WHAT WORKS FOR FORENSIC PSYCHIATRIC PATIENTS: FROM TREATMENT EVALUATIONS TO SHORT AND LONG-TERM OUTCOMES

EDITED BY: Björn Hofvander, Katarina Howner and James Tapp

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WHAT WORKS FOR FORENSIC PSYCHIATRIC PATIENTS: FROM TREATMENT EVALUATIONS TO SHORT AND LONG-TERM OUTCOMES

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Editorial: What Works for Forensic Psychiatric Patients: From Treatment Evaluations to Short and Long-Term Outcomes

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Editorial on the Research Topic

What Works for Forensic Psychiatric Patients: From Treatment Evaluations to Short and Long-Term Outcomes

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Howner K, Hofvander B and Tapp J (2020) Editorial: What Works for Forensic Psychiatric Patients: From Treatment Evaluations to Short and Long-Term Outcomes. Front. Psychiatry 11:615473. doi: 10.3389/fpsyt.2020.615473 In many west-world countries the number of psychiatric beds are decreasing while the number of forensic beds are increasing (1, 2). Most forensic psychiatric patients suffer from psychotic disorders, but co-morbidity frequently occurs, such as personality disorders and substance abuse, in combination with violent behavior. For clinicians and staff working with the patients, the role is two-fold, both the psychiatric care for the patient and also preventing re-offending and protecting society. The nature of forensic psychiatric care, and ethical principles that underpin it, make it hard to conduct randomized controlled studies, which can be seen as the gold standard to establishing the efficacy of interventions. In a recent review, evaluating the research within forensic psychiatric care, gaps of knowledge were identified in every aspect of multidisciplinary input (3). This Research Topic encourages researchers to perform and publish high quality research within the field of rehabilitation within forensic psychiatric care.

In a systematic review by Howner et al. the objective was to investigate the effects of pharmacological interventions for forensic psychiatric patients. Only 10 studies met inclusive criteria and most of them were retrospective and non-randomized. Mainly due to the high risk of bias the reliability of the evidence for all outcomes was assessed as very low, and highlights the shortage of knowledge on the effectiveness of pharmacological treatment within forensic psychiatry. Jordan et al. performed a review with the objective to examine if there are biomarkers to support diagnostic process, treatment evaluation, and risk assessment of pedophilic individuals and child sexual offenders. The authors present an overview of the current neurobiological, as well as physiological and psychophysiological approaches to characterize pedophilia and child sexual offending, and then discuss and evaluate the impact of these approaches on the development of biomarkers for diagnosis, therapy and risk assessment in these subjects. The conclusion was that none of the promising parameters is ready to serve as a clinically applicable diagnostic, response or predictive biomarker for pedophilia and child sex offending. The most promising

approach seem to be a combination of several measures like EEG, fMRI, eye tracking and behavior. The relative efficacy of The Reasoning and Rehabilitation Program (R&R) and Dialectical Behavioral Therapy-Forensic (DBT-F) was evaluated by Wettermann et al. in a forensic-psychiatric hospital for offenders with substance addiction in Germany. Both programs were associated with improvements in nearly all of the measured constructs, but surprisingly, they did not find superiority for one intervention over Treatment as usual (TAU) or differential effects between the two programs. One-to-One (OTO) is a treatment program based on cognitive-behavioral principles. Berman et al. examined predictive properties of pre- and post- program test scores and background characteristics regarding recidivism, as well as differences between subgroups, in the OTO-program, in Sweden among 776 prisoners shortly awaiting release. The most potent predictor for non-recidivism was program completion, with non-completers 64% more likely to re-offend. Walker and Tulloch performed a qualitative study using semi-structured interviews with 10 nurses working in a high security hospital with forensic psychiatric patients. The purpose of the study was to explore the staffs experience of using mechanical restraints (Soft Restraint Kit), an option in extremely high risk patients allowing other interventions to take place. The conclusion was that Soft Restraint Kits provided a useful risk management method, but prolonged use presents considerable challenges for staff and patient. Preparation, training and supervision were deemed essential. In England, Cornish et al. examined acceptability, feasibility, and practicality in the Forensic Psychiatric and Violence Oxford Tool (FoVOx), a risk assessment tool. In the study, the patient's FoVOx score was compared to clinical risk assessment. In approximately half of the cases the clinical assessment of risk agreed with the FoVOx categories. Clinicians were more likely to provide lower risk categories compared with FoVOx ones. Its use addressed a lack of consistency around risk assessment at the point of discharge and, if used routinely, could assist in clinical decision-making. In Denmark, Bengtson et al. studied rates and facets of long-term violent reoffending in a population of violent offenders who underwent pretrial forensic examinations (FPE). The authors compared the group sentenced to forensic psychiatric care with the group which received ordinary sanctions. The first group was also compared

to a group of violent offenders who did not underwent a FPE. During the follow up time FPE examinees; untreated followed by treated, reoffend violently more often than the offenders who did not underwent a FPE. Similar trends are suggested also for severe and recurrent violence suggesting a need for continua-ofservices for FPE examinees, independently of medico-legal status (i.e., sentencing to treatment or not). Filicide is tragic and largely understudied, particularly from the perpetrator's perspective. In South Africa, Moodley et al. performed a qualitative study to examine the perceptions of seven women regarding their offenses and their perceptions about their treatment and rehabilitation. Most of the women had been psychotic at the time of the offense, and perceived trauma and regret for their offenses. Support from the community as well as empathy and unconditional positive regard from the staff, notably psychologists and occupational therapists were overwhelmingly present. Forensic psychiatric patients have a reduced life expectancy and Ojansuu et al. aimed to explore to what extent substance abuse disorders accounted for this increased mortality. During the follow-up time a prominent proportion (16%) of all deaths and a majority of the accidental deaths (64%) occurred under the influence of substances. The standardized mortality ratio for the patients with a history of substance abuse disorders was 4.1 compared to 2.8 for those with no such history. The management of substance abuse problems should be one cornerstone of the treatment of patients with both severe mental disorders and substance abuse disorders, and should also be extended to outpatient care. In an opinion article Andiné and Bergman signpost forensic mental health professionals to the importance of interventions that improve brain health, with supporting evidence. They promote that this avenue of interventions should be a future research priority for forensic psychiatric care, given its wide reaching outcome benefits.

AUTHOR CONTRIBUTIONS

KH wrote the first draft of the manuscript. BH and JT provided critical revision of the manuscript and important intellectual contributions. All authors read and approved the submitted version.

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Substance Abuse and Excessive Mortality Among Forensic Psychiatric Patients: A Finnish Nationwide Cohort Study

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Ojansuu I, Putkonen H, Lähteenvuo M and Tiihonen J (2019) Substance Abuse and Excessive Mortality Among Forensic Psychiatric Patients: A Finnish Nationwide Cohort Study. Front. Psychiatry 10:678. doi: 10.3389/fpsyt.2019.00678 **Background:** Forensic psychiatric patients are known to have reduced life expectancy. The aim of this study was to explore to what extent substance abuse disorders account for this increased mortality.

Methods: Data up to December 31, 2016 for mortality (causes of death register) and substance abuse (forensic psychiatric examinations) were collected for all of the 950 patients committed to involuntary forensic psychiatric hospital care in Finland during 1980–2009 and discharged no later than December 31, 2016. Patients were then classified as suffering or not suffering from substance abuse disorders and their causes of death were examined. The standardized mortality ratio was then calculated for these groups on the basis of sex-, age-, and calendar-period-specific mortality rates for the general Finnish population.

Results: During the follow-up time (mean 13.4 years), 354 (320 men, 34 women) patients died, resulting in a standardized mortality ratio of 3.5. The standardized mortality ratio for the patients with a history of substance abuse disorders was 4.1 compared to 2.8 for those with no such history. Among men, but not women, the age-adjusted proportion of death was significantly higher for those with a history of substance abuse disorders. In addition, in patients with a history of substance abuse disorders, the male age-adjusted competing risk of mortality was higher for unnatural causes, but not natural causes. Furthermore, a prominent proportion (16%) of all deaths and a majority of the accidental deaths (64%) occurred under the influence of some substance.

