.

Discussing the Potential Course of Symptom Improvement

Several meta-analyses have shown that short-term effects of psychotherapeutic treatments may differ considerably from long-term effects (65–68). From a clinical as well as from an ethical and financial perspective, one could argue that a treatment would need to contribute to long-lasting, sustainable benefits in order to be recommended for clinical practice (69,

70). However, from a patient's perspective, even short-term improvements may be considered relevant, and may considerably impact well-being. For instance, in the context of medically unexplained symptoms, it has been argued that given the high personal burden associated with the mostly chronic course of symptoms without the hope for complete recovery, even short-term symptom relief might be considered as highly relevant by individual patients (67). In addition, therapists might argue that short-term deteriorations of symptoms or well-being may be part of the therapeutic process, which eventually lead to long-term improvements. For instance, crying during treatment sessions has been described as relieving distress and arousal, but can also be perceived as stressful in itself, and as contributing to the experience of increasing arousal (71). In this context, however, the ethical principle of doing no harm (nonmaleficence), for example the danger of introducing negative expectations, and increasing the risk for the occurrence of nocebo effects needs some attention (72). It could further be argued, that talking about potentially occurring symptom deteriorations might decrease patients' commitment to treatment and the therapeutic relationship. Previous research, however, identified potential and diverse ways how to deal with such difficult situations within psychotherapy (57, 73, 74). It is important however to respect patients' autonomy by allowing the patients an informed decision whether or not to adhere to a suggested treatment plan. Accordingly, the discussion of the potential course of symptoms over time, which may include temporal symptom deteriorations or possible discrepancies between expected short- and long-term effects of psychotherapy, requires a particularly sensitive and individualized process, which necessarily takes into consideration a patient's previous experience, expectations, and other patient-related characteristics.

Considering Patients' Previous Experiences

In the course of ethically sound psychotherapy, exploring and discussing patients' previous treatment experiences as well as their subjective illness narratives (i.e. their own understanding regarding how a certain illness is perceived, understood and managed; 75) seems most relevant. Besides exploring patients' previous treatment experiences, it is also relevant to explore what patients themselves have been doing in the past in order to deal with difficulties and crises in their lives, as well as pointing out previous successes and achievements in handling previous problems (56). Such explorations may give important hints regarding patients' strengths and resources, and can contribute to creating awareness and positive expectations while strengthening the patients' own capacity to cope with problems. In this sense, psychotherapy can be described as contributing to transforming non-adaptive narratives into adaptive ones (76). Thus, "psychotherapy is not simply the vehicle for the delivery of psychological ingredients but is, rather, a highly entwined system that uses language to construct or, better said, reconstruct the patient's interpretation of the world." (77, p. 862). In practice, acknowledging patients' previous experiences can be done for instance by responding

individually to patients' unique characteristics and emerging scenarios (44), or by the exploration of so-called exceptions of the problem (57).

Monitoring Treatment Progress

In shifting the focus towards the patient's perspective in clinical research, patient-reported outcomes measures (PROMs) were originally applied in clinical research in order to quantitatively assess health outcomes from the patient's perspective (78, 79). Meanwhile, however, they are increasingly used in clinical practice to monitor and improve health care for individual patients (80). Also in the specific context of psychotherapy feedback systems have been introduced (81, 82), which can be used to inform the therapist about the actual course of a particular patient, and may facilitate personalized planning and adapting of processes within psychotherapy. For example, the application of the routine outcome monitoring has been shown to be superior to "clinical judgment in predicting patients who are on or off track for treatment success" (82, p.459). Electronic feedback systems just as the use of PROMs in clinical practice are assumed to help improving the communication between patients and clinicians, to foster a shared decision-making process, and to develop and monitor personalized care plans (83). However, they are not to replace the necessary exchange between a clinical psychologist and the patient regarding the patient's idiosyncratic perceptions of and attitudes towards the course of treatment.

CONCLUSIONS

During the last decades, psychotherapy research just as other areas of mental health care research have largely focused on the one hand on the identification of clear-cut definitions of mental disorders with several revisions of the defining criteria over the years (84–86), and on the other hand on the identification of treatments that are specifically tailored to a diagnosis and which were assumed to help eliminate the defining symptoms of a diagnosis better than other more generic treatments (49, 87). This dominating view made psychotherapy research endeavors initially focus on proving the *efficacy* of psychotherapeutic treatments. Over the years, the focus slightly moved towards more naturalistic investigations of the *effectiveness* of treatments, and in recent years, the *efficiency* of psychotherapy gained more research interest, and an increase in publications on the cost-effectiveness of psychotherapeutic treatments can be observed (see e.g., 88–92).

In addition to *efficacy*, *effectiveness* and *efficiency*, however, *ethical considerations* are most relevant when talking about criteria of a 'good' psychotherapy. We have argued that treatment recommendations, which respect the ethical principles of respect for autonomy, beneficence, non-maleficence, and justice, reflect an individualized *patient-centered process* that should incorporate the relative importance of individual patient's history, values and needs.

Patients as Partners

We showed that an active involvement of patients is most relevant when including ethical principles in psychotherapy decision-making and practice. In this understanding, based on the ethical principles of respect for autonomy and beneficence, patients are to be seen as partners in clinical practice. In addition, it has been argued recently that patients' perspectives should be included in clinical research as well, for instance in study design and governance (93, 94), in order to increase the relevance of research findings for the patients and the actual clinical practice outside of the academic setting. These claims are nicely summarized in The BMJ's patient partnership strategy (95), as well as in the statements published by the Patient-Centered Outcomes Research Institute in the US (96, 97), as well as the National Institute for Health Research in the UK (98).

The addition of ethical considerations to the debate strengthens previous calls for shifting the focus from the treatment itself towards other relevant aspects of psychotherapy (99, 100). In particular, patients themselves as active agents within psychotherapy need more attention, including their idiosyncratic experiences with psychotherapy, as well as their perspectives on health and illness (i.e. their illness and health narratives), their moral and normative values, but also their financial and time-wise investments when initiating psychotherapy (10, 37, 99, 101).

Our call for more patient involvement in the course of psychotherapy is not new. In fact, some psychotherapeutic approaches exist which are not based on theoretical assumptions about the etiology of mental problems or disorders, but which focus more on the idiosyncratic process within psychotherapy. For instance, in solution focused brief therapy the patient is seen as the expert of therapeutic change rather than the therapist (102). Likewise, humanistic approaches, such as person-centered psychotherapy in general and, in particular, motivational interviewing, rely on establishing and safeguarding of a therapeutic alliance to allow and foster change. They have a strong focus on the processes of change rather than on etiological models or the adherences to protocols and manuals (103, 104). The three outlined psychotherapeutic approaches have in common that patients' views, experiences, values, and needs are actively involved throughout the whole course of treatment—an expression of the ethical principle of respect for autonomy, while the therapist supports and guides rather than directs the therapeutic process.

One Size Does Not Fit All

We conclude that the ethical principles of patient autonomy, beneficence, non-maleficence and justice can best be respected within an individualized and patient-centered process within psychotherapeutic treatment. In this context the principles described in person-centered psychotherapy (104) seem to be of high relevance just as the processes described for instance in the context of motivational interviewing (103), or in the therapist's attitude of 'not-knowing' in solution focused brief therapy (56, 102).

We have argued that throughout the course of psychotherapy, therapists need to remain in exchange with the patient regarding the process of change during the course or after finishing psychotherapy. This exchange may include discussions about first, multiple dimensions of potential treatment outcomes (i.e. not only focusing on symptom improvement but on a broader range of health-related outcomes), second potential symptom worsening or otherwise occurring adverse events, third, the long-term perspectives of expected treatment effects, and fourth, the costs of a psychotherapeutic treatment, financially but also time-wise. All four of them may differ considerably between individuals with respect to their actual content and the relevance of one aspect compared to the others. This exchange between patient and therapist should be tailored to individual patients and should be guided by their previous experiences, their individual illness narratives, their values, and needs.

It is important to keep in mind, however, that comprehensive patient information also bears potential risks. Just as in medical treatment, where unwanted events can be elicited by emphasizing them (e.g., 105, 106), the occurrence of so-called nocebo effects has also been discussed in the context of psychotherapy (72, 107–109). From an ethical perspective, risks should neither be exaggerated nor be concealed by a practitioner (110). In order to respect ethical principles, and in order to avoid the occurrence of nocebo-effects (maleficence), in the case of doubt, patients should explicitly be asked whether they care for knowing all details regarding potential risks that may be associated with initiating psychotherapeutic treatment thereby meeting the ethical principle of respect for the patient's autonomy.

Following our arguments there is probably not one recommendable 'good' or 'best' psychotherapy. Rather, the evaluation of certain psychotherapeutic treatments as a 'good' psychotherapy for a certain patient always constitutes an individual decision (99), and may thus differ across individuals depending for instance on their backgrounds, clinical conditions, personal values, and their illness and health narratives. The addition of the *ethical perspective* to the evaluation of psychotherapeutic treatments may therefore be seen as a key element which shifts the focus from a treatment itself (i.e. its *efficacy*, *effectiveness* and *efficiency*) towards the patient, and thus necessarily strengthens the patient's active role within psychotherapy.

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HG, AN, CL, JG, and MT wrote and reviewed the manuscript.

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The Significance of Justice in the Psychotherapeutic Treatment of Traumatized People After War and Crises

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In the aftermath of crimes against humanity, human rights violations, and genocide, the question arises whether and how justice can be restored. A lack of social justice and continuing injustice in post-conflict areas prevent survivors from processing their traumatic experiences. As a consequence, the individuals and often their families, their community, and the whole society are changed in a lasting way. The trauma can even be passed on over generations. Yet, if war has a negative impact on health, then, programs that focus on achieving justice, peace, and stability should be able to offset or reduce this negative impact. For this reason, the importance of psychosocial well-being and mental health for the reconstruction of societies is acknowledged. Various political, legal, and social programs, like transitional justice, are being implemented in post-war regions to develop justice. Developing or restoring justice also requires good psychosocial care, like a treatment that supports individuals when coping with injustice and gaining a new sense of justice. Such a psychological treatment can make an important contribution when it comes to building new trust and improving mental health. Ethical standards in coping with trauma and developing or restoring justice in post-conflict regions are indispensable to enable long-term peace. The course for new social justice can be set, through a just health system. Thereby, only programs and legal processes, which try to do justice to the survivors and take their needs into account, are ethically justifiable. Human rights and health cannot be separated in psychotherapy with survivors of war and terror. Based on ethical principles, new approaches must be generated for psychotherapy in war regions and with survivors of war and terror. The aim will be to make an important contribution to the mental and social reconstruction of countries after mass violence.

Keywords: trauma, justice, post-traumatic stress disorder, war, reparation, psychotherapy

INTRODUCTION

In 2019, the United Nations High Commission for Refugees (UNHCR) registered 70.8 million people who had been forcefully displaced. Out of these, 25.9 million were classified as refugees who had been forced to leave their homeland on account of persecution, war or violence (1). The consequences of prolonged exposure to conflict and persecution are frequently exacerbated by displacement and deprivations. This, in turn, increase the refugees' vulnerability to many mental health problems (2). As consequences of the traumatic experiences, post-traumatic stress disorder (PTSD) and depression are the most common mental health problems among refugees. One of the largest meta-analysis with refugees and other survivors of torture and war from over 40 countries suggests a prevalence of 30.6% for PTSD and 30.8% for depressive disorders (3). It is supposed that the number is a lot higher in displaced people, who live in countries with ongoing violence and a bad supply situation. Prolonged exposure to conflict and persecution and protracted conditions of deprecations and displacement are likely to increase the prevalence.

Medical doctors and psychologists who work with these people agree that some form of justice must be achieved to process what has been experienced. "No healing without justice" says Dr. Mukwege, Nobel Peace Prize laureate 2018, about his work with women and children who survived sexual violence in Eastern Congo. Referring to the victims of ISIS in Northern Iraq, psychotraumatologist Prof. Kizilhan and Nadia Murad, the other 2018 Peace Prize laureate, emphasize that the psychological wounds of women can only be healed if they are also given legal justice (4).

Yet, in many conflict areas, reparations, rehabilitation measures, and the prosecution of war crimes are only implemented after many years or not at all. Often national governments are not interested in pushing forward the right for justice of minorities, especially if they were involved in the conflict themselves. The international community and the International Criminal Court (ICC) are needed to intervene. Yet, their possibilities are often limited, especially when the affected country has not signed the Rome Statute. The Rome Statute is a treaty (1998) that allows the ICC to prosecute war crimes, crimes against humanity and genocide in the signed countries and to bring them to justice. But the harmed communities cannot wait years to have their desire for justice addressed (5).

There are further challenges. Neither legal compensation nor the prosecution of perpetrators is enough to cause effective justice. Those do not automatically help individual survivors or the collective community heal (6). Especially, when their demands and their cultural and societal background are not taken into account. Thus, a new, transcultural justice approach is needed to help individual survivors and harmed societies heal after mass atrocities.

Understanding how justice can be established or restored in conflict areas and war-traumatized societies, means, applying basic ethical standards. Equal access to health care, as a form of justice, is one of the main principles of biomedical ethics.

Consequently, restoring justice has to include the accessibility of health services. Mental health and support have to be addressed as much as physical health in this context, to increase the changes for long-term improvements.

Most psychological concepts of justice were developed and tested in Western countries and were discussed in terms of social inequalities. Thus, there is an information gap on the consequences of perceived injustice among survivors of war, mass violence, and genocide in non-Western societies (7). The understanding of justice and the ability to cope with injustice cannot be generalized. Culture, religion, the experiences of one's ancestors, and belonging to a persecuted minorities shape the perception of justice and the ability to cope with injustice.

The following article addresses the absence of justice and discusses its impact on individuals and societies that were affected by war and mass violence. Focusing on Middle Eastern minorities and the aftermath of the ISIS terror in 2014, the article examines justice programs and their effect on harmed individuals in post-conflict areas. Demands for psychotherapy programs for survivors of gross human rights violations are elaborated, to include coping with the experienced injustice (8).

THE AFTERMATH OF VIOLENCE

Violence leads to long-term physical, social, and psychological consequences for survivors and their families. This happens especially when socio-economic, political, religious, or ethnic discrimination continues after the conflict, and adequate health care is not provided (9–12). Persistent bad conditions, like lacking hygiene facilities in overcrowded camps, are keeping the risk of threats for people's health high, even after the end of conflicts. Physical consequences like dismemberments and the loss of walking or internal injuries, especially after sexual violence, as well as widespread malnutrition and weakened immune systems will only heal, if there is an immediate access to healthcare. Otherwise, survivors will likely experience everlasting problems.

Psychological Impact

Experience shows that about 50% of severely war-traumatized people develop trauma sequelae, of which about 25% become chronic (13). The most common psychological problems resulting from mass atrocities and war events are depressive disorders and PTSD (1, 14). Yet, there is a lack of data on the prevalence of mental health disorders among populations living in protracted displacement situations, especially in conflict-affected middle-eastern countries (1). In a study of Syrian Kurdish refugees in the Kurdistan Region of Iraq, almost all participants had experienced at least one traumatic event, while 86.3% had experienced three or more traumatic events. The prevalence of PTSD and the prevalence of depression were both about 60% in that population (15).

Prevalence is estimated higher among survivors of rape, military action, captivity, internment for ethnic or political reasons or genocide (16). In a random sample of female

survivors of the Rwandan genocide, researchers found a prevalence rate for PTSD of 58% (17). In a random sample of women affected by sexual violence in former Yugoslavia, the prevalence rate for depression amounted to 80% (18). The prevalence rate for PTSD (58%) and depression (55%) among female Yazidi women was found to be very high even 5 years after they had survived the 2014 ISIS genocide and captivity (19). This supports the assumption that about 71% of refugees who fled from their homeland and who have depression also suffer from PTSD (20).

Apart from mental disorders, there are many other psychological consequences reported by survivors. Dead and missing family members lead to grief and worries, especially in collective societies. Often, the social support system is destroyed and connections to neighbors and other groups in the societies are harmed by feelings of mistrust and hate (21). In addition to the lack of health service, the lack of education, employment, and shelter cause people to feel loss of control over life and security (22). Among people in refugee camps, daily stressors like the continuing concern for safety and a lack of basic resources, like water, shelter, and food, can exacerbate mental problems (23). A study among stateless Rohingya refugees in Bangladesh showed that the daily environmental stressors of living in the camp partially mediated the direct mental health effects of trauma exposure that were found (24). Furthermore, these upholding instabilities reduce the chance of a long-term recovery for individuals, their communities, and the entire society. For that reason, refugee camps should only be a short-time resolution.

JUSTICE AND INJUSTICE IN THE AFTERMATH OF VIOLENCE

One popular cognitive concept of justice is the idea of a belief in a just world (25). According to this theory, people generally believe that the world is a just place in which just things will happen to them. They assume that there is a reason why people experience injustice. Yet, when one experiences extreme violence like rape or other war crimes, or natural disasters, serious accidents, or the sudden loss of loved ones, this idea of a just world can get shattered (26). People, who hold on to the image of a just world want to understand why they experienced injustice (25). If they come to the conclusion that they must have done something wrong to deserve the injustice, they may react with feelings of guilt, desperation, or self-blame (27). Others, who cannot grasp that their assumptions of a just world do not stand, may react with embitterment (28).

So far, most of these assumptions were developed through studies with survivors of accidents and other non-man-made disasters (26, 29, 30). It is known that trauma that is intentionally evoked have a much higher damage potential. They are more likely to lead to severe stress reactions than accidental ones. The particularity of man-made disasters seems to be the extreme power gap and that the destruction is usually done with full

intention in order to humiliate the other person or, in the case of torture, to destroy their personality (31).

Furthermore, most of these ideas are based on Western concepts of justice, rightfulness and self-worthiness. For this reason, they cannot directly be transferred to the perspective of survivors from other cultures and religions, e.g., African or Middle Eastern. In collective societies, not only the personal experiences of injustice matter but also unjust experiences that happened to other members of the society or ancestors play a central role in one's perception of justice (32). With regard to shame and guilt as reactions to traumatic experiences, societies vary a lot (33). The ideas of reconciliation and revenge are influenced by culture and tradition. Different, traditional acts of reconciliation exist, and these have to be considered.

Despite these individual and cultural differences, atrocities and human rights violations can be generally seen as actions of injustice (5). In the aftermath of violence and war, these actions of injustice have to be addressed to give survivors back a sense of justice. It can be assumed that the long-term consequences of violence are often perpetuated by continuing injustice after the official end of conflicts. Low access to resources, persistent unjust treatment, and a lack of possibilities to restore justice maintain the trauma of many survivors.

Psychiatric disorders and mental health problems become chronic over time. This, in turn, hampers medical or psychological treatments. Children, families and social relationships in these communities become affected in consequence (22, 34, 35). When no interventions are set in place, the trauma and the feeling of injustice can be passed on over generations. In this way, they can weaken and change whole societies forever (36). Especially, when not only individuals but also whole communities are affected. This is most visible in survivors of genocide, such as Holocaust survivors, or Yazidi genocide survivors.

More research is needed to understand the reaction and needs of survivors from specific areas and of varying disasters. Then, once developed concepts for the restoration of justice, like transitional justice programs, have to be tailored to the respective cultural and regional characteristics.

Transitional Justice

Ordinary national legal systems in which public persecutors pursue individual offenders are not a sufficient response to mass atrocities and unable to restore justice for all the victims. Transitional justice refers to the ways in which countries emerge from conflicts, repression or systematic human rights violations, which are so numerous and severe that normal justice systems are not able to provide an adequate response (37). It is seen as an opportunity for reconciliation and prevention of future human right violations.

In this context, reconciliation is understood as a large-scale process with many aspects and approaches (38). The aim is not necessarily forgiveness (39), but the possibility for different individuals, parties, or peoples to live together or next to each other in peace, confronting their past (38). Nadler and Shnabel (40) define it as "the process of removing conflict-related emotional barriers that block the way to ending intergroup conflict".

The aim of all transitional justice processes is respecting and installing individual and collective rights and, most importantly (41), the prevention of future human rights violations. So far transitional justice mechanisms have been implemented in more than 90 countries with varying degrees of success. The *gacaca*, the Rwandan village tribunals for truth and reconciliation after the 1994 genocide, are often cited as a successful example of transitional justice (6).

There are four main approaches for transitional justice: The criminal prosecution of at least some of the most responsible for the most severe crimes; truth-seeking processes by non-judicial bodies, like the truth committees in South Africa; individual, collective, material, or symbolic reparations for human rights violations; reforms of laws and institutions, including police, judiciary, and military and approaches to restore new confidence in those (42). These different approaches should not be seen as alternatives for one another, but be combined according to the needs of the respective society.

For example, monetary compensation, although necessary, cannot be viewed as the only means for repairing the wrong done to the survivors. For this reason, prospective reparation programs should include moral or symbolic reparations, in addition to pecuniary redress and monetary benefits (43). Symbolic reparations, for example, aim at addressing less tangible harms arising from serious violations of international law. They may take several different forms such as apologies, memorialization, or truth-seeking (41, 44). Great potential is seen in the fact that they carry meaning and thus can help victims in particular and societies in general to make sense of the painful events of the past (44, 45).

Transitional justice should help with putting the victims and their dignity first, making sure that ordinary citizens are safe in their own countries, protected from abuses of their authorities and violations by others (37). For this reason, reparation and justice programs must be designed with the participation of survivors and relevant civil society actors and groups. Participation is also important to ensure that reparations are accessible, equitable, effective, and strengthen the agency and empower victims, as well as to strengthen awareness of rights (37).

However, an exact evaluation of these approaches through a meta-analysis is still missing. There are hardly any studies that examine the collective and individual satisfaction with the outcomes of transitional justice programs. Some studies show that, frequently, individual survivors do not agree with the reported success of these programs. For example, one survey reported that survivors in Croatia and Bosnia and Herzegovina were not supportive of the ICTY, although it was said the trials were for the victims and to provide reconciliation (46). Corkalo et al. (47) describe how all different national groups there felt that their group was the greatest victim and the ICTY was against them. Another study even suggested that the ICTY increased the hostility between the ethnic groups in Bosnia and Herzegovina instead of improving societal peace (48). On a political level, critics argue that pursuing justice in the midst of ongoing conflicts can have a domino effect. They argue that it can

interfere with the delivery of humanitarian aid, ongoing peace negotiations, and agreements, especially when powerful actors can block such an agreement, because they may fear punishment for past actions or have not signed the Rome status, like Syria or Iraq (49).

Transitional justice could promote social reconstruction and mitigate the consequences of trauma, as long as the right steps are taken and its outcome is closely monitored (50–54). Yet, further research and analyses are needed to understand the outcome of such programs for the affected individuals and societies, with regard to their physical and mental health.

Additionally, studies have shown that economic improvements and improvements in the rule of law have a positive impact on several health indicators, like life expectancy and reduced child mortality. In other words: Improvements in the rule of law lead to better health outcomes, either directly or indirectly through improvements in the level of development (55). Thus, economic support and prospects for the future often lead to better coping with the trauma and can, therefore, support the transitional justice process and increase the willingness for long-term reconciliation and peace (55).

JUSTICE AND MENTAL HEALTH

The Mental Health Outcome of Justice Initiatives

The implementation of transitional justice mechanisms have sparked a lively debate among some psychiatrists, lawyers, anthropologists, and international and local NGOs on how traumatic experiences shape the ability of individuals and groups to respond to transitional justice initiatives (35, 56). Yet, there are only a few empirical studies that have investigated the link between transitional justice and mental health (22, 57–59).

So far, existing studies have investigated how law initiatives affect the health of individuals and communities (34, 55, 60), social healing (61), and deterrence of violence (62). Yet, these studies have not revealed an effective relationship between the processes and mental health. This might be due to the methodology of the studies. There is a lack of standardization in how the various independent and outcome factors are defined and investigated (i.e., exposure to the trauma events, assessment of symptoms of PTSD, individual vulnerability to mental illness, resilience, reconciliation, revenge, forgiveness, etc.).

Yet, some of these studies challenge the claim that truth-telling has a healing effect for individuals, although it plays a pivotal role in post-conflict reconciliation processes around the world (6, 57, 59). For this reason, we assume that a difference between individual psychological healing and societal healing must be made when elaborating the outcome of such efforts. For example, on a societal level the *gacaca* in Rwanda seems to have helped the society to move forward (6). Yet, less is known about

the psychological and mental health effects of this program on the individual survivors.

On an individual level studies demonstrate that traumatic exposure and PTSD symptoms are associated with attitudes toward justice and reconciliation (56). Some studies prove a reduction of PTSD symptoms in traumatized people through reconciliation programs in general (36), while others show that a direct contribution of one's sense of justice toward PTSD symptoms exists (64).

On the other hand, it is shown that people with less openness to reconciliation, and more feelings of revenge, show higher PTSD symptoms (34). In many societies, mental health problems and feelings of anger or revenge are very common in survivors even years after the traumatic events (65). This impedes social coexistence and successful peace-building processes and calls for actions on several levels to install a sense of justice (65).

Justice in Psychotherapy

The question arises on how psychotherapy, if available, can contribute to the restoration of justice. In general, psychotherapy in post-conflict zones, refugee camps, and psychotherapy with people from different cultures should follow a culturally sensitive approach (2, 7). Especially in therapy sessions with severely traumatized people, it is important to consider their cultural and religious resources, coping strategies, and often their family system. Apart from the client's personal consequences and experiences, the psychotherapist must consider the following questions when working with clients from collective cultures. What does the event mean to the client's family and social system? How does it influence the way they behave to the client? (19).

Most of the concepts for therapeutic trauma interventions suggest that people need stabilization, orientation and security to be able to start a therapy. To assure that people can get involved in a therapeutic process, public health services must be quickly reconstructed and incorporated into justice programs. The main public health and medical goals in post-conflict areas have to be the treatment, reduction, and prevention of disease, mental illness, disability, and premature death.

A common goal of promoting and protecting individual and societal physical, mental, and social well-being can give survivors the impression that the country and the government are making a serious and long-term effort to care for them (66) and are trying to make amends for the injustices. Such recognition is closely related to the WHO's view of health, which defines health as a state of complete physical, mental, and social well-being and not merely as the absence of disease (67). For this reason, we suggest that health care and the restoration of justice (political, social, psychosocial, and medical) are closely linked to improving the health situation of survivors.

The existence of justice initiatives, including health programs, enables psychotherapy to focus on the actual trauma therapy process. Refugees cannot wait years to have their desire for justice addressed by the international community or local institutions (5). However, therapy in conflict zones must address the lack of justice initiatives and the feeling of injustice, as the ideal scenario is rarely the case.

So far, there are some cognitive behavioral trauma manuals which are specifically designed for survivors of severe human rights violations in general (68). This includes psychotherapeutic or psychoeducative programs and interventions that were tailored for specific post-conflict communities. Furthermore, some interventions for groups who are targets of systematic injustice, like Black communities in the US, have been developed to empower those affected (69). These existing ideas should be customized, integrated and expanded for a new psychotherapeutic justice approach. Tailored to survivors of gross injustice in post-conflict and crisis areas, this approach should provide a supplement to general mental health support and trauma therapeutic interventions.

Such a new approach could include empowerment strategies as well as rebuilding trust in people and social bonds. New waves of violence can be a long-term consequence of an upholding sense of injustice (56, 70). Thus, it is necessary to address reconciliation, in addition to legal procedures. According to Pham et al. (56), people might only be able to accept and promote social justice if they build trust. A shared vision and future can emerge by creating social bonds with sufficient economic and health care (56).

According to Range et al. (69), psychotherapy with members of traumatized communities should empower those who have been disempowered, by acknowledging their strengths and cultural resources. Psychotherapists can apply cultural empowerment by asking "what would right this awful wrong?" (69), supporting their clients to be self-advocating. Resources and successful coping mechanisms might be found, among others, in people's cultural and traditional heritage, and family systems.

As previously discussed, most people in post-conflict areas and refugee camps keep facing acts of injustice and instability after the main traumatizing event. If the required systematic changes of their situation do not happen, therapy should help with the acceptance and dealing with everyday life as well. Therapy can counteract these feelings of injustice, exhaustion, bitterness (28), or anger by making use behavioral strategies. This is needed, because studies found anger to be a negative predictor for PTSD outcomes in traumatized survivors (71). Yet, with some patience, acceptance of the unjust situation has to be developed.

Furthermore, the therapy itself can help people to achieve a sense of justice. For example by recognizing their suffering, the therapist can try to fulfill some of the survivors' demands for justice in the therapeutic setting. Going further, some authors emphasize that a psychotherapist's work is not limited to the therapeutic setting when they work with people who have survived actions of injustice. In this point of view, psychotherapists should get personally involved in actions for justice (69).

Some researchers argue that forgiveness should also be considered in therapy, as it allows survivors to regain control, leave their victim status, and experience themselves as self-effective (72). Positive connections between forgiveness and mental and physical health have been replicated several times (72). More forgiving people seem less likely to suffer from depression, anxiety, and anger, have lower cardiovascular vulnerability and better self-esteem than those who are not

forgiving (72). Yet, forgiveness is only likely to appear, if a sense of justice exists and, therefore, a successful justice initiative is a prerequisite for it.

In this context, we suggest that specific cognitive behavioral modules have to be developed and tested. These modules have to be based on the needs of the affected groups, addressing the sense of injustice in post-conflict therapy to improve mental health.

In the following paragraph, we introduce a theoretical framework for health and justice implementations after gross human rights violations and war. This framework will allow, among others, psychotherapeutic mental health interventions.

Framework and Model

To restore or develop justice in a society after mass violence and gross human rights violations committed by various actors, internal (state, military, ethnic, and religious groups, terrorist organizations) and external (foreign states, external terrorist organizations, etc.) steps must be taken on many levels. The individual survivors, witnesses, leaders of the affected group, as well as national and international agencies and the relevant governments have to be included in that process to assure that the result fits the cultural concept of justice and meets the expectations of the survivors and their organizations. The active participation of the affected people is urgently needed to increase the chances to successfully achieve change in the society and the physical and mental status of the individuals. **Figure 1** shows how different kinds of justice initiatives and tools must be set in place in order to enhance individual and collective health in affected regions, and the chances for peace, social reconstruction, reconciliation, and solidarity.

Recognition and consideration of all the involved and affected parties must be followed by investigations of crimes, which should be shared at national and international forums. Restoration of justice in the process of transitional justice must be defined and criteria must be established in accordance to the survivors' expectations. In a further step, the effects on health (psychosocial and medical) and social structures of all those involved must be investigated.

Subsequently, a political and legal basis must be created so that health practitioners can implement psychosocial, psychotherapeutic, and medical intervention programs including the support and implementation of national and international humanitarian aid programs. At the same time, political decision-makers have to develop long-term mechanisms to prevent violence, for example, between the various conflict parties in post-conflict situations or between the various ethnic and religious groups in a country.

Empirical data from nationwide health programs should be made available for programs to achieve or restore a sense of justice, to identify patterns, and to reveal the systematic nature of violence. In order to demonstrate the necessity of these interventions, one can collect data on the impact of human rights violations and mass violence on health, drawing on retrospective cross-sectional studies and informational monitoring systems. Health outcome measures include

mortality, injuries from violence, disability, morbidity, and mental illness (73). This allows patterns to be identified and can reveal the systematic nature of violence.

Furthermore, economic improvement and improvement of the rule of law in the affected region should be supported as soon as possible, as they support positive health outcomes and better coping with the trauma. Additionally, they can increase the chances for long-term peace (55).

CASE STUDY IRAQ—ISIS SURVIVORS

The genocide of ISIS against Yazidi in Iraq and Syria and the mass violence of this terrorist organization against other population groups led to a psychosocial breakdown in the entire society and thus to a dramatic decline in mental health. The fact that this genocide was perpetrated after decades of dictatorship and mass violence by the Saddam regime in Iraq and the Assad regime in Syria accelerated this decline. While, for example, the prevalence of various disorders in Iraq in 2006 was still comparable to that of the world population, current figures are different (74, 75). In the high-risk cities of Ramadi and Fallujah, which were occupied by ISIS, 55.8% of the population between 12 and 23 years of age suffered from an affective disorder and 63.4% from PTSD (76). In comparison, the prevalence of affective disorders in the Iraqi population in 2007 was 3.99% and the prevalence of PTSD amounted to 1.63% (76).

The systematic sexualized violence against the Yazidis has traumatized both the victims and the traditional patriarchal society in which the violation of female sexuality is both a collective violation of honor and humiliation. This change will presumably keep the medical-therapeutic field busy for generations to come. However, various forms of sexualized violence did exist before the invasion of the ISIS in Iraq (77). It is well known that in collective and traditional societies such as Northern Iraq, issues such as sexualized violence and torture are often concealed and tabooed to prevent dishonor or exclusion from the community (78). Disclosure of the abuse can lead to dishonoring the patient, but also the whole family. Consequences could be difficulties in finding a spouse (for the patient and her female siblings) or the murder of the perpetrator (honor killing) or, in case of indirect blame, the murder of the patient. For this reason, the consequences of revealing abuse may be more serious for the patient than continuing to bear it (79).

It is important to understand the connection between the exposure of violence and traumatization in the specific social context. Affected people need to get a psychotherapeutic treatment that takes into account their cultural background and their personal and collective sense of injustice. Thus, the consequences might affect them throughout their life if these and other forms of violence remain untreated due to a lack of psychotherapeutic care.

Psychosocial support is one aspect of rebuilding the society

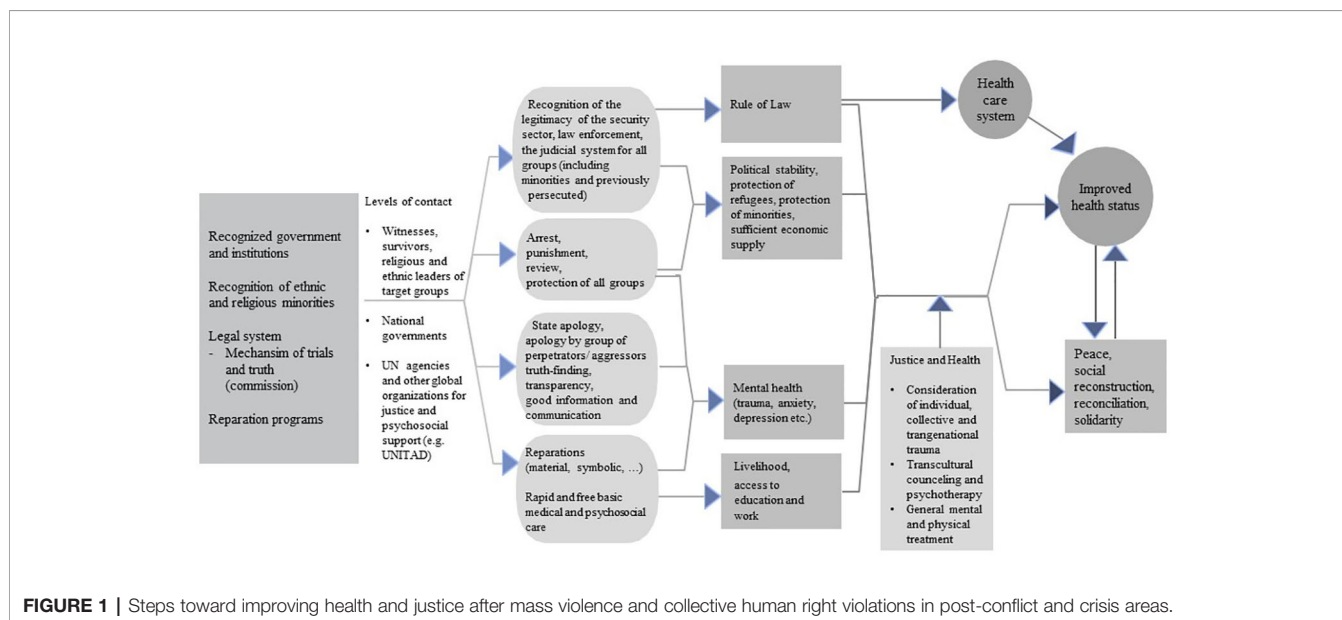


FIGURE 1 | Steps toward improving health and justice after mass violence and collective human right violations in post-conflict and crisis areas.

and responding to the desire for justice. Yet, to rebuild these societies in a just way, a combination of many justice initiatives is needed. Cross-sectional surveys can be designed to assess attitudes of the affected population toward justice mechanisms such as symbolic reparations, restitutions, truth commissions or amnesty provision (56). With regard to attempts of rebuilding these societies two aspects are essential. First, one must understand how traumatic experiences affect the ability of individuals and groups to respond to justice, when available. Secondly, one must understand how these initiatives, in turn, affect the health of individuals and communities.

A coalition of over 20 Yazidi NGOs has collected all the demands that female Yazidi survivors from Iraq have for just reparations (80). If Iraq could fulfill these demands with international help, a feeling of justice in survivors might be achieved. This, in turn, would also improve their personal and collective mental health. Fulfilling these demands is synonymous with the establishment of many actions emphasized in our introduced model. Several services and aspects are important in this context. It is crucial to establish rehabilitation and compensation services. Moreover, one must guarantee a non-repetition, drawing on the rule of law. These measures, in turn, would have numerous positive results. First, mental and physical health of those affected might improve. Secondly, members of the community might be able to move back in their original areas one day. This includes that they feel safe enough to live in peace eventually. This requires individual and collective replications as described in **Box 1**.

BOX 1 | Individual and collective reparations.
Reparations

Provide a mix of individual and collective reparations in the prospective reparation program(s). This is because both victims and specific communities were targeted.

Monetary compensation, which is necessary, cannot be viewed as the only means for repairing the wrong done to the victims. For this reason, prospective reparation program(s) should include moral or symbolic reparations, in addition to pecuniary redress and monetary quantifiable benefits

Restitutions

Undertake measures with the principal aim of restoring the victim, as far as possible, to a position occupied before the violations of international human rights or humanitarian law occurred. Measures should include: protect security to return, restoration/rebuilding of private property and of public infrastructure, reinstatement to employment, [...]

Compensations

Compensate victims for any economically assessable harm caused by violations of human rights and humanitarian law including physical and mental harm, lost opportunities, material damages, loss of earnings (including the loss of earning potential and moral damages) to the maximum of available resources (43). The amount of compensation should reflect the gravity of violations.[...]

Rehabilitation

Provide a range of rehabilitation services to victims (link) and, if required, their family members, meeting relevant quality standards and within physical proximity to those areas where victims reside. These services should go beyond medical and psychological care to encompass at least: social services, legal services, education opportunities, support for mothers with children of rape, vocational training

Satisfaction

Offer a range of non-monetary or symbolic measures specifically designed to afford satisfaction to the victims such as: ensuring adequate participation of victims in any criminal proceedings relating to violations committed against them; identifying remains of all deceased persons; recognizing that certain events amounted to international crimes (war crimes, crimes against humanity, genocide); memorialization efforts; satisfaction measures should be implemented in accordance with the traditions and sacred rituals of affected communities

Guarantees of non-repetition

Undertake a range of measures aimed at making sure that similar crimes will not happen again such as: ensuring that all the perpetrators of gross human rights violations (link) are prosecuted and adequately sentenced; stop extrajudicial punishment and discrimination of individuals and families with alleged ISIS ties; acceding to the Rome Statute of the International Criminal Court (ICC); [...]

DISCUSSION

We assume that health inequalities are rooted in social injustices (81). Furthermore, we suggest that peace, stability, and justice might offset or, at least, mitigate negative health consequences of war and injustice. This requires programs that use the means of the law to do justice to survivors and provide social, psychological, and medical care nationally and internationally. In this way, they can be quickly and effectively reintegrated into society and receive all the rights and duties of an equal citizen. This is only possible through health.

The ethical significance of the universal human rights should be indisputable; for this reason, efforts to restore justice after gross human rights violations, like torture and genocide should be obligatory. In article 25 of the Universal Human Rights Declaration it is stated that “[e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, [...]” (82). Moreover, justice, meaning among others, equal access to medical support and health services is one of the major ethical principles in bio-medical ethics (83).

Thus, when approaches of justice are made, health care services including mental health care services should be enrolled. The long-term effects of untreated PTSD and other mental disorders are severe. Experienced, untreated trauma often prevents reconciliation and peace processes and can even be passed on to the next generation (36, 70), resulting in further destabilization and conflict in the affected societies.

Health outcomes usually provide a good measure of political processes and of the programs that aim to respond to the conflicts (9, 84, 85). According to Salama et al. (12), traditional health interventions, for example vaccination campaigns, clinical treatment, water, and sanitation, alone have limited health benefits and cannot sufficiently minimize the impact of war on society. But still, ethically responsible action includes promoting traditional measures that support the health of many people, such as ensuring access to clean water or clean air (86), as well as health services for the affected individuals.

If war-traumatized people experiencing injustice are to learn how to deal with their traumatization and to participate in society, new ethical standards have to be considered when implicating justice, reconciliation, and reconstruction programs. Psychotherapy and psychosocial support play an important role in these processes.

They can be secure places in times that are shaped by insecurity and ongoing injustice. Symbolic collective reparations and other transitional justice mechanisms have to include the survivors' voices and demands. In therapy, they can learn to formulate those and to find their voice to call for justice. People can also develop strategies to accept and move on from unjust circumstances that cannot be changed. Furthermore, psychotherapy, especially trauma therapy, can help decrease the prevalence of mental health problems. This, in turn, can increase the stability in individuals and the society.

In conclusion, in the field of psychotherapy, the development of modules on justice and mental health and their evaluation are necessary for both individual and group therapies,

All of the previous considerations support the assumption that justice after massive human right violations and atrocities should not only be discussed from a judicial view. Instead, an interdisciplinary approach including law, social service, medical, psychological, and political professionals is needed when developing justice initiatives, like transitional justice programs. When doctors, therapists and counselors work with survivors of war and terror, a minimum of knowledge about the principles of humanitarian law and justice is necessary. The same applies for bureaucrats and political decision-makers in the health care system.

Furthermore, scientific research, especially in the context of war and mass violence, must discuss ethical questions that address entire societies, in addition to individual patients.