Conclusions: Substance abuse is a major factor causing excessive mortality among forensic psychiatric patients. The management of substance abuse problems should be one cornerstone of the treatment of patients with both severe mental disorders and substance abuse disorders during their time in hospital and this should be extended to outpatient care.

Keywords: forensic psychiatry, mental illness, substance abuse, mortality, accidental death

INTRODUCTION

All major psychiatric disorders are associated with an increased risk of premature mortality (1). The mortality of patients discharged from a psychiatric hospital has been found to be four-fold higher than the general population in a Finnish sample (2). The mortality associated with substance abuse disorders has been found to be even higher than that associated with serious psychiatric disorders, like schizophrenia, schizoaffective disorder, or bipolar disorder (3, 4). This risk for premature mortality seems, at least to some extent, to be additive, as patients with both comorbid substance abuse and serious mental disorders are at an even higher risk (5, 6, 7).

It is not surprising that the mortality of forensic psychiatric patients, who often suffer from both serious psychiatric disorders as well as substance use disorders (SUDs), is higher than that of the general population. In a Swedish sample, the mortality of forensic psychiatric patients was found to be higher, if the primary diagnosis was that they were suffering from a substance abuse disorder (8). This was also the case for forensic patients with a secondary diagnosis of a substance abuse disorder, unless they were suffering primarily from bipolar disorder. However, only 34% of the Swedish sample consisted of patients diagnosed with schizophrenia or some other psychotic disorder. This sample included patients from many decades, and it need be noted that the average treatment time of the sample was stated to have been only 5 months, which might not reflect current practice. In Finland, in order to treat individuals as forensic psychiatric patients, they are required to have a diagnosis of a psychotic disorder and the average treatment times are on average many years (9). In a Finnish study, the mortality among forensic psychiatric patients was found to be up to three-fold higher than the general population, but somewhat comparable to that of other schizophrenia spectrum patients (4, 9). When the causes of death were further examined, most of the deaths in the forensic psychiatric patients were due to somatic illnesses, although the largest difference, i.e., as much as seven-fold elevated risk, was attributable to suicide (10).

The problem in extrapolating these data for forensic patients from country to country is that the criteria for placing an individual into forensic psychiatric care vary between countries, as do treatment practices, even though in general, the psychiatric treatment protocols might be similar. Thus, results from different countries might not be generalizable, unless these criteria and their treatment protocols are similar. There is a rather sparse literature on the effect of substance abuse disorders on mortality in forensic psychiatric patients with psychotic disorders. It is evident that a more detailed knowledge of the factors behind the increased mortality observed in forensic psychiatric patients is needed to guide treatment decisions towards reducing these substantial risks.

The aim of this study was to explore the extent to which substance abuse disorders contribute to the increased mortality observed in forensic psychiatric patients, even when treatments times, and thus periods of abstinence, are long. This information would be of major clinical interest, since there is a

dogma surrounding many addictive disorders that the time of abstinence itself is a protective factor against relapse and further that relapse is a risk factor for increased mortality. If a long period of abstinence *per se* is not sufficient to prevent relapses for substance abuse disorders, then it is clear that there is a need to devise alternative treatment modalities for patients with substance abuse problems in forensic psychiatric hospitals.

MATERIALS AND METHODS

In Finland, the law court decides whether it is necessary to perform a forensic psychiatric examination which assesses the criminal responsibility of a defendant. Usually defendants committing homicides, or individuals who, due to their medical history or behaviour in detention, are thought to be affected by a psychiatric disorder, are subjected to a forensic psychiatric examination. After the forensic psychiatric examination, if the defendant is assessed as suffering from a serious mental disorder (psychosis or other disorders that affect reality testing, but not intellectual disability, autism or SUD by themselves), he/she can be exempted from legal punishment and be committed to involuntary forensic psychiatric hospital care. In the final stage of hospital treatment, the patient can be released on supervised leave, although he/she will still be under involuntary care. A supervised leave may be granted for up to 6 months at a time; furthermore, there can be multiple supervised leaves before ultimate hospital discharge. Most of the forensic psychiatric patients undergo this form of supervised leave prior to their final hospital discharge. After the patient's ultimate discharge from hospital, psychiatric outpatient care is not mandatory; in legal terms, ex-forensic psychiatric patients are regarded in the same manner as other psychiatric outpatients. Finnish legislation does not allow for compulsory or involuntary outpatient care for any psychiatric patient. The Finnish National Institute for Health and Welfare (THL) is responsible for both the initiation and termination of involuntary psychiatric forensic hospital care.

Data Acquisition

The material for this study was collected from the Finnish National Institute for Health and Welfare's archive, which houses data on all Finnish forensic psychiatric examinations and the information of patients who have been committed to or released from involuntary forensic psychiatric hospital care. The data from patients which constituted this study group were then linked to the national cause of death register of Statistics Finland, which contains information on all deaths in Finland, including data on causes of and events related to death, which made it possible to estimate mortality. Standard mortality data for the general population, to be used as control data, were also retrieved from this register.

Analyses

Our study population consisted of the 950 patients who had been committed to involuntary forensic psychiatric hospital care in Finland during the 30-year period from 1980 to 2009 and were discharged no later than 31.12.2016 (total number of patients committed during this time was 1,253). Follow-up started on hospital discharge and ended either on 31.12.2016 or when the patient died, whichever came sooner. The data for initial diagnoses (for psychosis and SUDs) were recorded from the forensic psychiatric examinations, which were then further screened for signs of SUDs not recorded in the diagnoses section, since the primary function of the examinations is to provide information on the individual's mental state (e.g., psychotic symptomology) and substance abuse disorders are sometimes omitted from the diagnoses section as they may be thought to either be secondary to the evaluation or to have arisen from the psychotic disorder. These data were pooled together to classify a patient as suffering or not suffering from an SUD according to ICD-10 criteria. Sometimes, it proved difficult to ascertain enough information to determine whether the criteria for addiction had been fulfilled, although harmful use was clearly evident. Patients with current unequivocal evidence of harmful use or addiction were classified as having an SUD, regardless of which substance was being abused (ICD-10: F1x.1 - F1x.2). Those patients for whom there was only evidence of intoxication or withdrawal symptoms without a longer standing substance abuse disorder, patients with only prior evidence of SUDs without current use, or patients without any evidence of an SUD were classified as not having an SUD.

Data on causes of death and events related to death from the patients were then retrieved up to 31.12.2016 from the cause of death register, and the causes of death were then categorized as being due to somatic diseases, suicides, accidents, homicides, or unclear. If signs of substance use at time of death or prior to death were evident from the death certificates, these were also recorded.

The Standardized Mortality Ratio (SMR) was then calculated for all patients, grouping the patients as either suffering or not suffering from SUD as described above. The SMR was calculated as the ratio of observed and expected number of deaths by using subject-years methods with 95% confidence intervals, assuming a Poisson distribution. The expected number of deaths was calculated on the basis of sex-, age-, and calendar-period-specific mortality rates in the general Finnish population. We used Cox proportional hazards model to calculate the age adjusted hazard ratios HR for death and adjusted survival (failure) function. A competing-risks regression model (Fine and Gray model) with a robust estimate of variance served to estimate the adjusted subhazard ratios (sHR) and cumulative incidence in the presence of competing risks. Stata 15.0 (StataCorp LP, College Station, TX, USA) statistical package was used for the analysis.

Ethical Considerations and Approval

This study is a part of the transnational After Care project. Ethics committee approvals for the study were sought and obtained from the Research Ethics Committees of Kuopio, Oulu and Turku Universities, Kuopio, Helsinki and Turku University Hospitals, Healthcare Centre of the City of Helsinki, Hospital District of Southern Savo, and the Hospital District of Pirkanmaa. This

study was also approved by and the study material gathered from the Finnish National Institute for Health and Welfare and Statistics Finland. This study was registry based, and no contact was made with the study subjects.

RESULTS

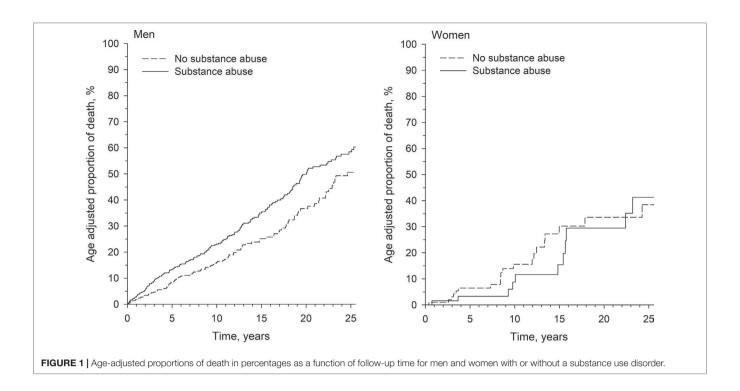
There was a total of 950 forensic patients detected and included in the analyses. All of the patients were diagnosed as suffering from a psychotic disorder; the majority of them had a schizophrenia spectrum disorder, more specifically 59% had schizophrenia (ICD-10: F20.x), 13% had delusional disorder (F22.x), 9% had schizoaffective disorder (F25.x), and the rest other psychiatric disorders affecting reality testing, such as severe bipolar disorder, psychotic depression, organic brain injuries, or severe borderline personality disorder. The vast majority (823 = 86.6%) of the 950 forensic psychiatric patients were men and 127 (13.4%) were women. The mean duration of forensic psychiatric treatment had been 6.7 years [standard deviation (SD) 5.5], and the mean age of the patient was 43 years (SD 13) at the time of his/her discharge. The mean follow-up time was 13.4 years (SD 9.3 years). In Finland, a substance abuse disorder in itself is not sufficient grounds for treatment as a forensic psychiatric patient, but the majority (567 = 59.7%) of the patients (514 men, 53 women) were noted as suffering from a comorbid SUD according to ICD-10 criteria (either addiction or harmful use) in conjunction with their psychotic disorder. Of these 567 patients with an SUD, 395 were diagnosed prior to or during the forensic psychiatric examination; the other 172 were classified as having an SUD according to the examination notes of the forensic psychiatrist, even though no official diagnoses had been set for them.

During the follow-up, a total of 354 patients died. The mean follow-up time for these patients was 10.3 years (SD 8.1), resulting in a SMR of 3.5 for the whole patient population. The vast majority of deaths (264 = 74.6%) were attributable to somatic diseases; 80 (22.6%) of the deaths were due to unnatural causes (accidents, suicides, homicides); and in 10 (2.8%) cases, the cause of death had remained undefined even after forensic autopsy and had therefore been classified as unclear in their death certificate.

Most, 320, of the 354 deceased patients were men and 34 were women. Among these deceased patients, 218 were noted as having a substance abuse disorder during their forensic psychiatric examination. The SMR for the patients with an SUD was 4.1, whereas the SMR for the patients without an SUD was 2.8.

Among men, the age-adjusted proportion of death was significantly higher among those with an SUD when compared to those without this disorder [hazard ratio (HR) = 1.34, 95% confidence interval (95% CI) 1.07 to 1.69, p=0.012], but this kind of difference was not observed among women (HR = 1.00, 95% CI 0.50 to 2.01, p=0.99). The age adjusted proportions of death are shown in **Figure 1**.

The age-adjusted competing risk of mortality among men with a known SUD was not higher for the risk of death due to diseases



(sHR 0.95, 95% CI 0.73 to 1.24, p = 0.70), but was significantly higher for the risk of dying from unnatural causes (sHR 2.63, 95% CI 1.55 to 4.47, p = 0.015). The competing mortality risks for men are shown in **Figure 2**.

Many of the examined death certificates mentioned that the current status of substance use preceding death was not known, though in many of the cases even when a background of substance use was recognized, the relationship between substance use and death remained somewhat obscure. However, in 56 of the 354 deaths, there was clear evidence of current substance use listed in the death certificates, such as evidence of intoxication or withdrawal symptoms at time of death or the fact that the subject had been found deceased with items for substance use, such as needles and syringes or alcohol. Of these 56 deceased, 47 had a history of SUD, only 9 did not (Chi² statistic 14.04, p > 0.001 for history of an SUD vs. evidence of substance use at time of death, Table 1). Deaths related to current substance use with regard to history of an SUD are presented in Table 1. The numbers of deaths with/ without current evidence of substance use, subdivided into causes of death, and the percentage of patients with or without clear evidence of current substance use at time of death are presented in Table 2.

If one assesses the natural deaths, then the cause of death was stated to have been directly caused by substance abuse in 10 patients; in more specific terms, three had alcohol related liver cirrhosis, three had alcohol related heart disease, one had combined alcohol related liver cirrhosis and heart disease, one had alcohol dementia, and for two, the main cause of death had been listed as SUD.

The majority (28/44 = 64%) of the unnatural deaths due to accidents were substance related. Fifteen of these deaths were attributable to substance overdoses or poisonings, 10 of which were alcohol intoxications. Of the remaining 13 substance related accidental deaths, four individuals had choked on food, two had died of subdural hemorrhage, one had frozen to death, one had drowned, one had died due to carbon monoxide poisoning, and one had suffocated after passing out in an awkward position, all while intoxicated. Three deaths happened during the withdrawal stage: one patient had frozen to death, one died of a subdural hemorrhage, and one due to clozapine poisoning after an extended period of drinking.

In 10 cases, the classification of death was unclear; for example, in some cases, it could not be determined whether a blunt force trauma was due to an accident or suicide, but in 5 of these cases, there was evidence of substance use.

DISCUSSION

Our results show that even after a long period of abstinence due to institutionalized forensic psychiatric care, especially men with a history of substance abuse disorders, in comparison with their counterparts without such a background, still have a significantly elevated risk for premature mortality after their release from care, especially due to unnatural causes. The same phenomenon was not observed in women, but this might be due either to actual gender-related differences or possibly due to the small sample size of our female study population. Furthermore, many of the deaths observed in the patient groups

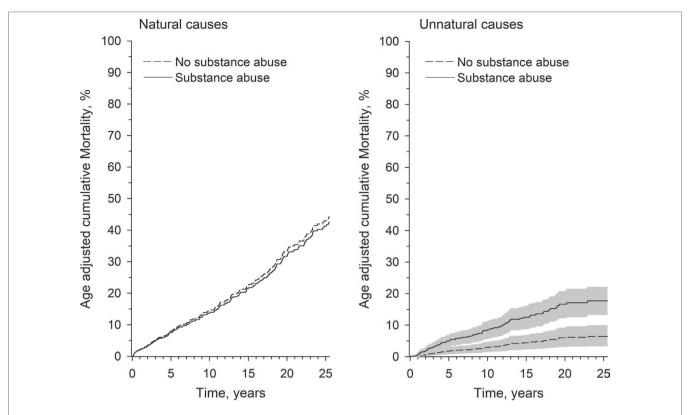


FIGURE 2 | Age-adjusted competing risk of mortality in percentages as a function of follow-up time in men with or without a substance use disorder for both natural and unnatural causes. The figure for unnatural death displays hazard ratios (lines) and confidence intervals (shadings around lines).

TABLE 1 Number of deaths related to current substance use with regard to history of substance use disorder (Chi² statistic 14.04, p > 0.001).

Chi ²	Deaths related to current substance use	Deaths unrelated to current substance use
History of SUD	47	171
No history of SUD	9	127

TABLE 2 Number of deaths with/without current evidence of substance use subdivided into causes of death and by gender. The percentage of patients with or without clear evidence of current substance use at time of death is given in parentheses.