In our globalized world, ethical principles cannot be limited to national borders. They are meant to be applied internationally (86). Hence, national and international players must be included in the development of such programs, particularly, when the government is involved in the conflict. When international researchers and professionals are involved, it must be ensured that the developed programs fit the targeted cultures and societies, instead of imposing, e.g., Western concepts on collective Middle Eastern societies (87). Therefore, a culture sensitive approach is needed.

AUTHOR CONTRIBUTIONS

JK and JN wrote the article. All authors contributed to the article and approved the submitted version.

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To Overcome Psychiatric Patients' Mind–Brain Dualism, Reifying the Mind Won't Help

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INTRODUCTION

Glannon (1) summarized recent research in Biological Psychiatry and discussed possible ethical implications of mind–brain dualism in psychiatry in this journal. He particularly addressed the risk that patients might disregard neuroscientific discoveries and subsequently neglect effective biological treatments for psychiatric disorders. In this opinion article, I want to emphasize how some philosophers and scientists still use dualistic language, leading researchers and, to a lesser degree, clinicians into unnecessary and possibly even confused debates on mind–body reductionism; I also briefly address empirical data suggesting that, in contrast to Glannon, patients at large presently don't seem to eschew biological treatments.

FROM SOUL–BODY TO MIND–BRAIN DUALISM

René Descartes distinguished a *thinking* substance (soul) and *extended* substance (body) and hypothesized, based on his physiological studies, that both interact primarily in humans' pineal gland (2, 3). Already his contemporaries criticized the lacking explanation of the *mechanism of interaction* between brain/body and soul, as documented, for example, in the letters between Descartes and Princess Elisabeth of the Palatinate (4). Even centuries later, philosophers and neuroscientists have pointed out that the *language use* of many scholars remains problematically dualistic, even when they believe to have long overcome mind–brain dualism (5).

Glannon favors a biopsychosocial stance on psychiatric disorders, acknowledging social, psychological, and neural factors. But he frequently mentions “mind–brain interaction”, though, without explaining this concept. This reiterates Descartes' unsolved problem. Philosophy of Mind has found no clear answer to the question what “the mind” is. One of the major schools of psychology, Behaviorism, actually found the whole concept suspicious and in need of replacement by more scientific terms (6); a similar idea was later formulated by philosophers as Eliminative Materialism (7). Speaking of “the mind” as if it were a thing interacting with the brain/body (1, 8) is thus by no means trivial.

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DESCRIPTIVE LEVELS

Instead, I propose to speak of *processes* which are *psychological* processes if and only if they fall under a psychological description. Similar to Dennett's *Intentional Stance* (9), this is a pragmatic proposal that requires no strict commitment about whether psychological descriptions will ever be reducible to neuroscientific (or even more basic: physical) descriptions. This is also reflected in psychological experimentation—as well as clinical or cognitive neuroscience inasmuch as they make use of psychological concepts—where researchers *operationalize* psychological concepts to explain people's experience and behavior without necessarily placing them “in the mind” or reducing them to the brain. Reductions are much less common even in the natural sciences than often assumed in that debate, anyway: Biology and chemistry, for example, are obviously necessary, because there are processes in the world (e.g. life) which cannot be described in purely physical language. And it is also not clear what the final, most basic level of a physical description should be (10, 11). That of energy, information, or yet something different? Thus, perhaps not even all physical descriptions might be reducible to the most basic physical level of description, whatever that may be.

The sciences, including human and social sciences like psychology, sociology, and economics, continue to develop in a pluralistic, non-reductive way, informing each other in many respects. And a much more promising alternative to reductive explanations are *mechanistic* explanations (12, 13). They *integrate* different levels of description, instead of replacing them. I will use an example to briefly explain what this could mean for psychiatric disorders.

AN EXAMPLE

Imagine Karla hearing that her spouse and children died in a traffic accident. Although that accident involved all kinds of physical and biological processes, described as changes of energy matter, molecules, tissues, and so on, they cannot express the significance for Karla that her beloved ones passed away so suddenly. But we need not assume an independent, reified¹ “mind” to state that at the moment she understands (psychology) the message, all kinds of processes will occur in her: Karla might first react with denial (psychology), a severe stress response might happen in her body (physiology), electric activity and molecules may change in her nervous system (neurophysiology) and likely also affect some neural structures permanently (neuroanatomy).

As time proceeds, Karla probably experiences grief and perhaps even depression; serious life events are indeed the strongest known risk factors for distress and Major Depressive Disorder (MDD) (14, 15). Again, this will also involve processes

¹ The term *reification* is derived from the Latin *res*, thing. Reification means thus to consider something as a thing. Talking about brain–mind–interaction thus assumes that there are two entities, brain and mind, which are interacting in some way.

on different levels, as described before, including neuroscientific levels. Glannon actually summarizes much neuroscientific research consistent with such multi-level descriptions. We may ask what is *specific* about hearing that one's loved ones died which is causing all these effects; but this does not require us to posit a “mind” entity mysteriously interacting with the brain. Instead, a mechanistic explanation can integrate all levels of description (16), also in line with the biopsychosocial model (17, 18). On the psychological level of description, philosophical concepts like *intentional* (e.g. what a thought is about) or *phenomenal* content (e.g. what it feels like) that are considered as unique features of the mental domain can play a role, too (19).

This pluralistic approach has much affinity with the way psychiatric disorders are classified: In the case of MDD, symptoms involve cognitive patterns (e.g. guilt or suicidal ideation), behaviors (e.g. inactivity or a suicide attempt), and physiological changes (e.g. losing weight). Taking the DSM-5 criteria (20), MDD could be expressed by 227 different variants of the symptoms, without even taking their severity into account (21). For attention-deficit/hyperactivity disorder (ADHD), actually even more than 10,000 variations could be distinguished on the basis of the DSM criteria. This demonstrates a high degree of *descriptive heterogeneity* of such disorder categories. As Glannon described, Biological Psychiatry found neuroscientific patterns statistically correlated with such instances of MDD and many other disorders. But not a single one of the hundreds of disorders classified in the DSM can generally be described, let alone individually diagnosed, on the neuroscientific level alone (22, 23). Reductionism does not seem to be a successful paradigm in psychiatry, with clinical researchers looking for a brain-based nosology since more than 170 years (24), when psychiatric disorders are not generally classified on the neuroscientific level, cannot be diagnosed on that level in individual cases, and a patient's treatment response cannot be assessed there alone. It has been discussed elsewhere that this can be partially explained by the limitations of present methodology (22, 25) or the normativity of psychiatric disorders (26, 27).

IMPLICATIONS FOR PATIENTS' TREATMENT CHOICES

So far, the discussion was primarily relevant to researchers and, to a lesser degree, clinicians. Glannon (1) raised concerns about mind–brain dualism in psychiatry and related patients' understanding of psychiatric disorders to the risk that they might eschew effective biological treatments when they take a limited psychological stance. Besides the new approaches on brain stimulation described by Glannon, medical consumption patterns indicate, though, that ever more people are taking psychopharmacological drugs. For example, the *annual* production of ADHD medication in the US is presently higher than during the whole *decade* of the 1990s (28). The pattern for other psychopharmacological drugs (**Figure 1**) and in many other countries is similar (30).

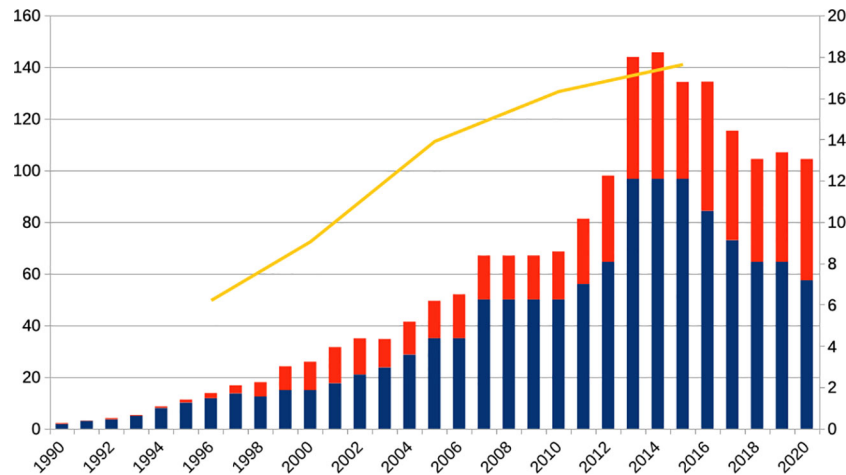


FIGURE 1 | Annual production of the schedule II regulated ADHD drugs amphetamine (red) and methylphenidate (blue, left scale, x 1,000 kg) and adult patients annually receiving antidepressant drugs in the United States (yellow, right scale, x 1,000,000). The production of the ADHD drugs has increased more than thirtyfold, the number of MDD patients receiving antidepressants about threefold in the shown period. It must be also noted, though, that in the period shown the criteria for diagnosing ADHD changed, for example, with respect to *adult* ADHD and the DSM-5 of 2013 (20). Source: updated from (28), US Federal Register; (29).

Humans have actually used substances (e.g. alcohol or other stimulating, relaxing, or hallucinogenic drugs) instrumentally, for their psychological effects, probably as long as we exist (31, 32). The recent neuro-enhancement debate exemplifies a similar trend to improve one's cognitive performance or feelings pharmacologically (28, 33). It thus seems to be common knowledge in human history that behavior and experience can be affected by consuming certain substances or performing particular rituals (e.g. dance, sports, or prayer). Whether or not many people have dualistic views, believing in the existence of independent "minds" or "souls", they nevertheless seem to endorse biological means to solve their problems or achieve their aims, perhaps even increasingly so. Many decades ago, Klerman described that people differ in their readiness to take pharmacological drugs, distinguishing the extreme poles of "Psychotropic Hedonism" on the one hand and "Pharmacological Calvinism" on the other, but rather due to their lifestyle choices than philosophical world-views (34, 35). After the "Decade of the Brain" and the Human Genome Project, the analysis of science communication patterns and people's descriptions of their psychiatric problems rather suggest, in contrast to Glannon's concern, that patients might presently rather underestimate the value of *psychotherapy*, not biological treatments (36, 37).

CONCLUSION: INTEGRATION INSTEAD OF REDUCTION

Variants of dualism have been discussed in philosophy for centuries. I tried to show here that we neither need to postulate "souls" nor "minds" to describe people's behaviors or experiences. To overcome dualism, reifying "the mind" won't help. Using a dualistic language that postulates "mind-brain

interactions" reiterates old questions about the nature of the mental entity, its mechanism of interaction with the brain/body, and gives rise to endless discussions on reductionism that neither seems to be fruitful nor relevant to empirical research in psychology or the neurosciences. The biopsychosocial model and mechanistic explanations can take different levels of descriptions into account, without demanding reductions; as colleagues and I explained earlier, neuroscience can also be integrative (38). That people probably always have and are still using different means to change their brain/body and thus facilitate certain behaviors and experiences is also rather compatible with a pluralistic than a dualistic or reductionistic view. Instead of proposing an either-or-account, it goes without saying that many biological treatments have psychological effects (i.e. effects that we can only describe on the psychological level) and that psychological treatments are changing the brain/body. To ensure that psychiatric patients can consent to the best available treatment, it is essential, in my view, that they are informed in a neutral, pluralistic, and comprehensible way about all different options.

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The author confirms being the sole contributor of this work and has approved it for publication.

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Employment, Studies and Feelings: Two to Nine Years After a Personalized Program of Cognitive Remediation in Psychiatric Patients

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Employment rate in psychiatry is around 10 to 30%. Cognitive remediation (CR) associated with psychosocial rehabilitation shows good functional outcomes, with a high level of satisfaction in participants provided by tailored CR. However, few studies looked at the long-term outcome in participants who experienced such a program. This retrospective survey examines the outcome of persons having psychiatric diseases 2 to 9 years after being treated with a personalized CR program. The survey included 12 domains with questions relevant to work, studies, before CR (T1) and at the moment of the survey (T2), questions about housing, relatedness, familiar relationships and daily activities at T2. Finally, a narrative interview was included to express feelings of the participants about CR. Sixty-six participants completed the survey, and were treated with neurocognitive or social cognition programs. Their diagnosis was: schizophrenia (80.3%), neurodevelopment disorder (autism as well as genetic or metabolic disease with psychiatric expression) (15.2%) and bipolar disorder (4.5%). The comparison between T1 and T2 showed significant difference for job employment ($P < 0.001$), even for competitive jobs ($p < 0.007$), for performing studies ($p = 0.033$), for practicing a physical activity (0.033) or reading (0.002). Outcome was also examined in reference to the delay from CR to highlight changes in patient characteristics and service delivery over the years. Hence, the total sample was split in two subgroups: CR delivered in 2009–2013 ($n = 37$); CR delivered in 2014–2016 ($n = 29$). While in the former group more participants were working ($p = 0.037$), in the latter group, which was younger ($p = 0.04$), more participants were studying ($p = 0.02$). At T2, a majority of persons experienced no relapse, three years (79.1%) to 8 years (56.8%) after CR, when referring to the anamnesis. Concerning subjective perception of CR, participants expressed feelings concerning positive impact on clarity of thought, on cognitive functions, self-confidence, perceiving

CR as an efficient help for work and studies. To conclude, even long years after a personalized CR program, good benefits in terms of employment or studies emerge when compared to the status before CR, with good determinants for recovery in terms of leisure or physical activity practice.

Keywords: cognitive remediation, long term outcome, employment, rehabilitation

INTRODUCTION

Employment rate for people with severe mental illness is only around 10 to 30% (1–3). The literature mentions that poor cognitive functioning affects vocational outcomes in patients with severe mental illness, and even for those receiving vocational rehabilitation services (4–9). The programs for cognitive remediation (CR) are generally categorized as manual-task training or computer-assisted training, and concern neurocognition as well as social cognition. CR improves cognitive functioning in schizophrenia (10, 11), in autistic spectrum disorders (12), bipolar disorders (13) or in complex neurodevelopmental disorders (14). This psychosocial therapy provides benefits on symptoms and improves self-esteem (4, 15, 16) as well as self-efficiency to achieve personal goals (17), with maintained long term benefits (12, 18). Meta-analyses demonstrated that CR associated with adjunctive psychosocial rehabilitation shows stronger effects on functional outcomes compared to programs not associated to rehabilitation (8, 10, 12). Psychosocial rehabilitation includes psychosocial therapies such as psychoeducation, for users and care-givers, cognitive behavior therapy or psychosocial skills intervention. These therapies can facilitate the transfer of benefits acquired during CR programs to everyday life (19). However, the vast majority of Research done around CR programs focused on internal validity rather than trying to extent findings on real world context (20). Recently, a CR program, called “Cognitive Remediation to Promote Recovery” (CR2PR), has been developed in 16 clinics in New York for patients with serious mental illness (21). The principle of CR2PR program insisted on the point that “cognitive remediation programs had to be delivered tied to overall recovery goals” to increase the impact on functional outcome (11, 22). The results in this study after the participation of the users averaged 90.5%. Also, with an average number of 138 patients across the clinical sites, 40% of the users self-reported a high level of satisfaction with the service, and 96.9% qualified it as an excellent or good experience. Most patients found that CR improved cognition, and for 90% CR helped them to deal more effectively with situations at home, school, work, or with friends (21). Furthermore, Medalia et al. (19), as well as Seccomandi et al. (23) suggested to provide a “personalized medicine” with tailored medical intervention for CR, bringing an answer to the fact that around 25% of the patients do not improve after CR.

The French Center for Cognitive Remediation and Psychosocial Rehabilitation (C3RP) was created in 2009, to deliver personalized CR programs as well as psychosocial rehabilitation course for persons with schizophrenia, autism or

complex neurodevelopmental disorders (psychiatric troubles with genetic or metabolic diseases). These programs are delivered in a patient-centered approach to provide services responsive to patients’ preferences and wishes, focusing on the cognitive profile of each patient, rather than on his diagnosis (22). Moreover, CR programs are fully personalized and delivered in coordination with the French care-units attached to the “sectors teams” associated to the patient residential home, or attached to the private medical practitioner in charge of the clinical follow-up. This coordination is efficient throughout the program. Also, the C3RP must organize an efficient relay with the unit that will accompany the user throughout his professional insertion or help to concretize his rehabilitation project. To see if a user is eligible to a CR program the practitioner must determine a core set of four characteristics: 1) if the user is clinically stable, 2) if the treatment is stable, with no sedative compounds (such as anxiolytics) delivered during the day, and well adjusted (for at least 1 month) 3) if the user is fully engaged to participate to CR programs and 4) if there is a concrete idea of a rehabilitation project. The CR schedule must be timely coordinated to the rehabilitation project, in order to act as a “stepping stone” and to increase the chance for the project to be successful (see **Figure 1**). The concrete phase of the project must begin 6 to 8 months after the end of the CR (mean duration for the maintain of cognitive benefits) (24). Whatever the type of CR program, neurocognitive or social cognition, the nodal point is the link between CR and transfer to daily life (19). For neurocognition or social cognition this transfer can take place in different ways: 1) through homework tasks such as in *Recos (Remédiation Cognitive dans la Schizophrénie—Cognitive Remediation for Schizophrenia)* (25, 26) or *CRT (Cognitive Remediation Therapy)* programs (27, 28), social cognition programs such as *SCIT (Social Cognition Interaction Training)* (29) or *TomRemed (Remédiation en Théorie de l’Esprit—Theory of Mind Remediation)* (30) programs. 2) transfer to everyday life can also be facilitated through group sessions oriented toward full explanations of the cognitive domains and consequences in daily life, and explicit work on transfer of benefits such as in the *NEAR (Neuropsychological Educational Approach to Remediation)* program (31) or as we develop it in the Virtual Reality serious game program “*Jeu Mathurin*”, which trains planning abilities and prospective memory in a virtual town (17). Finally, participants in their rehabilitation trajectory could also experience other psychosocial programs: psychoeducation (32–34), management and support for their caregivers (such as the Canadian program *Profamille—Profamilly*) (32), Cognitive Behavioral Therapy (CBT) (35) or physical adapted activity program (36). All the CR programs are delivered in a

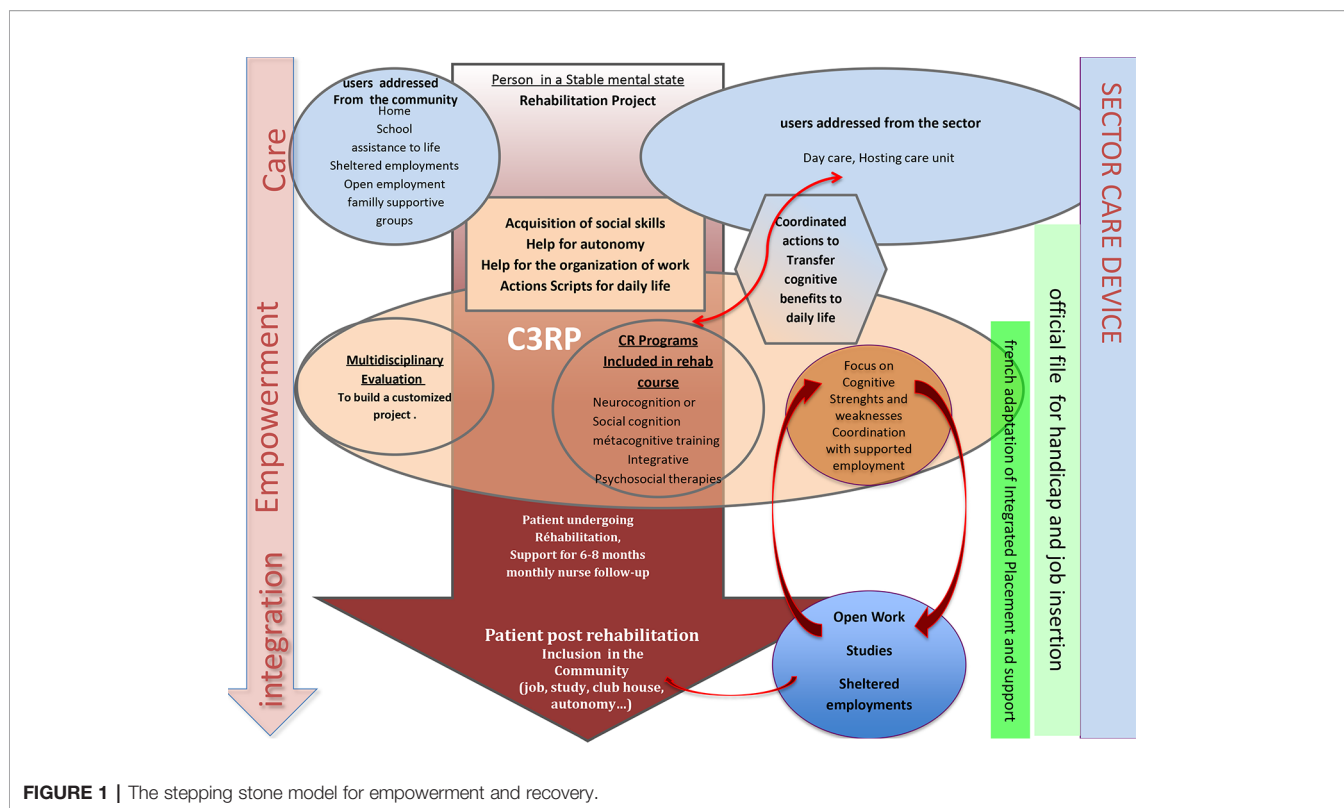


FIGURE 1 | The stepping stone model for empowerment and recovery.

standardized protocol: 1) multidisciplinary evaluation (medical, neuropsychological and functional), 2) feed-back to the user and eventually his family of his strengths and weaknesses, 3) psychoeducation session about neurocognitive or social cognition functions using a formalized handbook agreed by our national health agency (ETP 11106) 4) Questions about the handbook the users had to read carefully at home consecutively to the psychoeducation session. Then users and the C3RP team begin the CR sessions.

However, the crucial question is to see what the future is made of for participants enrolled in CR, several years after the end of the program. Therefore, a retrospective survey has been conducted to ask all of our participants about outcomes in terms of work, studies, but also clinical stability, functional environment, and the participant feelings about CR intervention. Our main assumption regarding our primary outcome was significant changes in terms of rate of employment or active student status between T1 (period of service delivery when the CR program took place) and since T2 (end of CR service delivery) at time of the follow-up survey. The survey was approved by the ethic committee (CPP Île-de-France VI, N° 2017-A00704-49).

MATERIALS AND METHODS

The survey included all the participants treated with CR since the creation of the unit from 2009 up to 2016. The survey was conducted in 2017–2018. Age of participants was ranged between 21 and 63. The DSM 5 (37) diagnosis of the users initially recruited

in the C3RP was predominantly schizophrenia and schizoaffective disorder, with a scarce number of bipolar disorders (the C3RP was initially focused on rehabilitation in schizophrenia). Progressively were also admitted persons with autism or presenting complex neurodevelopmental disorder. The users were contacted by phone by the C3RP team and informed that they will receive by post or mail a survey including 12 main domains, which could include one to five sub domains, and questions relevant to some determinants of their actual professional and functional outcome, housing, relatedness, familiar relationships, daily activities. There were 19 questions and 15 sub-questions related to questions if there was a “yes” answer were asked (see **Table 1**). A consent form was sent, after explaining the study orally by the clinician and the patients had to sign it. Lastly, the Narrative Evaluation of Intervention Interview (NEII) (38, 39) was also sent to express feelings about CR. The questionnaire encompassed 15 total questions, with an equal number of questions related to the process and to the results of the intervention. Participants had to give their fully written consent to participate to this survey. As many patients did not return this survey, we proposed them to come to visit us and fulfill the documents in our unit.

Type of CR Programs Delivered

From 2009 to 2012 only two individual neurocognitive programs were available in the C3RP: *CRT* (27), and *RECOS* (25). In mid 2013, we introduced a French program focused on Theory of mind difficulties—*TOM-REMEDIATION* (30) -, and in 2014 the *Mathurin Serious Game* (17). Finally, since 2015 we delivered *NEAR* (31) and the *SCIT* programs (29). Hence, from 2014 the

TABLE 1 | The survey questionnaire.

Survey Questions
Socio-demographic information
Years of CR
Before and after CR: job or no job employment, sheltered or not sheltered employment, studies, graduation.
Questions about the type of regular clinical follow-up they actually have (private or public visits to the psychiatrist)
Treatment users actually have (the treatment they had when they participated to the CR program was reported in the CR file)
If users regularly visit different type of French mental health units: day-care, therapeutic activities, day-life assistance. Also, users were asked about their putative registration in a club-house or a mutual help users associative group.
Leisure practice: sport, reading books, regular visits in libraries or others (verbatim).
Inner feeling of clinical stability, relapses, number of relapses, hospitalizations and if yes, the duration of these hospitalizations.
Questions about their private condition of living: independent housing or housing in the family, single or living as a couple, having children
Questions about participation to other psychosocial therapy programs: psychoeducation, programs for care-givers, cognitive behaviour therapy, physical adapted activity.

diversity of neurocognitive and social cognition methods provided a fully enriched panel of therapies with personalized rehabilitation course adapted to the cognitive profile of users.

Statistical Analysis

Statistical analyses were performed using Jamovi (40) for quantitative data and Iramuteq (41) for qualitative data. First descriptive statistics were produced. Numerical variables were summarized as mean and standard deviation (SD), whereas counts and frequencies were used for categorical variables. In order to investigate the difference on patient characteristics (sociodemographic, diagnostic, medication), delivered services (type of CR programs and psychosocial therapies) and outcomes (professional activity, studies, housing, leisure, physical activity and relapse) between before service entry and in 2017–2018 since the end of care, McNemar Chi²-Test for categorical variables and paired sample t-test for numeric variables were performed. For comparison between the different time period of service delivery (2009–2013 and 2014–2016) Pearson Chi²-Test for categorical variables and independent sample t-test for numeric variables were performed. Lastly, we use a multivariate logistic regression model to identify potential predictors of primary outcome (employment or active student status since the end of T2 in 2017–2018). Concerning textual data with the NEII questionnaires, a lexicometric analysis using the Reinert method (42) was performed in order to identify different cluster of patient subjective evaluation of CR effects.

RESULTS

The survey included 131 P-RC, but only 66 completed the survey and signed their consent, and 52 returned the NEII. Three eligible persons for CR died by suicide, unrelated to the rehabilitation course, with two of them who experienced a CR program but died several years after. Initially, our purpose was to compare users eligible for CR who achieved the program (n =

92), to users who dropped-out after the initial evaluation (n = 40), to obtain two comparable groups in terms of indication for CR. Unfortunately, among the drop-out users, only one questionnaire was returned. Hence, we analyzed only the data of participants achieving the CR (P-CR) (see **Table 2**).

Socio-demographic characteristics of the P-CR, as well as diagnoses and T1-Since T2 pharmacological categories of treatments they received are listed in **Table 3A**. Distribution concerning the type of programs participants achieved, number of P-CR experiencing single or combination of CR methods as well as other psychosocial therapies are presented in **Table 3B**. When users were invited to different CR programs, this was done consecutively, with neurocognitive program first, followed by a social cognition program if necessary. Patient could have done

TABLE 2 | Number of participants invited to fulfill the survey in reference to the starting year of cognitive remediation, completion and non-completion rates.

Cognitive Remediation	Survey Invitations 2017–2018	Drop-out Cognitive Remediation	Completed Cognitive Remediation	Survey Responses*
Starting year	N	n (%)	n (%)	n (%)
2009	16	5 (31.3)	11 (68.7)	6 (37.5)
2010	16	2 (12.5)	14 (87.5)	10 (62.5)
2011	8	4 (50.0)	4 (50.0)	2 (25.0)
2012	14	4 (28.6)	10 (71.4)	8 (57.1)
2013	21	8 (38.1)	13 (61.9)	11 (52.4)
2014	22	3 (13.6)	19 (86.4)	12 (54.5)
2015	32	14 (43.8)	18 (56.2)	14 (66.7)
2016	3	0 (0.0)	3 (100.0)	3 (100.0)
Total	131	40 (30.5)	92 (70.2)	66 (50.4)

*All respondents completed their cognitive remediation program.

TABLE 3A | Socio-demographic, diagnoses and T1-Since T2 treatments of the participants.

Cognitive Remediation	At T1 (Before CR)	T1-Since T2 (After RC)	p value*
	n or mean (% or SD)	n or mean (% or SD)	
Socio-Demographics			
Male Sex	41 (62.1)		
Age	38,7 (93.9)		
Years of study	13,4 (2.9)		
Diagnostics			
Schizophrenia	53 (80.3)		
Bipolar	3 (4.5)		
Neurodevelopmental Disorder	10 (15.2)		
Any Treatment			
Antipsychotics	62 (93.9)	63 (95.5)	0.317
Clozapin	23 (34.8)	25 (37.8)	0.564
Depot antipsychotics	8 (12.1)	9 (13.6)	0.564
Depot 1 injection/15 days	8 (12.1)	0 (0.0)	<0.001
Equivalent chlorpromazine	210,2 (184.8)	226,5 (197.4)	0.421
Antidepressants	30 (45.5)	26 (39.4)	0.317
Mood stabilizers	13 (19.7)	13 (19.7)	1.00
Benzodiazepins	7 (10.6)	10 (15.2)	0.366
Anxiolytics or hypnotics	12 (18.2)	3 (4.5)	0.020
Methylphenidate	2 (3.0)	3 (4.5)	0.317

*McNemar Chi-square Test or paired sample t test.

TABLE 3B | Panel of programs delivered in the CR center, number of patients who participated to these programs in single or combined course, and who experienced other psychosocial therapies.

Cognitive Remediation Programs	Reference	Principal method	n (%)
Remédiation Cognitive dans la schizophrénie (RECOS)	(25)	Neurocognition (Individual computer/ paper/pencil)	31 (47.0)
Cognitive Remediation Therapy (CRT)	(27)	Neurocognition (Individual paper/pencil)	28 (42.4)
Neuropsychological Educational Approach for Cognitive Remediation (NEAR)	(31)	Neurocognition (Group computer/ bridging group)	8 (12.1)
Social Cognition Interaction Training (SCIT)	(29)	Social Cognition (Group)	5 (7.6)
Jeu Mathurin (JM)	(17)	Neurocognition (Group Virtual Reality)	3 (4.6)
Remédiation of Theory Of Mind (TOM-REMEDI)	(30)	Social Cognition (Group)	1 (1.5)
Group format			13 (19.7)
Social cognition target			6 (9.1)
Single & combination			
Single		NC	58 (87.9)
RECOS	(25)	NC	27 (40.9)
CRT	(27)	NC	25 (37.9)
NEAR	(31)	NC	6 (9.1)
JM	(17)	NC	1 (1.5)
Combination			7 (10.6)
CRT + RECOS	(25, 27)	NC + NC	1 (1.5)
RECOS + SCIT	(25, 29)	NC + SC	1 (1.5)
CRT + TOM-REMEDI	(27, 30)	NC + SC	1 (1.5)
NEAR + SCIT	(29, 31)	NC + SC	2 (3.0)
JM + RECOS + SCIT	(17, 25, 29)	NC + NC + SC	2 (3.0)
Psychosocial therapies			25 (37.9)
CBT	(35)		16 (24.2)
Patient Psycho-Education	(33, 34)		11 (16.7)
Family Psycho-Education	(32)		8 (12.1)
Adapted Physical Training	(36)		7 (10.6)

previously or enter any psychosocial therapy program after having done a CR program in the C3RP unit. For the whole P-CR group the mean number of years with non-activity before CR was 4.2 with a standard deviation of 6.1.

Work or Study Outcome

Type of outcome results are presented in **Table 4**. A significant difference was found for job employment with more than half of P-CR being employed at since T2 ($p > 0.001$). Within job employment, competitive job (not specifically dedicated for persons with disabilities) also improved significantly with 36% of P-CR being with a competitive job since T2 ($P = 0.007$). Studying status also improved significantly between T1 and since T2 with 30.3% being with a student status since T2 ($p = 0.033$). Among this group, the proportion of subjects who enrolled in an open study curriculum (without adaptation or dedication to persons with disabilities) significantly improved with 25.8% P-CR at since T2 (0.013).

TABLE 4 | Type of outcome (work, studies, housing, leisure and physical activity) listed at T1 and T2.

Type of outcomes	At T1 n (%)	Since T2 in 2017–2018 n (%)	p value*
Professional activity (all types of jobs)	19 (27.3)	39 (57.6)	<0.001
Open jobs	13 (19.7)	24 (36.4)	0.007
Users performing studies (all type of studies)	12 (18.2)	20 (30.3)	0.033
Users performing open studies	8 (12.1)	17 (25.8)	0.013
Living situation (Independent Housing)	21 (31.8)	41 (62.1)	0.066
Leisure (Reading)	9 (13.6)	28 (42.4)	0.002
Physical activity	12 (18.2)	34 (51.5)	0.033

*McNemar Chi-square test.

Housing, Leisure and Physical Activity

When questioned about their leisure activities, a very significant difference was found between T1 and since T2 for P-CR who regularly read books or magazines, and a significant difference T1-Since T2 also existed for physical activity. At since T2, 62.1% of the group lived in an independent house, while the proportion was only 31.8% at T1.

Predictors of Employment or Active Student

A logistic regression model, tested the influence of potential predictors such as age, sex, years of study, existence of relapses, treatment dosage (chlorpromazine equivalent), diagnostic, CR in group or participation in other psychosocial therapies, on employment or active student status since the end of T2 in 2017–2018. Only quantitative variable age and CPZ were significantly associated with a positive outcome (respectively 0.018 and 0.014). However, caution is advised in the interpretation since an increase of 1 unit in the respective quantitative variables represent a decrease of respectively 10% and less than 1% in the odds being employed or having an active student status (data not shown). In other words, the only predictors of a positive outcome were being younger and having a lower treatment dosage (43).

One important point was to know if the functional status was related to the time when users participated to the CR program. Therefore, we split the whole number of participants in two subgroups: subgroup 1: 2009–2013 ($n = 37$) and subgroup 2: 2014–2016 ($n = 37$). Characteristics of the two subgroups of P-CR are mentioned in **Table 5**. The split-year of the whole sample was 2014, because that year represented the initiation of an enriched panel of CR programs, with more group methods in neurocognition or social cognition proposed in the unit.

When we examine socio demographical as well as clinical difference, subgroup 2 was younger than subgroup 1, with a higher proportion of males. Also, there were more persons with autism or complex neurodevelopment disorders. Considering the CR programs achieved, there was in subgroup 2 a higher proportion of combination of programs, of programs delivered

TABLE 5 | Characteristics of P-CR who participated to CR programs between 2009 and 2013 (Subgroup1) and between 2014 and 2016 (Subgroup2).

Cognitive Remediation	2009–2013	2014–2016	p value*
	(n = 37)	(n = 29)	
	n or mean (% or SD)	n or mean (% or SD)	
Socio-Demographics			
Male Sex	20 (54.1)	21 (72.4)	0.048
Age	41,3 (11.5)	34,0 (10.7)	0.041
Years of study	13,2 (2.9)	13,7 (2.7)	0.539
Diagnostics			
Schizophrenia	34 (91.9)	19 (65.5)	
Bipolar	1 (2.7)	2 (6.9)	
Neurodevelopmental Disorder	2 (5.4)	8 (27.6)	0.026
Programs			
CR Combination	1 (2.7)	6 (20.7)	0.019
CR in Group	1 (2.7)	12 (41.4)	<0.001
CR Social cognition	1 (2.7)	5 (17.2)	0.041
Psychosocial Therapies	11 (29.7)	14 (48.3)	0.123
Any Treatment at T2			
Antipsychotics	36 (97.3)	27 (93.1)	0.417
Clozapin	18 (48.7)	7 (24.2)	0.042
Depot antipsychotics	3 (8.1)	6 (20.7)	0.139
Depot 1 injection/15 days	0 (0.0)	0 (0.0)	0.325
Equivalent chlorpromazine	259,4 (199.3)	184,5 (190.1)	0.127
Antidepressants	17 (45.9)	9 (31.0)	0.219
Mood stabilizers	7 (18.9)	6 (20.7)	0.858
Benzodiazepins	5 (13.5)	5 (17.2)	0.675
Anxiolytics or hypnotics	2 (5.4)	1 (3.4)	0.705
Methylphenidate	2 (5.4)	1 (3.4)	0.705
Type of outcomes since T2 (in 2017–2018)			
Professional activity	26 (70.3)	13 (44.8)	0.037
Open jobs	18 (48.7)	6 (20.7)	0.019
Users performing studies	7 (18.9)	13 (44.8)	0.023
Users performing open studies	6 (16.2)	11 (39.3)	0.036
Independent Housing	23 (62.1)	18 (62.1)	0.994
Leisure (Reading)	16 (43.2)	12 (41.4)	0.879
Physical activity	21 (56.8)	13 (44.8)	0.336
No relapse	21 (56.8)	23 (79.1)	0.054

*Pearson Chi-square Test or independent sample t test.

in groups and of social cognition programs. The two subgroups did not differ for the number of other psychosocial therapies.

The type of outcome was also showing noticeable difference: there were significantly less P-CR in subgroup 2 having a professional activity and within them obtaining open jobs, but more users performing studies and among them open studies. Lastly, the number of no relapse was not significantly different in subgroup 1 and subgroup 2.

Narrative Evaluation of CR Intervention Effects

For the whole sample a global evaluation of the narrative feelings using the NEII questionnaire (38, 39) is presented **Table 6**:

- Class 1 (41%) was referring to the incidence of CR on the functioning of thought: P-CR were describing more “clarity of thought”, more control of thought disorders, and better abilities to be attentive and to listen to others.

- Class 2 (30%) was around the effect of CR on concentration and memory associated to self-confidence. P-CR was describing better concentration, memory abilities, easiness to speak. They linked these improvement with gain in self-confidence.
- Class 3 (29%) was referring to work and studies. P-CR mentioned that CR helped for work and studies, and even recommended this therapy for persons “having health problems” or “problems with the treatment”.

DISCUSSION

This survey clearly shows that in a sample of participants who experienced personalized CR programs, a significant proportion of users obtain a job, with a high number of persons who are employed in open works, doing studies, reading or practicing physical activity regularly, when referring to their status or leisure before CR. When we examine the interval of 8 to 4 years on one hand, and 3 to 1 year on the other hand, from the survey-period, there was a significant number of persons who got a job in the former group, and a significant number of persons to come or return to studies in the latter group, with similar determinants for outcome and a high number of no relapse for these two subgroups.

Concerning employment, in the literature, only 11.5% of persons with a psychic handicap exert an open job while this proportion turns around 62.2% in the general population, despite the fact that 55 to 70% of users with psychic handicap claim they would like to work (44). In an European cohort of persons with schizophrenia enrolled in a naturalistic study with a 2-year follow-up the overall employment rate of participants was 21.5%, but varied between countries and sites, with rates of 12.9% in the UK, and 11.5% in France. During the same period the general population employment rate in France was 62.2% (45). However, in certain conditions such as in rural china compared to urban environment, high rates of employment can be seen for persons having a severe mental illness. In our study, when open and sheltered jobs are considered, the rate of employment we find is 57.6% with a significant proportion of persons who exerts a job after CR, in comparison to the proportion before CR. This rate is nearly the same as the range of rates for employment after Computer assisted CR done by outpatients with schizophrenia or schizoaffective disorders listed in the meta-analysis of Chan et al. (8) (54 to 69% depending on the different studies). This rate was significantly reduced in the subgroups of participants who received CR during 2014–2016 compared to the group treated during 2009–2013. For the former period the rate is 70.3%, with 48.7% doing ordinary jobs. As a matter of example, the Individual Placement and Support (IPS) method's [Boardman and Rinaldi (1) listed in Pachoud and Corbière (46)], known as a particularly efficient method for supported employment, provides rates of open employment around 60%, compared with rates of around 25% obtained with the usual mental health services. In France, since 2016 an adaptation of the IPS

TABLE 6 | Global evaluation and lexicometric analysis of the narrative feeling written by the participants (n = 52).

Class	Main Topic	Most Prominent words	Most illustrative Verbatim
Class 1 (41%)	Incidence on the functioning of thought	thought; follow; feel; daily; test; organize; help	<i>Cognitive Remediation (CR) is a good help mainly to drive thought disorders This allows the development of attentive listening, of an active listening, an acute sense of observation, to establish a real dialog, to listen to the speaker and to the therapists; Also, it requires a constant effort to express correctly and clearly your thought. Acts on automatic thoughts, jumping to conclusions and recognize emotions of others. Clarity of thought as well as acuity for the selection of the terms and a refined spirit.</i>
Class 2 (30%)	Incidence on concentration and memory with an impact on self confidence	cognitive; task; concentration; enable; method; remediation; improvement	<i>CR was a real benefit, it allowed not only to work on my memory and concentration in a targeted way but also it gave me hope and confidence in abilities I thought were lost. The impact of CR for me are: rapidly to retrieve information, increase of concentration abilities, better memory, more fluent to speak, and more self- confidence CR brought many positive elements, it allowed to think to other things than making effort to be concentrated, less violent impulse, more self-confidence and a better quality in relationships. [recommend] to those who lost confidence in their abilities, or have difficulties in their studies consecutively to health problems or treatments effects I successfully returned studying and entered the professional world, and I think I cannot do better. I have been able to return to studies in a library and I am able to read books, because it's stimulating and it's a booster to make intellectual progress.</i>
Class 3 (29%)	Incidence on studies and work	return; therapist; world; a follow-up;	

method has been currently implemented all over the land. Our group of participants did not benefit from the pilot IPS experience beginning in 2016. Hence, we make the assumption that our CR personalized models for care added to the French IPS program should certainly reinforce the good outcome results for the users. In our group the percentage of users working in sheltered employment was 12%, while in the European cohort of Marwaha et al. (45), the same percentage in the French group was 30%. However, this cohort was collected before 2007 and psychosocial therapies were very scarce in France before 2009.