	Men	Women	Total
Suicide			33
 substance use related 	3	0	- 3 (9%)
- substance use unrelated	27	3	- 30 (91%)
Accident			44
 substance use related 	27	1	- 28 (64%)
 substance use unrelated 	14	2	- 16 (36%)
Homicide			3
 substance use related 	1	0	- 1 (33%)
 substance use unrelated 	2	0	- 2 (67%)
Unclear			10
 substance use related 	5	0	- 5 (50%)
 substance use unrelated 	5	0	- 5 (50%)
Disease			264
 substance use related 	18	1	- 19 (7%)
- substance use unrelated	218	27	- 245 (93%)

actually occurred while the patient was under the influence of substances, indicating obvious relapses of their substance abuse disorder.

As compared to previous studies investigating this topic, the strengths of this study are the large sample of forensic psychiatric patients, the prolonged mean follow-up time of 13.4 years, and the possibility to access the comprehensive and validated Finnish national registers (11). One weakness of this study was that we were unable to obtain information on the living arrangements, medication use and commitment to outpatient care, inpatient care episodes, or criminal convictions after discharge from the hospital. There was also no information available on what kind of treatment, if any, patients had received for their SUDs in addition to the forced abstinence during their hospital incarceration. Also, as only patients with clear evidence of current SUDs from the forensic psychiatric examinations were classified as having an SUD, some patients with marked substance use, but not clearly reaching diagnostic thresholds as assessed from the examination statements, were classified as not having an SUD, which serves to dilute the results presented here. It need also be noted that some 30% of the patients with clear diagnostic evidence of an SUD were left without a diagnosis of such in the initial forensic psychiatric mental state examinations, which could indicate a serious defect in recognizing substance abuse disorders and even possibly led to failure to provide proper treatment for them. It is also worth noting that knowledge of possible relapses to substance use was

only available for those patients in whom it was mentioned in their death certificates. Thus, it is possible, perhaps even likely, that the overall rates of substance use relapses were higher. Some of the patients in the "no prior history of substance abuse" group might also have developed SUDs during their follow-up time, i.e., the present findings may be an underestimation. The data are thus subject to confounding by indication. In addition, as the current study is an observational registry based study, the data presented are only correlations, and only speculations of causality can be made.

In this study, the presence of substance abuse was found to contribute to mortality in the background of some somatic diseases, but it was especially evident in the large proportion of deaths due to accidents. Thus, although substance abuse might not be the only problem responsible for poor coping in some individuals, it is likely to be a major factor causing excessive mortality among forensic psychiatric patients due to both natural and unnatural causes. Therefore, the management of substance abuse disorders should receive a high priority in this patient group, in an attempt to reduce the excessive mortality as well as gaining other health benefits associated with reduced substance use. When viewed against the background of the long psychiatric hospital treatment provided for these patients, these results must be viewed both as a sign that abstinence in itself is not sufficient to prevent relapses and able to reduce the excessive mortality, but also as an indication of a failure to provide treatment modalities with greater efficacies.

CONCLUSION

According to our study, a history of substance abuse is related to the excessive mortality observed in Finnish forensic psychiatric patients. Thus, the integrated management of addiction problems should be one cornerstone of the treatment of patients with both severe mental disorders and substance abuse disorders not only during their time in hospital but also extended to their outpatient care.

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DATA AVAILABILITY

The data analyzed in this study were obtained from Finnish national registers as described above. Due to the confidential nature of patient data, the data are not publicly available.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Research Ethics Committees of Kuopio, Oulu and Turku Universities, Kuopio, Helsinki and Turku University Hospitals, Healthcare Centre of the City of Helsinki, Hospital District of Southern Savo, and the Hospital District of Pirkanmaa. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

IO, HP, ML, and JT contributed to the conception and design of the study. IO organized the database and wrote the first draft of the manuscript. ML contributed to drafting and writing of the report. All authors contributed to manuscript revision and read and approved the submitted version.

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Long-Term Violent Reoffending Following Forensic Psychiatric Treatment: Comparing Forensic Psychiatric Examinees and General Offender Controls

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Bengtson S, Lund J, Ibsen M and Långström N (2019) Long-Term Violent Reoffending Following Forensic Psychiatric Treatment: Comparing Forensic Psychiatric Examinees and General Offender Controls. Front. Psychiatry 10:715. doi: 10.3389/fpsyt.2019.00715 **Background:** Long-term violent re-offending in forensic psychiatric (FP) patients *vs.* non-FP offenders is largely unknown.

Methods: We studied rates and facets of long-term violent reoffending among 1,062 violent forensic psychiatric examinees (FPE) consecutively undergoing pre-trial, forensic psychiatric examination (FPE) in Denmark during 1980–1992. Altogether, 392 were sentenced to *FP treatment* (FPE+T); the remaining 670 examinees received ordinary non-FP sanctions (FPE-T). FPE+T were compared to 392 contemporary *matched violent general offenders* (GEN) without FPE or other psychiatric contacts and sentenced to ordinary non-FP sanctions. FPE data were linked to population-based registers with sociodemographic, psychiatric, and crime information, and we estimated relative risks controlling for birth year, sex, educational and marital status, and previous violent crime.

Results: During follow-up (mean = 18.0–19.5 years), FPE+T and GEN had *any violent recidivism* rates of 43% vs. 29% [adjusted hazard ratio (aHR) = 1.5; 95% CI, 1.1–1.9], respectively. Corresponding findings for *severe violence* (21% vs. 14%; aHR = 1.3; 95% CI, 0.9–1.9) and *recurrent violence* (3+ violent convictions; 16% vs. 6%; adjusted odds ratio [aOR] = 2.5; 95% CI, 1.5–4.4) also suggested weakly to moderately increased risks in FPE+T, albeit non-significantly for the former. Comparing FPE+T to FPE-T suggested *decreased* risk of *any violence* (43% vs. 51%; aHR = 0.8; 95% CI, 0.6–1.1), *severe* (21% vs. 34%; aHR = 0.6; 95% CI, 0.4–0.8), and *recurrent violence* [16% vs. 22%; adjusted odds ratio (aOR) = 0.7; 95% CI, 0.5–1.0] in FP patients, though non-significantly for any violence and recurrent violence. Among all FPE examinees, violent reoffending was independently predicted by male sex, younger age, pre-index violent crime, personality disorder (vs. schizophrenia spectrum and other psychiatric disorder), substance use disorder, and 5+ hospital admissions.

Conclusion: FPE examinees, untreated followed by treated, reoffend violently more often than GENs. Similar trends are suggested also for severe and recurrent violence

suggesting a need for continua of services for FPE examinees, independently of medicolegal status (i.e., sentencing to treatment or not).

Keywords: forensic psychiatric patients, violent reoffending risk, facets of violence, long-term follow-up, forensic psychiatric evaluation

INTRODUCTION

Due to mental ill health, a small but important number of criminal offenders are committed to court-ordered psychiatric treatment. Recently, many Western countries including Denmark have experienced substantial increases in the number of forensic psychiatric (FP) patients (1-4). However, throughout Europe (5) and North America, FP patient care is organized and administered differently due to dissimilar legislation, judicial and court practices, and organization of forensic and mental health services. Such variability even occurs across otherwise quite comparable Nordic welfare states (6). In clinical practice with FP patients, on the other hand, treatment goals are generally two-sided—optimal treatment of psychopathology and reduction of criminal re-offending (7). However, complex comorbidity with neurodevelopmental conditions and substance misuse, socio-economic disadvantage, trauma and neglect, and fluctuating compliance with interventions complicates psychiatric care and risk management and increases reoffending risk (5, 8-10). These aspects also affect mental health budgets disproportionately, despite FP patients being a minority among psychiatric patients (11).