The overall number of users performing studies was also significantly different at T1 (18%) compared to T2 (30%), with also a higher number of users performing ordinary studies (36.4%). The noticeable point is that this number is significantly higher between 2014 and 2016, compared to the group doing CR in 2009–2013. However, the more recent group is younger. That could be part of the explanation of the higher proportion of users who obtained jobs in the former group, and the higher proportion of users performing studies after CR in the latter one. In a large group of persons with psychosis living in an Australian urban city, Jablensky et al. (47) found in a cohort of 980 individuals with schizophrenia 11.6% of persons achieving a tertiary education diploma degree, with 58.1% who had left school at age 16 years or earlier and 47.8% who completed secondary schooling. Moreover, plausibly our recruitment changed from 2009 to 2013 compared to 2014–2016 with younger participants to who psychosocial therapies have been proposed. Lastly, what is noticeable is that even before the enrichment of CR methods in 2014–2015, persons with neurocognitive deficits treated with tailored program of rehabilitation could find jobs and could maintain it after many years. During this earlier period persons were mainly treated with CRT and Recos, two neurocognitive methods. However, even if these two methods are focused on neurocognition, using CRT, Wykes et al. (48) found that for aged persons with schizophrenia, when they experienced a memory benefit, there was in parallel an improvement in social behavior. Finally using

Recos, Vianin (49) insisted on the mixed paper/pencil and computer program which brings positive effects on metacognition with more transfer in everyday life.

At the moment of the survey, 92.4% of the P-RC were feeling as clinically stable. The number of untreated patients was quite the same between T1 and since T2, and the CPZ equivalent were also very similar in the two subgroups. This survey sample was mainly composed of participants with schizophrenia. In the literature, the rate of relapses in schizophrenia is variable. As a matter of example, a systematic review (50) found in multiple episodes of schizophrenia remission rates from 16 to 62%. Moreover, these rates depend from several factors. Comparing the different periods, 2009–2013 and 2014–2016, there was quite the same proportion of subjects who experienced no relapse after CR. This result is in favor of a continuing benefit of psychosocial therapy even after several years. Mueller et al. (51) recently found convergent results showing that the INT-CR-Program prevent relapses in a one year follow up study in schizophrenia. When we look to some determinants of global functioning, at T1, 18% of users were regularly practicing physical activity (including frequent walk), and after CR this proportion was significantly higher, with nearly half of the P-CR. Also, a higher proportion of users were reading regularly. Moreover, since T2, 62.1% had independent housing, while there were less users in the same environment at T1.

Generally, to scrutiny analyze all these results, a control group might be necessary and is lacking in our study. It has to be done in the future. However, when we reconcile these results with the high percentage of employment and studies in this sample, we could state that our users show in their outcomes several determinants that have been mentioned in studies about recovery (52). However, without specific recovery or symptom questionnaire or scales we cannot go forward in this hypothesis. Morin and Franck (53) states that clinical remission and overall functioning are two main factors for recovery. We did not find any impact of confounding factors on our findings except for age and treatment dosage that could be obviously understood as the

lower the age and the level of symptomatology that needs to be treated with antipsychotics, the higher the chance is for a positive outcome, especially concerning employment or studies. However, Erim et al. (43) found in a group of persons with schizophrenia that a low dosage of antipsychotics was correlated with young age, shorter disease duration, symptomatic remission and higher rate of employment. Nevertheless, the small group of participants could raise insufficient power issues on analysis. Another point is the low rate of responses to the survey by the participants. This low rate has many explanations: 1) probably a low motivation of these drop-out subjects, who for some of them did not achieve the program or even did not begin the program after the baseline evaluation. 2) The long delay after the years of CR treatment could for other participants be also a reason of non-response. 3) The fact that persons come in our rehabilitation center from many parts of the very large Ile de France region. These persons could have changed their address, or even live in another region.

When looking carefully to the lexicometric analyses of the intervention evaluation extracted from the Narrative interview of the P-CR, three classes emerged, with three main topics (**Table 5**): one was concerning the thought functioning, with the positive impact on CR on clarity of thought and on benefits in driving thought disorders; the second topic establishes a link between the benefit of CR on cognitive functions and the association with self-confidence; and the third topic concerned the positive incidence of CR on work and studies. These topics are nodal objective of CR and the participants who responded fully perceive these effects. Confirmation of these benefits also come from literature: Farreny et al. (54) showed an association between improvement in executive functioning after CR and reduction of thought disorders. Seccomandi et al. (23) recently pointed out that the improvement in self-esteem might be a moderator of the response of CR with a link between higher self-esteem at baseline and better competitive employment as well as lower unemployment (55). However, in another study self-esteem had no influence on cognitive gains (16). Lastly, Bell et al. (56) demonstrated benefits of CR on supported employment for schizophrenia. Finally, participant subjective evaluation of CR effects converge with what experts of rehabilitation teams are expecting from this therapy. Interestingly, it was noticeable that “participants recommend this treatment for difficulties to study because of mental health problems.” Nowadays in France, CR for mental health difficulties is extensively growing all over the national territory. In each region rehabilitation centers have already been developed or are in an ongoing process of development. Every year, therapists are formally trained when they want to deliver CR programs. Our consortium for CR (Association Francophone de Remédiation Cognitive—AFRC—and therapy CR network) exists since 2009, and formal university graduations for CR and psychosocial rehabilitation exist in Lyon and Paris, while formal training concerning individual CR programs are delivered in a context of professional continuous training to nurses, psychologists, psychiatrists and other clinician stake holders. In the overall mental health policy in France, psychosocial therapies and mainly CR have been designed as

national priorities for mental health (Instruction DGOS/R4/2019/10).

Lastly, more forms exist in the responses given by subgroup 2 than by subgroup 1. Obviously one can more easily retrieve precise and rich details about a therapy when memories are more recent.

Limitations

This manuscript is a very preliminary study concerning long term outcome of a small number of persons. The main limitation of this study concern power issues and the absence of a control group which deeply limits the possibility to refer to a population of persons recruited during the same period in the same environment. Furthermore, outcomes might be measured on a different time scale for different subject since they're not assessed at the end of CR but in 2017–2018 since the end of service delivery (from 2009 to 2016). Also, are lacking formal clinical evaluation, as well as questionnaires exploring satisfaction, recovery and self-report memories of the participants themselves concerning the feeling of recovery. Our sample is probably biased; one of the indirect probe for this bias is the number of patients eligible for CR who dropped out (30.5%) or did not answer to our survey (response rate of 50.4%). The selection bias was reinforced by our model for rehabilitation care: to enter in a CR program users have to be motivated, and must have an idea of the concrete project of insertion they want to concretize. However, in a context of our French free medical health insurance, one has to keep in mind the cost of psychosocial therapies in general; Hence, we must obtain a minimum of guarantee that programs could be followed until the end to prove that these psychosocial therapies must continue and need an extension in France.

CONCLUSION

The main findings of this study highlight the plausible efficacy of personalized cognitive remediation in naturalistic conditions to promote overall functioning. Strikingly, these results are found even several years after the intervention and regardless of the time when it was applied, with a high percentage of participants who works after cognitive remediation in open jobs, who studies or who acquires training and graduation. Also, some determinants of overall functioning which are frequently expressed in recovery have also been pointed out. After cognitive remediation, inner feeling of increase of self-confidence, better clarity of thought, and feeling that cognitive remediation has been a real help for work, studies or mental health problems are directly expressed by the participants. Few relapses can be showed and these effects are maintained, even many years after the program. All these factors exist in a tailored care delivery for cognitive remediation and psychosocial therapies, in a precise timed course adjusted to the rehabilitation project, with huge efforts to transfer benefits of remediation in daily living, coordinated to the clinical follow-up of the sector team which continues to help the user in his rehabilitation project. However, to be confirmed undoubtedly

these findings have to be done in reference to a control group. Also, a follow-up prospective study has to be carried on. Cognitive remediation and psychosocial rehabilitation seem to provide actually modest but robust improvement. Comparative studies reporting long term effect of this psychosocial therapy are warranted to confirm these preliminary findings.

DATA AVAILABILITY STATEMENT

The datasets generated for this study are available on request to the corresponding author.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by CPP île de France VI. The patients/participants provided their written informed consent to participate in this study.

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AUTHOR CONTRIBUTIONS

IA, MM, and YM wrote the manuscript. All the other authors contributed to collect the data for this survey, to correct the manuscript, and to supervise the study. YM and FP performed the statistical analyses. LK completed some statistical analyses and supervised the collection of data concerning psychosocial therapies.

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Should Behavior Harmful to Others Be a Sufficient Criterion of Mental Disorders? Conceptual Problems of the Diagnoses of Antisocial Personality Disorder and Pedophilic Disorder

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Generally, diseases are primarily harmful to the individual herself; harm to others may or may not be a secondary effect of diseases (e.g., in case of infectious diseases). This is also true for mental disorders. However, both ICD-10 and DSM-5 contain two diagnoses which are primarily defined by behavior harmful to others, namely Pedophilic Disorder and Antisocial (or Dissocial) Personality Disorder (ASPD or DPD). Both diagnoses have severe conceptual problems in the light of general definitions of mental disorder, like the definition in DSM-5 or Wakefield's "harmful dysfunction" model. We argue that in the diagnoses of Pedophilic Disorder and ASPD the criterion of harm to the individual is substituted by the criterion of harm to others. Furthermore, the application of the criterion of dysfunction to these two diagnoses is problematic because both heavily depend on cultural and social norms. Therefore, these two diagnoses fall outside the general disease concept and even outside the general concept of mental disorders. We discuss whether diagnoses which primarily or exclusively ground on morally wrong, socially unacceptable, or criminal behavior should be eliminated from ICD and DSM. On the one side, if harming others is a sufficient criterion of a mental disorder, the "evil" is pathologized. On the other side, there are practical reasons for keeping these diagnoses: first for having an official research frame, second for organizing and financing treatment and prevention. We argue that the criteria set of Pedophilic Disorder should be reformulated in order to make it consistent with the general definition of mental disorder in DSM-5. This diagnosis should only be applicable to individuals that are distressed or impaired by it, but not solely based on behavior harmful to others. For ASPD, we conclude that the arguments for eliminating it from the diagnostic manuals outweigh the arguments for keeping it.

Keywords: antisocial personality disorder, psychopathy, dissocial personality disorder, pedophilic disorder, pedophilia, diagnostic criteria, definition of mental disorder, harmful behavior

INTRODUCTION

Generally, diseases are primarily harmful to the diseased individual herself either by being directly life-threatening or at least life-shortening, or by causing pain or suffering, or by impairing her ability to live in human symbiotic communities (1). Harm to others, however, may or may not be a secondary effect of diseases. A typical example are infectious diseases which harm the infected individual and possibly others as well. A mere infection, however, is not called a disease as long as it is not and will not be harmful to the infected individual herself, even if it poses a risk to others as a secondary effect. This is evident from the example of asymptomatic carriers of pathogens. Although they may transmit the pathogen to others and harm particularly vulnerable, e.g. immunosuppressed people, medicine does not regard them as ill.¹ Therefore, such persons should be described as being ‘disease-causing’ for others, rather than as being ‘diseased’ themselves.

If this is true for diseases in general, that they are primarily harmful to the individual herself, it should also be true for mental disorders as long as they are viewed as a subset of diseases. This is reflected in frequently cited attempts to formulate a general definition of mental disorder, like the definition in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) (3) or the “harmful dysfunction” model by Wakefield (4). Both definitions characterize a mental disorder by, broadly speaking, a dysfunction in mental processes that is associated with harm to the affected individual.

For some psychiatric diagnoses, however, it is questionable whether the presupposition of harm to the individual really applies. We will show that several diagnoses essentially rely on behavior that is harmful to others, but not necessarily to the individual herself. This is especially true for the diagnoses “Antisocial Personality Disorder” (ASPD) in DSM-5 (or “Dissocial Personality Disorder” in ICD-10) and “Pedophilic Disorder” in DSM-5 and ICD-11.² Instead, as we will show, another disease criterion comes in here: the criterion of “harm to others”.

In the case of Pedophilic Disorder, harm to others is a sufficient criterion. In the case of ASPD, it is a necessary one and, as we will argue, practically also a sufficient one. In addition to the harm criterion, getting another meaning, we will argue that the criterion of a mental dysfunction is unclear in these diagnoses. Thus, the diagnoses of ASPD and Pedophilic Disorder fall out of the general concept of diseases and even out of the general concept of mental disorders. Are they accordingly rather “moral disorders” than clinical disorders?³ If this is true, psychiatry contributes to a “medicalization” of morally wrong behavior (6). The conceptual

problems of ASPD and Pedophilic Disorder lead to the fundamental question which criteria define a mental disorder.

The aim of this paper is to discuss whether behavior harmful to others should be a sufficient criterion of mental disorder as it is the case in the diagnoses of ASPD and Pedophilic Disorder. If we come to the conclusion that this should not be the case, the question arises whether ASPD and Pedophilic Disorder should be eliminated from the diagnostic manuals.

MENTAL DISORDERS AND THEIR DIAGNOSTIC MANUALS

In probably no other specialty of medicine has the concept of “disease” been as contested as in psychiatry. Even though in psychiatry the term “disorder” is predominantly used, it can be regarded as synonymous to “disease”, especially regarding the practical consequences. Apart from the fundamental question whether there’s such a thing as “mental disorders” at all (7), and hence, whether psychiatry is a part of medicine at all, the nature and definition of mental disorders in general have been discussed (4, 8, 9). Other controversies concern the disorder status of specific mental conditions, the most famous example probably being the removal of homosexuality from DSM in 1973 (10, 11). A still missing stringent scientific basis and the important role of values (12) bring psychiatry into a position to constantly question its own presumptions about the concept of mental disorder.

Mental disorders are classified in two classification systems: First, the International Classification of Diseases and Related Health Problems, 10th revision (ICD-10), by the World Health Organization (WHO) (13). Second, for mental disorders only, the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5), published by the American Psychiatric Association (APA) (3). The latter is “viewed as representing the cutting-edge of the field” (14). Both manuals define the current state of the art in psychiatric diagnostics and thus have a huge impact on clinical use but also on public discussions about mental health and finally, through their use in forensic settings, even on court rulings. The practical implications of the diagnostic manuals thus range from the funding of treatments by the public health system to the assessment of someone’s capacity to work, and indirectly to the evaluation of diminished criminal responsibility.⁴

¹ Contrary to medical mainstream opinion, Hucklenbroich regards asymptomatic carriers of infectious diseases as ill. According to his theory (see *The general concept of disease*), asymptomatic carriers fall within the scope of disease criterion 5 (2).

² The rationale of our argumentation applies to other diagnoses as well, like for example “Coercive sexual sadism disorder” in ICD-11. We have chosen Pedophilic Disorder and ASPD because they are the most questioned and relevant diagnoses.

³ Charland (5) argues that only the personality disorders in Clusters A and C are genuine clinical disorders. In contrast, he considers the Cluster B disorders (which include antisocial, borderline, histrionic, and narcissistic personality disorder) as moral disorders since their definitions are “morally loaded” and they require “moral treatment”.

⁴ A psychiatric diagnosis *per se* is not a reason for assuming a lack of criminal responsibility or diminished responsibility but it is part of the forensic examination. According to German criminal law, “[a] person acts without guilt who, at the time the criminal act is committed, is incapable of understanding the wrongfulness of his or her action or is incapable of acting in accordance with this understanding due to mental illness, due to a profound disturbance of consciousness, or due to mental retardation or another serious mental abnormality” [Section 20, German Criminal Code, English translation cited from (15)]. Diminished responsibility is present in the case of a diminished capability of the offender to understand the wrongfulness of an action or to act in accordance with this understanding due to one of the reasons indicated in Section 20 and may lead to mitigated penalty (Section 21, German Criminal Code). Section 20 lists four mental conditions that are necessary prerequisites for assuming a lack of criminal responsibility. However, these mental conditions are not equivalent to specific psychiatric diagnoses. They are legal terms that refer to psychiatric diagnoses (16).

The diagnoses in both diagnostic manuals rely on polythetic criteria sets, of which a specified number of criteria needs to apply for a specified period of time. Since the neurobiological underpinnings and the etiology of many mental disorders are still scarcely understood, the diagnostic criteria sets consist of observable and subjective symptoms. Contrary to most cases in “somatic medicine”, there are only few additional objective tests in psychiatry to support a suspected diagnosis (*e.g.* for dementias or autoimmune encephalitis).

Given their importance in the diagnostic process, the selection and exact formulation of the criteria of mental disorders are crucial. Changes in these criteria sets have a huge impact on the prevalence of certain mental disorders and on the lives of many individuals. It is thus not surprising that every revision of the diagnostic manuals is accompanied by extended controversies about the inclusion or elimination of diagnoses and the formulation of the diagnostic criteria sets (17, 18). Frances (19), for example, sharply criticizes a “diagnostic inflation” in psychiatry which he thinks was intensified by DSM-5 by adding more diagnoses and expanding the existing ones.

MENTAL DISORDERS HARMFUL TO OTHERS

The most contested diagnoses in DSM and ICD are probably the paraphilias (20) and Cluster B-personality disorders (5).⁵ Especially Pedophilic Disorder and Antisocial Personality Disorder (ASPD) or Dissocial Personality Disorder (in ICD-10) are highly controversial diagnoses. Some authors question their status as clinical disorders [for ASPD, see Charland (5)] or even their place in the manuals [for Pedophilic Disorder, see Green (22)].

Pedophilic Disorder and ASPD are particularly contested because both diagnoses are highly linked to socially deviant or even criminal behavior. Persons with ASPD and pedophilic sexual offenders have a significantly increased risk of (re-)offending (23–25). Sadler (26) calls such diagnoses “vice-laden” disorders, vice being understood in a “technical sense—as simply criminal and/or immoral thought or conduct” (p. 452) by the legal and moral standards of the respective society. The notion of “vice-ladenness” indicates that those disorders imply thoughts and behaviors typically described and assessed in moral and/or legal rather than in medical terms.

Pedophilic Disorder and ASPD are not the only mental disorders associated with behaviors usually described in moral terms and potentially harmful to others, though. A person suffering from schizophrenia, for example, will presumably show in some way socially deviant behavior and may even cause harm to others when, for example, following the commands of imperative voices. The crucial point, however, is that in the case of schizophrenia the symptoms described in the diagnostic criteria

set are “relatively immune to misconstrual as vice” (6) (p. 9). Immoral or harmful behavior is not a defining criterion of the disorder, rather it may or may not be a secondary effect of it. In contrast, for ASPD and Pedophilic Disorder, behavior that is morally wrong and primarily harmful to others is a central part of the diagnosis: they are “vice-laden” at their core.

Pedophilic Disorder

In DSM-IV, the diagnosis of pedophilia required that the fantasies, sexual urges, or behaviors involving children cause clinically significant distress or impairment in social, occupational, or other important areas of functioning (Criterion B). This criterion was changed in DSM-IV-TR so that it was then sufficient to have acted on the sexual urges. From DSM-IV-TR to DSM-5, all criteria remained unchanged after the proposed changes were declined (27, 28) (Table 1).⁶

DSM-5, however, introduced a distinction between Pedophilia and Pedophilic Disorder. Pedophilia denotes the mere sexual preference for prepubescent children (Criterion A) and is not considered a mental disorder anymore. Pedophilic Disorder is Pedophilia with either personal distress or interpersonal difficulty, or sexual acts involving prepubescent children (Criterion B).

ICD-11, which has been presented by the WHO in 2019 and will foreseeably come into effect on 1 January 2022, adjusted the criteria of “Pedophilic Disorder” to the DSM-5 criteria (Table 2). Except for the time criterion (the sexual attraction to children must be present for at least 6 months), which is only required in DSM-5, the criteria in ICD-11 and DSM-5 are basically the same (Tables 1 and 2).

The age limit mentioned by DSM-5 (13 years) is clearly below the age of sexual consent, which ranges between 14 and 18 years in most countries (in the US states, for example, it ranges between 16 and 18 years). This means that the criterion of “has acted on these sexual urges” is equivalent to committing a criminal act.

This, however, does not apply to all countries in the world. According to the UNICEF child marriage report from 2014, about 250 million women alive today were married before age 15 (35). In some countries, this is even covered by law as it is allowed to marry before age 18 (in some cases there is no minimum age at all) under certain circumstances (36). This shows that not in every country sexual intercourse with children age 13 or younger is considered a criminal offense. Therefore, the legal and social reactions which individuals, who sexually abuse children, will have to face differ. Of course, even though tolerated by law in some countries, sexual acts involving children are harmful and should be legally forbidden all over the world.

Most researchers emphasize the difference between pedophilic interests and sexual offending against children. Not all individuals

⁵The general concept of the personality disorders has been criticized fundamentally. Lieb criticizes the concept of personality disorder as contradictory in itself and as harmful to the patient and to the therapeutic relationship (21).

⁶It was proposed to include the attraction to pubescent children and rename the diagnosis “pedohebephilic disorder”, to include a victim count and the use of child pornography in criterion B, and to include the specifiers “in remission” and “in controlled environment” (31). After the refusal of these changes, it was criticized that Pedophilic Disorder is the only Paraphilic Disorder in DSM-5 that lacks the specifiers “in full remission” and “in controlled environment” (32, 33). Further criticism was directed against the refusal to include the attraction to pubescent children (27). These discussions, however, are not in the focus of this paper.

TABLE 1 | Comparison of the diagnostic criteria of pedophilic disorder and pedophilia in the DSM-IV, DSM-IV-TR, and DSM-5.

DSM-IV—Pedophilia (302.2)	DSM-IV-TR—Pedophilia (302.2)	DSM-5—Pedophilic Disorder (302.2)
<p>A. Over a period of at least 6 months, recurrent, intense sexually arousing fantasies, sexual urges, or behaviors involving sexual activity with a prepubescent child or children (generally age 13 years or younger).</p> <p>B. The fantasies, sexual urges, or behaviors cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.</p> <p>C. The person is at least age 16 years and at least 5 years older than the child or children in Criterion A.</p> <p>Note: Do not include an individual in late adolescence involved in an ongoing sexual relationship with a 12- or 13-year-old. (29)</p>	<p>A. Over a period of at least 6 months, recurrent, intense sexually arousing fantasies, sexual urges, or behaviors involving sexual activity with a prepubescent child or children (generally age 13 years or younger).</p> <p>B. <i>The person has acted on these sexual urges, or the sexual urges or fantasies cause marked distress or interpersonal difficulty.</i></p> <p>C. The person is at least age 16 years and at least 5 years older than the child or children in Criterion A.</p> <p>Note: Do not include an individual in late adolescence involved in an ongoing sexual relationship with a 12- or 13-year-old. (30)</p>	<p>A. Over a period of at least 6 months, recurrent, intense sexually arousing fantasies, sexual urges, or behaviors involving sexual activity with a prepubescent child or children (generally age 13 years or younger).</p> <p>B. The individual has acted on these sexual urges, or the sexual urges or fantasies cause marked distress or interpersonal difficulty.</p> <p>C. The person is at least age 16 years and at least 5 years older than the child or children in Criterion A.</p> <p>Note: Do not include an individual in late adolescence involved in an ongoing sexual relationship with a 12- or 13-year-old. (3)</p>

Text that has been changed from the previous version is shown in italics.

TABLE 2 | Comparison of the diagnostic criteria of pedophilic disorder and pedophilia in ICD-10 and ICD-11.

ICD-10— Pedophilia (F 65.4)	ICD-11 – Pedophilic Disorder (6D32)
<p>A sexual preference for children, usually of prepubertal or early pubertal age. Some pedophiles are attracted only to girls, others only to boys, and others again are interested in both sexes. (13)</p>	<p><i>Pedophilic disorder is characterized by a sustained, focused, and intense pattern of sexual arousal—as manifested by persistent sexual thoughts, fantasies, urges, or behaviors—involving pre-pubertal children.</i></p> <p><i>In addition, in order for Pedophilic Disorder to be diagnosed, the individual must have acted on these thoughts, fantasies or urges or be markedly distressed by them.</i></p> <p><i>This diagnosis does not apply to sexual behaviors among pre- or post-pubertal children with peers who are close in age.</i> (34)</p>

Text that has been changed from the previous version is shown in italics.

with pedophilic interests sexually approach children, and not all child molesters have “recurrent and intense” pedophilic interests; about half of the cases of sexual abuse of children are committed by presumably non-pedophilic offenders.⁷

However, both criteria A and B of Pedophilic Disorder contain a behavioral aspect that is sufficient for the respective

⁷Data on the proportion of pedophilic and non-pedophilic child sexual offenders are quite scarce and come from small studies. According to Seto et al. (37), in a sample of 100 child pornography offenders (where the authors assumed a high probability of pedophilic interest due to phallometric responses), 57% were not known to have had sexual contact with children. Conversely, the prevalence of pedophilic preference among identified child sexual offenders is estimated at about 40–50% (based on their sexual arousal to stimuli depicting children or their sexual offense history) (23). First (38) notes that “compared with other paraphilic disorders, child molestation is even more likely to occur for nonparaphilic reasons”. Nonparaphilic reasons may be “a lack of more preferred sexual opportunities, hypersexuality, indiscriminate sexual interests, or disinhibition as a result of substance use or other factors” (23) (p. 393). Knack et al. (39) name “a general anti-social orientation”, “a sexual interest in coercion”, “attitudes accepting of sex between adults and children”, and “indiscriminate or opportunistic sexual behaviours” as reasons for non-pedophilic child sexual abuse (p. 183). Strassberg et al. found that non-pedophilic child molesters are more likely to show psychopathic traits than pedophilic child molesters (40).

criterion to be fulfilled. The use of the conjunction “or” before “behaviors” in criterion A makes it possible to meet this criterion solely by repeated acts of sexual behavior involving children (38). Regarding criterion B, sexual acts involving children are also sufficient to fulfill this criterion. This means that repeated sexual behavior involving children is sufficient to fulfill both criteria.

According to the criteria in DSM-5 and ICD-11, a diagnosis of Pedophilic Disorder requires neither suffering from the sexual fantasies, urges, or behaviors towards children nor experiencing any impairment in social, occupational or other important activities. The diagnosis can be made solely on grounds of behavior harmful to others. This has been criticized as a confusion of “mental disorder” and “crime” (20) or “immoral behavior” (41).

Antisocial Personality Disorder (ASPD)

In an attempt to define reliably measurable personality traits, the DSM focused on behavior in the definition of ASPD, which was intended to be an equivalent of psychopathy (3, 42). Psychopathy, conceptualized by the Hare Psychopathy Checklist Revised (PCL-R) (24), contains much more interpersonal and affective symptoms than ASPD (25, 43) but is not a diagnosis in ICD-10 or DSM-5 (44).⁸ Almost all criteria of ASPD in DSM-5 refer to behavior primarily harmful to others (Table 3). In accordance with the diagnostic criteria required for all personality disorders, the antisocial personality traits must be “inflexible, maladaptive, and persistent and cause significant functional impairment or subjective distress” (3).

The equivalent of ASPD in ICD-10, Dissocial Personality Disorder (DPD), refers less to behavioral and more to affective symptoms than ASPD in its criteria set (25) (Table 3). However, as Kröber and Lau (15) note, most of the criteria can still be “easily derived from the criminal behavior itself” (p. 681).

⁸ASPD and psychopathy are largely overlapping concepts. According to Ogloff (25), 81% of persons diagnosed with psychopathy also meet the criteria of ASPD, whereas only 38% of the persons with ASPD receive a diagnosis of psychopathy. This indicates that the population of persons diagnosed with psychopathy can more or less be considered a subset of the population of persons diagnosed with ASPD. Exceptions are typically fraudulent personalities (or so-called “white collar offenders”) who are psychopaths but do not meet the criteria of dissocial or antisocial personality disorder (45).

TABLE 3 | Comparison of the diagnostic criteria of Antisocial Personality Disorder (DSM-5) and Dissocial Personality Disorder (ICD-10).

DSM-5—Antisocial Personality Disorder (301.7)	ICD-10—Dissocial Personality Disorder (F60.2)
<p>A. A pervasive pattern of disregard for and violation of the rights of others, occurring since age 15 years, as indicated by three (or more) of the following:</p> <ol style="list-style-type: none"> 1. Failure to conform to social norms with respect to lawful behaviors, as indicated by repeatedly performing acts that are ground for arrest. 2. Deceitfulness, as indicated by repeated lying, use of aliases, or conning others for personal profit or pleasure. 3. Impulsivity or failure to plan ahead. 4. Irritability and aggressiveness, as indicated by repeated physical fights or assaults. 5. Reckless disregard for safety of self or others. 6. Consistent irresponsibility, as indicated by repeated failure to sustain consistent work behavior or honor financial obligations. 7. Lack of remorse, as indicated by being indifferent to or rationalizing having hurt, mistreated or stolen from another. <p>B. The individual is at least age 18 years.</p> <p>C. There is evidence of conduct disorder with onset before age 15 years.</p> <p>D. The occurrence of antisocial behavior is not exclusively during the course of schizophrenia or bipolar disorder.</p>	<p>Personality disorder, usually coming to attention because of a gross disparity between behavior and the prevailing social norms, and characterized by (at least three of the following criteria)</p> <ol style="list-style-type: none"> 1. Callous unconcern for the feelings of others. 2. Gross and persistent attitude of irresponsibility and disregard for social norms, rules, and obligations. 3. Incapacity to maintain enduring relationships, though having no difficulty in establishing them. 4. Very low tolerance to frustration and a low threshold for discharge of aggression, including violence. 5. Incapacity to experience guilt, or to profit from adverse experience, particularly punishment. 6. Marked proneness to blame others, or to offer plausible rationalizations for the behavior bringing the subject into conflict with society. <p>There may be persistent irritability as an associated feature. Conduct disorder during childhood and adolescence, though not invariably present, may further support the diagnosis.</p>

The general criteria of personality disorders in ICD-10 require that “the disorder leads to considerable personal distress but this may only become apparent late in its course” and “the disorder is usually, but not invariably, associated with significant problems in occupational and social performance” (13) (p. 202).⁹

However, Habermeyer states that persons with antisocial or dissocial personality traits subjectively do not suffer from their abnormalities and show little willingness to get treated (16). This is accentuated for inmates with high values on the Psychopathy Checklist (16). Many, if not the overwhelming majority of subjects with psychopathy are perfectly content with and identify with their traits; there is no subjective suffering involved in psychopathy (42). Because there is nothing painful or ego-dystonic in psychopathic symptoms, it is unlikely that a psychopath would seek or endure treatment (42). Also persons with ASPD rarely seek treatment (43, 46), indicating that they usually do not feel significantly distressed or impaired by their condition. This becomes evident from the description of the self-image of people with dissocial or antisocial personality traits by Müller-Isberner et al.: “These people generally see themselves as autonomous, strong loners. Some see themselves as exploited and mistreated by society and justify harming others by saying that they themselves are being harassed. Others see themselves as robbers in a world where the motto is ‘eat and be eaten’ or ‘the winner takes it all’ and where it is normal or even desirable and necessary to violate social rules.”¹⁰ (47) (p. 373).

This raises the question whether the diagnosis of ASPD could be made for anyone at all if the criteria of subjective distress and/or functional impairment were strictly applied. In clinical practice, distress can be presumed if someone seeks help

voluntarily. The question is why this person seeks help and what distresses her. According to the literature on antisocial personality cited above, it is probably not her antisocial personality. However, subjective distress “in general” is not sufficient to make this specific diagnosis, even if all the other criteria of ASPD apply. According to DSM-5, the subjective distress must be caused by the antisocial personality traits.

It could be objected that a lack of personal distress in ASPD is precisely part of its psychopathology, in the sense that not recognizing one’s own problems is even more pathological than recognizing them. However, the general problem with this argument is that it allows the attribution of mental disorders to persons without personal distress from the outside. Even though there are cases in which this can be justified (e.g. in the case of severe psychosis/delusions where the individual doesn’t recognize her psychosis/delusions), there is a high risk of misusing psychiatric diagnoses for pathologizing socially deviant or nonconformist behavior.

The questionable personal distress in ASPD is especially relevant in the forensic context where the prevalence of ASPD is much higher than in the general population. The base rate in the population is estimated at 2%, whereas the prevalence among male prisoners is estimated at between 47 and 80% (25, 48). Prisoners are certainly distressed. However, distress because of the legally justified consequences of antisocial behavior, like a loss of freedom, must not be confused with distress because of the antisocial personality traits themselves (49). Distress because of society’s negative reaction to deviant behavior is not a sign of a mental disorder. Rather, it is normal. We suspect that the criterion of subjective distress and/or impairment often is not considered correctly when the diagnosis of ASPD is made, especially not in forensic contexts. The great difference between the prevalence of ASPD in the general population and among male prisoners indicates a strong correlation between ASPD and imprisonments.

⁹For the sake of clarity, we will mainly refer to Antisocial Personality Disorder in this paper, even though many of the points made equally apply to Dissocial Personality Disorder. However, because of the stronger focus on behavior in ASPD compared with Dissocial Personality Disorder, we consider the diagnosis of ASPD as more problematic.

¹⁰Translated by Sabine Müller.

This means that either most criminals have a mental disorder or that ASPD is a construct mainly depicting criminal behavior.

We conclude that, strictly speaking, many persons diagnosed with ASPD in fact only have antisocial personality traits, which are not a mental disorder according to DSM-5. This conclusion is supported by the observation of Herpertz that a lack of considering the general definition of personality disorder and instead a focus on the easily applicable specific criteria lists led to an “inflationary diagnosis frequency” of personality disorders (50). We suspect that, especially in the case of ASPD, many persons are mistakenly classified as “mentally ill” because of a wrongful interpretation or even neglect of the distress/impairment criterion.

ICD-10 and DSM-5 present a categorial classification of personality disorders with ASPD/Dissocial Personality Disorder being a distinct disorder-entity. This categorial approach to personality disorders, however, is broadly contested (50). DSM-5 already introduced an alternative “hybrid” model for personality disorders, mixing categorial and dimensional approaches.¹¹

According to the alternative model, the typical features of ASPD are “a failure to conform to lawful and ethical behavior, and an egocentric, callous lack of concern for others, accompanied by deceitfulness, irresponsibility, manipulative-ness, and/or risk taking” (p. 763). Psychopathy is described as a distinct variant that is “marked by a lack of anxiety or fear and by a bold interpersonal style that may mask maladaptive behaviors (e.g., fraudulence).” (3) (p. 765).

ICD-11 goes even further in replacing the categorial model by a dimensional one (50). According to this model, the diagnosis of a personality disorder comprises three steps. First, the general criteria of a personality disorder must be met (“problems in functioning of aspects of the self [...], and/or interpersonal dysfunction [...] that have persisted over an extended period of time (e.g., 2 years or more)”, “the disturbance is manifest in patterns of cognition, emotional experience, emotional expression, and behaviour that are maladaptive”, “the disturbance is associated with substantial distress or significant impairment in personal, family, social, educational, occupational or other important areas of functioning” (34)). Then, the severity of this general personality disorder must be determined (mild, moderate,

severe). Eventually, the specific underlying personality structure is assessed according to five personality domains (negative affectivity, detachment, dissociality, disinhibition, anankastia). Thus, in ICD-11, there will be no category “Dissocial Personality Disorder” anymore. Instead, dissocial and disinhibited traits and behaviors may be a specifier among others in a diagnosis of a (general) personality disorder.

Interim Conclusion

In both the definitions of ASPD and Pedophilic Disorder behavior harmful to others or even criminal behavior is a criterion for the diagnosis of a mental disorder. For Pedophilic Disorder, even though harming others (for a period of at least 6 months) is not a necessary criterion, it can be a sufficient one. For ASPD, repeated harming of others is a necessary criterion, and—not formally, but practically—also a sufficient one.

The key question is: Should criminal behavior/harm to others be a sufficient criterion of a mental disorder? Or does this lead to a “medicalization” of vice conditions, meaning that “all problematic deviance reflects human illness or injury, including criminality and ‘immoral’ conduct” (6) (p. 12)? The crucial point is: can behavior harmful to others alone indicate the presence of a mental disorder? Or is this rather an attempt to “pathologize the morally wrong”? We will come back to this question later.

The conceptual problems of Pedophilic Disorder and ASPD lead directly to a more fundamental question: which criteria define a mental disorder?

THE DEFINITION OF MENTAL DISORDER

The General Concept of Disease

If psychiatry claims to be a part of medicine, a general definition of disease should be the basis of a definition of mental disorders. Hucklenbroich developed a profound reconstruction of the general concept of disease (51). He distinguishes four levels of the concept of disease. The first level is the life-world and personal concept of disease (person X is ill). On the second level, a distinction can be made between healthy and pathological life processes (X is pathological). At the third level, reference is made to a standard model of the human organism (X is pathologically altered). At the fourth level, disease entities and categories are postulated (X is a disease). The basis of the determination of disease entities is an etiopathogenetic model that comprises an identification of primary causes and the typical clinical course.

According to this reconstruction, life processes that meet four criteria can be described as pathological: 1. They are states, processes, or procedures in individuals, 2. which are attributable to the organism, not the environment, 3. which take place independently of the will and knowledge of the affected individuals, and 4. for which there is at least one non-pathological alternative course.

¹¹The alternative model for personality disorders in DSM-5 has been developed for further research (Section III). In the alternative model, personality disorders are generally characterized by impairments in personality functioning (Criterion A) and pathological personality traits (Criterion B). Personality functioning (Criterion A) involves self-functioning (identity and self-direction) and interpersonal functioning (empathy and intimacy). For each of these four elements, five levels of impairment (ranging from no impairment to extreme impairment) can be differentiated. Pathological personality traits (Criterion B) are organized in five broad domains, namely negative affectivity, detachment, antagonism, disinhibition, and psychoticism. The impairments in personality functioning and personality trait expression are relatively inflexible and pervasive across a broad range of personal and social situations (Criterion C). They are relatively stable with onset in at least adolescence or early adulthood (Criterion D), cannot be better explained by another mental disorder (Criterion E), are not attributable to the physiological effects of a substance or another medical condition (Criterion F), and not better understood as normal for an individual’s developmental stage or sociocultural environment (Criterion G) (3) (pp. 761–3).

To determine which processes are diseases, Hucklenbroich distinguishes positive and negative disease criteria. Positive criteria of a disease are: 1. lethality; 2. pain, discomfort, suffering; 3. disposition for 1 or 2; 4. inability to reproduce; 5. inability to live together. The two negative criteria of disease, which determine a condition as non-pathological, are 1. universal occurrence and inevitability, *e.g.* gender, intrauterine and ontogenetic phases, pregnancy, menopause, old age, natural death; 2. knowingly and intentionally self-induced behavior (as long as self-determination is not diminished), *e.g.* suicide, value judgements, risky behavior, abstinence, intentional lying.

Hucklenbroich argues that this general concept of disease also applies to mental disorders, even though an etiopathogenic disease model like in “somatic” medicine is still missing in psychiatry (2). According to his model, especially the positive criteria 2 and 5 are relevant for mental disorders. Mental disorders are often associated with significant pain, discomfort or suffering. Additionally, they may impair the ability to live together with others in a community. However, Hucklenbroich notes that due to the lack of knowledge about the etiopathogenesis of mental disorders there are still diverging concepts of mental disorder (2).

The DSM-5 Definition of Mental Disorder

One of the mostly cited definitions of mental disorder is given in DSM-5. While conceding that “no definition can capture all aspects of all disorders in the range contained in DSM-5” (3) (p. 20), it is stated that the definition is rather meant to formulate elements required for considering something a mental disorder:

“A mental disorder is a syndrome characterized by **clinically significant disturbance** in an individual’s cognition, emotion regulation, or behavior that reflects a **dysfunction in the psychological, biological, or developmental processes underlying mental functioning**. Mental disorders are usually associated with significant **distress or disability in social, occupational, or other important activities**. An expectable or culturally approved response to a common stressor or loss, such as the death of a loved one, is not a mental disorder. **Socially deviant behavior** (*e.g.* political, religious, or sexual) and **conflicts that are primarily between the individual and society are not mental disorders** unless the deviance or conflict results from a dysfunction in the individual, as described above.” (3) (p. 20, emphasis added)

The definition starts with 1. an observable symptom level (“clinically significant disturbance”) that is 2. caused by an underlying dysfunction in the “mental domain” of an individual, and that has 3. some expected consequences, namely distress or disability in important activities of daily life. The rest of the definition specifies circumstances under which certain conditions are not deemed mental disorders: Socially deviant behavior and conflicts between the individual and society, which are not the result of a dysfunction, are not considered mental disorders.

The last point seems to be crucial. Pedophilic Disorder and ASPD are, *prima facie*, conditions that are mainly based on a conflict between the individual and other individuals and/or society.¹² A person with Pedophilic Disorder could argue that his sexual orientation simply does not fit in his society’s current concepts of approved sexual relationships while denying that sexual contacts with children are actually harmful to them.¹³ Or a person diagnosed with ASPD could argue that he does not feel bothered by his antisocial behavior because he has many advantages by it, although he might come into conflict with the law unless he is careful.

According to DSM-5, socially deviant behavior can be a sign of a mental disorder only if it results from a dysfunction in the individual’s “psychological, biological, or developmental processes underlying mental functioning”. However, the behavioral symptoms described in the diagnoses of ASPD and Pedophilic Disorder can have very different causes. Indeed, the lack of differentiation between the different causes of mental disorders is a fundamental problem of the nominalistic approach of DSM and ICD.

If hypersexual and even pedophilic behavior occurred in previously normal people after a brain tumor, a brain trauma, or epilepsy surgery, the brain pathology probably causally contributed to the abnormal behavior (54, 55). This is reflected in the differentiation between “developmental” and “acquired” pedophilia in the literature where acquired pedophilia is etiologically associated with a structural brain abnormality and developmental pedophilia is not (54, 56). However, the diagnostic manuals do not differentiate between these two types of pedophilia, as the diagnoses are symptom-based and do not consider etiology.

Also for antisocial behavior, there are associations between damage of the prefrontal cortex, be it due to a head injury or due to neurodegeneration like in Frontotemporal Dementia, and the occurrence of antisocial behavior in previously normal people (57). Cases of severe ventromedial prefrontal lobe epilepsy have been described that were associated with persistent antisocial behavior that was reversible after epilepsy surgery (58). In these cases, abnormal behavior is associated with a brain pathology which suggests a causal link between this pathology and the deviant behavior.

On the other hand, someone can behave in the same way for completely different reasons. For example, someone could live in a subculture where it is normal to behave in an antisocial or even criminal way to be “successful”. If it is normal in the social environment to make a living from, for example, drug dealing or criminal financial transactions, it could be reasonable to follow this tradition. Another example is someone who shows

¹² As soon as a crime is committed against an individual person, the perpetrator comes into conflict not only with the victim but also with the society whose moral or legal norms have been violated.

¹³ As an example, in Germany there were fierce debates about the harmfulness of sexual interactions between adults and children in the 1960s to the 1980s. Some sexologists, psychologists, and psychiatrists denied the harmfulness of sexual interactions with children (52). Pedophilic activists demanded the abolition of the legal age limit of sexual interactions, a position that was supported even by several leaders of the Green party (53).

hypersexual behavior because he simply has no reason to confine himself due to money and power. In these cases, there is no reason to assume an underlying pathology. It is rather a morally questionable behavior.

The point here is: the fact that there are cases of brain pathologies leading to disinhibited or antisocial behavior doesn't imply that all people behaving in the same way have a brain pathology.

Wakefield's "Harmful Dysfunction" Model

The question of the underlying dysfunction in ASPD and Pedophilic Disorder seems to be crucial for defending their status as mental disorders. A frequently cited concept related to the DSM definition of mental disorder is Wakefield's "harmful dysfunction" model (4). This model assumes that a mental condition can be classified as a mental disorder when two criteria apply: Firstly, it is the result of a dysfunction, understood in an evolutionary sense as the failure of a process to perform the function it was biologically designed for; secondly, it is harmful to the individual according to sociocultural standards (4). By this definition, Wakefield tries to escape definitional problems by combining, as he calls it, a "value term" (harm) and a "scientific and factual" term (dysfunction) (4). The idea is to evade two problems: On the one hand, a mere "scientific" concept of mental disorder leads to the problem that every deviation from a scientifically defined standard could be viewed as a mental disorder even though the affected individual is neither suffering nor impaired. On the other hand, a mere value-based concept of mental disorders entails the risk of pathologizing socially disvalued behavior. Thus, according to Wakefield, only a harmful dysfunction represents a mental disorder, not a dysfunction without any harm to the individual nor something evaluated as harmful (according to sociocultural standards) but without representing a dysfunction.

We will come back to the notion of dysfunction in Pedophilic Disorder and ASPD later. Regarding the harm criterion, ASPD and Pedophilic Disorder are special since most mental disorders are primarily harmful to the affected individual. For "vice-laden" disorders like ASPD and Pedophilic Disorder, however, the "harm-criterion" primarily concerns others. Of course, some persons with Pedophilic Disorder might experience personal distress, probably after having internalized the society's negative attitude towards pedophilia. Some persons with ASPD, however, may even enjoy real benefits through their special personality traits, both in terms of income and reproductive success. Malon (11) introduces the concept of "dangerous dysfunction" instead of "harmful dysfunction" in the case of Pedophilic Disorder, arguing that it is actually the concept of "dangerous dysfunction" that explains the presence of Pedophilic Disorder in DSM.

Alternative Definitions of Mental Disorder

In the diagnoses of ASPD and Pedophilic Disorder, harm to the individual in the sense of personal distress or impairment is not necessarily implied. However, harm to the individual might be present even without the person concerned being aware of it. The philosopher Graham (59) states that having a mental disorder does not necessarily comprise the recognition of its harmfulness by the affected individual herself. According to Graham, a mental

disorder is a disability, dysfunction or impairment in one or more basic mental or psychological faculties or capacities of a person that has harmful or potentially harmful consequences for the person concerned (59) (p. 28). It is a disorder because it is harmful in the sense that the person is worse off with the disorder than without the disorder, that she cannot control it, and that it cannot be removed by using additional psychological resources, e.g. by simply "pulling oneself together".

Insofar, a person with Pedophilic Disorder could be regarded as worse off with the disorder than without it because having it means that either he has to abstain from fulfilling sexual relationships his whole life or he will commit a criminal act and possibly be punished for it. However, this argument is valid only for pedophilic persons living in societies which condemn and regularly punish child sexual abuse. In the case of ASPD, one could argue that the person is worse off with the disorder than without it because he is, for example, not able to have good relationships with other people. This, however, presupposes a certain model of good relationships and a "good life", and therefore is value-laden and moralistic.

Heinz et al. (60, 61) argue for a differentiation between mental diseases in a narrow sense and states of suffering or disorders in a broader sense that do not meet the criteria of a disease. This differentiation, however, is not made by DSM and ICD where the notion of mental disorder is used for all diagnoses. Heinz et al. demand that the notion of mental disease should only be applied when life-relevant functional abilities are impaired and the affected person suffers from it or is impaired in her ability to cope with everyday life. Applying such a standard, many currently classifiable disorders are not diseases in this sense (60, 61). However, they are more or less easily classifiable states of suffering for which psychotherapeutic help and possibly drugs can be offered (60, 61). In this sense, Pedophilic Disorder and ASPD are not mental diseases.

What is a Mental Dysfunction?

The concept of mental dysfunction is central in most definitions of mental disorder. However, there is no consistent definition of this concept. For example, DSM-5 uses the notion of dysfunction without elucidating it.

Schramme (62) distinguishes four models of mental functions. The first model, for which Wakefield's concept of dysfunction is the most prominent example, is based on evolutionary psychology. According to Wakefield, mental functions result from selection processes and thus enable individuals to solve problems of adaptation (4). Schramme rightly criticizes the historical orientation of this theory: Some processes may have been adaptive to past environments but not to our present environment. The second model of mental functions comes from cognitive psychology. Functions in this sense are best understood in formal terms as "input-output-relations", not in any teleological sense. Schramme notes that this theory hardly applies to the concept of mental disorder, because it does not imply "normativity", that means, it has no concept of how a mental function should work, and thus no concept of dysfunction. The third model supports a goal theory of function and is close to Boorse's disease theory that identifies survival and

reproduction as the highest goals of organisms (8). Mental functions are thus understood through their relation to these goals. In contrast to evolutionary psychology, this model does not refer to the evolutionary selection of these functions but evaluates them with regard to the present environment. Schramme, however, criticizes that this model lacks a plausible model of the “psychological species design” with regard to survival and reproduction. The fourth model is the ‘value-theory’, for which there is no established psychological account. This model determines functions according to their contribution to human welfare and the good human life. A mental function thus allows for the individual to live a good life. However, such a theory is always at risk of confounding a certain way of life with mental health.

DISCUSSING THE DISORDER STATUS OF PEDOPHILIC DISORDER AND ASPD

As we have argued, in both the definitions of ASPD and Pedophilic Disorder behavior harmful to others or even criminal behavior is a criterion for the diagnosis of a mental disorder.

If we thus conclude that ASPD and Pedophilic Disorder are just a “medicalization” of vice conditions, we have to ask whether and, if so, how these diagnoses can still be justified within a medical model.

Neurobiological Findings in Pedophilic Disorder and ASPD

The most influential argument to justify the diagnoses of ASPD and Pedophilic Disorder within a medical model seems to be a “conservative” one. These diagnoses are well established, they have a long clinical tradition and some prognostic utility (18). This supports the argument that they should only be changed if there is strong empirical evidence that another nosological construct is more valid than the established ones.

The idea of a validation of the existing nosological constructs is pursued by researchers investigating underlying neurobiological and neuropsychological alterations in persons with ASPD or Pedophilic Disorder. There is a growing body of research indicating that there might be deviations in the brains of persons with ASPD and Pedophilic Disorder. However, the interpretation of these findings needs to be handled with care: Are the neurobiological deviations a sign of a pathology, or a sign of a vulnerability, or a consequence of a disease, or only a normal variant? And further, can these neurobiological differences causally explain the behavior (at least partly)?

For ASPD, studies show structural and functional deviations mainly in the areas of the amygdala, the striatum and the prefrontal cortex (43, 57, 63). Genetic etiological studies suggest an association of a gene x environment interaction of MAOA enzyme deficiency and childhood maltreatment with antisocial behavior (57, 63). Evidence for developmental factors in the etiology of ASPD comes from studies that suggest a link between prenatal factors, such as birth complications, maternal smoking and alcohol consumption during pregnancy, or

prenatal nutritional deficiency, and the occurrence of antisocial and violent behavior (57, 64). Also, an association between maltreatment during childhood and maternal withdrawal in infancy and ASPD has been found (64). These findings suggest, that biological and social factors play a role in the development of ASPD, while “the presence of both factors exponentially increases the rates of antisocial and violent behavior” (64) (p. 4).

For Pedophilic Disorder, reduced amygdala volumes were found in several studies (65, 66). The association between pedophilia and increased rates of left-handedness, more head injuries before age thirteen, and lower intelligence suggest that neurodevelopmental factors play a role in the development of pedophilia (66). These findings support, though do not prove, the idea of underlying neurobiological alterations in Pedophilic Disorder.

However, most of the studies have severe methodological flaws.

For Pedophilic Disorder, most of the studies show a sampling bias in investigating only incarcerated pedophilic child sexual offenders with very scant evidence on non-offending pedophiles (65, 66). It is thus not clear whether alterations found in the brains of pedophilic child sexual offenders are causally contributing to their pedophilic preference itself or whether they are rather associated with offending in general by, for example, contributing to diminished behavioral control or lower intelligence. The latter assumption is supported by a MRT study by Schiffer et al. (67), which provided first evidence that child sexual offending in pedophilia rather than pedophilia alone is associated with structural brain differences. Their study was published in the context of the German multi-sided research network NeMUP that investigated differences between pedophilic and non-pedophilic men, between child sexual offenders and non-offenders, and between convicted and non-convicted (pedophilic) child offenders.¹⁴

In the case of ASPD, the main methodological problem seems to be confounding variables, since most of the persons with ASPD show psychiatric comorbidities like substance use disorder or mood disorders (43). Another problem is the questionable homogeneity of persons that fulfill the criteria of ASPD. A study by Gregory et al. (71), for example, found significant differences in gray matter volume in the prefrontal cortex between offenders with ASPD and additional psychopathic traits and offenders with ASPD without psychopathic traits, but not between offenders with ASPD without psychopathic traits and non-offenders.

These findings show the need for better study designs to get more reliable results. However, even if we get better results, we still face the general problem of interpreting neurobiological

¹⁴The NeMUP researchers found that executive dysfunctions are related to offense status rather than pedophilic preference (68). Furthermore, they revealed that offenders and non-offenders differed in age, intelligence, educational level and experience of childhood sexual abuse, whereas pedophiles and non-pedophiles mainly differed in sexual characteristics (e.g., additional paraphilias) (69). When they compared convicted and non-convicted pedophilic child sexual offenders, they found only two significant differences between the two groups. The convicted offenders had a higher interest in prepubescent children and had committed significantly more sexual offenses against children compared to non-convicted subjects (70). However, significant differences regarding clinical characteristics, inhibition performances, neuronal activation, empathy and impulsiveness between the two groups were not found (70).

differences as indicated above. The finding of a neurobiological difference is not equivalent to a dysfunction, understood in psychological terms. The question of dysfunction is superior to it. An atypical structure or function of the amygdala, for example, is not per se dysfunctional or pathological. The assessment of its dysfunctionality depends on its assumed effects on the psychological and behavioral level, and how these effects are evaluated. An atypical function of the amygdala could even be evaluated as advantageous because it is associated with less anxiety.

Dysfunction in Pedophilic Disorder and ASPD

A crucial point in any discussion about the disorder status of a mental condition is the question if there is a convincing model of dysfunction, understood in psychological terms.

Pedophilic Disorder

With regard to pedophilia, one could argue under an evolutionary account of dysfunction, that it is a form of a sexual dysfunction, assuming that the biologically defined function of sexual arousal (*i.e.* the reason the mechanism of sexual arousal was selected for) lies in its contribution to (potential) reproduction (72) (p. 499), which is clearly not the case in pedophilic sexual behavior. This, however, is an insufficient model of the function of human sexuality. Human sexuality has important functions beyond reproduction, particularly promoting pair bonding and fulfilling emotional needs. Many forms of sexuality that do not pursue reproduction are broadly accepted, *e.g.* sexual intercourse of infertile people, under birth control, or homosexuality. Furthermore, there is no reason not to use a certain function for other, possibly purely hedonistic purposes that have nothing to do with its evolutionary function. The fact that a function is used for other than the alleged evolutionary purposes does not mean that this is dysfunctional.

Some pedophilic men actually state that they are not only interested in sexual contact with children but also look for romantic relationships with them (73). The dysfunction in Pedophilic Disorder thus cannot simply stem from the fact that the sexual arousal is not associated with (potential) reproduction. The concept of a dysfunction in an evolutionary sense falls too short here.

According to DSM-5 and ICD-11, a pedophilic sexual interest is only deemed a mental disorder when it leads to subjective distress or impairment, or has been acted upon.

To assume that having certain sexual fantasies or urges is not pathological but acting according to them is, seems inconsistent. It might be explained by the implicit assumption that there is another dysfunction involved, namely an impaired ability to control one's behavior. To illustrate this point: if a heterosexual teleiophilic man (*i.e.* a man sexually attracted to physically mature individuals) sexually assaults a woman, it is not generally supposed that he must be mentally disordered because he couldn't control his sexual urges. For it is just as possible that he thought the assault was justified, *e.g.* because the woman dressed "lewdly". There is no reason to regard the case of

the heterosexual teleiophilic sexual offender differently from the case of a pedophilic sexual offender who is convinced that his behavior is morally justified, or who just does not respect the rights of children.

Moser (74) rightly argues that a diagnosis of a paraphilia does not imply a lack of the ability to control one's behavior: "Those individuals who cannot control their sexual impulses may qualify for another diagnosis based upon their inability to control their impulses, but not based upon the specific sexual behavior." (p. 323).

This analysis shows that a model of dysfunction measured by moral standards is employed for Pedophilic Disorder. This argument is supported by the fact that the appraisal of sexual activities with children depends on historical and cultural contexts and has been accepted at varying times and cultures (22). This, of course, does not morally justify sexual acts with children. Only cultural relativists would conclude that sexual acts involving children are morally permissible because they are accepted in some cultures. We, however, regard child sexual abuse as a violation of universal human rights, including children's rights. Thus, the fact that child sexual abuse is not sanctioned in some countries is no valid argument against its moral wrongness and its legal prohibition.

ASPD

In the case of ASPD, one could argue that antisocial behavior represents a dysfunction in social functioning. This argument implicitly presupposes that prosocial behavior is normal human behavior. However, under an evolutionary account, in many or even most societies during human history antisocial behavior was probably "adaptive" because it was the "normal and efficient" way to success, both in terms of reproduction and material wealth. Only in civilized societies governed by the rule of law, antisocial behavior becomes less adaptive than prosocial behavior and is considered abnormal and dysfunctional.

Some authors suggested that psychopathy could also be understood in evolutionary terms due to frequency-based selection as "adaptive" behavior (49, 75). According to this idea, a society with a prosocial majority can tolerate a small number of psychopaths that pursue their goals without being restrained by "other-regarding norms". Reimer (49) argues that the typical personality traits of psychopaths, like experiencing less anxiety and being able to resist attempts of "moral" social reinforcing, can also be understood as advantageous under a pro-individualist account of human existence. Maibom argues that psychopathy is not a disorder at all, but "from a certain perspective, what we call deficits are actually advantages" (75) (p. 34).

PRACTICAL ARGUMENTS FOR CONSIDERING PEDOPHILIC DISORDER AND ASPD AS MENTAL DISORDERS

Classifying something as a mental disorder is not only a theoretical question, but also has practical implications that need to be considered.

Most persons with Pedophilic Disorder and ASPD don't seek help (11, 43). For ASPD, individuals presumably often don't feel pain and thus have no motivation to change their condition (46). For Pedophilic Disorder, the possible reasons for not seeking help range from not feeling distressed by it, or not recognizing its potential harmfulness towards others to a lack of knowledge about possibilities to get help and shame and fear of stigmatization (76).

However, as the study of Levenson et al. (76) also shows, some persons with Pedophilic Disorder are willing to get help. As an example, the Dunkelfeld ("dark field") project in Berlin, Germany, a voluntary prevention project for pedophilic men at risk of offending, shows that a significant number of pedophiles seeks help (77).

In many countries, the diagnosis of a mental disorder justifies treatment within the publicly funded health system. For that reason, the diagnoses of ASPD and Pedophilic Disorder can serve a useful purpose for individuals who feel distressed by their condition. If the health system with its long clinical experience can offer help, then it should do so (72).

However, the question is whether we need the diagnoses of Pedophilic Disorder and ASPD so that these persons can get help. For social problems social institutions outside the health system could be conceivable that offer help. Even if these diagnoses were removed from the diagnostic manuals, people could get help within the health system for comorbid conditions like depression or anxiety disorder if these mainly cause their personal distress. In the case of paraphilias, Moser et al. argue that "other psychological characteristics describe these individuals and their concerns more accurately than their sexual interests do" (20). Indeed, 93% of a sample of pedophilic sex offenders showed psychiatric comorbidities, mostly mood and anxiety disorders and substance use disorders (78). ASPD is also associated with anxiety disorders and substance use disorders. For the latter a prevalence of 80–85% among persons with ASPD was reported (43).

One could object that these comorbidities possibly are a consequence of the Pedophilic Disorder or ASPD and therefore the focus of treatment should be the Pedophilic Disorder or ASPD as the primary condition. However, the fact that there are almost no effective treatments for Pedophilic Disorder or ASPD yet indicates that what actually can be treated within the health system might rather be associated disorders like depression, anxiety, or substance use disorder and not ASPD or Pedophilic Disorder itself.

Both, ASPD and Pedophilic Disorder, are supposed to be associated, besides others, with neurodevelopmental factors (57, 66), which makes it difficult to therapeutically intervene as late as in adulthood. The goal of therapies is thus rather the prevention of future deviant behavior in order to avoid harm to others. As Seto (79) puts it regarding Pedophilic Disorder: "Instead of a 'cure', the focus of treatments for nonoffending individuals with pedophilia or hebephilia is the development of more effective self-management, to prevent sexual offending." (p. 209).

The idea of drug treatment with antiandrogens or GnRH analogs (androgen deprivation therapy, ADT) in Pedophilic

Disorder is not to change sexual preference but to reduce sex drive and thereby reduce the risk of (re-)offending. There is, until now, very limited evidence of the efficacy of ADT, and the level of willingness to undergo this kind of treatment is quite low (79, 80). Furthermore, according to a review of studies on behavioral and cognitive-behavioral treatments of pedophilia, there is no reliable evidence of their long-term efficacy (23). There are, however, few hints that it might be possible to actually modify sexual interest in children by, for example, strengthening self-esteem, coping skills, emotional self-regulation, and relationship skills in order to enable men with a sexual interest in children to fulfill their emotional and sexual needs with adult partners (81). Studies on specific techniques, like masturbatory reconditioning in order to suppress deviant sexual interests and/or enhance normative sexual interests, show scant evidence of their efficacy to date (82).

For ASPD, a meta-analysis by Wilson (83) shows no significant effects of treatments. A lack of high-quality studies and small sample sizes might contribute to these findings. Better designed studies with larger sample sizes are required for future research.

It seems necessary to classify ASPD and Pedophilic Disorder as mental disorders in order to facilitate further research on them, gain better insights into their etiology, and develop new therapies. The example of the "psychopathy"-concept, however, shows that there can be a lot of research on a concept without being an official diagnosis in DSM and ICD (44). The psychopathy-checklist (PCL-R) is widely used in forensic contexts to reliably assess the risk potential of criminals with psychopathic traits (24). Since psychopathy does not need to be a diagnosis in DSM and ICD to be a broadly applied concept, it seems that ASPD and Pedophilic Disorder do not need it either.

Similar to psychopathy, ASPD and Pedophilic Disorder are most relevant in forensic contexts (25, 38). Apart from clinical utility, the forensic implications of these diagnoses need to be considered. According to Sexually Violent Predator laws in many U.S. states, sex offenders with a "mental abnormality" and a high risk of re-offending can be indefinitely committed after the prison sentence to protect society from them (84). Even though "mental abnormality" is a legal term referring to an impairment in emotional and volitional capacity that predisposes to the commission of criminal sexual acts and not synonymous with "mental disorder" (85), the diagnosis of a paraphilic disorder, as specified in DSM, is practically mostly accepted as sufficient to ascertain "mental abnormality" (86). Regarding these severe consequences, the definition of the paraphilic disorders in DSM seems especially critical.

CONCLUSIONS

"Vice-Laden Disorders" in Psychiatry

Diagnoses that primarily rely on behavior harmful to others, like Pedophilic Disorder and ASPD, fall out of the general disease concept. They even do not meet the general criteria of mental disorders as defined by DSM-5 or the "harmful dysfunction"

model by Wakefield. Neither the criterion of harm to the individual himself, nor the criterion of a dysfunction are met in these two diagnoses.¹⁵ Instead, they rely on another disease criterion: the criterion of harm to others. Psychiatry brings itself into great conceptual difficulties by making behavior harmful to others/criminal behavior a central part of the definition of some mental disorders, while at the same time lacking a clear concept of dysfunction in these cases. When diagnoses are formulated in a way that makes it possible to apply them to mere antisocial and criminal behavior, psychiatry is at risk of confounding the medical and the moral.

Furthermore, the purely behavioral diagnoses do not reveal whether the behavior is based on a mental dysfunction or whether it was chosen voluntarily or for specific reasons.

Therefore, the formulation of the criteria sets of “vice-laden” disorders needs to be done very cautiously in order to avoid a confusion between criminal/immoral behavior and mental disorder. It should not be possible that harming others/criminal behavior defines a mental disorder. A psychiatric diagnosis should not only rely on observable behavior, but consider psychological, cognitive, or affective factors as well.

After considering the arguments for and against the disorder-status of Pedophilic Disorder and ASPD, we come to different conclusions regarding both diagnoses.

The Disorder-Status of Pedophilic Disorder

In the case of Pedophilic Disorder, we think that the diagnosis should be kept but reformulated in accordance with the general definition of mental disorder in DSM-5 in order to make it consistent with a medical model of mental disorder. This means it should only be applicable to individuals that are distressed or impaired by it so that they can get treatment within the health system. It should not be possible to make the diagnosis solely based on behavior harmful to others. Therefore, we suggest reformulating Criterion B of Pedophilic Disorder as follows: “The sexual urges or fantasies cause marked distress or interpersonal difficulty (e.g. in the context of occupation, family life, friendships, intimate life).” That means, the criterion “The individual has acted on these sexual urges” is cancelled.

Our suggested reformulation of Criterion B is indeed consistent with the form it already had in DSM-IV. As De Block et al. (87) note, the DSM-IV diagnostic criteria were “by far the most consistent vis-à-vis the DSM’s own definition of mental disorder” (p. 291). It was, however, criticized that this criteria set leads to the situation that someone acting on his pedophilic interests without feeling distressed would not be considered mentally ill (88). O’Donohoe et al. (89) argue that rather the lack of experiencing subjective distress when being sexually attracted to children than the experience of distress is a

sign of psychological problems. They do not accept that, according to DSM-IV, a “contented pedophile” does not meet the criteria of a mental disorder. They argue that a person sexually interested in children must be considered in some way socially impaired “because societal norms dictate that it is abnormal for a person to be sexually interested in children” (p. 102). They clearly want to classify pedophilia as a mental disorder for social and forensic rather than for medical reasons. Their postulation that “a single instance of sexual behavior with a child should be sufficient to label someone as having a disorder” (89) (p. 103) confounds criminal behavior with mental disorder.

If pedophilia by itself is not a mental disorder according to DSM-5, then acting according to it cannot be a mental disorder unless there is clear evidence of a dysfunction of volitional control. Impairment of volitional control, however, is not implied in the diagnosis of a paraphilic disorder (85). If we assume that sometimes such impairment is given, then it probably stems from another disease (like e.g. dementia, a brain tumor or mental retardation). If there is no such impairment, we have to assume that this person acted deliberately, and it is not clear why this should be a sign of a mental disorder rather than simply a criminal act.

The DSM-5 warns of the dangers of using a diagnostic manual developed for clinical purposes in the forensic context. For assigning mental disorder in the legal sense “additional information is usually required beyond that contained in the DSM-5 diagnosis, which might include information about the individual’s functional impairments and how these impairments affect the particular abilities in question” (3) (p. 25).

It is important to note that there is a difference between a mental disorder and the US-American legal concept of “mental abnormality”.

We suggest that it should be possible to diagnose a “mental abnormality” in the forensic sense for a person with pedophilia who is neither distressed nor impaired by his pedophilic condition (i.e., who fulfills criterion A but not B according to our suggestion). Even though this person does not meet the criteria of a mental disorder as suggested by us, he might still meet the concept of “mental abnormality” if there is evidence of a high risk of reoffending. We thus suggest that this difference in clinical and forensic use is clearly annotated in the diagnostic criteria of Pedophilic Disorder in DSM. This suggestion is important with regard to other countries than the USA. The DSM is used worldwide for research, and therefore its diagnostic criteria should not be distorted in order to adapt them to the US legal system. In Germany, for example, no diagnosis of a mental disorder is required to order preventive detention after imprisonment; rather the assessment of danger and the prognosis of the probability of recidivism is decisive.

Our intention is not to protect the “contented pedophile”, as long as he is dangerous, from preventive detention or to downplay the harm that child molesters do to their victims in any sense. On the other hand, our suggestion is not meant to preclude the detained child molester from getting treatment if at some point he starts to show insight into his problems and wants

¹⁵However, this conclusion is not equally applicable to definitions of mental disorder that do not require that the individual recognizes the harmful consequences of his condition, like the definition of Graham (59).

to get treated. Rather, we want to separate the medical aspects of Pedophilic Disorder from the societal and forensic implications.

To summarize, our suggestion is as follows. We agree with the differentiation between Pedophilia and Pedophilic Disorder in DSM-5 and suggest adding a category “Pedophilia with mental abnormality” for forensic purposes. Thus, we suggest defining Pedophilia as pedophilic preference without distress/impairment; Pedophilic Disorder as pedophilic preference with distress/impairment; and Pedophilia with mental abnormality as pedophilic preference with sexual offending and high risk of re-offending with or without distress/impairment.

The Disorder-Status of ASPD

In the case of ASPD, however, we think that the arguments to remove it as a distinct diagnosis from the diagnostic manuals are stronger than the ones to keep it. Especially the presumed lack of personal distress of individuals with ASPD and the strong correlation with criminal behavior and incarceration indicate that this diagnosis is more of a social than a mere health-related problem.

We agree with Kröber and Lau (15) who said: “If those with antisocial personalities, like anyone else, are subject to social influences and learning processes, they act as rational and competent citizens; their decision against behaving in compliance with standards should not be considered as pathologic.” (p. 687).

Herpertz and Sass (90) warn of the consequences of confounding antisocial behavior with “real” disorders in forensic psychiatry: “If the forensic psychiatrist fails to distinguish clearly between simple antisocial behaviour and a profound disturbance in personality, psychiatry runs the risk of being charged with handling all kinds of recurrent social deviance and delinquency. This would greatly hamper our capacity to treat those offenders who show real and treatable mental disorders.” (90).

As Gert & Culver (41) put it: “If psychiatry is to take its place as a branch of medicine, mental disorders, like physical disorders, should be limited to conditions that cause harm to the person with the disorder.” (p. 489).

We think that the implementation of a dimensional model of personality disorders, as introduced by ICD-11, will mitigate the problem of attributing a diagnosis of mental disorder to mere criminal behavior. The ICD-11 does not contain the diagnosis “Dissocial Personality Disorder” anymore. Antisocial or dissocial personality traits will then be a specifier among others in the diagnosis of a general personality disorder. Thus, with this new model, the focus will hopefully be more on the cognitive, affective and interpersonal dimensions of personality disorders while avoiding an overly focus on deviant behavior.

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To summarize: We suggest removing ASPD from the DSM, and support the planned removal of the diagnosis DPD from the ICD-11.

Practical Implications

Our suggestion to remove or reformulate the “vice-laden” diagnoses does not imply the demand for stopping research on them—quite the contrary. Especially in the forensic context, it is important to find opportunities to effectively prevent their harmful consequences and develop treatment methods insofar this is possible. The concept of psychopathy shows that an official diagnosis is not necessary for research to be done on forensically relevant conditions.

Regarding Pedophilic Disorder, our suggestions strongly support therapeutic offers (like the Dunkelfeld project) for people who feel distressed or impaired by their condition and seek help.

Regarding antisocial behavior, we think that it is much more of a social problem that has to be addressed more by other societal systems than the health system.

Finally, our suggestions have legal implications in some legal systems. Particularly for the USA, we suggest adding the category of “pedophilia with mental abnormality” in DSM for forensic use in order to separate the clinical and forensic aspects of pedophilia. However, the requirements of the legal systems in some countries are no valid argument against clear conceptual differentiations in the psychiatric diagnostic systems.

AUTHOR CONTRIBUTIONS

Development of the concept (SM, RM). Writing of the paper (RM). Literature research (RM, SM). Discussion of the concept (RM, SM, HW). Editing the text (SM, HW). All authors contributed to the article and approved the submitted version.

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The Role of Parental Capacity for Medical Decision-Making in Medical Ethics and the Care of Psychiatrically Ill Youth: Case Report

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Introduction: Parents/legal guardians are medical decision-makers for their minor children. Lack of parental capacity to appreciate the implications of the diagnosis and consequences of refusing recommended treatment may impede pediatric patients from receiving adequate medical care. Child and adolescent psychiatrists (CAPs) need to appreciate the ethical considerations relevant to overriding parental medical decision-making when faced with concerns for medical neglect.

Methods: Two de-identified cases illustrate the challenges inherent in clinical and ethical decision-making reflected in concerns for parental capacity for medical decision-making. Key ethical principles are reviewed.

Case 1: Treatment of an adolescent with an eating disorder ethically complex due to the legal guardian's inability to adhere with treatment recommendations leading to the patient's recurrent abrupt weight loss.

Case 2: Questions of parental decisional capacity amid treatment of an adolescent with schizoaffective disorder raised due to parental mistrust of diagnosis, disagreement with treatment recommendations, and lack of appreciation of the medical severity of the situation with repeated discharges against medical advice and medication nonadherence.

Discussion: Decisions to question parental capacity for medical decision-making when risk of imminent harm is low but concern for medical neglect exists are controversial. Systematic review of cases concerning for medical neglect benefits from the assessment of parental decisional capacity, review of ethical standards and principles.

Conclusion: Recognition of the importance of parental decision-making capacity as relates to parental autonomy and medical neglect and understanding key ethical principles will enhance the CAP's capacity in medical decision-making when stakes are high and absolute recommendations are lacking.

Keywords: medical neglect, child and adolescent psychiatry, decisional capacity, harm principle, ethical dilemma

INTRODUCTION

With few exceptions, youth under 18 years of age are generally considered to lack capacity and legally cannot provide consent to medical or psychiatric care. Parents/legal guardians are typically viewed as best suited to make treatment decisions for their minor children and as most inclined to act in their child's best interest (1). Child and adolescent psychiatrists (CAPs) treat dependent minors, and it is the parents or guardians who seek services from the CAP. This unique situation creates the potential for ethical conflicts to arise, in that the CAP has obligations to both the minor patient and to the youth's guardian(s). The first principle in the American Academy of Child and Adolescent Psychiatry (AACAP) Code of Ethics is the developmental perspective, which underscores the CAPs duty to "optimize the emotional, cognitive, social and physiological development of all children and adolescents" (2). The developmental perspective is to be incorporated into the CAP's considerations and actions and has implications for the implementation of treatment recommendations. Serious ethical dilemmas arise when the parental right to make decisions about their child (*parental autonomy*) conflicts with the CAP's moral obligation to promote the pediatric patient's welfare (*beneficence*), and provide treatment consistent with best practices. Given the inherent nature of these obligations and likelihood of disagreement regarding treatment recommendations, CAPs are frequently faced with clinical and ethical dilemmas.

Although parental autonomy is widely accepted as the pre-eminent ethical value in the care of minors, the construct of parental decisional capacity provides an important lens in which to view parental autonomy. Decisional capacity is characterized by four key factors: (1) *the ability to demonstrate a consistent preference over time*, (2) *factual understanding* of the situation and treatment proposed, (3) *appreciation of the significance of the information presented*, and (4) *rational manipulation of information* (3). Inability to perform any of the four tasks may result in medical neglect, defined by the American Academy of Pediatrics (AAP) as "... the inability to heed obvious signs of serious illness or follow through a physician's instructions once advice has been sought" (4). Five components have been identified by AAP as necessary to diagnose medical neglect: (1). *A child is harmed or is at risk for harm because of lack of health care*; (2). *The recommended health care offers significant benefit to the child*; (3). *The anticipated benefit of the treatment is significantly greater than its morbidity*; (4). *It can be demonstrated that access to health care is available and not used*; (5). *The caregiver understands the medical advice given* (4).

Medical neglect accounted for 0.8% of reported child maltreatment cases in the United States and accounted for 8.1% of child neglect deaths in 2018 (5). This statistic is likely an underrepresentation, as children who experience medical neglect along with another subtype of maltreatment (i.e., physical or sexual) are reported in a separate, combined category making it difficult to fully appreciate the impact of medical neglect (5). The lack of disease-specific guidelines for managing or reporting medical neglect and wide variation among state reporting requirements have added to the complexity of determining

medical neglect (6). Mental health neglect, defined as "*limiting a child's access to necessary mental health care because of reasons other than inadequate resources*" (4) does not capture the complexity of the factors that may contribute to its diagnosis. Consequently, CAPs may experience a lack of support for their advocacy of minor patients given the limitations of the definition and the lack of attention mental health neglect has received in the literature. A review of available literature yielded only two articles. One article addressed parental medical neglect in the treatment of pediatric depression, and the other examined two case reports of parental medical neglect in the treatment of anorexia nervosa (7, 8).

From an ethics perspective, three main ethical standards have been applied to pediatric cases when issues regarding medical neglect and parental autonomy arise. These are the *best interest standard (BIS)*, *harm principle (HP)*, and *constrained parental autonomy (CPA)*. The BIS articulates the primacy of the child's interests, "protecting the moral claims of children against being undermined or reasonably set aside" (9). The HP delineates the condition for state action to override parental decision-making using the threshold of increased likelihood of imminent harm to the child, in contrast to the child's best interest (1). CPA respects the rights of parents to raise their child according to their values unless their decisions do not promote their child's basic needs and interests (10).

METHODS

Two de-identified cases are presented to illustrate the significant clinical and ethical challenges that arise when parental decisional capacity is questioned in light of nonadherence with recommendations for pediatric psychiatric treatment. Each case is analyzed with respect to AAP's criteria for medical neglect and the four pillars of decisional capacity. The ethical standards relevant to medical neglect as well as core medical ethics principles are discussed. Practical guidance is offered for CAPs and treating clinicians facing similar situations.

CASE 1

An adolescent was referred to the outpatient child and adolescent psychiatry clinic for odd affect, cognitive blunting and psychomotor retardation by a pediatric neurologist who ruled out an underlying neurologic condition upon the request of the patient's legal guardian. The legal guardian was a significantly older sibling who had been independently raising the patient over the last several years. As the adolescent was unaccompanied to the psychiatric appointment it was not possible to elucidate the development of the clinical findings over time. Further assessment was delayed due to a missed follow-up appointment and unreturned phone calls by the guardian. Case management was established after a report concerning for medical neglect was filed by the outpatient CAP. With intensified follow-up, concerns mounted regarding the patient's weight and eating habits, given the BMI drastically dropped from the 50th to the 3rd percentile in 6 months, with clinical signs of an eating disorder. Adequate

food availability at home was confirmed by the case manager. Behavioral interventions and guidelines for close monitoring were outlined by the CAP; however, these were not adhered to at home despite numerous care conferences between the CAP, legal guardian, case manager, and school counselor. The patient demonstrated lack of insight into the illness and endorsed a lack of motivation for change. Psychiatric symptoms progressed to social withdrawal, and self-imposed seclusion in the context of minimal oral intake. The guardian repeatedly vocalized hopelessness considering the patient's unwillingness to eat and hesitation to follow through with the treatment plan due to concern that the patient may run away from home, although the patient had never expressed this intention. Over the course of treatment, the patient was medically hospitalized on multiple occasions due to malnutrition and unstable vital signs. While weight restoration in the hospital occurred without difficulty, weight drastically plummeted soon after discharge home. Reports of concern for ongoing medical neglect were raised to CPS but were not substantiated by the agency.

Case 1 Analysis

AAP's criteria 1–4 for medical neglect are met. The patient experienced malnutrition and unstable vital signs (criterion 1). Most would agree that the benefits of behavioral interventions in context of an eating disorder, namely limit setting and consequences for refusal to eat, are significant (criterion 2) and outweigh the risk of the patient's anger over such limit setting (criterion 3). The access to outpatient providers who wish to work with the patient and the guardian, as well as insurance coverage to do so, satisfies criterion 4.

Criterion 5 (*the caregiver understands medical advice given*) warrants further reflection as the guardian's severely compromised ability to implement treatment recommendations was not clearly due to a lack of understanding those recommendations. Factual understanding is only one of the four pillars of decisional capacity and is not enough to ensure the caregiver is able to make decisions for a minor patient. In this case, it was the lack of *ability to appreciate the significance of the information* about the child's clinical situation (the patient's lack of insight regarding the illness) and limited *ability to rationally manipulate information* (i.e., the concern that by setting consequences the guardian would inadvertently push the patient to run away) which resulted in harm to the patient. Boos and Fortin argue that AAP's criterion 5 (along with criterion 4) "*do not truly differentiate between neglected children or not*," but rather addresses the etiology of the medical neglect. The authors suggest that medical neglect be considered when criteria 1–3 are met (11).

CASE 2

An adolescent was referred to the psychiatric emergency department due to the pediatrician's concerns for psychosis during a routine sports physical. The evaluation revealed irritability, flight of ideas, psychomotor agitation, grandiose delusions, response to internal stimuli, and disorganized speech. Consent for psychiatric hospitalization and medication initiation

was obtained from the patient's legal guardian, a single parent. Collateral information obtained from the patient's teacher and school counselor suggested the presence of prodromal symptoms a year prior, with an episode of psychosis without obvious mood symptoms during the previous academic year. School staff highlighted the parent's rationalization of symptoms as a reaction to psychosocial stressors, which was also prominent throughout hospitalization. The treatment team attempted to form a therapeutic alliance with the patient's parent and provide psychoeducation on schizoaffective disorder, its course, prognosis, and treatment. Despite this, the parent rejected the diagnosis and requested early discharge against medical advice. This was honored as the patient's response to internal stimuli, reality testing, and overall function had improved with psychotropic agents (a mood stabilizer and an antipsychotic). The parent began tapering the patient off of the psychotropic agents without medical guidance immediately after discharge, perceiving them toxic and unnecessary.

Several months later, the symptoms recurred and hospitalization was pursued, again upon the recommendation of the patient's pediatrician, with a similar course and outcome. Several days after discharge, the patient was again brought to the emergency department by police due to an uncharacteristic episode of severe agitation at school. Medication nonadherence was inferred, based on subtherapeutic mood stabilizer levels, as a causal factor in this and each of the subsequent three psychiatric admissions, which occurred over a several-month period and with progressively more serious presentations (with delirious mania and catatonia). Throughout treatment the parent discussed matters related to diagnosis and treatment recommendations with clear overestimation of understanding and knowledge of the clinical situation, and frequently challenged the treatment team's recommendations. The parent continued to identify the patient's restlessness as "*nervousness*" around strangers, delusions as "*humor*," and hypersexuality and intrusiveness as "*friendliness*." Parental underestimation of the seriousness of psychosis and mania, overestimation of ability to provide adequate supervision to the patient in the outpatient setting without treatment, and lack of appreciation as to the deleterious consequences of untreated or undertreated symptoms on future likelihood of symptom response and remission were the concerns highlighted to Child Protective Services (CPS) by the treatment team; however, medical neglect was not substantiated by the CPS agency.

Case 2 Analysis

As in case 1, AAP's criteria for medical neglect 2–4 are easily met. However, how one defines harm and lack of healthcare can generate diverging opinions relative to criterion 1 (harm due to lack of healthcare) (9, 11). Unlike the outcome of refusal to consent for chemotherapy or a blood transfusion (or insulin treatment when applied to a more chronic condition), lack of psychiatric treatment does not generally result in death. Notable exceptions, of course, are hospitalization in the context of acute suicidality and electroconvulsive treatment for catatonia. Failure to treat and failure to adequately maintain continuing therapeutic interventions in cases of

childhood psychiatric illness, however, can result in harm as evidenced by profound negative long-term sequela, including loss of cognitive capacity and significantly reduced lifespan (12). The whole is greater than the sum of its parts; it is the collection of independently non-life-threatening neglectful decisions that truly pose harm to the population of youth with significant mental health disorders, warranting an expansion of the definition of harm beyond acute, immediate life-threatening situations.

Concern for lack of parental capacity for decision making, raised in this case by parental inability to *demonstrate a consistent preference* of the use of medication (i.e., consenting to psychotropic management in the hospital and discontinuing after discharge); a significant deficit in *factual understanding* (of the diagnosis of schizoaffective disorder and indication of medications used); lack of *appreciation of the significance of information presented* (misattributing psychiatric symptoms to the patient's personality); and subsequently the inability to *rationaly manipulate this information*, yet again poses a problem for the fifth criterion. AAP's guidelines place the onus of responsibility on the provider to address any communication barriers or parental medical illiteracy so that the parent may provide informed consent; however, do not offer guidance in the event that such factors are not amendable due to the lack of decisional capacity.

DISCUSSION

The ethical tensions in both cases illustrate the conflicting ethical principles of parental autonomy to make medical decisions for the minor child and the CAP's professional code of ethics to demonstrate benevolence and obligation to treat the patient. Both cases reflect progressive concerns of the minor patient's well-being and attempts made by the treatment teams to resolve disagreements with parent/legal guardian surrounding their care. The characteristics of chronic, complex and unstable medical conditions present in these cases have been recognized as creating the perfect storm that sets the stage for more chances for medical neglect to occur, and for the outcomes of neglect to be quite detrimental (13). The cumulative effects of parental inability to follow through with treatment recommendations is considered by the treatment team to endanger the long-term physical and emotional well-being of the patient. Furthermore, the inability to follow through with recommendations is considered secondary to a compromised parental/guardian decisional capacity rather than malicious or selfish reasons.