Prior research investigated criminal reoffending in FP patients (12-17). Naturally, reoffending figures increase with extended follow-up to reconviction rates of 40-50% in any crime (12, 18) and violent reoffending alike (12, 14, 16). Prevention of violence recurrence includes also qualitative aspects such as of imminence, severity, and recurrence of violent reoffending and concerns regulatory authorities, service providers, and clinicians alike. However, Douglas and Ogloff (7) reported lower reliability and incremental validity of clinicians' HCR-20based (19) structured professional judgments of imminence and severity of violent recidivism among 100 FP patients following discharge, compared to the assessment of any violent reoffending risk. Beyond insufficient rater training and risk communication structures, poor knowledge about base rates of these violence facets might be critical. Monahan (20) argued that proper base rate information of a predicted outcome might be the most important single piece of information needed for risk assessments. However, humans tend to ignore generic and general base rate data and instead focus case-specific information, referred to as base rate neglect (21). Similarly, Coid and co-workers (22) reminded that studies of FP patients require sufficient sample size and statistical power to quantify long-term reoffending risks following psychiatric treatment and identify those at highest risk and, specifically, address violent re-offending in FP patients with one or more violent offences at baseline. Beyond a few exceptions (22-25), studies of violent offenders rarely investigated violence risk as multifaceted constructs, including also information on the imminence, severity, and recurrence of violent reoffending, although these aspects might be particularly helpful to forensic psychiatry clinicians (7).

Another long-standing question is whether offenders with severe or major mental illness, usually defined as schizophrenia spectrum or bipolar disorders, are at higher reoffending risk than those without. A recent systematic review of 35 studies following patients discharged from secure hospitals (n=12,056), of which 53% were violent offenders found overall reoffending rates of 0-24,244 per 100,000 patient years, a pooled mean estimate of 4,484 per 100,000 patient years and substantial heterogeneity across studies (11). Reported violent reoffending rates ranged from 273 to 8,403 per 100,000 person years with a pooled mean of 3,902 and showed considerable heterogeneity across studies (k = 15). The findings suggested that FP patients have lower reoffending rates overall than comparison subjects such as released prisoners. However, comparisons are difficult as FP patients constitute a highly selected sample who often commit more severe or violent, but not necessarily more frequent, offences and are incapacitated for longer periods at baseline than non-FP offenders. They often have supportive treatment or aftercare, usually associated with lower reoffending risk. Further, between-country comparisons are difficult because of different legislation, recording, reporting and sentencing practices, heterogeneous samples with both prisoners and probationers, varying follow-up periods, and outcome definitions (12, 26). Fazel et al. (11) attempted to adjust for some of these confounders by matching violent FP patients with prisoners having received longer sentences and comparing FP patients with prisoners from the same country, year, and, when possible, the same age span. Even with such adjustments, FP patients still had lower rates of reoffending, including violent recidivism. However, only a few individual comparative studies have compared FP patients with otherwise similar, non-FP offenders within the same legislation and judicial practice. Also, few comparative studies accounted for differential prevalence of confounders in FP and control offender samples: birth year, previous violence, educational and marital status, length of psychiatric hospitalization, and imprisonment (reflecting time at risk for reoffending).

Along with long-term violent reoffending risk estimates in FP patients, information on individual risk factors would help risk assessment and management. Prior research mostly focused on sociodemographic and criminological factors: age, gender, and prior violent offences (27–29). While most individuals with psychiatric disorders do not engage in violence, the risk of committing violence is higher for individuals with a mental disorder than for those without (30). Specifically, links have been established between violent offending and schizophrenia (31, 32), bipolar disorder (33), and psychosis (34) with risks mostly

confined to patients with emotional dysregulation, paranoid beliefs, or substance abuse comorbidity (31–33, 35–39). Whether psychiatric disorders are risk factors for reoffending in convicted offenders' needs, however, further examination (12, 40).

We followed a large, nationally representative Danish cohort of violent and treated FP patients; FP examinees sentenced to FP out- or inpatient treatment at medium secure units (FPE+T). We examined absolute and relative risks of long-term (on average 18+ years at risk) overall, severe, and recurrent violent reoffending compared to 392 individually matched non-examinee non-psychiatric violent general offenders (GEN) and 670 violent non-treated FPE examinees sentenced to ordinary sanctions (FPE-T), respectively. Risk factors for recidivism among FP examinees were identified, and we matched or controlled statistically for unbalanced distributions of possible confounders across cohorts.

MATERIALS AND METHODS

Study Population

Violent offenders referred to court-ordered, pre-trial FP examinations in Copenhagen and Aarhus, Denmark, between 1980 and 1992 were either sentenced to FP treatment (FPE+T; n = 392) or regular non-treatment sanctions (FPE-T; n = 670). We compared FP patients (FPE+T) to matched violent general offender (GEN) control subjects selected from population-based registers run by Statistics Denmark (see matching procedure below).

Forensic Psychiatric Examinees

In Denmark, FP evaluations (FPE) are requested to inform court sentencing. FPEs are conducted with selected cases, for example, when a suspected offender has a history of mental illness or shows current psychiatric symptoms or offence-related behaviors that may be signs of severe mental illness. Other determinants include young age (from age 15, the age of criminal responsibility in Denmark) or being elderly (60+ years) as well as indications of a high risk of severe violent reoffending where an indeterminate sanction may be mandatory by law to prevent reoffending (41). The multidisciplinary evaluation leads to a report documenting the mental state of the accused individual and a statement on whether FP care (outpatient or inpatient in moderate or high-security wards, respectively) is recommended. The court independently decides whether to follow the FP team recommendation or not.

FPE examinee data were consecutively collected for a historical population-based cohort of all subjects admitted January 1, 1978, to December 31, 1992, for court-ordered, mandatory pre-trial FP evaluation in Denmark's two largest cities, at the Department of Forensic Psychiatry, Aarhus, or the Forensic Psychiatry Clinic, Ministry of Justice, Copenhagen, Denmark (N = 2194). Approximately 85% of all FPEs in Denmark during the inclusion period were conducted at these two settings. We included offenders convicted of the violent non-sexual or sexual *index* crime motivating the FP examination and sentenced to either psychiatric treatment (in- or outpatient) or an ordinary sanction, who were possible to be identified in Statistics Denmark registers and did not have an ICD diagnosis of mental

retardation (generally IQ < 70). If examined more than once, we selected the first FPE. Importantly, death and emigration were not exclusion criteria; subjects provided follow-up data until death or emigration (when they were censored). Since the Danish Crime Register did not become a research register at Statistics Denmark until 1980, individuals convicted in 1978-1979 were excluded (n = 370). Another 762 (42%) FPE subjects did not meet the inclusion criteria; 128 were not identified in registers (e.g., total population and Danish Psychiatric Central Research Registers), 219 did not have a violent offender control because of narrow matching criteria, 21 were acquitted or sentenced to indeterminate detention or placement at a maximum secure facility, 66 had a diagnosis of mental retardation, and 328 were convicted of a non-violent index offence. The remaining 1,062 violent FPE examinees were divided into two cohorts according to index sentence/sanction: FP care (n = 392; treated FPE examinees, FPE+T: 20% were sentenced to outpatient psychiatric care, 43% to inpatient psychiatric care, and 10% to placement in a FP hospital; 24% unknown) or an ordinary, non-FP sanction (n = 670; non-treated FPE examinees, FPE-T; 86% were imprisoned and 14% received non-custodial sentences).

Matched Violent General Offender Controls

Violent general offender controls (GEN) were individually matched (1:1) to FPE+T individuals on sex, birth year (\pm 3 years), specific violent offence type according to criminal law paragraphs (e.g., if an FPE+T patient was convicted of manslaughter or a sexual offence against a minor; his matched control was indicted or convicted accordingly), and index conviction date (\leq 2 years within the FPE+T subject's sentence date) and had never been diagnosed with a psychiatric disorder before or after the violent index offence. We matched on the first four variables according to nationwide register data at Statistics Denmark, while information on the fifth came from the Danish Psychiatric Central Research Register (42). The index sentence for GENs was imprisonment (69%) or non-custodial sentences (31%). Among controls, 69% were imprisoned, and 31% received non-custodial sentences; one control was acquitted.