There is debate within pediatric ethics as to the preferred ethical standard to be given precedence in challenging situations with regards to parental autonomy, harm to the child, and questions of medical neglect. How do the main pediatric ethical standards address parental autonomy and parental decisional capacity in the context of chronic illness? Parental decisional capacity is not explicitly discussed in the prevailing ethical standards. We support the application of the best interest

standard, as it prioritizes the best interests of the child, and protects the well-being of psychiatrically ill children who often suffer from conditions of longer durations, and who are at risk for or have experienced medical neglect. The BIS can serve as tool for clinicians to help define what is most critical in the treatment of a child (13). The harm principle supports state interference only during imminent harm, excluding the risk for medical neglect associated with chronic illness. To protect parental autonomy, courts grant permission for treatment over parental objections typically in situations where illness or injury is potentially life-threatening (1). Diekema argues, "when a parental refusal does not place a child imminently at significant risk of serious harm, state intervention should be postponed, and attempts made to work with the child's parents or guardians in a non-confrontative manner to resolve the issue" (1). The HP standard, however, does not meet the needs of pediatric patients with severe and persistent psychiatric illness. As criticized by Bester, it "sets the bar too low." Bester claims "parents owe their children much more than harm avoidance," "by using only serious imminent harm as a limiter, we would have to accept some seriously inadequate decisions," and views the best interest standard as the best standard to use in pediatric ethics (9). The constrained parental authority framework states that parents should be able to raise their children in keeping with their own values but are constrained by the basic interests of their children. The term basic interests is open to interpretation, with different value judgments that may not completely align with clinical rationale for course of action and medical decision-making (9).

CAPs appreciate the unique and vital role of parents, the primacy of the parent-child relationship, and often work to strengthen healthy bonds between children and their parents. However, the actions taken by child psychiatrists will be driven by their professionalism, adherence to ethical principles, and sense of duty to act accordingly on behalf of the minor child, especially when failure to act can result in serious harm. CAPs should incorporate the assessment of parental decisional capacity into their practice and re-assessments should occur throughout treatment, particularly as new diagnostic interventions or treatment recommendations are introduced. Children whose parents/legal guardians lack such decisional capacity should be protected against harm as adult patients who lack capacity are protected against harm by the appointment of a surrogate decision-maker. We concur that AAP's first three criteria for medical neglect are the most relevant in diagnosing medical neglect. Rather than using the fifth criterion, we encourage CAPs instead to assess for parental decision-making capacity.

CONCLUSION

This paper adds to the limited literature on psychiatric neglect. The use of case illustrations serves to underscore the concern that the harm principle as applied to medically ill children may significantly miss the mark in protecting children with psychiatric illness from serious, albeit longitudinal, harm.

Medical neglect as applied to pediatric psychiatric conditions may be significantly underrecognized and underreported, and thus, lead to mistreated, undertreated or untreated psychiatric disorders. The AAP criteria for diagnosing medical neglect creates an unintended consequence with criterion 5, in that if a parent/caregiver does not understand the advice given, the threshold to diagnose medical neglect is not met. Child and adolescent psychiatrists and their pediatric medical colleagues are urged to consider the role of parental decisional capacity assessments and appreciate the strengths and limitations of the three prevailing pediatric ethical standards.

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The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

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Moral Dilemmas in Contact-Based Care: The Relevance of Moral Case Deliberation for Forensic Psychiatry

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Currently, forensic psychiatry shows a shift from a control-based to a contact-based approach. Working from contact may, however, entail new moral questions and dilemmas. How to secure safety when focusing on contact? Does contact imply being physically close to the patient, or should one refrain from intimate relations? In order to help care professionals to deal with these moral issues, clinical ethics support can be useful. A specific approach in clinical ethics support is moral case deliberation (MCD). An MCD is a structured dialogue between professionals on a moral issue they experience in practice, structured by a conversation method and guided by a facilitator. In this article, we describe the background and procedures of MCD. Furthermore, we present a case example in which care professionals reflect on the moral question of whether provision of care in forensic psychiatry may entail physical closeness. The MCD shows that an open conversation results in a better understanding of different perspectives and creates the basis for finding a joint way to proceed in the case. We conclude that MCD can enable professionals to reflect on moral issues and develop shared values in forensic psychiatry.

Keywords: forensic psychiatry, clinical ethics support (CES), moral case deliberation, safety, contact-based approach, physical intimacy, moral dilemma

INTRODUCTION

Traditionally, forensic psychiatry is known for a controlling way of working. Consequently, the use of coercion is common, often resulting in seclusion (1). However, control-based care can result in an increased level of aggression and incidents (2, 3). Interventions based on contact instead of control may contribute to less aggression and incidents (4). Moreover, a focus on contact can foster attention for patient autonomy and care. Consequently, a shift can be seen in forensic psychiatry, resulting in increased attention for reduction of coercive measures and an increasing emphasis on patient perspectives and needs (5, 6).

A contact-based approach in forensic psychiatry is promising, but the question is how to shape this in daily practice (4, 6, 7). In a complex situation, many care professionals tend to fall back on control (8). Should one refrain from control, if safety of professionals, the patient, or fellow patients is at stake? Working from contact may also involve new moral questions. Does contact entail physical proximity to the patient? If the patient is angry, should one try to calm him by holding him? If a patient is sad, should he be comforted? How far does a contact-based approach in forensic psychiatry go? These questions can cause moral tensions and doubts among care professionals.

How can professionals in forensic psychiatry be assisted in dealing with moral tensions involved in working from contact? One way to do this is to provide clinical ethics support (CES), fostering reflection on difficult moral issues and providing professionals with tools to handle them. In mental health care organizations, the use of CES is common. However, compared to general psychiatry, CES is not well-established in forensic psychiatry (9). A specific approach in CES is moral case deliberation (MCD). In an MCD meeting, care professionals jointly reflect on a moral dilemma experienced by one of the participants, guided by a facilitator who uses a structured conversation method (10, 11). In this article, we describe the background and procedures of MCD. We also present an example in which professionals in forensic psychiatry reflected on a case in practice. Finally, we discuss the relevance of MCD for dealing with moral tensions in forensic psychiatry.

MATERIALS AND METHODS

MCD is a specific approach in CES that aims to foster systematic reflection on moral questions (10). MCD has a theoretical background in pragmatic hermeneutics and dialogical ethics (12). This background manifests itself by an emphasis on a concrete, practice-oriented case, which is experienced by the participating care professionals themselves, or is easy to envision for them. In an MCD, care professionals engage in a dialogue, aiming at openness to and exchange between perspectives. This can result in a deeper understanding of the concrete moral issue. Overall, the use of MCD aims for a joint learning process of care professionals in which awareness and mutual understanding are fostered (10). Over the years, increased attention has been paid to the use of MCD in Dutch care settings, especially in psychiatry (13).

A widely used conversation method used for MCD is the dilemma method (11). In this method, care professionals are stimulated to reflect on their own moral experiences in practice. Jointly, care professionals with a multidisciplinary background reflect on a case that is brought in by one of the participants. Participants proceed through a series of steps under the guidance of an independent, trained facilitator. In the dilemma method, the situation is defined in terms of two options, two possible actions that are mutually exclusive, and both have moral disadvantages. By doing so, the moral problem becomes concrete for the participants. As a result, care professionals can place themselves in the situation and make their own moral considerations explicit (11). The purpose of this method is to reflect on each other's perspectives in order to come to a new and richer view of the situation. An overview of the steps of the dilemma method is as follows:

Steps of the Dilemma Method (14)

1. Presentation of the case
2. Formulating the moral dilemma
3. Questions for clarification
4. Analysis of the perspectives in the case
5. Exploring alternatives
6. Making an individual judgment

7. Dialogue
8. Evaluation

RESULTS

A Case Example

In this section, we describe an MCD on a ward of a medium-security level forensic care organization in the Netherlands. The MCD was organized because the team was confronted with a complex situation in which it was difficult to prevent escalation. A patient at the ward, S., was agitated, and two care professionals involved in taking care were unable to calm the patient. They did not know how to establish contact with the patient and provide adequate care. By means of a joint reflection, the team aimed to gain more insight into the situation and to find ways to deal with this and comparable situations. In total, 11 care professionals participated with different professions: seven forensic mental health nurses (with a background as nurse or social therapist) and a social worker, psychologist, psychiatrist, and team manager. The duration of the MCD was 120 min. Below is an elaboration of the MCD, following the steps of the dilemma method. Because of privacy reasons, the case has been modified, and all identifying details have been removed, including the gender of the patient.

Presentation of the Case

One of the two forensic mental health nurses involved in the dilemma presented the case. S. is an adult diagnosed with autism and has a low IQ, resulting in S. having a developmental age of a child. S. was referred from another forensic psychiatric hospital in the Netherlands, where S. caused a serious incident, involving verbal aggression and serious physical threats to others and to oneself. Consequently, S. was recently admitted to the present forensic psychiatric hospital.

Because the staff wanted to reduce the stimuli, S. had to remain in a private room most of the day. Four times a day, S. was allowed to go to the living room for half an hour. During these moments, S. was supervised by two care professionals to prevent escalations with fellow patients. This was considered challenging. S. was now 3 weeks on the ward, was often angry, and refused to be supervised by certain care professionals. As the needs of S. differed from the usual population that remains at this ward, care professionals tried to adjust the provision of care.

One morning, two forensic mental health nurses went to the room of S. to wake S. After an hour, they returned to guide S. to the living room. The care professionals noticed that S. acted in a peculiar way, and they asked what was wrong. S. did not respond, became angry, and left the room to go to the laundry room to wash some clothes. S. did not manage to get the washing machine running and became frustrated. S. went to the smoking room, the computer room, the kitchen, and so on. Despite various attempts of the care professionals, it appeared impossible to get in touch with S. S. fell to the ground and started to rage wildly with both legs. As S. was lying on the floor, the two care professionals were in doubt what to do. Should they force S. to go back to the private room, in order to calm down, or should one of them sit down next to S. and try to comfort S.?

Formulating the Moral Dilemma

Based on the explanation of the situation and the doubts of the two professionals, the dilemma was formulated as follows:

A: I force S. back to the private room

B: I sit down next to S. and physically comfort S.

After formulating the dilemma, the participants were asked to make explicit negative consequences of both options. Option A would probably lead to resistance. S. would not cooperate and refuse to go to the private room. As it was likely that S. might get more angry, it would take at least six care professionals to take S. to the room. Consequently, the relation between S. and the care professionals would be damaged. While S. would have to be locked up in the room, contact would be impossible. Also, S. would be confined to the room and deprived of freedom.

Option B would entail that one of the care professionals would sit down next to S. This would make the care professional vulnerable and potentially at risk, as S. was angry and moving wildly. Touching S. might work counterproductive and result in an increase of tension and possible physical risks. Another negative consequence might be that touching S. could result in an uncomfortable feeling, both in the professional who would do so in order to comfort and in other professionals. Finally, care professionals mentioned that other patients might find it unfair as they would receive less attention.

Professionals were also asked to define the moral question central in this dilemma. They formulated the following question: "How (physically) close are you allowed to be in the provision of forensic psychiatric care?"

Questions for Clarification

Next, participants were asked to place themselves in the position of the two care professionals. In order to do so, they might need more information. Thus, all participants were invited to ask questions about the situation. This resulted in a further explanation: the situation took place in the kitchen; other patients watched the situation, and apart from the two care professionals, there were two trainees and a facility worker present at the ward.

Analysis of the Perspectives in the Case

In the next step, participants were invited to consider what was important for the people involved in the case. They focused on the perspective of the two care professionals, S., and other patients at the ward. In order to specify what was important for each perspective, they were asked to formulate values (moral motivations) and for each value the associated norm (rule for action). In this section, we will elaborate on the most important values and norms that were mentioned. For a schematic overview of all the values and norms per stakeholder, see **Table 1**.

First, the care professionals analyzed the perspective of the two care professionals involved in the case. They all regarded safety as an important value. However, while placing themselves in the position of the nurses in the case, the participants translated the value of safety into different norms. For one participant, realizing safety implied: "I should work de-escalating" (care professional A, sociotherapist); another participant translated the

TABLE 1 | Schematic overview of all the values and norms per stakeholder.

Perspective	Value	Norm
Care professionals	Safety	"I should work de-escalating" (care professional A, sociotherapist)
		"I have to provide safety for the patient" (care professional B, nurse)
		"I should avoid danger" (care professional C, nurse)
		"I have to protect my own boundaries" (care professional D, nurse)
	Rest	"I have to limit the amount of stimuli" (care professional E, psychiatrist)
	Good care	"I have to make contact" (care professional F, nurse)
	Professionalism	"I shouldn't make physical contact with patients" (care professional G, sociotherapist)
	Predictability	"I want to be on the same page with my colleagues and with the patient" (care professional H, social worker)
S. (patient)	Clarity	"I should understand"
	Equality	"I would like the same approach from everyone, structure"
	Safety	"I need to know what is about to happen"
	Trust	"I have to be able to trust the staff, that they do what we agreed upon"
	Autonomy	"I have to be able to express myself (unleash emotions)"
	Empowerment	"I should be able to be in the living room, to do my laundry whenever I want"
Other patients at the ward	Equity	"We should receive the same treatment"
	Attention	"We want attention"
	Safety	"We don't want to risk the patient attacking us"
	Rest	"We don't want tension on the group"
		"I already have enough on my mind"

value of safety into "I should avoid danger" (care professional B, nurse); a third participant proposed as a norm: "I have to provide safety for the patient" (care professional C, nurse). Next, the value of care was identified as relevant. Care professional F, a nurse, translated this value into the norm: "I have to make contact." Also, professionalism was regarded as important; one of the participants formulated as corresponding norm: "I shouldn't make physical contact with patients" (care professional G, sociotherapist).

Second, participants placed themselves in the perspective of S. In contrast to the analysis of the perspective of the care professionals, which resulted in differences between participants, they agreed on relevant values and norms for the patient. They regarded clarity to be an important value for S., which was translated into the norm "I should understand." Also, safety was seen as important, which gave rise to the norm "I need to know what is about to happen." Participants also mentioned the values autonomy ("I have to be able to express myself and unleash emotions") and empowerment ("I should be able to be in the living room, to do my laundry whenever I want").

Third, participants identified important values for other patients staying at the ward. Again, they agreed on relevant values and norms. They specifically mentioned equity (“we all should receive the same treatment”) and safety (“we don’t want to risk the patient attacking us”).

Exploring Alternatives

After the participants had identified the values and norms relevant for the different people involved, they were asked to mention possible alternatives. In this step, participants were stimulated to think creatively and let go of standard solutions. Various alternatives were identified, for instance, “ignore S.,” “sing/turn on children songs,” and “put S. in the seclusion room.”

Making an Individual Judgment

The next step was to make an individual moral judgment. Each participant was asked to consider for themselves whether it was morally right to force S. to the private room (A) or sit down next to S. and physically comfort S. (B). Furthermore, care professionals were asked to indicate which value was most important to them in this decision, what they envisioned as the consequential damage of their decision, and how they would try to diminish or repair the damage.

Some care professionals considered it morally correct to do A, which was to force S. to the private room based on the value of safety. A negative consequence of this option was that they would put their own safety first. Also, they would not help S. and damage the values of trust and freedom. To diminish these damages, they would try to clearly communicate and explain the decision to S. This would imply that they would need other colleagues to bring S. to the private room.

Other care professionals considered it morally correct to do B, which implied to sit down next to S. and physically comfort S. based on the value of good care. According to one of the care professionals, S. was actually a child in an adult body. The care professionals choosing this option also saw disadvantages. For example, some care professionals might feel uncomfortable to physically touch a patient. It would also deviate from the usual care at the ward. An extra challenge was that S. would accept certain actions from one professional but not from another. And S. might respond negatively, which would result in danger. To diminish this risk, some care professionals suggested to talk to S. and to explain what they were about to do. To be able to realize this option, they mentioned that they would need sufficient care professionals nearby whom they trust.

Dialogue

After exchanging individual judgments, participants investigated similarities and differences. Similarities entailed the importance to provide good care, to get in contact with S., and to foster safety. There were, however, differences in how to realize these values, especially regarding safety. There were also different views on whether or not to come physically close to and touch the patient.

In a dialogue, the focus is not on defending one’s own position, but on trying to understand the position of the other and its relevance for oneself. How can the action proposed by someone else be helpful in realizing one’s own values? Can different ways

to realize the value of safety be relevant, given the situation? The professionals who went for option B explained that the anger of S. was caused by feelings of insecurity and that forcing S. would probably make this feeling even more pronounced. On the other hand, comforting S. might reduce the fear for not being in control. This might result in de-escalation and more safety for everyone. Of course, the risk remained that this would not work; thus, they proposed to closely monitor the situation and go for option A if necessary. Having option A as a last resource supported the views of those who are afraid that other means might not work and therefore chose this option in their individual judgment.

Next, the question whether physical comfort can be part of forensic psychiatric care was examined in dialogue. Everyone agreed that a professional attitude requires some distance. Yet, in care for children, physical contact is important. Because S. reacted as a child, comforting S. seemed to be in order. Morally speaking, not every care professional could be expected to take this role. Thus, those who did not regard touching a patient as part of their professional identity should not feel obliged to do so. It was agreed that those professionals who tended to respond to S. by sitting down and touching might try to do so, in order to see whether this would work. Thus, the decision was made to first try option B, with professionals positive about touching sitting next to S.; if this would not work, option A would serve an alternative solution, and S. would be brought to the private room.

A subsequent topic for investigation was how to secure good cooperation, as not all professionals responded in the same way. The participants wanted to prevent that the team would become polarized, with a distinction between those who are willing to provide physical comfort and those who do not. The conclusion was that one should be open about this, both to each other and to the patient. As patients’ needs are different, and professionals’ attitudes diverge, it would be important to work together in providing the best care for the individual patient. This should not mean that everyone would provide the same care, but that all would agree on the division of care tasks and support each other, whatever care they individually would provide.

Evaluation

The participants evaluated the deliberation positively. They noticed that the moral concerns and motivations of care professionals for certain decisions, including underlying values and norms for action, had become clear. The participants decided to organize a follow-up meeting. In this meeting, a joint crisis plan would be made. They agreed that everyone should be informed about the plan and feel comfortable with it. The personal limits of care professionals in regard to physically touching this patient should be respected in this plan.

DISCUSSION

The shift in forensic psychiatry from control to contact leads to moral concerns and questions in daily practice. MCD can support professionals in dealing with moral issues, by fostering joint reflection and dialogue. By making explicit core values as

well as various views on how to realize them, MCD can create a basis for more mutual understanding and better cooperation. The case example shows that having a dialogue on how to foster safety and whether to provide physical comfort results in finding new ways to deal with a complex situation, doing justice to the concerns, and experiences of all parties involved.

The case example shows that solutions should be fitted to the specific situation. S. required another approach than other patients. This approach could not be provided by all professionals. The conclusion that professionals should take into account the specific situation is in line with pragmatic hermeneutics, underlining the importance of focusing on concrete, practical problems (10). It is important that care professionals reflect on what is best for a specific patient and on their own boundaries and do not blindly follow a framework that tells them what they should or should not do (15).

This study reveals that in difficult situations, care professionals can be tempted to take control and diminish possible risks (8). Therefore, it is important that care professionals are open to various options and learn how to achieve alternative values. This is also concluded by Steinert: “Eventually, it is necessary to further develop the current practices, away from safety measures imposing severe distress to patients and staff toward interventions, which integrate relationship-building, trust, and the search for agreement into every coercive approach” (16). However, working from contact and dealing with the tensions involved require more than just practical tools. It calls for a change in culture and attitude of care professionals (17). MCD can help to shape this new culture by supporting reflection on values and developing shared way of dealing with difficult situations.

The use of MCD was shown to be useful for the care professionals in the case example. Care professionals concluded that they gained more awareness of each other’s motives and more insight into their own boundaries as a professional. They also appreciated the structure, which in their perception created more mutual understanding and a direction for next steps to take. One of the conclusions in this MCD was that everyone should be respected in their views concerning whether or not to physically comfort a patient and to discuss this openly. These findings are in line with the conclusions of Weidema et al.: “Moral case deliberation is related to mutual support and consultation; improves communication, quality of care, and connection; stimulates critical reflection and brings assertiveness or emancipation to the nursing profession” (18). Other studies likewise emphasize the importance of sharing experiences through reflection and having a dialogue on moral issues in forensic practice (8, 9, 14, 19, 20).

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In this study, we focused on a single MCD to give a concrete and in-depth description of the method and discussed dilemma. In line with case study research, the results are not generalizable; yet, they are transferable to other contexts as they can provide suggestions for interpretation of experiences and for practice improvement (21). This study is in line with other studies, signaling difficulties in comparable transitions within forensic psychiatry, and a need for support and supervision to deal with this (22, 23). Dilemmas of whether or not to touch a patient can arise in this transition, as is also noticed by Weiskopf (24). We recommend follow-up research on dilemmas experienced in the transition from control-based to contact-based care in forensic psychiatry and will undertake such studies in the Netherlands.

CES, in general, and MCD, in particular, may help professionals in dealing with dilemmas in forensic psychiatric care. The case example presented here shows that an open conversation results in a better understanding of different perspectives and creates the basis for finding a joint way to proceed in the case. We conclude that MCD can enable professionals to reflect on moral issues and develop shared values in forensic psychiatry.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

ETHICS STATEMENT

Ethical review and approval was not required for the study on human participants in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

SG was the facilitator of the MCD. BB was team manager of the ward where the MCD took place. All authors participated in the analysis of the MCD, discussions about the analysis and results, revising the work critically and read, revised, and approved the final manuscript.

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Sharing Clinical Notes in Psychotherapy: A New Tool to Strengthen Patient Autonomy

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Clinical psychologists and psychotherapists have an ethical duty to respect patient autonomy (1). This means that before a patient can consent or decline to undergo psychotherapy, clinicians are obliged to present adequate and understandable information about the benefits and risks of the treatments. This conceptualization of informed consent differs from the written legal document executed before many medical procedures in the US. Before patients' right to self-determination, providing the appropriate information may also lead to positive therapeutic benefits: demystifying the psychotherapy process can reduce anxiety, enhance patient trust, and strengthen the therapeutic alliance (2). However, informed consent to psychotherapy is "still not routine" (3) and evidence suggests that its importance is, "probably vastly underestimated by many psychologists" (4).

Against the current shortcomings with disclosure practices in psychotherapy, healthcare is becoming more transparent and "open notes"—inviting patients to read their clinical notes via online portals—is a growing movement. Numerous health institutions in over a dozen countries have begun to share health records with patients (5). In the USA, from November 2020, new federal rules mandate, with few exceptions, the sharing of medical notes; psychotherapy notes remain exempt from this ruling (6). Although fewer health organizations have chosen to share mental health notes (7), all patients have the right to understand their care (8). While many clinicians anticipate workflow problems from sharing notes (9, 10), studies suggest that clinicians do not experience major burdens to documentation practices (11–13).

Addressing the perceived challenges with informed consent processes in psychotherapy contexts, we propose that open notes may provide an important new strategy to strengthen patient autonomy and improve clinical outcomes without sacrificing professional autonomy.

FAILURES AND PERCEIVED CHALLENGES OF INFORMED CONSENT TO PSYCHOTHERAPY

Surveys across different psychotherapy modalities indicate that many therapists may still fail to disclose relevant information about the nature of the treatment being offered, with practitioners expressing divergent views about the importance of informed consent (14, 15). Psychiatrists and practitioners of psychodynamic psychotherapy appear to be more skeptical about the value of informed consent than adherents of other psychotherapy schools, such as cognitive behavioral therapy (14, 16).

In light of ongoing debates about what constitutes evidence in psychotherapy (17–19), questions about the kind of information that should be disclosed presents a challenge to informed consent. Some psychotherapists may worry about confusing or overwhelming individuals who are already vulnerable or anxious by presenting them with too much

information, especially on risks (20). Complicating matters further, consent to psychotherapy is often understood as a process rather than a “one-shot” event with awareness about how psychotherapy works conceived as “procedural knowledge” whereby, it is argued, patients are only able to grasp the nature of therapy as a result of participating in the process (16).

Acknowledgment of these challenges, however, does not obviate the importance of furnishing patients with adequate, relevant, and comprehensible disclosures about psychotherapy (2, 21, 22). Patients have a right to obtain accessible information about the range and nature of psychotherapy treatment options relevant for their condition. Prospective patients should be advised about the estimates of the timing and duration of the treatments, and the risks associated with different psychotherapy options including the decision to decline treatment (23). Although still not standard practice across all psychotherapy traditions, ethicists have strongly urged that brief disclosures about the techniques associated with different modalities should also be communicated (3, 21, 24).

Relatedly, despite disagreements about the relative value of specific techniques in psychotherapy (e.g., of cognitive restructuring in cognitive-behavioral therapies, insight-oriented techniques in psychodynamic therapies) (25–27), there is a widespread agreement among psychotherapy traditions and researchers that the non-specific or so-called “common factors,” such as the working alliance and therapist empathy, mediate the outcomes. Some ethicists propose that there is a moral duty to communicate this to patients (21, 24, 28–30).

Notwithstanding advancements in psychotherapy ethics about the kinds of information that should be disclosed to patients, advice about how best to communicate it remains generic: for example, recent recommendations suggest that disclosures should be conveyed “*verbally and in written form*” [e.g., (21)]. Considerably less attention has focused on how to convey relevant information effectively. Indeed, it is estimated that between 40 and 80% of verbally communicated information in clinical encounters is immediately forgotten or misremembered (31)—a figure that is likely to be even higher among persons who are stressed, anxious, or depressed. Such confusions and misunderstandings may also be exacerbated if patients are reluctant to ask for more information out of embarrassment, fear of “doctor-bothering,” or being perceived as a difficult patient (32).

OPEN NOTES: A TOOL FOR PATIENT AUTONOMY

We propose that giving patients access to their clinical notes may provide an important route to support informed consent in psychotherapy by enhancing patient autonomy, procedural knowledge, and recall about psychotherapy processes.

Enhancing Relational Autonomy

Many clinicians predict that reading clinical notes might lead to widespread patient confusion (9, 12, 33). However, recent research suggests that when patients are invited to read their

mental health notes, this can enhance patient empowerment (7, 34). Expanding on these preliminary findings, we suggest that open notes in mental health contexts may be a valuable tool to augment patient autonomy when this is understood as a relational construct. “Relational autonomy” is the idea that an individual’s capacity to make autonomous decisions is socially-situated, and contingent on interpersonal relations and dependencies. By signaling trust in the patient as a “grown-up” care partner, and by facilitating greater time to reflect on disclosures, open notes may strengthen patients’ sense of agency and can conceivably play a role in improving outcomes (35). Patients express considerable interest in accessing their clinical records, including their mental health notes, and surveys suggest that only small numbers of patients are confused by what they have read (7, 12, 36, 37). These findings are supported by qualitative research where many patients describe enhanced levels of trust and confidence in clinicians, greater understanding about their health and treatment plans, and feelings of personal validation on reading their notes (7, 38–40).

In interpreting autonomy as a relational concept, the role of patients’ trust in clinicians and the strength of the therapeutic alliance are crucial factors to foster a sense of control. Aside from providing adequate and understandable information disclosures, the therapeutic tone and content of clinical notes may also play a causal role in strengthening or diminishing patient autonomy. Importantly, however, some patients do report negative consequences of reading their notes. For example, some survey respondents report being offended or feeling judged by what they read, or detect inconsistencies between the notes and what transpired in therapy sessions (7, 34). Therefore, to cultivate relational autonomy, clinicians will require training on how to write clear, accurate, respectful, and supportive notes (8, 41–43).

Fostering Procedural Knowledge

As noted, a major perceived difficulty with informed consent to psychotherapy is adequately communicating procedural aspects of care; yet, as a result of accessing their psychotherapy notes some patients report a better understanding of what goes on in sessions and greater insight into their personal goals and their progress (7, 34, 36); for example: “[H]elps affirm what I’m working on” (7). Supporting these findings, in a recent study involving patients’ access to psychotherapy notes ($n = 85$), more than half of those surveyed reported that reading their notes was “very important” or “extremely important” for feeling in control of their care (7). Similarly, some psychotherapists observe patients as demonstrating a firmer grasp of what goes on in therapy as a result of reading their clinical notes; as one clinician observed: “[I]t lessens that knowledge gap between the treatment team and the patient in terms of what we’re working towards and how...” (44).

Improving Patient Recall and Engagement

Although research has not directly explored the use of open notes in communicating information about psychotherapy treatment options, techniques, or information about the common factors, evidence from primary care suggests that rapid online access to clinical notes may help to address the limitations of one-shot

disclosures. In major surveys, significant numbers of respondents report better remembering next steps, test results, and referrals (45), and improved adherence to their medications (46).

Preliminary evidence also suggests that patients may derive similar benefits from reading their mental health notes by facilitating recall about what was discussed in psychotherapy sessions; as one patient attested, “[M]y notes came in handy when I had a really bad breakdown. I walked through all of the steps that she taught me” (7). Benefits in helping patients with homework and other skills rehearsal are also clear. Recent findings also suggest that access to clinical notes can deepen patient engagement (36); for example: “Better informed and aware of when something needs clarification” (7).

Limitations

Although findings indicate that open notes in the context of psychotherapy presents a promising approach to augment patient autonomy, currently, survey research has been restricted to small sample sizes limiting the generalizability of the results. As with all surveys, findings are based on self-report which may be biased in favor of participants who feel strongly about open notes, or those who are already more engaged with their psychotherapists and/or health care. Many psychotherapists keep very brief notes and, instead of generalized statements around progress toward goals, the full benefit of sharing will only be realized when proper documentation of sessions is shared. Finally, both in psychotherapy and psychiatry settings, further research is required to investigate whether individuals suffering from severe and persistent mental illness are more vulnerable to harm, anxiety, or confusion as a consequence of accessing their notes.

CONCLUSIONS

Informed consent to psychotherapy presents distinctive problems, including perceived barriers. It is the duty of clinicians to find ways to overcome these challenges. Open notes may present a novel solution to extend the patient’s visit into “online” settings facilitating disclosure about psychotherapy treatment

options, techniques, and other information relevant to decisions about care. To ensure ethical best practice and to harness benefits, and prevent harms (47), we strongly advocate a thorough and practical training and support for psychotherapists on how to write notes that are clear, helpful, and comprehensive, and how to open up dialogue with patients about questions and concerns with what they read in clinical sessions. Such training will not be a “one-shot” event, instead, we envisage that open notes in psychotherapy will require a change of mindset in education and practice. Inevitably, this also mandates a deeper debate about the training of therapists who have learned and adopted styles of note-keeping over the years, or even decades of service. Culture change in healthcare is never easy. However, open notes are here to stay. We argue that clinical notes should not merely be regarded as a repository for documenting patients’ health, rather, open notes should be reconceived as a tool with the potential for ethical functionality—one that has the capacity to strengthen patient autonomy.

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CB wrote the first draft. JW, JT, SO’N, and CB revised the draft multiple times until all authors signed off on the manuscript. All authors contributed to the article and approved the submitted version.

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Corrigendum: Sharing Clinical Notes in Psychotherapy: A New Tool to Strengthen Patient Autonomy

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Keywords: psychotherapy ethics, open notes, patient autonomy, informed consent, electronic health records, evidence-based practice, psychotherapy

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In the original article, there were errors.

1. A correction has been made to the Introductory section, under main heading of paper,

Paragraph 2: “Numerous health institutions in over a dozen countries have begun to share health records with patients.”

2. A correction has been made to the section under heading “**FAILURES AND PERCEIVED CHALLENGES OF INFORMED CONSENT TO PSYCHOTHERAPY**”

Paragraph 1: “such as cognitive behavioral therapy.”

3. A correction has been made to the section under heading: “**FAILURES AND PERCEIVED CHALLENGES OF INFORMED CONSENT TO PSYCHOTHERAPY**”

Paragraph 2: “worry about confusing or overwhelming individuals.”

4. A correction has been made to the section under heading: “**FAILURES AND PERCEIVED CHALLENGES OF INFORMED CONSENT TO PSYCHOTHERAPY**”

Paragraph 4: “Some ethicists propose that there is a moral duty to communicate this to patients.”

5. A correction has been made to the section under heading: “**FAILURES AND PERCEIVED CHALLENGES OF INFORMED CONSENT TO PSYCHOTHERAPY**”

Paragraph 5: “Notwithstanding advancements in psychotherapy ethics about the kinds of information that should be disclosed to patients.”

6. A correction has been made to the section under heading: “**OPEN NOTES: A TOOL FOR PATIENT AUTONOMY**”

Paragraph 1: “We propose that giving patients access to their clinical notes may provide an important route to support informed consent in psychotherapy by enhancing patient autonomy.”

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7. A correction has been made to the section under heading: **“OPEN NOTES: A TOOL FOR PATIENT AUTONOMY and subheading Enhancing Relational Autonomy”**

Paragraph 1: “this can enhance patient empowerment.”

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Paragraph 1: “These findings are supported by qualitative research where many patients describe enhanced levels of trust.”

9. A correction has been made to the section under heading: **“OPEN NOTES: A TOOL FOR PATIENT AUTONOMY and subheading Enhancing Relational Autonomy”**

Paragraph 2: “relational concept, the role of patients’ trust in.”

10. A correction has been made to the section under heading: **“OPEN NOTES: A TOOL FOR PATIENT AUTONOMY and subheading Improving Patient Recall and Engagement”**

Paragraph 1: “suggests that rapid online access.”

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Paragraph 2: “that access to clinical notes can deepen patient engagement.”

12. A correction has been made to the section under heading: **“CONCLUSIONS”**

Paragraph 1: “including perceived barriers.”

13. A correction has been made to the section under heading: **“CONCLUSIONS”**

Paragraph 1: “and how to open up dialogue with patients.”

The authors apologize for this error and state that this does not change the scientific conclusions of the article in any way. The original article has been updated.

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Influencing Factors and Machine Learning-Based Prediction of Side Effects in Psychotherapy

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Background: Side effects in psychotherapy are a common phenomenon, but due to insufficient understanding of the relevant predictors of side effects in psychotherapy, many psychotherapists or clinicians fail to identify and manage these side effects. The purpose of this study was to predict whether clients or patients would experience side effects in psychotherapy by machine learning and to analyze the related influencing factors.

Methods: A self-compiled “Psychotherapy Side Effects Questionnaire (PSEQ)” was delivered online by a WeChat official account. Three hundred and seventy participants were included in the cross-sectional analysis. Psychotherapy outcomes were classified as participants with side effects and without side effects. A number of features were selected to distinguish participants with different psychotherapy outcomes. Six machine learning-based algorithms were then chosen and trained by our dataset to build outcome prediction classifiers.

Results: Our study showed that: (1) the most common side effects were negative emotions in psychotherapy, such as anxiety, tension, sadness, and anger, etc. (24.6%, 91/370); (2) the mental state of the psychotherapist, as perceived by the participant during psychotherapy, was the most relevant feature to predict whether clients would experience side effects in psychotherapy; (3) a Random Forest-based machine learning classifier offered the best prediction performance of the psychotherapy outcomes, with an F1-score of 0.797 and an AUC value of 0.804. These numbers indicate a high prediction performance, which allowed our approach to be used in practice.

Conclusions: Our Random Forest-based machine learning classifier could accurately predict the possible outcome of a client in psychotherapy. Our study sheds light on the influencing factors of the side effects of psychotherapy and could help psychotherapists better predict the outcomes of psychotherapy.

Keywords: side effects, psychotherapy, machine learning, online survey, China

INTRODUCTION

Psychotherapy is the process in which a trained professional therapist uses guided conversations to facilitate changes in thoughts, feelings, and behaviors (1). People receiving psychotherapy expect positive change because it has proven to be effective for most clients or patients (2). However, one issue that has not been seriously considered is that after an individual enters psychotherapy, symptoms or clinical outcomes may be aggravated or worsen, and even cause harm (3). Unfortunately, many psychotherapists or clinicians fail to identify and manage these side effects, mainly due to insufficient awareness of the side effects of psychotherapy (4–6). Most studies on the effects of psychotherapy to date have focused on positive outcomes, with little attention paid to negative effects. To better understand whether harmful outcomes of psychotherapy were routinely collected and reported, a study analyzed 132 randomized, controlled trials. The researchers found that only 21% of these trials monitored harm to patients, and only 3% of the trials described adverse events (7).

A national survey (National Audit of Psychological Therapies, NAPT) conducted in England and Wales showed that 5.2% of people reported the long-lasting negative effects of psychotherapy (8). In a study about the adverse effects of psychotherapy in depressed patients ($n = 135$), 38.5% of patients reported having at least one side effect (9). Another study reported that the incidence of side effects in psychotherapy was 21%, and the most frequent side effects were “negative wellbeing/distress” (27% of patients), “worsening of symptoms” (9%), and “strains in family relations” (6%) (10). In outpatient cognitive behavioral therapy (CBT), up to 84% of outpatients reported having at least one unwanted side effect (11). It was estimated that the incidence of the adverse effects of psychotherapy, including long-lasting effects, was between 3 and 15% (12). Therefore, reports of the negative side effects of psychotherapy differed.

Many factors may affect the occurrence of side effects in psychotherapy. In the NAPT (8), people over 65 reported relatively few lasting negative effects of psychotherapy, while sexual and ethnic minorities were more likely to report them. Interestingly, when patients’ treatment preferences were satisfied, they were more likely to report that the treatment had helped them solve their problems (13). Otherwise, they would experience more negative effects. The treatment preferences included “choice of venue,” “time of day of appointments,” “gender of the therapist,” “language/ interpreter,” and “type of treatment.” Therapist factors were also closely related to the outcomes of psychotherapy. The National Institute of Mental Health Treatment of Depression Collaborative Research Program (14) indicated that approximately 8% of the outcome variance in psychotherapy was attributed to the therapist. Another study showed that ~8% of the total variance and ~17% of the variance in rates of patient improvement could be attributed to the therapists (15). The personal attributes of the therapist, such as rigidity, uncertainty, criticism, alienation, tension, and distraction could negatively affect the outcomes of psychotherapy (16). In addition, many surveys have shown

that the type of psychotherapy was also an important factor that affects side effects (8, 13, 17). Significantly more patients were treated with psychodynamic therapy and reported having “lasting negative effects” than those without psychodynamic therapy (8). Among the high-risk patients with side effects of psychotherapy, 11.6% were treated with CBT, 4.2% were treated with systemic therapy, 16.8% were treated with humanistic psychotherapy, and 67.2% were treated with psychodynamic therapy (17). In short, many factors are related to the side effects of psychotherapy, but we are still not sure which factors are the most relevant predictors of side effects in psychotherapy. Psychotherapists or clinicians cannot obtain a clear clinical practice outline of psychotherapy from past studies to reduce or avoid these side effects. Moreover, sensitivity to the side effects of psychotherapy is a characteristic of good therapists, which can significantly improve the quality of treatments (18). To solve these problems, our study implemented machine learning in the prediction of the side effects of psychotherapy.

Machine learning is a subfield of artificial intelligence, which builds a model to make a prediction or decision by learning from data. In the field of clinical psychology and psychiatry, this technique has been used for disease diagnosis, treatment prediction, and to some extent, the detection as well as the monitoring of potential biomarkers (19). There is currently no computational model that can predict whether a client/patient will experience side effects in different conditions. This study focuses on the side effects of psychotherapy, examining whether we can use machine learning technology to find out the potential clients/patients who might experience side effects in psychotherapy. This may have practical significance for improving the effectiveness of psychotherapy.

In the present study, we adopted six supervised machine learning-based models to predict whether clients or patients would experience side effects in psychotherapy, and compared the efficacy of these models to achieve the best prediction classifier. We analyzed various factors related to the generation of side effects and explored which factors were more relevant to these side effects. This research aims to provide psychotherapists with valuable information about the side effects of psychotherapy, thereby improving the effectiveness of daily clinical practice.

METHOD

Psychotherapy Side Effects Questionnaire (PSEQ)

Based on previous research results (20, 21), the “*Psychotherapy Side Effects Questionnaire (PSEQ)*” was compiled. In the PSEQ, the side effects in psychotherapy were defined as unwanted events that clients perceived during psychotherapy, which were inconsistent with expected goals and had a negative impact on clients. The side effects of psychotherapy were judged according to the answers to the first question: “Have you experienced any side effects or harm during your psychotherapy?”. An

TABLE 1 | Features of participants included in the dataset.

Features	With side-effects (n = 115)	Without side-effects (n = 255)	Overall	P-value
Gender				0.643
Male	14 (12.2%)	49 (19.2%)	63 (17.0%)	
Female	101 (87.8%)	206 (80.8%)	307 (83.0%)	
Age				0.029*
≤29	41 (35.7%)	89 (34.9%)	130 (35.1%)	
30-49	71 (61.7%)	145 (56.9%)	216 (58.4%)	
≥50	3 (2.6%)	21 (8.2%)	24 (6.5%)	
Marriage status				0.274
Single	40 (34.8%)	63 (24.7%)	103 (27.8%)	
Single with partner	12 (10.4%)	28 (11.0%)	40 (10.8%)	
Married	56 (48.7%)	152 (59.6%)	208 (56.2%)	
Divorced, separated or widowed	7 (6.1%)	12 (4.7%)	19 (5.1%)	
Kids				0.313
Yes	51 (44.3%)	148 (58.0%)	199 (53.8%)	
No	64 (55.7%)	107 (42.0%)	171 (46.2%)	
Psychotherapy at least once within the past 3 months				0.771
Yes	81 (70.4%)	189 (74.1%)	270 (73.0%)	
No	34 (29.6%)	66 (25.9%)	100 (27.0%)	
The form of psychotherapy				0.208
Face to face	88 (76.5%)	216 (84.7%)	304 (82.2%)	
Phone	9 (7.8%)	19 (7.5%)	28 (7.6%)	
Video	18 (15.7%)	20 (7.8%)	38 (10.3%)	
Cost (China Yuan/Time)				0.869
<200	25 (21.7%)	77 (30.2%)	102 (27.6%)	
200~400	45 (39.1%)	54 (21.2%)	99 (26.8%)	
400~600	19 (16.5%)	50 (19.6%)	69 (18.6%)	
600~800	15 (13.0%)	38 (14.9%)	53 (14.3%)	
>800	11 (9.6%)	36 (14.1%)	47 (12.7%)	
Effects of psychotherapy				0.011*
Invalid	17 (14.8%)	7 (2.7%)	24 (6.5%)	
Limited effect	21 (18.3%)	32 (12.5%)	53 (14.3%)	
Some effect	41 (35.7%)	100 (39.2%)	141 (38.1%)	
Good effect	23 (20.0%)	68 (26.7%)	91 (24.6%)	
Very effective	13 (11.3%)	47 (18.4%)	60 (16.2%)	
Problem solved completely	0 (0.0%)	1 (0.4%)	1 (0.3%)	
The main causes of side-effect in psychotherapy				
The characters of psychotherapy skills	34 (29.6%)	65 (25.5%)	99 (26.8%)	0.483
Improper use of psychotherapy skills	44 (38.3%)	75 (29.4%)	119 (32.2%)	0.165
Limited professional ability of psychotherapists	81 (70.4%)	127 (49.8%)	208 (56.2%)	0.014*
Client's mental activity	45 (39.1%)	151 (59.2%)	196 (53.0%)	0.014*
Psychotherapist's mental activity	63 (54.8%)	76 (29.8%)	139 (37.6%)	<0.001*
Other unpredictable factors	43 (37.4%)	120 (47.1%)	(4.1%)	0.195
Assessment and diagnosis by psychiatrists				0.622
Yes	54 (47.0%)	102 (40.0%)	156 (42.2%)	
No	61 (53.0%)	153 (60.0%)	214 (57.8%)	
Medicine or physical therapy by psychiatrists				0.738
Yes	47 (40.9%)	92 (36.1%)	139 (37.6%)	
No	68 (59.1%)	163 (63.9%)	231 (62.4%)	

(Continued)

TABLE 1 | Continued

Features	With side- effects (n = 115)	Without side-effects (n = 255)	Overall	P-value
The willingness to seek psychotherapy in the future				0.040*
Yes	79 (68.7%)	211 (82.7%)	290 (78.4%)	
No	6 (5.2%)	11 (4.3%)	17 (4.6%)	
Not sure	30 (26.1%)	33 (12.9%)	63 (17.0%)	
The theoretical orientation of psychotherapy				0.002*
Psychoanalysis or psychodynamic therapy	53 (46.1%)	81 (31.8%)	134 (36.2%)	
Cognitive behavioral therapy	12 (10.4%)	20 (7.8%)	32 (8.6%)	
Humanistic therapy	6 (5.2%)	8 (3.1%)	14 (3.8%)	
Family or couple therapy	15 (13.0%)	59 (23.1%)	74 (20.0%)	
Narrative therapy	6 (5.2%)	26 (10.2%)	32 (8.6%)	
Unclear	23 (20.0%)	61 (23.9%)	84 (22.7%)	
The place for psychotherapy				0.048*
Hospitals	29 (25.2%)	82 (32.2%)	111 (30.0%)	
Schools	11 (9.6%)	26 (10.2%)	37 (10.0%)	
Commercial psychological counseling agency	40 (34.8%)	107 (42.0%)	147 (39.7%)	
Commercial psychological counseling network platform	17 (14.8%)	17 (6.7%)	34 (9.2%)	
Others	18 (15.7%)	23 (9.0%)	41 (11.1%)	

* $P < 0.05$ was considered statistically significant.

answer “yes” was considered to have side effects, otherwise, there was no indication of side effects. Seven questions in the PSEQ were designed to assess these side effects from three dimensions: symptoms, relationships, and social function (Table 2). Three questions were designed to assess the presence of new symptoms, which included negative emotions (Does psychotherapy make you feel bad?), bad behaviors (Does psychotherapy make you behave badly?), and physical discomfort (Does psychotherapy make your physical health uncomfortable?). One question was used to assess the original problem (Does psychotherapy make your problem worse?). Two questions were used to assess negative changes in family relationships (Does psychotherapy make your family relationship tense?), and interpersonal relationships (Does psychotherapy make your personal relationships tense outside of your family?). The last question was used to assess negative changes in social function (Does psychotherapy make your job worse?).

In order to predict the outcomes of psychotherapy, we collected the following information from each participant in the PSEQ: participant demographics (gender, age, marriage status, kids), whether they had received psychotherapy in the last 3 months (yes/no), the form of psychotherapy (face to face, phone, video), cost per psychotherapy, the effects of psychotherapy (invalid, limited effect, some effect, good effect, very effective, problem solved completely), the main causes of side effects in psychotherapy (the characters of psychotherapy skills, improper use of psychotherapy skills, limited professional ability of psychotherapists, client’s mental activity, psychotherapist’s mental activity, or other unpredictable

factors), assessment and diagnosis by psychiatrists, medicine or physical therapy by psychiatrists, the willingness to seek psychotherapy in the future, the theoretical orientation of psychotherapy (psychoanalysis or psychodynamic therapy, cognitive behavioral therapy, humanistic therapy, narrative therapy, or unclear), and the place where psychotherapy took place (hospital, school, commercial psychological counseling agency, commercial psychological counseling network platform, others). Table 1 lists detailed information on each feature. The prepared questionnaire was sent to ten examiners for content feedback, and then revised again based on this feedback to create the final version of the PSEQ. In this survey, the Cronbach’s α of the PSEQ is 0.74, indicated an acceptable internal consistency. The sociodemographic information and characteristics of the psychotherapy the participants received were also investigated.

Procedure

The questionnaire was edited and released through the WeChat platform on February 11, 2019. WeChat is the leading mobile social network in China, with over 1 billion users. Participants read and decided whether to fill out the questionnaire according to the inclusion criteria. The questionnaire could only be submitted after participants agreed and gave their informed consent. The questionnaire was anonymous. The mode of dissemination was mainly based on reposting and sharing among WeChat users. Participants were encouraged to forward the questionnaire to various professional WeChat discussion groups of which they were part. They filled out the questionnaire online using the mobile phone interface provided by WeChat. The

TABLE 2 | The types of consulting side effects experienced by participants.

Content of side-effects in the survey	n (%)
Does psychotherapy make you feel bad?	91 (24.6%)
Does psychotherapy make you behave badly?	41 (11.2%)
Does psychotherapy make your physical health uncomfortable?	40 (10.8%)
Does psychotherapy make your family relationship tense?	36 (9.7%)
Does psychotherapy make your personal relationship tense outside of your family?	33 (8.9%)
Does psychotherapy make your problem worse?	32 (8.6%)
Does psychotherapy make your job worse?	30 (8.1%)

completion time for each questionnaire was about 3 min. Each WeChat user could only fill in the questionnaire once. The information collected by the questionnaire was automatically generated into an excel form. Data collection stopped on March 17, 2019.

Participants

Participants were enrolled through an online questionnaire on their WeChat official account from February 11 to March 17, 2019. The inclusion criteria were: (1) that they had received at least one session of psychotherapy in the last six months; (2) that they were aged between 18 and 70 years old; and (3) that they gave informed consent. The exclusion criteria included: (1) a serious mental disorder with a risk of suicide and injury; (2) an education level below primary school; and (3) if they did not consent to the public release of research data.

Machine Learning-Based Analysis

We aimed to build a binary classifier that was able to distinguish participants with or without side effects from psychotherapy, based on their selection in the designed PSEQ. In our dataset, we chose participants “with side effects” category as the positive class. All the features used for machine learning analysis are described in **Table 1**. The process of our supervised machine learning-based analysis included the following steps: raw data preprocessing, feature selection, algorithm selection, parameter tuning, and performance evaluation. The workflow is described in **Figure 1**.

In the collected dataset, 115 participants reported having side effects from psychotherapy, while 255 participants had no or unclear side effects (“without side effects” group). To solve the unbalanced sample problem, we oversampled the minority type to 255 by the SMOTE technique (22). Then, we randomly split the entire dataset into a training and validation dataset and a test dataset. We used 70% of participants for training and validation and the remaining 30% for the test. We further used the 5-fold cross-validation method, where the training dataset was randomly divided into 5 subsets with equal sample sizes. Each of the 5 subsets was retained as validation data to evaluate the

model, with the remaining 4 subsets used for training. The cross-validation process was repeated 5 times, with each of the 5 subsets used once for validation.

The machine learning algorithms selection used classical algorithms such as Random Forest (23), Logistic Regression (24), Support Vector Machine (SVM) (25), and AdaBoost (26), as well as emerging algorithms, i.e., XGBoost (27) and CatBoost (28). In particular, Random Forest is a widely used machine learning algorithm that uses a number of decision trees for learning. These decision trees collaborate as an ensemble to make the prediction. For a selected algorithm, we needed to determine an optimal set of parameters. Based on the training dataset, we applied a grid search to go through the parameter space. We selected a finite set of values for each parameter to form the parameter space. The grid search was iterated through a set of parameter combinations. For each combination, we evaluated prediction performance. Finally, we recorded the parameters leading to the maximum F1-score based on the training and validation dataset. Scikit-learn, a Python-based machine learning library, was used to train and evaluate the classification models (29).

For the model evaluation, we used precision, recall, F1-score, and the AUC (Area Under the ROC Curve) value to evaluate the prediction performance of our trained models (30). Specifically, precision is the fraction of participants with psychotherapy side effects classified by the model who did have side effects. The recall is the fraction of participants with side effects who had been correctly identified by the model. The F1-score is the harmonic mean of precision and recall, and was calculated as follows:

$$F1 = \frac{2 \times \text{precision} \times \text{recall}}{\text{precision} + \text{recall}} \quad (1)$$

An F1-score reached its best value at 1 and the worst value at 0. From the perspective of psychologists, high precision means that our prediction rarely over reported and indicates that participants will likely have side effects when they are predicted with psychotherapy negative outcomes. Meanwhile, high recall means that our predictions rarely under report participants that will have side effects. A higher value of the F1-score indicates a better overall prediction performance of a classifier.

AUC is another important evaluation metric for examining the performance of a classification model and denotes the probability that a classifier will rank a random positive instance higher than a randomly chosen negative instance. The value of AUC is also between 0 and 1. For a perfect classifier, the AUC value will be 1. For a completely random classifier, the AUC value will be 0.5. In our work, the higher the AUC value, the better the model was at distinguishing participants with or without side effects from psychotherapy.

Statistical Analysis

Statistical analyses used the Python programming language. The *P*-values in **Table 1** were calculated by the Chi-Square test. *p* < 0.05 was considered statistically significant. We used the Chi-Square (χ^2) statistics (31) to evaluate the dependence of a selected feature and the categories of participants (with or without side effects). We calculated the χ^2 value based on the category

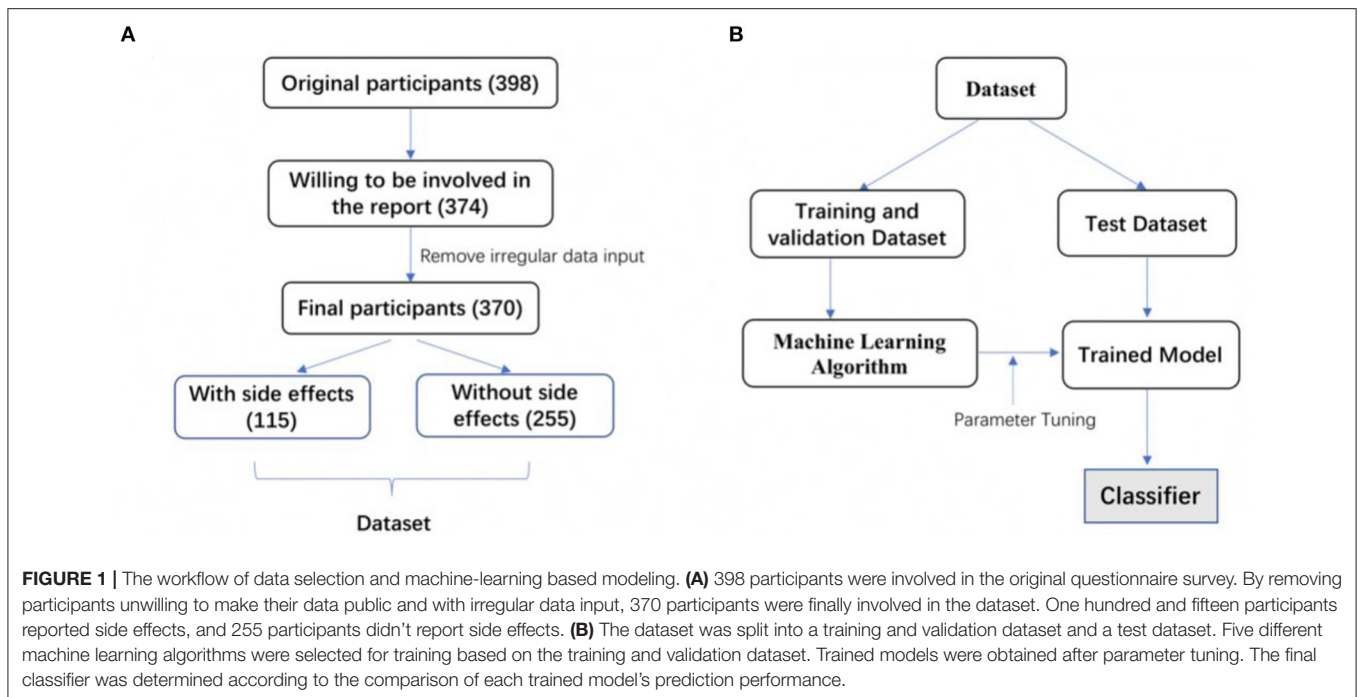


TABLE 3 | The ranking of feature importance.

Rank	Features	Chi-square value
1	Psychotherapist's mental activity	13.163
2	The theoretical orientation of psychotherapy	9.715
3	Effects of psychotherapy	6.455
4	Client's mental activity	6.036
5	Limited professional ability of psychotherapist	6.001
6	Age	4.758
7	The willingness to seek psychotherapy in the future	4.228
8	The place for psychotherapy	3.906

information of participants and feature values. A larger χ^2 value indicated a better discriminative power of a feature. According to the χ^2 values, the top 8 ranked features that contributed most to differentiating participants with or without side effects from psychotherapy are presented in **Table 3**.

RESULTS

Participant Demographics

A total of 398 participants filled in the PSEQ online. Twenty-eight participants (7.0%) were excluded from analysis because of their unwillingness to be included in published data or irregular data input. As a result, 370 participants were included for further analysis. The mean age of the participants was 34.6 years (SD = 10.4 years). The database comprised 14 main features, where each feature was either numerical or categorical. The detailed number, percentage, and classification of participants with each feature were shown in **Table 1**.

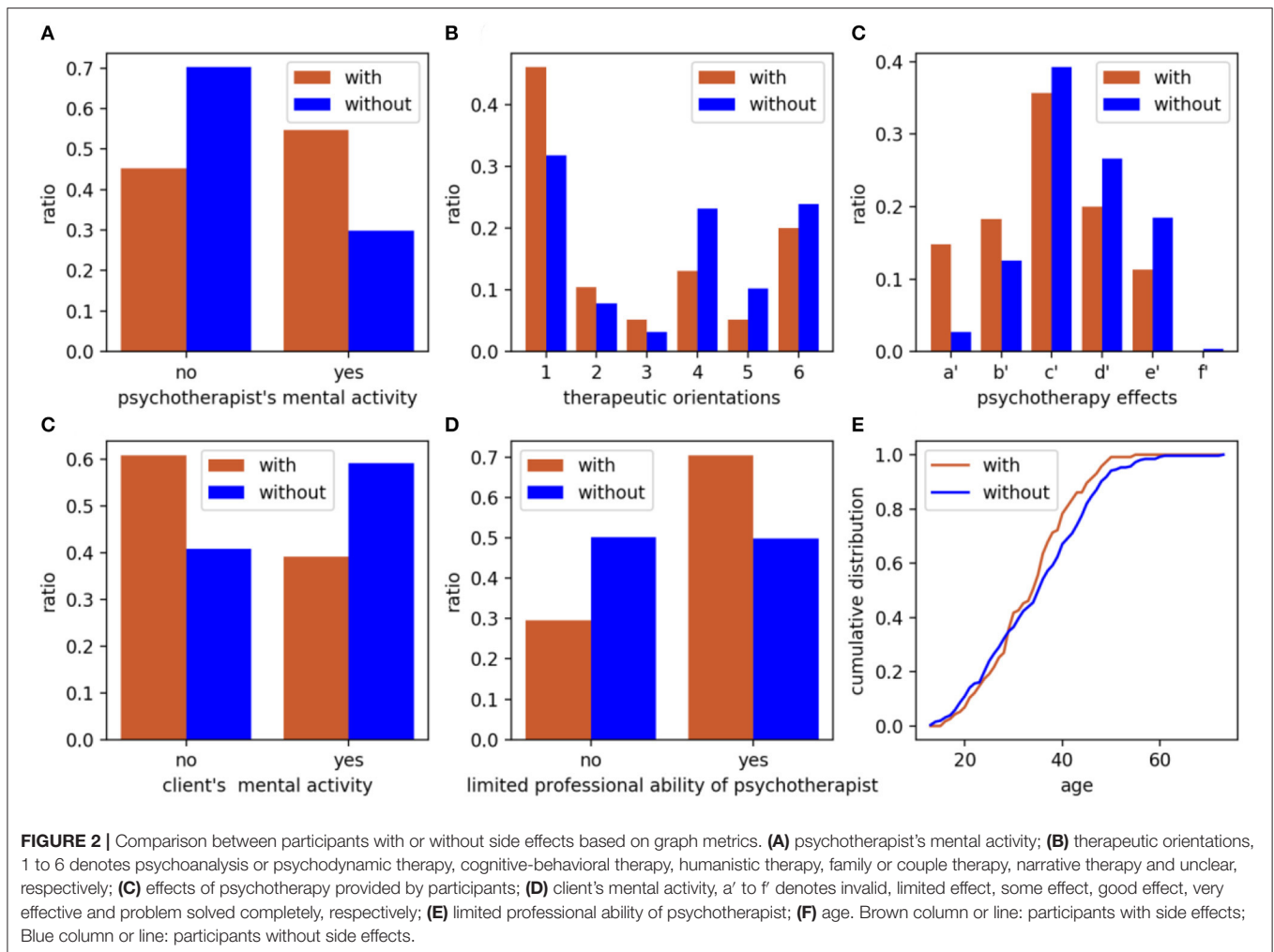
The Types of Side Effects Experienced by Participants

Except for positive outcomes, many participants experienced different kinds of side effects in psychotherapy. Among the 370 participants, 115 participants reported having experienced side effects in psychotherapy. The incidence of side effects in the survey was 31.1%. The most common side effect was that participants “feel bad in psychotherapy” (24.6%), while the response “psychotherapy makes your job worse” (8.1%) was less common. In our PSEQ, we listed 7 types of common psychotherapy side effects. The detailed types and the incidence of each side effect are described in **Table 2**.

Feature Importance in Differentiating Participants With or Without Side Effects

The effectiveness of psychotherapy varied with the characteristics of each participant, as well as the different treatments provided by the psychotherapist. Next, we employed the Chi-Square statistics to quantify the discriminative power of each feature to the categories of participants. In total, 19 detailed features were included in this analysis. “Psychotherapist’s mental activity” contributed most to the side effects of participants. The second highest ranked feature was “the theoretical orientation of psychotherapy.” The top 8 ranked features that have the greatest impact on distinguishing whether participants have side effects are listed in **Table 3**.

To visualize the difference between participants with or without side effects, we compared the two groups of participants in terms of the psychotherapist’s mental activity, the theoretical orientation of psychotherapy, the effects of psychotherapy, the client’s mental activity, the limited professional ability of



psychotherapist, and age, as shown in **Figure 2**. Participants who experienced side effects were more likely to think that the mental activity of the psychotherapist would cause harm to them, according to **Figure 2A**. Participants who experienced side effects were more concentrated in the middle age range, as shown in **Figure 2F**. Overall, we found that there were significant differences between the two groups in terms of the psychotherapist's mental activity, theoretical orientation, and the ability of psychotherapists, and the mental activity and age of clients.

Machine Learning Algorithms and Predicting the Outcomes of Psychotherapy

In the present study, we employed supervised machine learning algorithms to predict whether a participant would experience side effects of psychotherapy treatment. In our dataset, 115 participants reported having side effects after psychotherapy, and 225 participants did not report side effects (**Figure 1A**). We then built a binary classifier that was able to classify participants with or without side effects more accurately. We used six different representative machine learning algorithms, Random Forest,

XGBoost, CatBoost, Logistic Regression, SVM, and AdaBoost, to build classification models. Our results showed that the F1-scores of each of these six models (Random Forest, XGBoost, CatBoost, Logistic Regression, SVM, and AdaBoost) were 0.797, 0.788, 0.768, 0.765, 0.760, and 0.739, respectively (**Table 4**). Each model's precision and recall are also described in **Table 4**. The AUC values of each of these six models (Random Forest, XGBoost, CatBoost, Logistic Regression, SVM, and AdaBoost) were 0.804, 0.802, 0.772, 0.772, 0.765, and 0.735, respectively. Our data indicate that the Random Forest-based classifier achieved the highest F1-score of 0.797 and AUC value of 0.804, thus offering the best prediction between participants with or without side effects from psychotherapy.

DISCUSSION

To the best of our knowledge, the present study was the first to explore the side effects of psychotherapy in a Chinese sample. This study analyzed the side effects of psychotherapy and the related factors that cause them and applied machine learning techniques to predict whether clients or patients would

TABLE 4 | Comparison of the performance of different machine learning algorithms to predict the side effects in psychotherapy.

Classifier	Precision	Recall	F1-Score	AUC
Random Forest	0.787	0.808	0.797	0.804
XGBoost	0.812	0.767	0.788	0.802
CatBoost	0.744	0.795	0.768	0.772
Logistic Regression	0.750	0.781	0.765	0.772
SVM	0.740	0.781	0.760	0.765
AdaBoost	0.690	0.795	0.739	0.735

experience side effects. Based on our results, we concluded that: (1) the most common psychotherapy side effect was a negative emotion during psychotherapy, such as anxiety, tension, sadness, and anger, etc. (24.6%); (2) that the mental state of the psychotherapist, as perceived by the participant during psychotherapy, was most relevant in determining whether clients would experience side effects; and (3), that the Random Forest-based machine learning classifier offered the best prediction performance for distinguishing participants with or without side effects, with an F1-score of 0.797 and an AUC value of 0.804. In summary, our classifier can help therapists identify clients who may have side effects in psychotherapy, enabling therapists to provide patients/clients with better services.

In the survey, 31.1% of respondents reported experiencing side effects during psychotherapy. The most common side effect was that they “feel bad in psychotherapy” (24.6%). In the PSEQ, “feel bad” referred to a negative emotion experienced by participants in psychotherapy, such as anxiety, tension, sadness, and anger, etc. The results of our study were similar to those of previous studies (11, 12). However, more research has shown that the incidence of side effects in psychotherapy varied greatly from 3 to 84% (8, 11, 12, 20), and the clinical features were also different. The main reason for inconsistent results on the side effects of psychotherapy could be because there was no unified definition of side effects, and there was difficulty in selecting samples, especially concerning the influence that different theoretical approaches to psychotherapy can have on potential side effects (20, 21).

In the present study, we further analyzed the influencing factors related to psychotherapy side effects. Our results showed that the “psychotherapist’s mental activity” was the most relevant feature in determining whether participants experienced side effects. In our survey, “psychotherapist’s mental activity” referred to the psychotherapist’s psychological state as deduced by the client during their interaction. Therapist factors mediate the outcomes of psychotherapy mainly through therapeutic alliance. On average, therapists who developed stronger alliances with their patients achieved better therapeutic results (32). According to Jennifer, Jonas, and Sylke (33), the negative effects of psychotherapy were particularly evident after a therapist had used controlling and challenging statements. In other words, failure to establish a strong therapeutic alliance between the therapist and the patient is a potential risk factor for treatment side effects. A good therapeutic alliance can be fostered in

a supportive and reinforcing context, where less stressful interventions take place and the therapeutic relationship is comfortable. The therapist’s activity and perceived mood affect patients through their therapeutic relationship, which was the most critical factor related to psychotherapy side effects in this study.

The “theoretical orientation” is the professional theoretical background of psychotherapy that the client learns from the therapist. Our results suggested that the theoretical application of psychotherapy had a significant predictive effect on the side effects experienced, which was consistent with previous studies (8, 13, 17). In our study, participants who received psychodynamic therapy had significantly higher rates of side effects than other treatments (Table 1). Leitner et al. (17) found that psychodynamic therapy had the highest risk of side effects in psychotherapy. Psychoanalysis or psychodynamic therapy focuses on the past life process based on defect orientation and externalizes internal conflicts into some traumatic events or experiences, which may cause the patient to attribute current difficulties to other people (especially parents), thus forming an isolated victim role (34). However, even though this therapeutic process is effective, it puts a lot of pressure on patients. Meanwhile, family therapy and other postmodernism psychotherapy (such as narrative therapy, solution-focused therapy) are more resource-oriented than system interactions, resources, and solutions, which may reduce the pressure on a client (8, 17).

Our study found also that other factors can cause side effects. These included the perceived limited professional abilities of the therapist, the client’s mental activity, age, willingness to seek psychotherapy in the future, and the place where psychotherapy takes place. Parry, Crawford, and Duggan (35) conclude that the main factors that cause negative effects and harm in psychological therapies are as follows: (a) damaging interactions between the therapist and patient and unresolved ruptures in the therapeutic alliance; (b) therapist factors such as using an inappropriate therapeutic method or errors in delivering a recommended therapy; (c) patient factors that increase the risk of iatrogenesis; (d) a poor fit between therapist and patient; (e) the risks attached to specific interventions; and (f) organizational systems. Hardy et al. (12) have constructed a model of risk factors for negative experiences and describe how a “lack of fit” between patient needs, therapist skills, and service structures, could result in tensions between safety, containment, power, and control. This tension led to strain and poor engagement, resulting in a negative therapeutic experience. The side effects of psychotherapy involve a confluence of many factors, which should be considered a whole effect system between the therapist, the patient, and the organizational system.

Patients seek psychological treatment to solve problems and side effects do inevitably occur in some patients. Therefore, finding out which patients may have side effects is of great interest, and could provide useful information that will enable the therapist to obtain better results. In the present study, we demonstrated the usefulness of supervised machine learning algorithms in the prediction of side effects based upon information from participants as well as therapists. After

evaluating a number of algorithms, we found that Random Forest-based classification is an effective tool to predict whether participants will experience side effects, with an F1-score of 0.797 and an AUC of 0.804. In the field of translational clinical psychology and psychiatry, machine learning has been widely used for disease diagnosis, differentiation, and outcome prediction (36, 37). In our study, we demonstrated that this classifier can accurately differentiate whether patients/clients are likely to experience side effects. For therapists, this result could have practical significance. If a client is predicted by the classifier as being potentially prone to side effects, the therapist could pay more attention to their treatment. Using the rank of feature importance, it is possible to adjust the treatment strategy. For example, the therapist could consider whether their mental state is stable, whether the therapy orientation adopted is suitable for the client, and so on, with the ultimate goal of better relieving or solving psychological problems. To the best of our knowledge, this is the first study to predict the potential side effects of psychotherapy using machine learning. The machine learning approaches described in this study are sufficiently accurate and meaningful and could be integrated into clinical psychology.

LIMITATIONS

Although this study did develop an accurate model for predicting the side effects of psychotherapy, there are limitations connected to using PSEQ, a simple self-designed questionnaire, as the primary evaluation tool, meaning the validity and reliability of data on side effects might not be strong. At the same time, the participants conducted a self-assessment according to the inclusion criteria in the online survey which was disseminated via social media, which does not guarantee the validity or accuracy of the relatively small sample. That said, some important factors, such as treatment dosage and patient characteristics, were not included in the evaluation. This study did not explore which mental states or perceived moods of the therapist are likely to cause side effects in the client/patient, which could be the subject of future research.

CONCLUSION

This study came to the following conclusions: (1), that the side effects experienced by patients during psychotherapy are common, and the most common side effect experienced by participants was negative emotion, such as anxiety, tension, sadness, and anger, etc.; (2), that the mental state of the therapist, as perceived by the participant during psychotherapy, was the most relevant feature in predicting whether clients would experience side effects; and (3), that our Random Forest-based

machine learning model offered the best prediction performance of patient side effects after psychotherapy, with an F1-score of 0.797 and an AUC value of 0.804. In conclusion, these results could provide clinicians, therapists, and patients with important information that will help them to ensure that the side effects of psychotherapy are minimized or avoided in future clinical practice.

DATA AVAILABILITY STATEMENT

The datasets generated for this study are available on request to the corresponding author.

ETHICS STATEMENT

The project involving human participants were reviewed and approved by the Ethics Committee of Shanghai Pudong New Area Mental Health Center, Tongji University School of Medicine (Approved Number: 2019tjdx9). The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

LY and FC made substantial contributions to the conception, design, analysis, and manuscript draft, ensuring that the work was appropriately investigated and resolved. XZ, LL, and QF contributed to the study design and critical review of the manuscript for intellectual content. ZX and YC implemented machine learning algorithms and statistical analysis. All authors read and approved the final manuscript.

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A German Version of the Staff Attitude to Coercion Scale. Development and Empirical Validation

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Background: Individual staff factors, such as personality traits and attitudes, are increasingly seen as an important factor in the reduction of coercion in mental health services. At the same time, only a few validated instruments exist to measure those factors and examine their influence on the use of coercion.

Aim: The present study aimed to develop and validate a German version of the Staff Attitude to Coercion Scale (SACS).

Methods: The original English version of the SACS published was translated into German. Subsequently, it was empirically validated on a sample of $N = 209$ mental health professionals by conducting an exploratory factor analysis.

Results: The three-factor structure in the original version of the SACS, consisting of critical, pragmatic and positive attitudes toward the use of coercion, could not be replicated. Instead, the German version revealed one factor ranging from rejecting to approving the use of coercion.

Conclusion: The SACS is one of the first instruments created to assess staff attitudes toward coercion in a validated way. The version of the instrument developed in this study allows for a validated assessment of those attitudes in German. Our results highlight the ethical importance of using validated measurements in studies on the role of staff factors in the reduction of coercion.

Keywords: psychiatry, mental health care, coercive measures, attitudes research, test adaptation, compulsory treatment, involuntary admission

BACKGROUND

Strong efforts have been made in recent years to reduce the use of coercion in psychiatry (1, 2). These efforts have been driven by the firm ethical belief that coercive measures are *prima facie* morally problematic because they are associated with negative consequences for those affected (3). Against this background, the demand has been raised to reduce the use of coercion to an absolute minimum, and some even completely renunciate the use of all measures against a person's will, often with reference to the United Nations Convention on the Rights of Persons with Disabilities

(4–11). Several guidelines (12, 13) and specific programs (14, 15) have been developed in the area of clinical psychiatry to reduce coercion.

It is essential to determine the underlying causes and justifications for the use of coercion in clinical situations to develop further innovative strategies to reduce coercive interventions in psychiatry. In this context, staff characteristics have recently been receiving more attention regarding their role in the clinical decision-making process and the use of coercion in mental health services (16, 17). Mental health professionals' attitudes have been examined in empirical studies, mostly in relation to their impact on the use of coercive interventions (18–22), such as mechanical restraint or seclusion (23–26). It is assumed that mental health professionals' cognitive and emotional attitudes toward coercion influence the way in which they decide and behave in certain situations and, consequently, influence the frequency and type of coercive interventions. Even though studies underline the relevance of the staff attitudes toward the use of coercion (18, 24), little is known about its precise impact on the actual use of coercive measures (27). Furthermore, only a few studies have addressed the question how staff attitudes evolve (28–30) and whether the latter can be modified (e.g., by means of training) (31–35).

The empirical investigation into the role of staff attitudes in the use of coercion is paramount from an ethical perspective because it yields important insights into the potential effectiveness of programs to reduce coercion. If it turns out that staff attitudes play a key role in the use of coercion, providing training for mental health professionals and achieving culture change might, for example, be more efficient in reducing coercion than the reform of mental health law and policy. From a theoretical point of view, the clarification of the aforementioned questions requires a clear and appropriate concept and operationalization of attitudes, which is applicable in the context of coercion in psychiatry. Attitudes toward coercion in studies on staff attitudes in psychiatry tend to be interpreted in a variety of terms, ranging from the appraisal of ethical or legal legitimacy, the degree of approval of coercive measures to self-reported preparedness to use coercion (19, 36, 37). Attitudes in psychology, are commonly divided into three components: A cognitive component, including thoughts and beliefs, an affective component, including feelings and emotions, and a behavioral component, including concrete actions (38). Attitudes can, thus, be understood as cognitive, emotional and behavioral dispositions that are, at least to some extent, under our voluntary control. It is assumed here that the cognitive and affective components have an impact on the behavioral component (39, 40). While the behavioral component is easily measurable, the measurement of the cognitive and affective proportions turns out to be challenging (41).

Furthermore, cognitive and emotional attitudes can be explicit or implicit (41). Measurements of implicit attitudes rely on the assumption that participants are often not consciously aware of certain beliefs or emotions or do not want to express them due to social desirability. Many tests for implicit attitudes use reaction time to respond to certain items as a variable to identify unconscious preferences or pre-judicial attitudes. The Implicit

Association Test is a notable example. The validity of such tests has been questioned (42). Explicit measurements of the cognitive and affective components of attitudes are based mainly on self-reports in the form of agreements and disagreements with certain statements and, as such, address aspects of which people are consciously aware. An example of an instrument that measures explicit attitudes is the Attitudes to Containment Measures Questionnaire (43), which uses images to assess participants' approval of different kinds of coercive measures. Another questionnaire assesses nurses' attitudes toward and knowledge and practices of mechanical restraint (44). Various underlying concepts and definitions used in empirical studies and different scopes of coercion (i.e., specific coercive interventions or coercion in general) complicate the measurement of explicit attitudes and the comparison of research results. Consequently, many international studies have relied on either qualitative research designs or questionnaires that were developed or adapted for specific research questions and whose validity often remains unclear (23, 26, 29, 34, 45).

Regarding the Staff Attitude to Coercion Scale (SACS), Norwegian researchers developed and validated an instrument which facilitates a standardized and quantitative measurement of the cognitive component of mental health professionals' attitudes toward coercion in general (46, 47). Based on focus groups with mental health professionals, the researchers developed items for a questionnaire in the form of statements that represent certain beliefs about coercion. They created a self-report questionnaire with 15 items, which are assessed with a 5-point Likert scale ranging from total disagreement to total agreement. The principal component analysis seemed to reveal a three-factor structure. Based on this, the researchers proposed three independent types of attitudes toward coercion: A pragmatic attitude (coercion as care and security), a critical attitude (coercion as offending) and a positive attitude (coercion as treatment), with sufficient reliability for all three subscales (47). The subscales are scored as the sum of the corresponding items. After the development and validation of the SACS, the authors used the questionnaire to examine attitudes of mental health professionals and their influence on the use of coercive measures (48). They could show that there were differences in the attitudes between different staff members, but the actual use of coercive measures on different wards was not associated with staff attitudes on these wards. The original version was developed in Norwegian and used in the first studies published by Husum et al., but the items were translated from Norwegian to English through a validated process for the publication of the results from the validation study (Husum, personal communication, 2020). The SACS has been widely used in international studies, but it remains unclear whether the respective research teams used the published English translation of the original version or a (perhaps unpublished) validated further translation (31, 49–51). The SACS has also been used in studies from German-speaking countries (52–54), even though no validation of a German version has yet been published.

Against this background, the major aim of our study was, firstly, to develop and adapt the original version of the SACS into the German language and context. Secondly, an empirical

validation of the instrument should examine its feasibility, reliability and validity. During the process, we reflected critically on conceptual and methodological aspects of the SACS and drew conclusions about the interpretation of results from studies relying on the SACS and future research on staff attitudes toward coercion.

METHODS

Translation and Adaptation of the Instrument

The translation and adaptation of the SACS followed the guidelines of the International Test Commission (55) for the translation and adaptation of questionnaires. In a first step, the English items were translated by native German-speaking researchers. Mental health professionals were then asked for feedback on these items. Subsequently, all items were back translated by a bilingual researcher and an independent lay person raised bilingually in English and German. Regarding items with notable differences between the back translation and the original version, the German translation was further adapted with consultation of the bilingual researcher who was involved in the back translation. Afterwards, the final items were once again presented to different mental health professionals to receive feedback regarding linguistic and logical comprehensibility.

Empirical Validation: Feasibility, Reliability, and Validity

After finishing the translation and adaptation of the original version of the SACS, the final German version was validated empirically with data assessed in three steps. The empirical validation was approved by the Research Ethics Committee of the Medical Faculty of the Ruhr University Bochum (Reg. No.: 17-6284). The validation was conducted as a developing process in which findings obtained at one stage determined the following steps at the next stage. Furthermore, important aspects (feasibility, reliability, and validity) were addressed at different stages of the validation. The options to assess validity and reliability were limited. The former were limited because no comparable measurements exist which could be used to assess criterion validity. The latter were limited because our data had to be collected anonymously, as a result of which we could not assess retest-reliability. Consequently, our examination of reliability and validity focused on internal consistency, face validity, and construct validity.

We performed a pretest before collecting the data to assess feasibility and face validity for the adapted version of the SACS. To this end, several professionals and researchers from various backgrounds (e.g., psychology, psychiatry, philosophy, sociology, and medical ethics) received the adapted version of the SACS and were asked to report on aspects of feasibility, such as duration of completion and comprehensibility of the items, as well as on the face validity of the items. Analyses on internal consistency and construct validity were conducted on the broad data collection.

Data Collection

The data for the validation of the SACS were collected in three ways. Firstly, we conducted an online survey, which included our German version of the SACS and additional sociodemographic questions, among mental health professionals working in two psychiatric hospitals of the Regional Association of Westphalia-Lippe (LWL), a large mental healthcare provider in North Rhine-Westphalia, Germany. Mental health professionals, mainly nurses and doctors, received the link to the online survey *via* email and were invited to participate anonymously. Since the number of responses ($n = 81$) from this survey was insufficient, we looked for further recruitment strategies and asked all participants of a one-day conference (“LWL-Fortbildungstag”) to fill out a paper version of the questionnaire anonymously. On this occasion, we received $n = 25$ questionnaires from mental health professionals. As a third recruitment strategy, we visited multidisciplinary team meetings in four additional psychiatric hospitals in North Rhine Westphalia, of which two belonged to the Regional Association of Westphalia-Lippe and two to other healthcare institutions. Paper versions of the questionnaire from $n = 103$ mental health professionals were gathered here.

Data Analysis

The analysis was conducted using IBM Statistics SPSS 26 and the results presented in this paper refer to the combined sample of $N = 209$. Sociodemographic variables were analyzed regarding descriptive aspects, such as measures of central tendency and variability. During the translation and adaptation doubts about the original factor structure arose, which will be further described in the results. These doubts indicated that it would not be sufficient to assess the goodness of fit of the existing empirical model (i.e., the original factor structure) with our data, but also an alternative model had to be provided, which would better represent the underlying structure of the items. For this reason, we conducted an exploratory factor analysis instead of a confirmatory factor analysis to be able to examine the item structure of the developed German version of the SACS in an unbiased way. Furthermore, the three-factor solution was specifically tested within the factor analysis to verify the original structure with three independent subscales. The total sample seemed to be sufficient for this analysis considering the common advice for sample sizes for factor analyses (56). Furthermore, the suitability of the data set for the following factor analysis was checked using the Kaiser-Meyer-Olkin criterion. The cut-off for the factor loadings was set at 0.4 (57), and Cronbach's Alpha was interpreted as acceptable when > 0.7 , good when > 0.8 and excellent when > 0.9 (58).

RESULTS

Translation and Adaptation

All English and German items can be found in **Table 1**, including their assignment to the subscales according to the original version of the SACS. Difficulties with the wording and content of some of the original items were observed during the process of translation and adaptation. Items that refer to two different aspects within one sentence are especially problematic. An

TABLE 1 | Items of the original English version and the adapted German version of the SACS.

Original subscale	Item	English wording	German translation
Coercion as offending	3	Use of coercion can harm the therapeutic relationship.	Die Anwendung von Zwang kann der therapeutischen Beziehung schaden.
	4	Use of coercion is a declaration of failure on the part of the mental health services.	Die Anwendung von Zwang ist ein Zeichen für das Versagen des psychiatrischen Hilfesystems.
	8	Coercion violates the patients integrity.	Zwang verletzt die Integrität des Patienten.
	13	Too much coercion is used in treatment.	In der Behandlung wird zu viel Zwang angewandt.
	14	Scarce resources lead to more use of coercion.	Knappe Ressourcen führen zu mehr Anwendung von Zwang.
	15	Coercion could have been much reduced, giving more time and personal contact.	Zwang könnte stark reduziert werden durch mehr Zeit und persönlichen Kontakt.
Coercion as care and security	1	Use of coercion is necessary as protection in dangerous situations.	Die Anwendung von Zwang ist notwendig zum Schutz in gefährlichen Situationen.
	2	For security reasons, coercion must sometimes be used.	Aus Sicherheitsgründen muss manchmal Zwang angewandt werden.
	5	Coercion may represent care and protection.	Zwang kann Fürsorge und Schutz darstellen.
	7	Coercion may prevent the development of a dangerous situation.	Zwang kann die Entstehung einer gefährlichen Situation verhindern.
	9	For severely ill patients, coercion may represent safety.	Für schwerkranke Patienten kann Zwang Sicherheit darstellen.
Coercion as treatment	6	More coercion should be used in treatment.	In der Behandlung sollte mehr Zwang angewandt werden.
	10	Patients without insight require use of coercion.	Patienten ohne Einsicht benötigen die Anwendung von Zwang.
	11	Use of coercion is necessary toward dangerous and aggressive patients.	Die Anwendung von Zwang ist notwendig bei gefährlichen und aggressiven Patienten.
	12	Regressive patients require use of coercion.	Regressive Patienten benötigen die Anwendung von Zwang.

example is item number 5, which associates coercion with both care and protection simultaneously, although care and protection are qualitatively different aims of coercive intervention. This difficulty also appears in the designation of the second subscale, which is called “coercion as care and security” and, thus, also addresses two different aspects simultaneously. Furthermore, some items refer to the same aspect but are merely conversely phrased, such as the items 6 (“more coercion should be used in treatment”) and 13 (“too much coercion is used in treatment”). Such conversely phrased items can be used to prevent biases when filling out the questionnaire. However, item 6 is assigned to the third subscale “coercion as treatment” and item 13 to the first subscale “coercion as offending.” The reason for this is unclear.