Procedures

For all FPE examinees, we obtained baseline offender data from FPE reports and national registers. Six trained raters (SB, JL, and four master-level psychology graduate students trained by SB) extracted sociodemographic information, psychiatric diagnoses, and type and date of index sanction.

Principal ICD-8 psychiatric diagnostic codes were extracted from FPEs according to the International Classification of Diseases (ICD), 8th revision (43) used in Denmark 1966–1994, followed by ICD-10 from 1995 (44). ICD-9 was never implemented in Denmark. Since the WHO did not publish algorithms for translation between ICD-8 and ICD-10, ICD-8 diagnostic codes for Copenhagen and Aarhus FPE subjects were converted to corresponding ICD-10 entities by two senior general psychiatrists, the editor of the psychiatric section of the Danish version of ICD-10 and JL, respectively. We differentiated between major mental disorder categories: *schizophrenia spectrum and*

other psychotic disorders (ICD-10: F20-29); bipolar, depressive, and related disorders (ICD-10: F30-39); personality disorders (ICD-10: F60-61); and other disorders (all remaining psychiatric disorders in ICD-10). Complementary diagnostic data for any substance use disorder (SUD) were obtained from the Psychiatric Central Research Registers (PCRR) (42) and diagnosed according to ICD-8 (code 303 [alcoholism] and 304 [drug dependency]) or ICD-10 (all ICD-10 F1 disorders except uncomplicated use of a substance [F1x.10], caffeine [F17], or nicotine [F15]). We had no information on psychiatric morbidity including substance abuse in matched violent general offender controls (GEN) because of the "no psychiatric diagnosis" inclusion criterion. Further, data on the specific psychological and pharmacological treatment of major mental and personality disorders in FP examinees and controls were unavailable, both before and after discharge from FP care or release from prison, respectively. Complete treatment data were neither available from registers nor ethically or logistically possible to extract reliably from patient files.

For all subjects, information on most risk factors (sociodemographic, criminal history, and substance use disorder), time-dependent covariates during follow-up (psychiatric hospitalizations, imprisonment, emigration, and death), and outcome measures (criminal reoffending) was obtained from population-based registers. All Danish residents have a unique identification number that was used to link baseline data with high-quality, longitudinal population registers (Statistics Denmark): The National Patient Register, The Crime Register, causes of death, total population, and Psychiatric Central Research Registers (PCRR) (42). The PCRR holds information on all inpatient assessment and treatment, and high validity has been reported for specific PCRR psychiatric diagnoses, including schizophrenia, single episode depression, dementia, and autism (45).

Together with the Swedish Crime Register (31), the Danish Crime Register is one of the most comprehensive and accurate nationwide criminal registries in the Western world (46) and accurately reflects officially resolved criminality by covering all sentences in lower court regardless of type (custodial, noncustodial, FP, etc.) for individuals from 15 years (age of criminal responsibility). Also, consumption of offences (that more severe offences can "consume" less severe, so the latter will not be tried and receive a sentence and, hence, not be visible in crime statistics) and plea bargaining are seldom practiced in the Danish legal system (47).

Outcome Measures

Data on all criminal convictions from January 1, 1980 (the earliest date such data were accessible at Statistics Denmark), to December 31, 2011, were retrieved from the Danish Crime Register for the two FPE examinee cohorts and matched violent offender controls. We extracted information on any violent reoffending, offence severity, and frequency of violent sentences. We followed previous studies (31, 48) and applied a broad definition of *any violence* (i.e., any non-sexual [homicide, assault, robbery, arson, illegal threats, and intimidation] or sexual [contact or non-contact, including child sexual exploitation

material use/child pornography] offences). Attempted and aggravated offences were counted when applicable. We also differed between *severe violence* (homicide, serious/aggravated assault, robbery, rape, sexual coercion, or child molestation) and *recurrent violence* (defined as 3+ separate court sentences for any violence).

We counted all reconvictions during follow-up, independently of the sentence: ordinary sanctions (e.g., fines, probation, conditional/unconditional imprisonment), preventive measures (e.g., placement or treatment orders, indeterminate detention), and withdrawal of charge. The latter is included since the accused is viewed guilty as charged, although the legal proceedings are completed without trial. Withdrawal of charges is rarely applied, typically for minor offences, for mentally ill offenders already sentenced to treatment at a psychiatric hospital, young offenders, or those already serving time in correction settings (49).

For FPE examinees, reoffending was operationalized as offences committed after the day of FPE completion and for controls as offences committed from the day of the index sentence. First reoffence was the first day of the commission of a violent crime after index. If the date of committing violence was not applicable, date of charge or conviction was applied. We followed subjects until end of follow-up (December 31, 2010), date of death, or emigration, whichever occurred first. Since information on the date of last conditional discharge for treated FP examinees (FPE+T) was not accessible, we calculated time at risk during follow-up as time alive in Denmark not being hospitalized at a psychiatric hospital or imprisoned. Since information on the exact date of release from prison was unavailable for imprisoned offenders (FPE-T and GEN), imprisonment periods were calculated as 2/3 of court-determined prison sentence length; prisoners in Denmark are regularly paroled after serving 2/3 of their sentence.

During follow-up, 43% of FP patients (FPE-T) were censored (41% died, 2% emigrated) vs. 27% of GEN (22% died, 5% emigrated) and 40% of FPE-T (37% died, 3% emigrated).

Statistics

We conducted pairwise comparisons of sample characteristics: first with FP patients (FPE+T) vs. matched general offender controls (GEN), and second, with FPE+T vs. non-treated FP examinees (FPE-T). Subgroup differences were analyzed with chisquare (categorical data) or t-tests (normally distributed interval or ratio data). Effect sizes are provided as standardized mean differences (Cohen's d). We estimated treated FP patients' (FPE+T) reoffending risk relative to controls (GEN) and to FPE examinees receiving ordinary sentences (FPE-T), respectively, using Cox proportional hazard regression. The latter method was also used for survival analyses. In Cox regression models, we adjusted for previous violent sentences and educational and marital status at index offence. Additionally, we either matched (violent offender controls; GEN) or adjusted (untreated FPE examinees; FPE-T) for birth year and sex. Finally, we also used Cox regression to model the long-term predictive ability of potential risk and protective factors on any violent recidivism among all FPE examinees. The latter analysis did not include comparisons with matched

violent general offender controls (GEN) since several factors (e.g., substance abuse) were unavailable for them. Across analyses, we compared treated FP patients (FPE+T) to either of the two control groups (i.e., FPE+T *vs.* GEN and FPE+T *vs.* FPE-T).

An independent government agency (Statistics Denmark) merged and pseudonymized the data, and we conducted statistical analyses with SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). The Regional Research Ethics Committee in Aarhus County, Denmark, determined that the study did not need formal ethical approval. We also registered the study with the Danish Data Protection Agency and Region of central Jutland (2002-41-2073, 2007-58-0010, 2011-41-7058, and 1-16-02-530-18).

RESULTS

The results of pairwise comparisons of sociodemographic, psychiatric, and criminological baseline characteristics of FP patients (FPE+T) vs. matched general offender controls (GEN)

and FPE+T vs. non-treated FP examinees (FPE-T) are presented in **Table 1**. Expectedly, all three cohorts were characterized by single, unemployed males in their thirties with low education and a violent, non-sexual index offence. Overall, we followed subjects for a mean of 20.3 years, without significant differences across cohorts. This corresponded to an overall time-at-risk (i.e., follow-up time when not hospitalized or imprisoned) of 18 to 20 years, with matched general offender controls (GEN) having a slightly longer time-at-risk.