Feasibility and Face Validity

Participants of the pre-test reported that all items were understandable and that it was feasible to fill out the adapted version of the SACS efficiently on their own. Regarding face validity, most professionals and researchers in the pre-test claimed that items seemed to address cognitive attitudes about the use of coercion.

Sample Characteristics

Regarding the sociodemographic aspects, our total sample consisted mainly of nurses, while doctors and other members of the multi-professional healthcare team, such as psychologists, were less represented. Mental health professionals had an average of $M = 14.88$ ($SD = 11.86$) years of work experience within psychiatric institutions. In accordance with that, over 90% had already experienced situations in which coercive measures had

to be applied. While over three-quarters of the sample had also participated in de-escalation training, only half of the participants had additionally attended training or conferences about the use of coercion in psychiatry. Further sociodemographic information of the sample can be found in **Table 2**. Ratings of the participants as means and standard deviations for each item can be found in **Table 3**.

Reliability (Internal Consistency) and Construct Validity

The Kaiser-Meyer-Olkin value for the 15 items of the German SACS was 0.828, indicating that the sample was appropriate for conducting the factor analysis. The results from the anti-image correlation further showed only values higher than 0.75 on the diagonal. Thus, all items were suitable. The initial solution revealed four factors with Eigenvalues higher than 1, with the first factor having an Eigenvalue higher than four. The Eigenvalues for all factors can also be found in the scree plot in **Figure 1**. Further factor solutions were examined as the curve of the scree plot and loading of the items within the rotated component matrix did not support the initial solution.

Firstly, the original structure consisting of three factors and, secondly, a single-factor solution, as indicated by the Eigenvalues and the scree plot, were analyzed. Factor loadings for all items for both solutions can be found in **Table 4**. As can be seen, the three-factor solution represented mainly the original structure but with some items not loading clearly on one factor or, conversely, two factors. Furthermore, not all items loaded on the same factor as in the original structure. Internal consistency in the form of Cronbach's alpha of these subscales was merely sufficient, with

TABLE 2 | Sociodemographic characteristics of the total sample.

	<i>n</i>	%
Group of age (<i>n</i> = 208)		
Up to and including 25 years	17	8.2
26–35 years	70	33.7
36–45 years	31	14.8
46–55 years	60	28.6
56 years and over	30	14.3
Gender (<i>n</i> = 208)		
Female	87	41.8
Male	121	58.2
Professional group (<i>n</i> = 207)		
Nurses	151	72.9
Doctors	24	11.6
Psychologists, social workers and co-therapists	25	12.1
Other members of mental healthcare teams	7	3.4
Previous experiences with the application of coercive interventions (<i>n</i> = 202)		
Yes	189	93.6
Participation in the additional training on the application of coercive interventions (<i>n</i> = 209)		
Yes	111	53.1
Participation in de-escalation training (<i>n</i> = 208)		
Yes	169	81.3

TABLE 3 | Ratings of participants (mean, standard deviation, range) for each item.

Item number	Range (min-max)	<i>M</i>	<i>SD</i>
1	1–5	4.01	0.96
2	1–5	4.11	0.82
3	1–5	3.91	1.06
4	1–5	2.28	1.07
5	1–5	3.72	0.90
6	1–5	1.81	0.92
7	1–5	3.52	1.12
8	1–5	3.68	0.98
9	1–5	3.64	1.01
10	1–5	2.42	1.02
11	1–5	3.70	1.09
12	1–5	2.35	0.85
13	1–5	2.80	1.00
14	1–5	3.58	1.20
15	1–5	4.04	0.96

$\alpha = 0.76$ for the first factor, $\alpha = 0.762$ for the second factor, and $\alpha = 0.76$ for the third factor.

The second solution with only one factor was also examined and, as can be seen in **Table 4**, the factor loadings speak strongly for one general factor with two opposite poles, as all items load highly either positively or negatively on this factor. All items of the original subscale “coercion as offending” loaded negatively on this factor, while all other items (of the original subscales “coercion as care and security” and “coercion as treatment”)

loaded positively on this factor. All items loading negatively on the factor were conversely recoded to calculate the internal consistency of this scale. The scale revealed a high internal consistency with Cronbach’s alpha $\alpha = 0.84$.

DISCUSSION

Empirical Validation

Difficulties already appeared with the wording of the items of the SACS and the aspects they referred to during the translation and adaptation of the original items. It could be recognized, *inter alia*, that some items refer to the same aspect but in a conversely phrased way. Some items apparently seem to belong to more than one of the original subscales and can, thus, be neither translated nor interpreted by mental health professionals in a clear way. Such difficulties represent general problems in the process of developing self-reported questionnaires. This can result in ambiguous answers and, consequently, also affect the item structure (59).

The validation of the original version (47) had already revealed items that loaded on two factors simultaneously, either in the same direction or in a converse way. Moreover, the basic assumption of three independent kinds of attitudes was revealed to be problematic. Independent factors, as proposed in the original validation study, would imply that staff members could have a critical, pragmatic and positive attitude simultaneously. Such a finding would only make sense if the attitudes assessed were not mutually exclusive, as is the case in the assessment of personality traits, such as the Big Five, as measured by the Neuroticism-Extraversion-Openness Five-Factor Inventory (60). In contrast to the Big Five (extraversion, agreeableness, openness, conscientiousness, and neuroticism), the attitudes assessed by the SACS are mutually exclusive inasmuch as it does not make sense that mental health professionals have a positive and a critical attitude toward coercion at the same time. Consequently, the original distinction between critical, pragmatic and positive attitudes toward the use of coercion cannot be maintained as independent simultaneous attitudes.

Instead, the wording of the items and our results seem to predominantly justify one factor representing two opposite poles, ranging from a rejecting to an approving attitude toward the use of coercion. Based on our results, staff members could be categorized into three groups (rejecting coercion, approving coercion, or ambivalent) according to their value on this scale. Interestingly, the results of this classification correspond to the initial results from the research of Husum et al. (47), which could identify these three groups in a focus group with mental health professionals. It also reflects the study of Alem et al. (61), which was the source of inspiration for Husum et al. for the item construction of the SACS. The study by Alem et al. operationalized attitudes toward coercion as the tendency of mental health professionals to view coercive interventions as ethical or unethical. This would strengthen the idea that mental health professionals can be classified according to their cognitive attitudes about the use of coercion. The important differences lie in the concrete assessment and generation of these categories or groups.

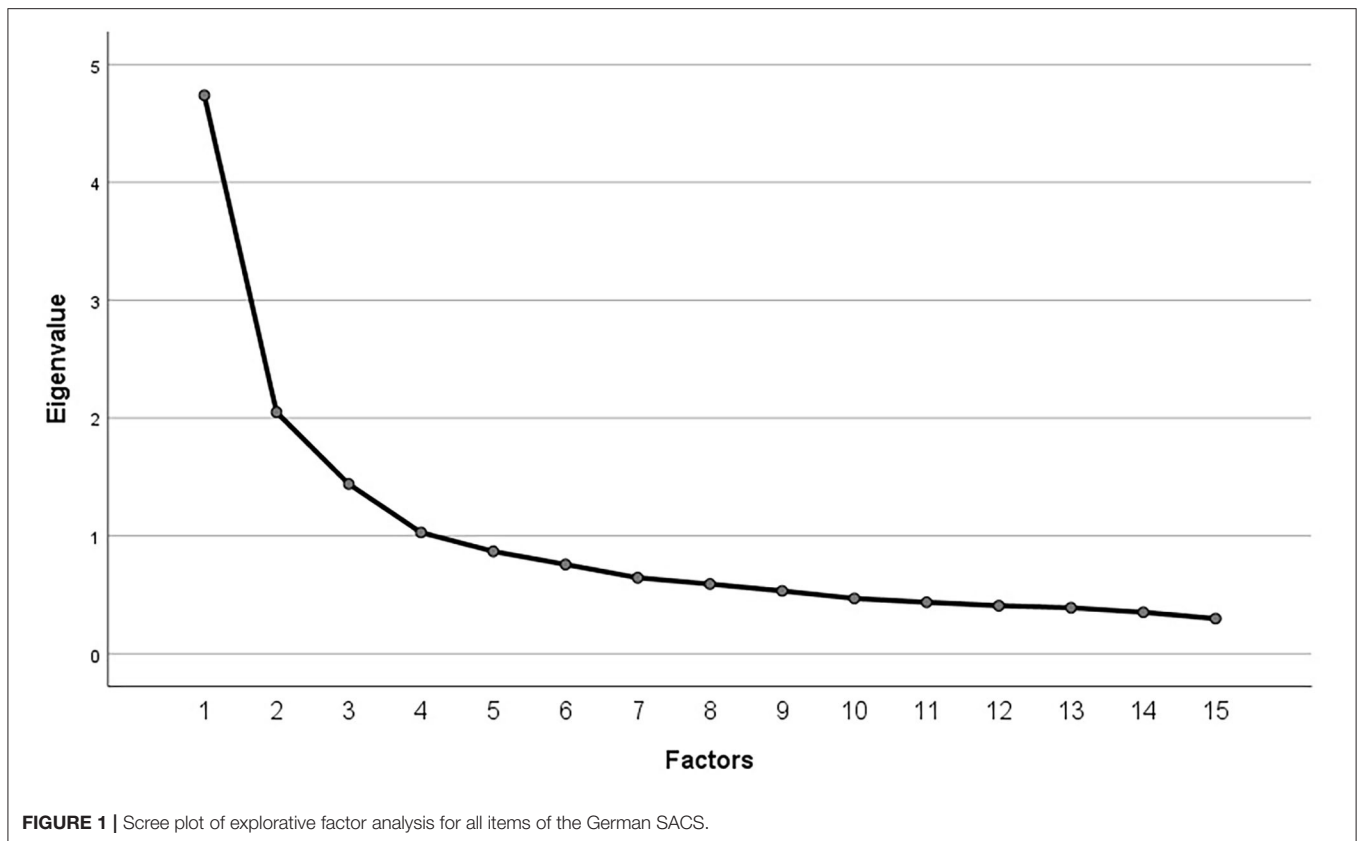


FIGURE 1 | Scree plot of explorative factor analysis for all items of the German SACS.

TABLE 4 | Factor loadings in (rotated) component matrix for three-factor and single-factor solution.

Number of item	Three-factor solution			Single-factor solution
	Factor 1	Factor 2	Factor 3	Factor 1
1	0.71	-0.11	0.27	0.65
2	0.75	0.09	0.12	0.48
3	-0.08	0.54	-0.44	-0.59
4	-0.51	0.56	0.09	-0.55
5	0.71	-0.17	0.09	0.58
6	0.19	-0.27	0.65	0.64
7	0.62	-0.06	0.17	0.51
8	0.03	0.63	-0.36	-0.52
9	0.63	-0.09	0.26	0.59
10	0.19	-0.13	0.78	0.65
11	0.36	0.04	0.66	0.59
12	0.14	-0.13	0.76	0.60
13	-0.21	0.71	-0.07	-0.55
14	0.01	0.76	-0.04	-0.42
15	-0.03	0.71	-0.11	-0.46

Bold values indicate those \geq the cut-off set for factor loadings.

Further Implications

From a conceptual perspective, it can be observed that all items on the SACS measure the staff's beliefs about coercion, and

particularly that no item measures their emotional dispositions toward coercion. Consequently, the SACS focuses exclusively on the cognitive components of staff attitudes to the neglect of emotional components. This is problematic, inasmuch as it can reasonably be expected that emotional components of staff attitudes will play a role in the use of coercion (54) as coercive situations are also associated with strong emotions in the staff involved. Furthermore, reasons to use coercive measures might also be of an emotional quality, for example, anger or fear as a result of aggressive behavior or compassion toward the patient.

The development of the original SACS (47) was an important step toward a validated assessment of mental health professionals' attitudes toward coercion and prompted important research on coercion in psychiatry in various countries in the past few years. From a methodological perspective, our findings have implications for results from previous research relying on the original three subscales of the SACS (31, 48–50, 52–54). The results of these studies should be interpreted with caution, as they might not be able to be maintained. From an ethical perspective, the use of unvalidated scales to measure staff attitudes toward coercion is problematic, insofar as it may yield unjustified hypotheses about which strategies might be effective in reducing coercion and, thus, pose an obstacle to evidence-based practice.

Further research on staff attitudes toward coercion is important because it can yield useful hypotheses for the development of strategies to reduce coercion and studies that test their effectiveness. This research, in turn, can inform the priority setting in the reduction of coercion. Researchers using

a validated version of the SACS should be aware of the restriction that the SACS assesses explicit cognitive attitudes exclusively. Recent research, though without using validated measurements, suggests that emotions might also be relevant in this context (54). Validated instruments to measure attitudes toward coercion that encompass cognitive, emotional and behavioral aspects should be developed and used to examine their role in the use of coercion in psychiatry. This would make the development of more focused strategies to reduce coercion possible. If future research, for example, were to find that emotional attitudes play a bigger role in the use of coercion than cognitive attitudes, it would make sense to shift the focus of professional training away from forging cognitive change (e.g., by providing information about the criteria of using coercive measures) toward forging emotional change (e.g., by inviting a peer support worker or a service user to share his or her personal experiences of coercive measures).

Strengths and Limitations

The key strength of our study is the fact that it is, to the best of our knowledge, the first empirical validation of a German version of the SACS. Moreover, our approach to the review of the original version and the interpretation of the empirical data is broader than usual in validation studies as we also discussed conceptual and ethical implications. Regarding limitations, it must be stated that we only recruited mental health professionals in one German state: North Rhine Westphalia, which limits our data to a rather specific sociocultural and legal context. Additionally, our sample was skewed, as most of our participants were nurses and we only had a small proportion of doctors and other members of the multi-professional mental healthcare team. However, the sample size was comparable to the validation study of the original version (47) and seems to be representative of the clinical reality, as nurses represent the largest professional group in psychiatric hospitals in Germany. Furthermore, nurses are usually directly involved in situations in which coercive measures are applied and are, therefore, highly relevant for the topic examined in our study.

CONCLUSION

We provide a validated German version of the SACS in our study. All items of the original version could be adequately translated into German and it could be verified that they are comprehensible and suitable for mental health professionals working in German psychiatric institutions. Even though our validation did not replicate the original factor structure (47) consisting of three independent subscales, it did reveal a single-factor solution with good internal consistency. Therefore, the German version of the SACS enables researchers to assess staff members' explicit cognitive attitudes toward the use of coercive measures in mental

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health services in German-speaking countries in a self-reported and validated way.

Wider methodological and ethical conclusions can be drawn from the results presented. Our study highlights the importance to reflect critically on the use of unvalidated instruments in research, especially when these results are used as the basis for the development of clinical interventions (e.g., to reduce the use of coercion). If results from empirical studies are used as premises in ethical debates, foundations of clinical interventions or models of care, those results should be free of biases and methodological difficulties.

DATA AVAILABILITY STATEMENT

The datasets generated for this article are not readily available because they contain data that has not been analyzed and published yet. Upon reasonable request, they will be made available by the corresponding author. Requests to access the datasets should be directed to Simone A. Efkemann, simone.efkemann@rub.de.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Research Ethics Committee of the Medical Faculty of the Ruhr University Bochum. The participants provided their informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

SE, RB, GJ, and JG designed the study. SE wrote the protocol. SE and JG managed the collection and preparation of data. SE, MS, and JG conducted the analysis and interpretation of data. SE wrote the first draft of the manuscript. MS and JG corrected and edited the manuscript. All authors contributed to and have approved the final version of the manuscript.

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Informing About the Nocebo Effect Affects Patients' Need for Information About Antidepressants—An Experimental Online Study

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Relevance: Understanding patients' informational needs and adapting drug-related information are the prerequisites for a contextualized informed consent. Current information practices might rather harm by inducing nocebo effects.

Objective: To investigate whether informing about the nocebo effect using a short information sheet affects patients' need for information about antidepressants.

Methods: A total of 97 patients taking recently prescribed antidepressants (≤ 4 months intake) were recruited over the internet and randomized to receiving either a one-page written information about the nocebo effect or a control text about the history of antidepressants. After experimental manipulation, informational needs about the side effects and mechanisms of antidepressants were assessed with 3 and 7 items on categorical and 5-point Likert scales. Group differences in informational needs were calculated with Chi-square tests and ANOVAs.

Results: Patients received antidepressants for depression (84.5%) and/or anxiety disorders (42.3%). Three participants (6.0%) of the nocebo group reported previous knowledge of the nocebo effect. After the experimental manipulation, participants in the nocebo group reported a reduced desire for receiving full side effect information [$\chi^2_{(4,97)} = 12.714$, Cramer's $V = 0.362$, $p = 0.013$] and agreed more frequently to the usefulness of withholding information about possible side effects [$\chi^2_{(4,97)} = 14.878$, Cramer's $V = 0.392$, $p = 0.005$]. Furthermore, they desired more information about the mechanisms of antidepressants ($F = 6.373$, $p = 0.013$, partial $\eta^2 = 0.063$) and, specifically, non-pharmacological mechanisms, such as the role of positive expectations ($F = 16.857$, $p < 0.001$, partial $\eta^2 = 0.151$).

Conclusions: Learning about the nocebo effect can alter patients' informational needs toward desiring less information about the potential side effects of antidepressants and more information about general mechanisms, such as expectations. The beneficial

effects of including nocebo information into contextualized informed consent should be studied clinically concerning more functional information-seeking behavior, which may ultimately lead to improved treatment outcomes, such as better adherence and reduced side effect burden.

Keywords: informed consent, antidepressants, nocebo effects, ethics, shared decision making, expectation, adverse (side) effects

INTRODUCTION

In today's Western healthcare systems, informed consent represents a fundamentally ethical and legal requirement for any medical intervention. It is considered an inherent part of evidence-based practice. However, by providing information about the medications' potential side effects, practitioners may induce nocebo effects and cause harm (1, 2). Even reading the package leaflet of any given medication has been shown to increase side effect reporting (3, 4). Thus, informing a patient about a treatment provides a direct link to this treatments' efficacy and tolerability. Ethically and clinically, this association has direct implications for informed consent procedures (5).

Nocebo effects may account for 38–100% of side effects reported in pharmacological trials, including serious adverse events (6). Particularly large placebo and nocebo effects have been documented in antidepressant treatment (7–10). A meta-analysis focusing on adverse event reporting showed that side effects specific to the drug emerge in the placebo groups of antidepressant medication trials, indicating that expectations are powerful enough to bias double-blind randomized trials (8). The role of expectations to predict the outcome of antidepressant treatment is prominent (11), but implications regarding the prevention of potential harm through negative expectations are rare. Clinical and experimental evidence suggests that nocebo-related side effects are caused by patients' expectations (12–14), prior experiences, and conditioning processes (15, 16) as well as misattributions of pre-existing bodily symptoms (17) and social observation (18). Patients with depression might particularly be at risk due to frequent catastrophic thinking and, hence, are more prone to developing negative expectations (19, 20). In some patients, fear of side effects can be strong enough to motivate them to discontinue their antidepressant medication (21).

Antidepressant use is common, with an annual average of 1.52 billion daily doses prescribed in Germany (22). In the US, antidepressants are used by 13% of the country's population, with a continuously increasing trend from 1999 to 2014 (23). Even though patient information procedures are essential to prescribing new drugs, their potential to optimize patients' expectations remains untapped. Among other reasons, prescribing physicians might be unaware of the importance of contextual factors, such as the relevance of side effects information and patients' expectations contributing to side effect burden (24). Common side effects associated with antidepressant treatment include headache, weight gain, dizziness, and dry mouth, as well as adverse effects of long-term antidepressant intake, such as emotional numbing (25).

Providing patients with comprehensive information about their medication is essential in light of patient autonomy. However, informing about side effects might also cause harm (26). To handle this ethical dilemma, promising approaches targeted to reduce expectation-induced side effects while still respecting patient autonomy and truthfulness have been suggested. Experimentally validated strategies include framing side effect information positively (4, 27), personalizing informed consent and educating about the medication's mechanism of action (28), and explicitly informing about the nocebo effect itself (29). An important theoretical proposal suggests to contextualize the informed consent by providing medication information in a manner that is personalized to the patient's characteristics, underlying disease, health status, and informational needs (30).

Contextualized informed consent might entail withholding information that may induce harm to patients. Being a theoretically discussed approach among experts, the patient's view regarding this so-called authorized concealment remains unknown. Relevantly, very few individuals are aware of the nocebo effect and thus might not be able to express the need for respective medication information (29).

In this study, we will examine whether patients undergoing antidepressant treatment are open to receiving contextualized medication information, and in specific, what kind of information they wish or wish not to receive. Based on the assumption that knowledge about the nocebo effect might be prerequisite to contextualizing side effect information, we will inform one group of patients about nocebo effects and test whether this will influence patients' informational needs. We assume that patients informed about the nocebo effect express a decreased need for detailed information about side effects and an increased need for information about the non-pharmacological mechanisms of side effect development in comparison with patients who were not informed about the nocebo effect.

METHODS AND PROCEDURES

Participants

Participants for this study were recruited *via* four online depression forums, an advertisement on a local newspaper's website, information sheets distributed in three different hospitals in the Hamburg metropolitan area, and four self-help groups. Inclusion criteria included a minimum age of 18, good knowledge of German, and having started a new antidepressant within the last 4 months.



FIGURE 1 | Illustration of nocebo effects in everyday life. ©Timm Kinitz.

Study Design and Procedure

Ethics approval was obtained from the Psychotherapy Chamber Hamburg, Germany. The survey was assessed *via* an online link. On the first page, all participants were informed about study procedure and data storage. By checking a box on the website, informed consent was provided by all participants prior to study start. Participants were then asked to provide information on socio-demographic data, illness-related data, and their satisfaction with the received medication information. Then, participants were randomized to receiving either a short information about the nocebo effect or neutral information.

The nocebo information group received a one-page text about the nocebo effect and its mechanisms; the control group received a text of the same length about the history of antidepressants. The nocebo information consisted of three main parts: a comprehensive explanation of the experienced nocebo effect, a distinction of pharmacological and non-pharmacological effects of a drug, and a description of expectations as one possible mechanism of the nocebo effect (31). Within the first paragraph, examples of expectations stemming from prior negative treatment experiences or from learning about the potential side effects from package inserts were given. It was further described that these negative expectations can lead to heightened side effects, that these symptoms are real and not “made up,” and that studies have shown that over half of the experienced side effects can be caused by expectations rather than by biomedical factors (17). The second paragraph detailed that medication side effects can be caused *via* two routes: through pharmacological mechanisms that are specific for the type of antidepressant medication and through non-pharmacological mechanisms, such as patients’ expectations. The third paragraph detailed that expectations can trigger biomedical changes within the body; furthermore, that expectations can lead to focused bodily attention, thereby making it likely for a person to attribute normal bodily sensations, such as benign headaches, as a side effect of a given medication. The text was followed by a three-panel comic illustrating the effect (see **Figure 1**). The control group text did not include information on the efficacy or mechanisms of action of antidepressant treatment. It described the clinical use of antidepressants since the 1950s and the different types of

antidepressants that have since been prescribed to patients. A manipulation check was conducted using three single choice questions about the texts’ content. Participants were then asked about which medication information they would like to obtain and what degree of side effect disclosure they considered to be useful.

Measures

Demographic and Medical Characteristics

The online survey assessed basic socio-demographic data, self-reported diagnosis, type of antidepressant medication, and utilized sources to receive information about their medication. Depression severity was assessed with the German short version of the Center for Epidemiological Studies—Depression (CES-D) scale (32, 33). Adherence was assessed *via* self-report using a prior validated single item (“How many pills have you actually taken during the last week?”) (34). Patients who took 80% or more pills were classified as adherent.

Satisfaction With Information About Medication

We developed five items to assess the satisfaction with the information about the antidepressant treatment: overall satisfaction, comprehensibility of the information, time and occasion to pose questions to the clinician, feeling sufficiently informed to take part in decision-making about the antidepressant treatment, feeling sufficiently informed to take part in decision-making about side effect treatments, and whether the information was delivered with kindness and respect. Each item is rated on a scale from 1 to 5 (1 “not at all,” 2 “rather not,” 3 “unsure,” 4 “rather satisfied,” 5 “very much satisfied”). We dichotomized the items for easier interpretation, with ratings of 4 and 5 grouped as “satisfied.” The satisfaction with the consultation time was assessed additionally.

We also used the Satisfaction with Information about Medicines Scale (SIMS) (35). The subscales satisfaction with information on “action and usage of medication” and “potential problems of medications” ranges from 0 to 9 and 0 to 8, with higher scores indicating a higher degree of satisfaction. A total score is calculated by adding up all items.

Outcome: Preferred Information Disclosure Disclosure About Risks of Side Effects

We operationalized the preference for information by addressing two aspects. Patients were asked about their wish to be informed about the side effects and about the mechanisms of antidepressants.

The extent of informational needs about side effects was assessed with three items: (1) “Would you find it beneficial if your practitioner did *not* inform you about all possible side effects?” rated as “very beneficial,” “beneficial, but only with my consent,” “undecided,” “not very beneficial,” or “not at all beneficial”; (2) “How thoroughly would you like your practitioner to inform you about possible side effects?” rated from 1 “not at all” to 5 “very thoroughly”; and (3) “Which side effects would you like to be informed about?” rated as “all side effects,” “only the most common ones,” “only the most severe ones,” “only the personally relevant ones,” or “none.”

Disclosure About Antidepressant Mechanisms

Informational needs about antidepressants’ mechanisms were measured with seven items on a scale from 1 “fully disagree” to 5 “fully agree.” Two items refer to the pharmacological mechanisms of antidepressants, whereas another five items refer to non-pharmacological mechanisms. In specific, patients were asked to indicate whether they would like their practitioner to inform them about the fact (1) “that antidepressants target messenger substances (neurotransmitters) in the brain,” (2) “that antidepressants have a pharmacological effect on the body *via* its biochemical pathways,” (3) “that my expectations about the treatment influence the effectiveness of the antidepressant,” (4) “that the antidepressant would be less effective if I was not convinced of its benefits,” (5) “that antidepressants have a non-pharmacological effect on the body (placebo effect) conveyed by hope for recovery or the attentive care of a physician,” (6) “that time itself can contribute to easing my suffering,” and (7) “that side effects can develop due to heightened attention to bodily sensations.”

Statistical Analyses

To compare the nocebo information group and the control group, Chi-square tests were conducted for categorical data, and *t*-tests for continuous variables. Welch *t*-tests were conducted if variances were unequal. Analyses were conducted using IBM SPSS 24. All tests were two-tailed with the alpha level set at 0.05.

RESULTS

Sample Characteristics

Of 347 participants who started the online questionnaire, 102 participants completed the survey. Participants who could not identify their antidepressant medication (i.e., by checking a box within a comprehensive list of antidepressants) or who reported an intake time of more than 4 months were excluded. After completing the study, participants were excluded if completion time was two standard deviations above mean ($n = 2$), if they did not remember having received medication information from their prescribing physician ($n = 2$), or if they failed all questions

TABLE 1 | Socio-demographic, medical characteristics, and satisfaction with medication information.

	Nocebo information group ($n = 49$) $M \pm SD$ or % (n)	Control group ($n = 48$) $M \pm SD$ or % (n)
Age	39.6 \pm 10.0	38.6 \pm 13.7
Female	59.2 (29)	54.2 (56)
Married/with partner	40.8 (20)	39.6 (19)
13 or more years of education	22.4 (11)	35.4 (17)
Employed	51.0 (25)	43.8 (21)
Diagnosis ^a		
Depression	85.7 (42)	83.3 (40)
Anxiety disorder	46.9 (23)	37.5 (18)
Bipolar disorder	6.1 (3)	10.4 (5)
Pain disorder	2.0 (1)	10.4 (5)
Obsessive compulsive disorder	2.0 (1)	4.2 (2)
Other	0.0 (0)	4.2 (2)
Type of antidepressants		
Citalopram	24.5 (12)	83.3 (13)
Venlafaxine	14.3 (7)	14.6 (7)
Escitalopram	14.3 (7)	4.2 (2)
Mirtazapine	8.2 (4)	10.4 (5)
Sertraline	8.2 (4)	10.4 (5)
Fluoxetine	6.1 (3)	6.3 (3)
Amitriptyline	0 (0)	8.4 (4)
Opipramol	4.1 (2)	2.1 (1)
Agomelatine	2.0 (1)	4.2 (2)
Other ^b	20.4 (10)	16.7 (8)
Depression severity (CES-D)	19.9 \pm 9.6	17.9 \pm 8.67
Adherent (80% or more pill intake)	86 (42)	81 (39)
Prescriber		
Psychiatrist	55.1 (27)	54.2 (26)
General practitioner	22.4 (11)	10.4 (5)
Practitioner in the clinic	16.3 (8)	14.6 (7)
Neurologist	6.1 (3)	18.8 (9)
Other	0 (0)	2.1 (1)
Satisfaction with Information (SIMS)		
Action and usage of medication ^c	6.1 \pm 2.7	6.10 \pm 2.6
Potential problems of medication ^d	3.7 \pm 3.0	3.25 \pm 2.9
Satisfaction with consultation duration		
Just right	49.0 (24)	68.8 (33)
Too short	42.9 (21)	31.3 (15)
Too long	8.2 (4)	0 (0)
Additional sources of information ^a		
Internet	81.6 (40)	81.3 (39)
Package leaflet	71.4 (35)	75.0 (36)
Patient brochures/psychoeducation	24.5 (12)	12.5 (6)
Family/friends	10.2 (5)	12.5 (6)

(Continued)

TABLE 1 | Continued

	Nocebo information group (n = 49) M ± SD or % (n)	Control group (n = 48) M ± SD or % (n)
Newspaper/TV	4.1 (2)	6.3 (3)
Self-help groups	2.0 (1)	4.2 (2)
Other	6.1 (3)	6.3 (3)
None	2.0 (1)	4.2 (2)

M, mean; SD, standard deviation; CES-D, Center for Epidemiological Studies–Depression scale.

^aMultiple responses allowed.

^bOther antidepressants include drugs mentioned ≤2 times: Duloxetine, Clomipramine, Paroxetine, and Quetiapine.

^cRange 0–9.

^dRange 0–8.

of the manipulation check ($n = 1$). A total of 97 participants were included in the analyses, of which 49 and 48 were randomly allocated to the nocebo information group and to the control group, respectively.

Patients in both study groups were comparable with respect to socio-demographic characteristics (Table 1). When asked about their diagnosis, participants predominantly stated to receive antidepressants as treatment for depression (84.5%) and/or anxiety disorders (42.3%). More than 80% were still taking at least 80% of their medication; 10 participants have already discontinued antidepressant treatment. A majority received the medication information by their psychiatrist (54.6%) and used the internet (81.4%) or the package leaflet (73.2%) as an additional information source. Pre-existing knowledge of the nocebo effect was assessed in the nocebo information group using an open question; three participants (6%) could describe the effect correctly.

Satisfaction With Information About Medication

Figure 2 portrays the patients' satisfaction with the medication information received from the prescribing physicians; 59% of patients were overall satisfied, yet 41% were not. Information was judged inadequate to participate in shared decision-making about side effect-related treatments by over 40% (44% not satisfied), and 41% felt inadequately informed to participate in shared decision-making about the antidepressant treatment (41% not satisfied). Considering consultation time, 58.8, 4.1, and 37.1% viewed the duration to be “just right,” “too long,” and “too short,” respectively.

Similarly, the SIMS indicated that patients were rather not satisfied with the obtained medication information. In comparison with the German norm population that consisted of $n = 212$ chronically ill patients in the primary care system (hypertension, musculoskeletal diseases, diabetes type 2, cardiac insufficiency), our patient sample reported lower satisfaction (SIMS scores) for the total information received [$M = 9.59$, $SD = 4.87$; $t_{(307)} = 2.18$, $p = 0.006$, Cohen's $d = 0.34$], for the subscales action and usage of medication [$M = 6.10$, $SD = 2.59$; $t_{(307)} =$

2.19 , $p = 0.029$, Cohen's $d = 0.27$], and for the potential problems of medication [$M = 3.48$, $SD = 2.91$; $t_{(307)} = 2.83$, $p = 0.006$, Cohen's $d = 0.34$].

Informational Needs

Disclosure About Side Effects

Figure 3 shows that the control group more strongly desired to be informed about all side effects. Chi-square tests revealed significant group differences regarding all three items on side effect disclosure. The groups differed considering the perceived benefits of not being informed about all possible side effects [$X^2_{(4)} = 14.88$, $p = 0.005$, Cramer's $V = 0.39$], considering the desire to be thoroughly informed about possible side effects [$X^2_{(4)} = 12.71$, $p = 0.013$, Cramer's $V = 0.36$], and considering the types of side effects they wish to be informed about [$X^2_{(3)} = 8.86$, $p = 0.031$, Cramer's $V = 0.30$].

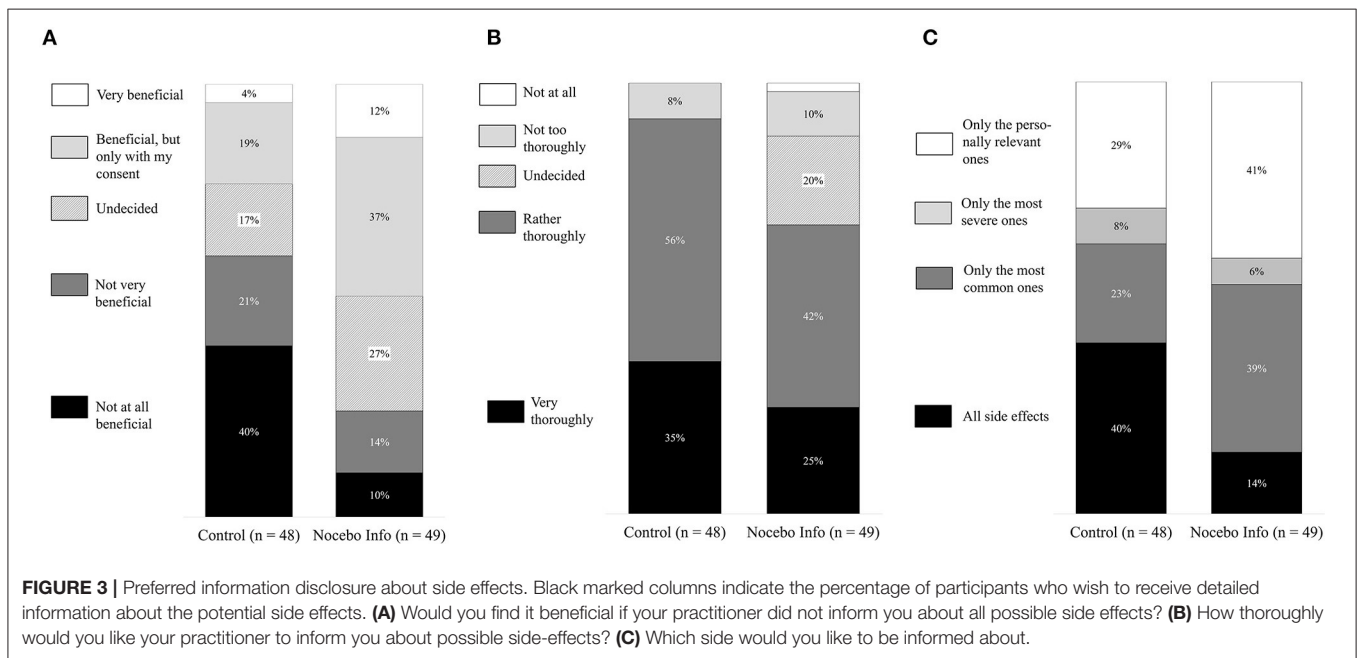
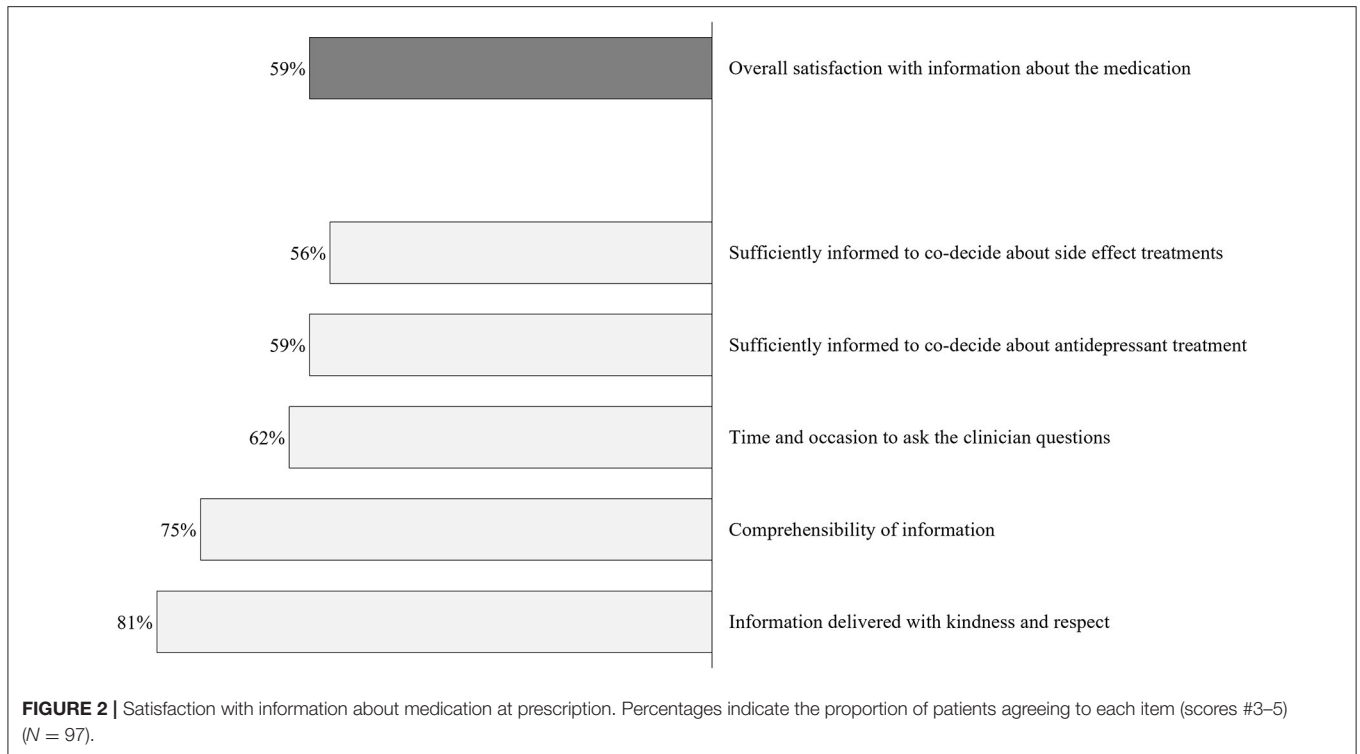
Disclosure About the Antidepressant's Modes of Actions

A multivariate analysis of variance (MANOVA) revealed a significant multivariate effect of the study group on informational needs about the mechanisms of antidepressants [Wilks' $\lambda = 0.75$, $F_{(7, 89)} = 3.64$, $p = 0.001$, partial $\eta^2 = 0.25$]. Except for information on “effects of antidepressants on neurotransmitters in the brain” (Figure 4), participants in the nocebo information group indicated an increased wish for information in all domains. *t*-Test for independent samples showed that the nocebo group desired more information about the pharmacological actions of antidepressants [$t_{(95)} = 2.53$, $p = 0.013$, Cohen's $d = 0.52$], about the non-pharmacological actions of antidepressants [$t_{(95)} = 2.52$, $p = 0.013$, Cohen's $d = 0.52$], on how expectations can influence the antidepressant's effectiveness [$t_{(95)} = 2.05$, $p = 0.043$, Cohen's $d = 0.42$], on how not believing in the antidepressant's benefits can make it less effective [$t_{(88,07)} = 2.98$, $p < 0.001$, Cohen's $d = 0.83$], on how time itself can ease suffering [$t_{(95)} = 3.02$, $p = 0.003$, Cohen's $d = 0.61$], and about how side effect can develop due to heightened bodily attention [$t_{(95)} = 2.98$, $p = 0.004$, Cohen's $d = 0.61$].