FP patients (FPE+T) were characterized by more pre-index violence (any violence and number of violent convictions) and less protective factors (higher educational level, current employment, having a partner) compared to GENs. As opposed to GEN, all FP patients were diagnosed with at least one psychiatric disorder; a total of 21% also had a comorbid substance use disorder (SUD) diagnosis.

Untreated FPE examinees (FPE-T) were, on the contrary, characterized by far more known risk factors (significantly younger age, lower educational level, personality disorder [PD]

TABLE 1 Characteristics of violent offenders who underwent pre-trial forensic psychiatric evaluation (FPE) in Denmark in 1980–1992 and matched controls.

Characteristic	FPE+T ^a	GEN ^b	FPE-T°
	(N = 392)	(N = 392)	(N = 670)
Age, y, mean (SD)	32.7 (11.5)	32.9 (11.9) ^{ns}	30.5 (10.1)**
Male sex, n (%)	374 (95.4)	374 (95.4) ^{ns}	635 (94.8)ns
Highest education: 9th grade, n (%)	240 (61.2)	230 (58.7)**	447 (66.7)***
Currently employed, n (%)	86 (21.9)	190 (48.5)***	183 (27.3)*
Single marital status, n (%)d	331 (84.4)	287 (73.2)***	549 (81.9)ns
Principal psychiatric disorder at FPE, n (%)			
Schizophrenia spectrum disorder (F2)	225 (57.4)	§	21 (3.1)***
Bipolar, depressive, and related disorder (F3)	17 (4.3)	§	33 (4.9)
Personality disorder (F6)	79 (20.2)	§	531 (79.3)
Other psychiatric diagnosis	68 (17.3)	§	74 (11.0)
No psychiatric diagnosis	3 (0.8)	392 (100)	11 (1.6)
Substance abuse comorbidity (F1.1-F1.9), n (%)	81 (20.7)	§	86 (12.8)***
Index offence			
Any violence ^e , n (%)	317 (80.9)	317 (80.9) ^{ns}	499 (74.5)*
Sexual violence ^f , n (%)	75 (19.1)	75 (19.1) ^{ns}	171 (25.5)*
Severe non-sexual/sexual violence ⁹ , n (%)	222 (56.6)	219 (55.9) ^{ns}	469 (70.0)***
Prior violence conviction			
Any violence, n (%)	75 (19.1)	51 (13.0)**	194 (29.0)***
No. of violence sentences, mean (SD)	0.28 (0.67)	0.18 (0.53)*	0.50 (0.99)***
Severe non-sexual/sexual violence, n (%)	40 (10.2)	31 (7.9) ^{ns}	121 (18.1)***
Follow-up/time-at-risk			
Total follow-up time, y, mean (SD)	20.3 (7.5)	20.5 (7.1) ns	20.6 (8.1)ns
Time in prison, months, mean (SD) ^h	3.1 (14.2)	12.0 (22.5)***	31.6 (33.1)***
Time in psychiatric hospital, months, mean (SD)	25.6 (40.7)	0 (0)***	3.6 (13.5)***
Time-at-risk, y, mean (SD) ⁱ	18.0 (7.6)	19.5 (7.4)***	17.8 (8.3) ^{ns}

^aFPE+T, FPE examinees sentenced to FP treatment

bGEN, matched violent general offender control subjects.

[°]FPE-T, FPE examinees sentenced to regular, non-FP treatment, sanctions.

^aSingle denotes divorced, widowed, or never married.

[&]quot;Refers to any attempted or completed sexual (any sexual contact or non-contact offence) or non-sexual (homicide, violent assault, robbery, arson, unlawful threats, or offences against personal liberty) violent offence.

Refers to any attempted or completed sexual offence (contact or non-contact).

⁹Denotes any attempted or completed homicide, aggravated assault, robbery, rape, sexual coercion, and child molestation.

Calculated as 2/3 of the total prison sentence length since prisoners in Denmark are generally paroled after having served this proportion of the full sentence.

Refers to time at risk during follow-up (excluding time imprisoned or hospitalized within Danish psychiatric hospital-based services).

^{§,} is zero by definition of the control group.

ns, non-significant, $p \ge 0.05$; *p < 0.05; **p < 0.01; ***p < 0.001.

diagnosis, higher rates of any violence and severe violence, and number of violent sentences) as compared to treated FP patients (FPE+T). Yet, a significantly larger proportion of the latter had a SUD diagnosis than FPE-T.

Absolute and relative rates [adjusted hazard (any and severe violence) or odds ratios (3+ violent sentences)] for facets of violent reoffending are reported in Table 2. Some bivariate between-group differences in risk disappeared upon adjustment for previous violence, education and marital status, birth year, and sex. Violent recidivism rates were higher for FPE+T as compared to GENs for any violence (43% vs. 29%; aHR = 1.5; 95% CI, 1.1-1.9), severe (21% vs. 14%; aHR = 1.3; 95% CI, 0.9-1.9), and recurrent violence (16% vs. 6%; aOR = 2.5; 95% CI, 1.5-4.4) but did not reach statistical significance (p < 0.05) for severe violence. Reoffending risk was lower for FPE+T patients than FPE-T examinees for any violence (43% vs. 51%; aHR = 0.9; 95% CI, 0.7-1.0), severe violence (21% vs. 34%; aHR = 0.7; 95% CI, 0.5-0.9), and recurrent violence (16% vs. 22%; aOR = 0.7; 95% CI, 0.5-1.0) than for non-treated FPE examinees, albeit running short of formal statistical significance for any violence and recurrent violence. To assess the robustness of Cox regression findings, we also conducted corresponding multivariable logistic regression analyses, finding essentially comparable results as with the Cox models (data not shown).

Kaplan–Meier survival curves suggested similar violent reoffending trajectories for the first 2 years across all three groups while reconvictions were quite unlikely beyond about 20 years, despite substantial numbers of individuals still at risk (**Figure 1**).

A Cox regression model identified weak to moderately strong independent effects of male sex, previous violent crime, multiple admissions to psychiatric hospital (5+) during follow-up, SUD, younger age, and personality disorder as main diagnosis (as compared to schizophrenia spectrum disorders and "other psychiatric disorders") on violent reoffending among FPE examinees, independently of their medico-legal status (involving a conviction to FP care or an ordinary sentence) (**Table 3**).

DISCUSSION

This controlled, nationwide, long-term follow-up study addressed rates and facets of violent reoffending in violent FPE examinees treated in forensic psychiatry (FPE+T) relative to two comparison cohorts of violent offenders. Violent offenders were consecutively referred for court-ordered pre-trial FPE in Aarhus and Copenhagen, Denmark, between 1980 and 1992 (FPE examinees) or drawn from nationwide longitudinal registers [violent general offender controls (GEN) individually matched to FPE+T]. During an 18+ year follow-up, the absolute risk of any violent reoffending was 43% for treated FP patients (FPE+T), 29% for GENs, and 51% for non-treated FPE examinees (FPE-T). We found a similar trend for reoffending facets severe and recurrent violent reoffending; GENs had the lowest reoffending risk followed by FP patients and non-treated FPE examinees.

TABLE 2 | Facets of violent recidivism until 2010 in violent offenders who underwent pre-trial forensic psychiatric evaluation (FPE) in Denmark 1980–1992 and matched controls.

Reoffending facet		Reoffending rate (%, n)		Relative reoffending risk in FPE+T compared to:	
	FPE+ ^a (N = 392)	GEN ^b (N = 392)	FPE-T° (N = 670)	GEN ^g Adjusted [a] HR/OR (95% CI)	FPE-T ^h Adjusted [a] HR/OR (95% CI)
Any violenced	43% (168)	29% (114)§***	51% (344)§**	aHR = 1.5 (1.1-1.9)**	aHR = 0.8 (0.6–1.1) ^{ns}
Severe violence ^e	21% (84)	14% (54)§**	34% (225)§***	aHR = 1.3 (0.9–1.9)ns	aHR = 0.6 (0.4–0.8)**
Recurrent violence ^f	16% (63)	6% (24) ^{§***}	22% (147) ^{§ns}	aOR = 2.5 (1.5-4.4)***	aOR = 0.7 $(0.5-1.0)^{ns}$

ns, non-significant, $p \ge 0.05$; *p < 0.05; **p < 0.01; ***p < 0.001.