DISCUSSION

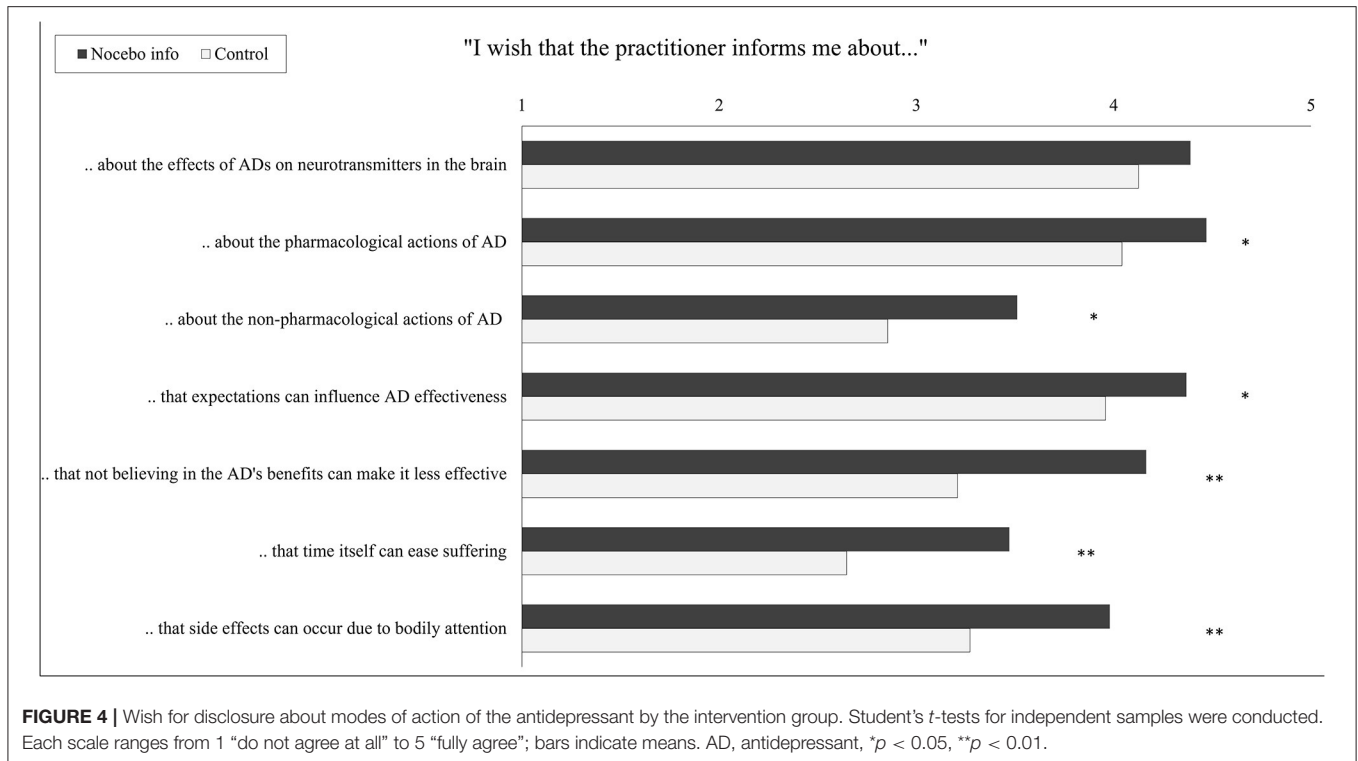
This study showed that patients, who have learned about the nocebo effect, are more open to contextualized information about their antidepressant medication. Patients with an indication for antidepressant treatment, in general, wish to be informed about the effects and potential side effects of their antidepressant medication. However, the group who has received information about the nocebo effect—in comparison with the group who did not receive that information—indicated that withholding the potential side effects and a less thorough disclosure of side effects would be beneficial. They also wished for a more personalized approach, i.e., 41% of participants wished to only be informed about personally relevant side effects (vs. 29% of participants in the control group).

Patients in the nocebo information group also reported an increased wish to be informed about the antidepressants'



mode of action, which includes pharmacological and non-pharmacological treatment mechanisms. This suggests that, once aware that psychological factors can contribute to side effects, participants were more receptive to information considering the medication’s non-pharmacological mechanisms. Especially

for antidepressants, for which placebo effects determine up to 75% of the effectiveness (8–10, 36), nonspecific factors, such as expectations and positive beliefs, may influence treatment outcomes. Knowing about the nocebo effects provides the groundwork for learning more about non-pharmacological



treatment mechanisms, which again, might positively affect treatment efficacy.

When asked about their overall satisfaction with the medication information they received at prescription, only 59% of the $n = 97$ participants indicated overall satisfaction. For most participants, the information was delivered with kindness and respect (81%) and was well comprehensible (75%). However, in view of "time and occasion for questions to the clinician," fewer participants were satisfied (62%). Notably, many participants did not feel adequately informed to make decisions considering managing the potential side effects and their antidepressant treatment (satisfaction rates: 59 and 56%). In addition, the consultation time at prescription was evaluated as "too short" in 37% of all cases. These results can be interpreted as compatible with the current public health crisis of long-term antidepressant intake. About 14% of antidepressant users report an intake duration of 10 years (37), although there is no evidence for increased benefits for long-term intake (38, 39). On the other hand, many patients discontinue their medication without consulting their practitioner (40), which can result in heightened recurrence risk and burdening symptoms. Providing patients with more information at prescription might be an essential component of preventing abrupt discontinuation or the "better safe than sorry"-motivated long-term intake.

Up to 57% of patients experience nocebo effects from antidepressants (8, 41). Symptoms include dry mouth, fatigue, drowsiness, constipation, sexual problems, and

vision/accommodation problems. Since all types of side effects seemed equally amendable to nocebo (8), it can be assumed that side effects from antidepressants in general might be influenced in terms of their incidence and intensity by patients' negative expectations. Furthermore, 40% of the patients in the placebo groups of clinical trials discontinue antidepressant treatment because of intolerable side effects (8, 10). Taken together, nocebo effects from antidepressant treatment constitute a serious clinical problem affecting patients' well-being as well as medication adherence. Clinical ways of tackling this problem, for example, through optimized informed consent procedures, thus seem promising not only for the benefit of the patient but also for the benefit of the healthcare systems struggling with costs from increased long-term antidepressant intake and self-directed discontinuation.

While there have been suggestions to inform patients about the nocebo effect (42), to the best of our knowledge, this study is the first to assess the patients' wish for information after learning about the nocebo effect. A previous study showed that explaining the nocebo effect reduces symptomatic experiences in people reporting symptoms attributed to windfarm generated infrasound, supporting the potential positive impact of providing improved information about nocebo effects (43). Further strengths include the use of a control condition and the standardized presentation of the information, which could be easily implemented into medication package leaflets.

LIMITATIONS

While the study's online format minimized context effects and bias toward investigators, it does not provide opportunities for questions to a clinician, which could have enhanced the understanding of the nocebo effect. Clinically more valid routes to provide disclosure to patients about the nocebo effect include semi-structured individual consultations (31) or might be offered *via* shared clinical notes. Sharing clinical notes with patients *via* digitally accessible records, a practice that is becoming increasingly common in northern European countries and worldwide, might provide the opportunity to directly augment expectation effects (44). However, the ability to do this depends on the clinicians' knowledge about the influence of expectations on treatment efficacy and tolerability (24). The claim to promote nocebo literacy by addressing expectation effects in clinical education has been recently raised in a consensus paper (45).

The sample size with 97 participating patients was rather small. Among other benefits, such as increased power, larger samples with an increased chance of including patient with diverse interests in expectation or nocebo effects might help to control for a potential responder bias, since interest in and experiences with these effects might influence patient's informational needs. However, the study was promoted as a survey on experiences with antidepressants, which should have reduced a bias toward selective interests in the topic. All measures within this study were patient self-reports. Future studies should aim to include objective measures, such as pill counts as measures of adherence. Furthermore, the focus of this study was on patients taking antidepressants; thus, conclusions on other samples need to be drawn with caution. Since participants were not scheduled to receive a new prescription and had to answer hypothetically, future research should examine the information needs where the outcome actually determines the information of new medication given by a doctor.

Our study did not explore whether patients who are informed about the nocebo effect and prefer to receive fewer side effect information within their doctors' consultation actually change their behavior in terms of decreased searching for negative information online and in their conversations with fellow patients. Thus, the potential of adapted informed consent procedures, such as authorized concealment, to really prevent nocebo effects should be investigated in further studies (46). Importantly, these future studies might also consider the potential risks and downsides of authorized concealment, such as increased anxiety or overlooking and downplaying of potentially serious adverse events due to their attribution to the nocebo effect (5). Moreover, physicians should not misinterpret a preference for lesser side effect information as a justification for providing less information about side effects in general. Conclusions from this scientific debate should always emphasize that patient autonomy, as one of the fundamental principles of informed consent, and in this case of authorized concealment, should remain intact.

CONCLUSIONS

To our knowledge, our study is the first to investigate patients' views of the potential contextualized informed consent procedures. In contrast to experts' suggestions of withholding certain side effect information, most patients wish to receive information about all possible side effects. Only when patients have been informed about the nocebo effect, they agreed to receive adjusted medical information. Hence, patients should be informed about the underlying rationale of preventing nocebo effects before informed consent is contextualized. Future studies should investigate whether contextualized informed consent can optimize expectations as shown by Heisig et al. (28) and, furthermore, reduce side effect burden and improve the efficacy of medications.

Clinicians should be aware of the nocebo effect and provide information to the patient accordingly. This study shows that knowing about the nocebo effect can alter the need for information, which should be considered to achieve a truly informed consent and ensure patients' autonomy.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Psychotherapy Chamber Hamburg, Germany. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

YN and MS-M initiated the study design. TK, EW, and MS-M conducted the study. TK, EW, YP, YN, and MS-M analyzed and interpreted the data. YN, YP, and TK drafted the manuscript. All authors made refinements and approved the final manuscript.

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Types of Ethical Problems and Expertise in Clinical Ethics Consultation in Psychiatry – Insights From a Qualitative Empirical Ethics Study

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Background: Ethics consultation has been advocated as a valuable tool in ethically challenging clinical situations in healthcare. It is paramount for the development and implementation of clinical ethics support services (CESS) in psychiatry that interventions can address the moral needs of mental health professionals adequately and communicate the nature of the services clearly. This study explores types of ethical problems and concepts of ethical expertise as core elements of CESS in mental healthcare with the aim of contributing to the further development of ethical support in psychiatry.

Methods: We conducted 13 semi-structured interviews with mental health professionals and CESS members and triangulated them with four non-participant observations of ethical case consultations in psychiatry. Data were analyzed according to principles of grounded theory and are discussed from a normative perspective.

Results: The analysis of the empirical data reveals a typology of three different ethical problems professionals want to refer to CESS: (1) Dyadic problems based on the relationship between patients and professionals, (2) triangular problems, where a third party is involved and affected as a side effect, and (3) problems on a systemic level. However, CESS members focus largely on types (1) and (2), while the third remains unrecognized or members do not feel responsible for these problems. Furthermore, they reflect a strong inner tension connected to their role as ethical experts which can be depicted as a dilemma. On the one hand, as ethically trained people, they reject the idea that their judgments have expert status. On the other hand, they feel that mental health professionals reach out for them to obtain guidance and that it is their responsibility to offer it.

Conclusion: CESS members and professionals in mental healthcare have different ideas of the scope of responsibility of CESS. This contains the risk of misunderstandings

and misconceptions and may affect the quality of consultations. It is necessary to adapt concepts of problem solving to practitioners' needs to overcome these problems. Secondly, CESS members struggle with their role as ethical experts. CESS members in psychiatry need to develop a stable professional identity. Theoretical clarification and practical training are needed.

Keywords: mental healthcare, clinical ethics support services, qualitative interviews, nonparticipant observation, ethical expertise

INTRODUCTION

Ethics consultation has been advocated as a valuable tool in ethically challenging situations in various healthcare settings in recent years (1–6). The development of clinical ethics support services (CESS) in Germany is supported by various medical bodies (7, 8) and sometimes even on a legal basis (39). The CESS are now widely implemented in somatic medicine in many western countries and have become an accepted tool to improve patient care (9–14).

It has often been suggested that CESS are less developed in psychiatric settings than in somatic care. Different medical cultures (e.g., lower hierarchies) and needs in consulting and competencies, such as the more communication-oriented attitude of mental health professionals, were assumed to be the reason (15–17). However, recent surveys revealed that more than half of the psychiatric hospitals in Germany, in fact, offer some kind of CESS which often includes ethical case consultation (18–20). Notwithstanding this fact, data indicate a mismatch in supply and demand since many of the hospitals reported ethical consultations in only a very few or even no cases per year. Despite the existence of CESS interventions, frequent occurrence of ethical issues and clinical routines demanding high ethical standards (21), ethical problems often seem to be discussed implicitly or elsewhere, such as in interdisciplinary team meetings or during supervision (18, 22, 23).

In addition to organizational and structural challenges, such as lack of resources or support (19), the successful implementation of CESS in psychiatry seems to hinge, *inter alia*, on two important challenges. Firstly, interventions must be able to respond adequately to the moral distress of mental health professionals (16). Moral distress is a psychological response which includes the experience of suffering (e.g., from anxiety, fear or anguish) connected to moral dilemmas, uncertainty or certainty accompanied by constraints (24, 25). Successful CESS, therefore, requires an understanding of the nature of an incoming request for support and the ability to tailor interventions to the needs of mental health professionals and the specific type of problem. Secondly, CESS members need to develop a professional role as ethicists on an equal footing with other professional roles in healthcare settings. This would allow the delimitation of their service from other interventions and to display their range of expertise and the value of ethical support clearly (16). However, very little is known about the ethical problems mental health professionals want to refer to CESS and how professional ethicist roles should be developed.

Against this background, this empirical ethics study investigates, at first, the types of ethical problems mental health professionals want to refer to CESS. It then explores assumptions about the professional roles of CESS members in mental healthcare settings. In a final step, the study's empirical data are analyzed from a normative perspective. The study aims, firstly, at improving the understanding of the needs for and expectations of mental health professionals regarding ethical advice in clinical psychiatry. Secondly, it aims at gaining an in-depth understanding of the underlying concepts and challenges in developing professional identities and ethical expertise as clinical ethicists based on the views of CESS members. Finally, different starting points for the promotion of CESS in psychiatry and the improvement of existing CESS in mental healthcare institutions are identified and discussed.

MATERIALS AND METHODS

Theoretical Considerations

We hypothesized that learning more about the ethical problems referred to CESS by mental health professionals in the form of a typology provides a way of gaining a deeper understanding of the underlying needs and expectations. We adopted a narrow approach to defining "ethical problems" to ground this typology theoretically. According to this, an ethical problem can be determined by two propositions: Firstly, ethical problems are based on a relationship between a bearer of moral rights and an addressee of a claim. Secondly, in terms of content, ethical problems can be characterized by uncertainty regarding an ethically acceptable course of action or inability to carry out an accepted course. This can, for example, be the case when basic principles are in conflict or it is unclear which moral principle to apply (22, 26).

Regarding the professional role of an ethicist in CESS, we hypothesized that "ethical expertise" constitutes the core of this role. Ethical expertise can be generally described as a property of a person or group, consisting of certain skills, knowledge or both. Ethical expertise enables its carriers to exercise ethical considerations with a certain quality, legitimacy or authority (27). It, therefore, denotes a domain of expertise and a standard to distinguish experts from non-experts, resulting in a good reason to pay special attention to the advice of those fulfilling these standards (28, 29).

Data Collection

We chose an explorative qualitative approach triangulating different data sources (30). Triangulation of different data sources can be used to mitigate bias and increase saturation. It is especially suitable for novel research questions and exploratory studies in which small sample sizes are to be expected and little is known about the phenomena in question. Data were collected from interviews with mental health professionals and CESS members. In addition, we conducted non-participant observations of ethical case consultations in different mental healthcare institutions.

The interviews followed a semi-structured guideline comprising three main parts: The first part aimed at learning more about the participants' professional expertise and their experiences with CESS. The second part investigated the interviewees' understanding of ethical problems and paid special attention to their experiences regarding moral distress and moral needs. We used a card sorting approach for the third part to learn more about the participants' concepts of ethical expertise and their expectations of and attitudes toward experts. Card sorting approaches have been shown to be especially suitable for interviews on complex conceptual questions and mappings of ideas (31). The content of the cards was derived from two recent systematic reviews on the outcomes of CESS, which revealed certain connections between the role of an ethics consultant and the outcomes of a consultation (13, 32). Cards were iteratively supplemented with participants' suggestions and included 20 different properties and skills an ethics consultant might be equipped with to fulfill his/her professional role. All participants were invited to rank the importance of the properties or skills on a five-point scale while commenting on their decisions. Interviews were conducted from January 2018 to June 2019 in four different psychiatric hospitals in two different federal states in western Germany.

Non-participant observations were made following a structured observation scheme. The focus was on the question how CESS members fulfilled their role during consultations and how they introduced and described themselves and their role. When possible, the observer also took notes of the CESS members' impressions of the consultation subsequently. All notes were protocolled manually and transcribed within the same day. The cases were observed in two different psychiatric hospitals and a psychiatric long-term care facility in western Germany.

All observations and interviews were carried out by the first author (JH), who has a background in applied ethics, medical ethics and social sciences. Cases to observe were purposively sampled. Participants for interviews were theoretically sampled according to the principles of grounded theory to maximize the variety of the phenomena observed (33). All participants were informed about the study and gave their written informed consent. The study was approved by the research ethics committee of the Medical Faculty of the Ruhr University Bochum (Reg. no.: 17-6194).

Data Analysis

Interview transcripts and observation protocols were analyzed according to principles of grounded theory following an iterative

process of data analysis and data gathering (33). Grounded theory methodologies have proven to be of special advantage in situations where new fields and new questions are addressed and theories of social phenomena (such as the professional role of an ethicist) are investigated (34). Grounded theories enable researchers to gain an in-depth understanding of these phenomena by creating a detailed reconstruction within a shared social horizon of researcher and participants. We deemed this methodology to be suitable insofar as all these criteria apply to our research question.

Preliminary categories were constructed by the main author (JH) based on the first interviews and observations. The initial coding was presented within the research group and discussed during several presentations. These categories served as a basis for the analysis of the remaining material. Finally, all categories were generalized through axial coding. The emerging themes were discussed with several external experts and then presented to national and international experts from the field of clinical ethics consultation or psychiatry and to interview participants on several occasions. Data analysis was used to inform conceptual analysis from a normative perspective. The data analysis was ended after theoretical saturation, that is, the point during the study at which essential changes in the coding by the emergence of new data material was deemed to be unlikely by the researchers.

RESULTS

A total of 13 interviews with healthcare professionals and CESS members were conducted. In addition, four ethical case consultations were observed. The interviews took an average of 47 min, lasting from 35 to 66 min. The observations lasted from 1.25 to 2.5 h, with an average of 1.6 h. On two occasions, participants in the consultations provided additional information about their impressions in subsequent discussions. **Table 1** gives an overview of the interview and observation characteristics.

Types of Ethical Problems in Psychiatry

Mental health professionals were asked about their experience with ethical problems. We wanted to know what kind of moral needs are raised and what kind of problems mental health professionals want to refer to CESS. It became clear that the identification and description of an ethical problem was in itself a matter for concern. One participant, for example, stated:

And/where ethics. That would have to be defined carefully, in the first place, what it is exactly at all, in everyday life, where ethics and moral aspects play a role, where one does not only talk about, but also some relevancy for further acting can be derived. (Interview 01)

In addition, the observations and interviews showed that this also applied to the results of ethical consultations. Participants of consultations often felt uncertain how to describe and delimit ethical problems. Asked for a rough definition, the participants voiced the impression that ethical problems might be "personal matters" at first and not necessarily an issue on

TABLE 1 | Overview of data material.

Gender	Profession	Length of interview (min.)	Experience with CESS (self-assigned)
Study participants (interviews)			
m	Nursing	53	Low experience
f	Occupational therapy	66	None
f	Psychology/Nursing	45	Some experience
m	Psychiatry	37	None
m	Psychiatry	49	Very experienced
m	Psychiatry	45	None
f	Psychiatry	44	CESS member
f	Psychology	51	CESS member
f	Nursing	51	Some experience
f	Nursing	44	CESS member
f	Nursing	50	CESS member
m	Psychiatry	33	Very experienced
f	Nursing	43	Experienced
No.	Facility	Length of observation (h.)	Additional notes
Observations			
1	Psychiatric long-term care	2.5	Yes
2	Geriatric psychiatry	1.5	No
3	General psychiatry	1.5	Yes
4	General psychiatry	1.25	No

which consensus could be reached due to their subjective nature. A participant explained:

This is a [pausing] this is a subjective evaluation, uhm, and that the question is [for example] when does a patient have permission to go out? Of course, we have psychiatric arguments, too. However, there is a margin and this is often based on morality and we try to discuss it once more. (Interview 07)

It was very important for mental health professionals that CESS members were able to react to this subjective dimension of uncertainty in the problem. All interviewees agreed in the card sorting that analyzing and determining ethical problems might be one of the fundamental features of ethical experts.

Applying a typological perspective relying on the definition of an “ethical problem” as mentioned above, the narratives of the participants finally revealed three different ethical problem types that interviewees wanted to refer to CESS. We called these types (1) “dyadic problems,” (2) “triangular problems” and (3) “intersystem problems.” A graphical representation of these types is given in **Figure 1**.

(1) Dyadic problems are based on a doctor-patient relationship between individual patients and mental health professionals. A typical example might be the use of coercive measures in situations of self-endangerment. One participant told us:

Well, the first thing that meets the eye is, of course, that we use compulsory treatment, in part. Surely, this is, too, ehm, difficult for patients. Nobody wants that. However, there is no way to get

around it, to treat somebody in a compulsory way on the ward, to give medication against his will, to restrain him against his will. (Interview 04)

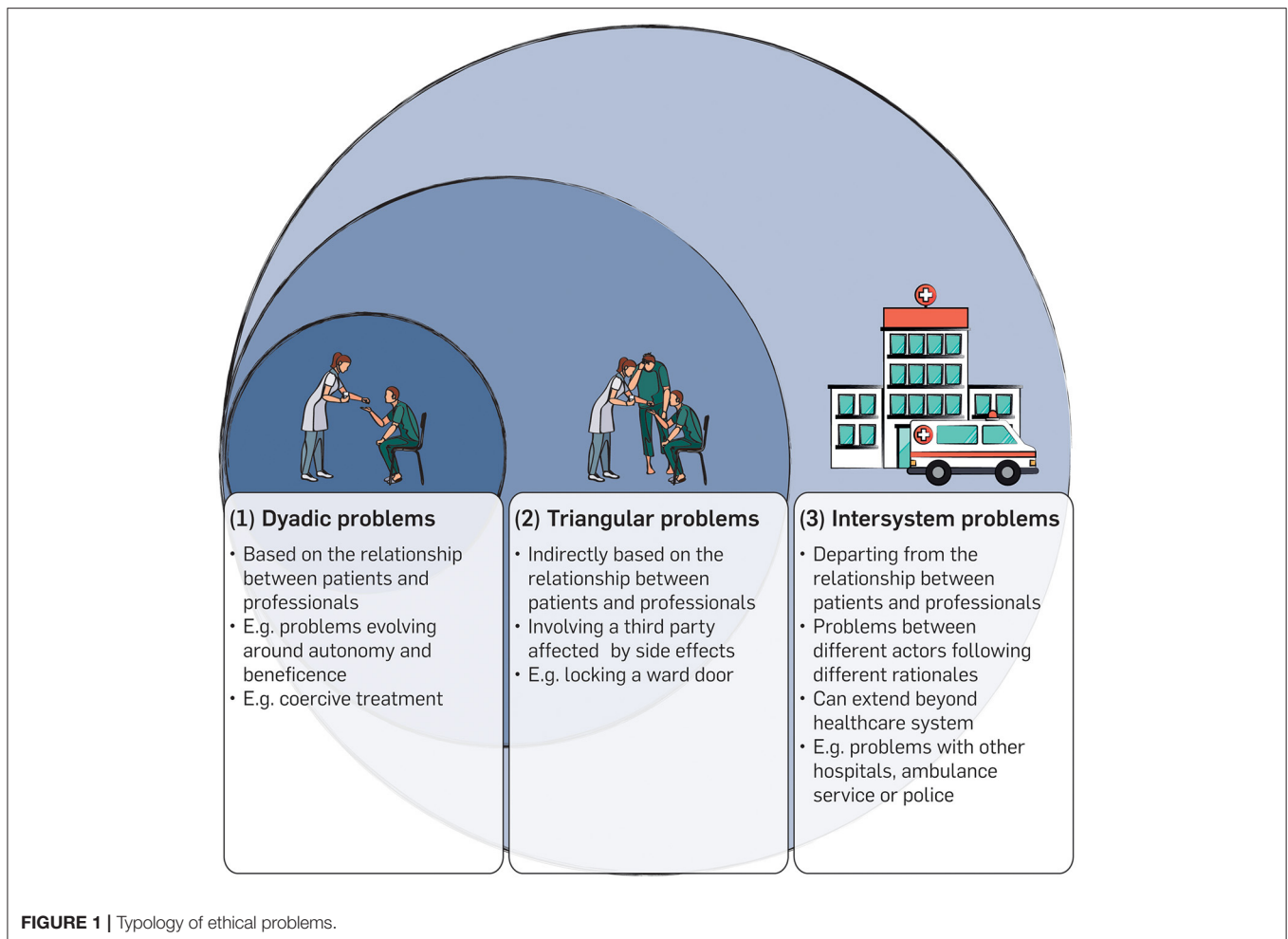
These problems evolve around the patients’ right to self-determination, on the one hand, and the professionals’ duty to beneficence, on the other.

(2) Triangular problems often differ from dyadic problems regarding the bearer of the burden, that is, the person whose interests are at stake. One participant used the open-door policy being implemented in his hospital to make clearer what is meant here.

Every locked door implies some sort of violence for professionals and for the patients, because, the fact is, it is about one patient who is coming to the ward, resulting in probably 15 others, who are also in this area which, then, is locked, having to, ehm, live. They have to suffer because they depend on us opening and locking the door. (Interview 01)

In these problems, a third party (i.e., the other patients on the ward) is affected by ethically relevant “side effects” which emerge from a relationship between a patient and mental health professional and, in fact, has nothing to do with them.

(3) Intersystem problems seem to be more complex and are situated on a different level. In contrast to dyadic problems and triangular problems, these ethical problems are neither directly nor indirectly based on the relationship between patients and healthcare professionals. An example of such problems was given



in the statement of an interviewee recalling different situations with colleagues from somatic medicine:

So actually, we have really bigger conflicts with other professional groups with our patients if they are somatically ill, and it is about [pausing] An example: A patient needs a transfer to the intensive care unit and there we often find that the medical staff in the general hospital have great reservations about psychiatric patients and we are called again and again to restrain patients mechanically or similarly and that causes friction. Also the topic: The patient is not really stable yet, but he is “psychiatric,” so they try to move him back as soon as possible. (Interview 08)

In another example of this type, an interviewee told us about his concerns about the ambulance service when he was asked which parties usually have stakes in ethical problems. In this case, the implementation of an open-door policy led to patients repeatedly absconding from the ward and making emergency calls to be finally brought back by the rescue services. The participant recalled this situation as an example for the weighing of differing views about ethical obligations:

[That] weighing between different parties involved: treating party, patient, relatives [pausing] ambulance service! Very often. Who

might well have claims on us, like, look! “This patient has to be locked up now! You have to end this, now!” (Interview 06)

These problems evolve around different parts of the healthcare system. These different actors (e.g. different wards, hospitals or services outside the institution, such as ambulance services) often follow different rationales concerning the use of different resources to fulfill their purpose. Study participants were severely concerned about problems in which, for example, a different prioritization of resources led to a clash between two or more actors. Regarding the latter quote: While there seem to be ethically justified reasons to adopt an open-door policy to reduce coercion, such an approach might stress the resources of the ambulance services as some patients absconded from the ward and then had to be brought back. As was recalled by the interviewee, the paramedics accused him of an unjustified use of their resources since their necessary reaction prevented them from being available for other (perhaps more urgent) calls at the same time.

These intersystem problems were understood as very demanding by the interviewees. They were connected to deep-rooted concerns. Mental health professionals expressed the need for help, especially in such contexts. Interestingly, perceptions

of the CESS members differed. Intersystem problems involving different stakeholders and complex problem schemes sometimes went unnoticed in the CESS members' statements. Some said that these problem types should not be labeled as ethical problems and did not feel responsible for them or were of the opinion that they were not able to deal with such problems. One long-serving CESS member stated:

Yes, well, that would be a little like, mmh. Well, I, yes. It would, well, be a bit of a justice of distribution, or how what amount of resources is occupied by people, which could also be used somewhere else, if you need the ambulance service five times in a situation that does not require somebody to be rescued, right? [pausing] Yes, mmh. Well, in my opinion, the patient always comes first. Of course, it is somehow good if everybody involved feels comfortable or consents to a certain course. But for me, the patient would be in focus and not any claims of paramedics or colleagues in somatic medicine. [pausing] Of course, it might not be that helpful for patients if there is this back and fore or no decision can be made and they are stuck in between. [pausing] I don't know whether this is really an ethical question or an organizational problem. (Interview 11)

Concepts of Ethical Expertise in Psychiatry

All participants reflected on a strong tension regarding their concept of the role as a "professional ethicist." This became particularly clear during the card sorting process in the interviews. Many of the participants developed concepts of a tense or contradictory nature. They reflected in detail on the tension between two poles. On the one hand, they described the concept of a neutral and "ethical" person who is equipped with knowledge on the medical context and philosophical theory. According to this, the professional's primary task is to detect and analyze ethical problems. Ethicists should take their own position based on their knowledge and skills. This position was, however, described as not being directive regarding solutions to problems or the ethical content of a problem. One participant stated:

[I also] think that too much is required of an expert to be able to solve an ethical problem, but to recognize and name it, he/she has to be able to do that, but he doesn't have to solve it at all. In turn, however, he/she should be able to make a decision. (Interview 03)

On the other hand, participants expressed their need for ethical guidance. Mental health professionals, especially, described the role as somebody who is able to make better judgements than others. According to this, the ethicists task would be to provide clear recommendations, for example, for the further course of the treatment, and to alleviate the subjective uncertainty, as mentioned above. One interviewee explained:

So, I am the main person responsible for the patient, but I hope that the expert would make a decision of his/her own and that he/she would tell us. (Interview 04)

One participant expressed her expectations regarding the role of a CESS member by comparing it to a situation in court she had experienced some time ago.

I just remembered; I was at law school. Once I was at a court hearing where a judge pronounced a judgement and afterwards, when the students were there, he gave himself time to explain why he had just made that decision. And I found that incredibly helpful, because from the outside, his considerations, which he took into account, that was for me, ehm, I could understand this decision much better and I think maybe in such things the issue simply overlaps a bit. (Interview 03)

According to her understanding, the judge in the example was able to pronounce a judgement due to his function and training, but his efforts to make himself understandable were equally important. In the same way, CESS members were expected to be able to take a clear position and give clear advice. However, participants felt that the authority given to these recommendations depends solely on their ability to make themselves comprehensible.

On the side of the CESS members, this conceptualization led to a situation which was understood as a kind of a dilemma. Participants literally felt torn between the two poles of the concept. On the one hand, they felt that people reach out for their guidance and that it is their responsibility to offer advice in difficult situations. On the other hand, they felt that their matter of expertise, that is, ethics, seems to preclude the idea of outstanding expertise and authoritative guidance. It seems that these people try to master the art of being directive (to offer guidance in difficult cases) without being directive (to offer guidance in an ethical way). This dilemma resulted in very complex and partially contradictory self-descriptions, as in the following case. One CESS member stated:

Am I an ethical expert, surely not. [pausing] But I would say that my experience, and I mean I have been doing this for some years now, it enables me to make somehow better judgments. (Interview 08)

On some occasions, this led to severe frustration because the person did not feel that he/she fulfills both requirements:

Well, I guess we are all rather small-scale ethicists here in medicine, right. (Interview 07)

DISCUSSION

Successful implementation of CESS in mental healthcare requires interventions and consultants to be able to react to the moral distress of healthcare professionals adequately. As Hem et al. (22) put it, there is a need for qualitative and reflective research to understand how mental health professionals deal with ethical problems and what kind of support might be suitable for them.

Our data reveal three different ethical problem types that can be seen to arise in mental healthcare practice which professionals want to refer to CESS: (1) Dyadic problems, (2) triangular problems and (3) intersystem problems.

Dyadic problems are directly connected to the doctor-patient relationship between individual patients and mental health professionals. They often develop between patient autonomy, on the one hand, and duties to beneficence in medical care, on

the other. Although these cases raise serious ethical questions and require careful consideration, our data show that existing structures, including CESS, can deal with them adequately. Cases of this type have, therefore, rarely been a cause for concern in our sample.

Triangular problems also emerge from the relationship between patients and professionals but involve a third party as the bearer of burden whose interest is at stake. Triangular problems pose a certain challenge for the practice of CESS in psychiatry for two reasons. Firstly, these cases are more complex in structure than dyadic problems. There are, for example, more stakeholders whose indirect involvement may be more difficult to assess and evaluate. Secondly, triangular problems raise a need for further theoretical clarification, especially regarding the underlying ethical questions. In many cases, triangular problems are concerned with the fair distribution of burdens. Should, for example, an individual coercive measure (such as seclusion or mechanical restraint) be applied against the will of a person under involuntary commitment who poses a danger to self or to others and repeatedly tries to abscond from an open ward, in order to maintain an open door for all other patients? Such a measure would mean a much stronger restriction of freedom for this individual person while it might benefit others (35). Or vice versa: Do all other patients in this case have to accept a stronger restriction of their freedom than needed in order to minimize the burden for their fellow patient as far as possible? Problems of this kind have rarely been discussed in the literature of ethics in psychiatry. As a consequence, there is a lack of concrete ethical approaches concerning the question of how the burdens could be distributed in an ethically justifiable manner to which CESS could refer.

Intersystem problems describe conflicts between different actors and levels of the healthcare system as a result of the different use of resources, rationales or purposes. This involves complex conflicts that can even extend beyond the healthcare system, including many different stakeholders. Effects emerging from these problems concern health professionals deeply. Intersystem problems seem to result in moral distress, which is not characterized by overarching uncertainty or moral dilemma but by certainty accompanied by constraints. These are typical situations “when one knows the right thing to do, but institutional constraints make it nearly impossible to pursue the right course of action” (36, 37). In terms of content, these problems often reflect the basic tension between psychiatry that is geared toward further opening up and the rather restrictive consequences of society’s protective interests. These problems are, therefore, likely to increase in importance in the future as psychiatry continues to develop on its chosen course.

It is notable that CESS members often do not understand this type as an ethical problem or do not feel equipped to deal with it. Problems are not perceived as ethical issues but rather as organizational questions. In addition, CESS members are very reluctant to include this area as part of their ethical responsibility. Different expectations of CESS members and mental health professionals regarding this issue bear a severe risk of misunderstandings and frustration on both sides. However, this finding must be seen against the background

that intersystem problems particularly pose great challenges for CESS. Furthermore, it must be argued that, from a conceptual perspective, this type of ethical problem does not correspond to the types of problems in medicine for which CESS was developed originally. These problems are more complex than other types of ethical problems on other levels and clearly depart from the individual relationship between patients and professionals. They include, for example, more stakeholders and institutions from the healthcare sector and can even reach out beyond this system. Including intersystem problems into the responsibility of CESS comes at the price of extensive adaptations in processes and structures. Bringing all perspectives involved to the table and finding solutions on this more systemic level requires high organizational efforts. This includes more sophisticated communication and moderation skills to bridge fundamentally different perspectives and is, doubtless, resource-intensive if it is ever possible at all for simple practical reasons. Moreover, a second point must be added to these pragmatic considerations: Some ethical problems might not even be open for a solution on the level of CESS due to the lack of competencies, power or the addressee of moral complaints. This results in a practical and conceptual challenge for dealing with ethical problems. On the one hand, it is the primary goal of CESS to develop concrete recommendations for ethically justifiable clinical decisions and, thereby, to prevent intersystem problems from being returned to practice as unmanageable. Failure to do so would equal the inability to react to the moral distress of mental health professionals and simply reproduce it on the level of CESS. On the other hand, from a theoretical perspective, recommendations given under such circumstances must be classified as non-optimal moral solutions. They are only justified because the actual problem is out of range. Challenges are, therefore, 2-fold. Firstly, in a practical perspective, ways to communicate this status of advice as non-optimal but justified by circumstances need to be developed. The awareness in CESS members and mental health professionals of the provisional nature of this advice needs to be raised. Secondly, from a conceptual perspective, structures have to be improved to ensure that intersystem problems can be taken up at higher levels. This is necessary to ensure that implications of ethical problems concerning the systematic level are not left unprocessed once a case on the clinical level has been handled. For these cases, a much stronger network with superior ethical bodies (e.g., at the level of medical associations, or regional or national ethics councils) and policymakers would have to be created. Such a network might be able to counteract the loss of the systematic implications.

Consequently, this would change the nature of CESS significantly compared to their original direct clinical focus. It also requires careful and resource-intensive training of the CESS members and, once again, underlines the importance of ethical expertise as the core of CESS. Our data show a strong inner tension regarding this core of a professional ethicist’s role. On the one hand, ethical experts are understood to be neutral people equipped with skills and knowledge to detect and analyze ethical problems. These people’s task is to bring together all perspectives on an equal footing. On the other hand, professional ethicists are expected to give advice and guidance

and defend ethically justified options in consultations to pave the way for further actions. The CESS members struggle with this role, feeling torn apart between its poles and sometimes even feel unable to satisfy the demands from both sides. Data show considerable inconclusiveness in statements about the professional identities of CESS members. This inconclusiveness of participants' statements mirrors a conceptual problem. As Iltis and Sheehan (29) rightly note, there is a considerable clash between being an expert and exercising advice in the domain of ethics: Expert recommendations give strong reasons to act in accordance with them and experts are mostly appreciated for this guiding force. However, the special character of ethics that assigns moral responsibility to the acting agent seems to preclude giving such authority to others over one's own ethical decisions (29). As a result, CESS members' descriptions of their range of expertise fluctuate between fulfilling the requirement of being an expert in an action-guiding sense and respecting the decision-making capacities and responsibility of those people they counsel.

Although this tension might be ubiquitous in CESS and may never be released completely due to its conceptual nature (38), we suspect its practical emergence to be more typical in mental healthcare. One of the reasons could be the flatter hierarchies in many psychiatric settings. These make it easier to question the status and role of experts and expert knowledge. Another reason could be the relatively small number of case consultations in psychiatry. This implies that there is less experience among professionals and the development of stable professional roles might be still at an early stage. We suggest, however, that this tension needs to be acknowledged as a practical fact that may lead to severe frustration and misunderstanding in CESS members. It should, at least, be mitigated as far as possible in clinical practice to avoid feeling torn apart between the two poles of this professional role. As a starting point, this requires CESS members to be aware of the special difficulties of their expert status and to include constant reflection of one's own position into the training and education of CESS members. A deeper understanding of the typology of ethical problems, as we have developed it here, is an important component to be able to assess the possibilities and the limits of one's own expertise better. It should, therefore, be taken into account in the training and further education of CESS members in psychiatry. A second measure, here, is to emphasize not only the differences and individuality of CESS in psychiatry but also the similarities with somatic medicine. In essence, the question of professional identity concerns all ethical experts. A stronger exchange, for example, through interdepartmental consultations, would contribute to a further development of existing roles on all sides and make it possible to create additional opportunities for exchange and experiences.

CONCLUSION

Strengths and Limitations

Qualitative research enables the exploration of complex social phenomena and underlying assumptions, such as typologies of ethical problems and concepts of expertise, within their native social horizon. In our study, the qualitative data form the basis of a normative and conceptual analysis. This has the strength of ensuring that the theoretical work on concepts

is grounded in empirical data and is, hence, both practically relevant and real-world oriented. It creates the opportunity to generate generalizable hypotheses on the challenges highlighted above and sketch ways to improve CESS in psychiatry.

Limitations to be considered in qualitative research concern, *inter alia*, representativity and transferability of the results. It must be stated clearly that results gained in this study cannot be representative due to the qualitative methods applied. Furthermore, the relatively small sample size limits the transferability of our results. In addition, the fact that we gathered our data in the specific German mental healthcare context reduces the scope of our results. We neither want nor are able to make any statement concerning a correlation between a certain institutional or societal context and the occurrence or frequency of any type of ethical problem. These limitations may also influence our normative analysis in terms of the accuracy of the conceptual model as its grade of detail corresponds with the explorative approach of the study. However, this does not limit the applicability of the model itself as a helpful tool for the further advancement of CESS in mental healthcare and especially in psychiatric hospitals.

Directions of Further Research

Our study warrants further research regarding the ethical problem types in psychiatry and the professional role of an ethicist, putting ethical expertise at its core. The findings concerning the typology of ethical problems show, firstly, a need for research concerning the handling of triangular problems. So far, ethics in psychiatry has devoted comparatively little attention to the question of what an ethically justified distribution of burdens might look like in these cases. Accordingly, there are few points of reference that could help CESS members to translate these difficult theoretical questions into practical counseling processes and ethical recommendations. Secondly, the handling of intersystem problems raises questions concerning the conceptual nature of CESS as an initially clinical intervention that focuses on the relationship between professionals and patients. In mental healthcare – more than elsewhere – CESS members are confronted with ethical challenges that go far beyond this relationship. The fact that this type of ethical problem often cannot be resolved satisfactorily within the limits of CESS and that it can result in non-optimal ethical recommendations can compromise the acceptance of CESS among mental health professionals and the implementation of CESS in mental healthcare institutions. Further research is needed to investigate the quality and quantity of the occurrence of such cases in clinical contexts. In addition, existing strategies of handling and communication need to be reconstructed by means of social science research to generate starting points for the implementation of targeted and practical recommendations for improvements.

Regarding the roles of ethical experts and the professional roles of CESS members in psychiatry, a more systematic development of the professional role of ethics consultants is needed. The role of an ethicist is poorly defined compared to other professional roles in healthcare. However, this is not only because these roles are still at an early stage of development but is due, above all, to the special nature of

ethical expertise, which seems to differ from other forms of expertise. There are currently only a few approaches in the theoretical literature to a consistent conceptualization of the specific roles of ethics consultants, which urgently need to be developed further.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Research Ethics Committee of the Medical Faculty of the Ruhr University Bochum. The participants provided their informed consent to participate in this study.

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AUTHOR CONTRIBUTIONS

JH, JG, JS, and JV designed this study. JH, JG, and GJ contributed to the implementation of the research. JH carried out the field work and the data analysis with input from JG, JS, GJ, and JV. JH wrote the first version of the manuscript. All authors contributed to and approved its final version.

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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