^aFPE+T, FPE examinees sentenced to FP treatment.

^bGEN, matched violent general offender control subjects.

[°]FPE-T, FPE examinees sentenced to regular, non-FP treatment, sanctions.

^aRefers to any attempted or completed sexual (any sexual contact or non-contact offence) or non-sexual (homicide, violent assault, robbery, arson, unlawful threats, or offences against personal liberty) violent offence.

Denotes homicide, aggravated assault, rape, sexual coercion, child molestation, and robbery.

Defined as at least three separate sentences for any violence during follow-up.

[§]Pairwise chi-square comparison of violent reoffending rates: FP patients (FPE+T) vs. matched general offender controls (GEN) and non-treated FP examinees (FPE-T), respectively, aHR/aORs > 1 indicate higher reoffending among FPE+T patients than GEN or FPE-T subjects, respectively, while aHR/aORs < 1 indicate lower reoffending rates in FPE+T patients.

aHR, adjusted hazard ratio; obtained with Cox proportional hazard regression modeling accounting for varying time at risk and other covariates mentioned under (g). aOR, adjusted odds ratio; obtained with logistic regression and adjusted for covariates mentioned under (h). CI, confidence interval.

⁹We also adjusted analyses for any previous conviction of violence, highest education, and marital status at FPE.

^hWe did not match these subjects with FPE+T patients. However, comparisons were similarly adjusted for birth year, sex, any previous violent conviction, highest education, and marital status at FPE.

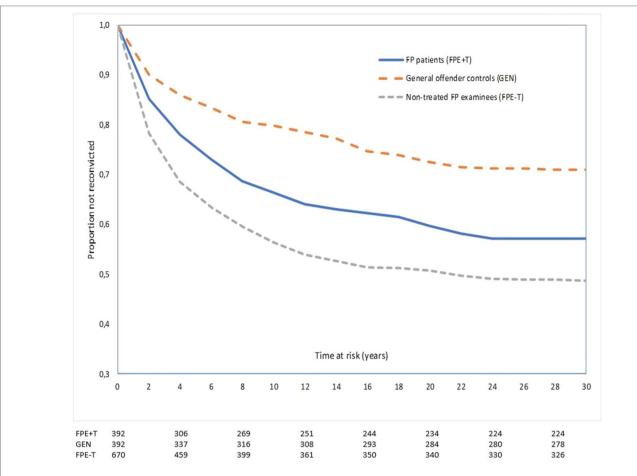


FIGURE 1 | Proportion not reconvicted for any violent reoffending as a function of time at risk among violent offenders who underwent pre-trial forensic psychiatric evaluation (FPE) in Denmark 1980–1992. We compared 392 FPE examinees consequently treated (+T) in forensic psychiatry (FPE+T), 392 matched violent general offender controls (GEN), and 670 FPE examinees with ordinary sanctions (e.g., prison) treated as usual outside forensic psychiatry (FPE-T). Numbers below graphs represent the remaining number of non-censored subjects that had not recidivated at the beginning of each 4-year interval indicated on the X-axis.

Base rates of violent reoffending in FP patients were similar to those reported in prior longer-term studies of FP patients, 46% (14) and 40% (12). While length of follow-up and base rate in Lund et al. (14) were comparable to ours, Pedersen and colleagues (16) reported a high 40% violent reconviction rate during a substantially shorter 5.6-year follow-up of 107 FP patients discharged from a medium secure FP unit in Denmark in 2001–2002. The base rate in Pedersen et al. may reflect that FP patients followed more recently may experience increased reporting of psychiatric patients' violent episodes against staff leading to higher observed rates of violent re-offending in FP patients (49). Alternatively, the base rate suggests faster reoffending and then little additional recidivism after a longer follow-up, or the sample consisted of a more recidivism-prone group of treated FP patients.

Prior comparative studies typically reported *lower* violent reoffending rates in FP patients than among non-FP general offenders, such as prisoners with similar ages, lengths of stay, and offence types (12, 15, 50). In contrast, a smaller long-term Swedish study reported higher violent reoffending rates in FP

patients than what we have found, although not significantly higher than that for offenders with other sanctions (14). Different relative risks across studies of FP patients vs. controls might be related to variations in sample composition. As discussed by Fazel and colleagues (12), many FP patients exhibit factors linked to lower reoffending risk. These include later onset of offending, fewer prior convictions, more severe index offences, shorter time-at-risk to reoffend because of extended hospitalization periods, and access to psychiatric treatment. Further, primary drivers of (re)offending may be acute symptoms of severe mental illness rather than criminogenic aspects characterizing general offenders, factors rarely controlled for in research. Further, the source of admission (court vs. community) was not reported in most studies in the Fazel et al. review (12). We followed offenders sentenced to psychiatric care by the court. Some research for example, UK studies of patients discharged from medium secure settings may also include complex general psychiatric patients that were placed in medium secure settings, without technically being "true" FP patients.

TABLE 3 | Multivariable Cox regression analysis of risk factors for any violent reconviction among 1,062 violent offenders subjected to pre-trial forensic psychiatric evaluation (FPE) in Denmark during 1980–1992, followed for 18–31 years. a,b

Risk factor	Adjusted hazard ratio	95% CI
Male sex vs. not	2.08	1.3–3.5**
Age (y) ^c	0.95	0.9-1.0***
Married vs. not	0.79	0.6-1.0 ^{ns}
Unemployed vs. not	1.21	1.0-1.5 ^{ns}
Pre-index violent conviction vs. not	1.95	1.6-2.3***
Personality disorder (F6)	Reference	
Schizophrenia spectrum disorders (F2) vs. F6	0.49	0.4-0.7***
Bipolar, depressive, and related disorders (F3) vs. F6	1.17	0.8-1.7 ^{ns}
Other psychiatric diagnosis vs. F6	0.76	0.6-1.0*
No psychiatric diagnosis vs. F6	0.99	0.4-2.2 ^{ns}
(Severe) substance use disorder (SUD) (F1.1-	1.29	1.0-1.6*
F1.9) vs. not		
No admissions to psychiatric hospital after index	Reference	
1-4 admissions to psychiatric hospital after index	1.24	1.0-1.6 ^{ns}
vs. no admission		
5+ admissions to psychiatric hospital after index vs. no admission	1.95	1.5–2.5***

We obtained adjusted hazard ratios from multivariable Cox proportional hazards regression modeling accounting for varying time at risk and all other predictors included in the model. Bolded figures are significant at p < 0.05. Cl, confidence interval. ns, non-significant, $p \ge 0.05$; *p < 0.05; *p < 0.05; *p < 0.01; ***p < 0.001.

We tried to overcome some of the limitations of prior studies. After matching and adjusting for several known confounders, FP patients were found to have significantly higher risks of any violence and recurrent violence than non-FP, general offender controls (GEN). Time at risk was quite similar for the cohorts; thus, its variability could not explain FP patients' increased risk. GENs, however, had longer education, were more often employed and had an intimate partner than both treated FP patients and non-treated FPE examinees. Hence, despite controlling for covariates, our matched general offender controls remained more high functioning than FP patients. And, possibly, due to the matching on index offence, they were even more well-functioning than violent non-FP general offenders. That is, the index offence may have been representative for FP patients but less so for general offenders. Contrarily, nontreated FPE examinees were characterized by factors typically found among general offenders: younger age, poorer education, PD diagnoses, and more extensive prior violence including severe and repeated violence. Hence, our non-treated FPE examinees may have been more similar general offenders included in prior comparative studies, although with more violent reoffending than commonly reported (51, 52). The elevated recidivism rates suggest that FPE referral partly and inadvertently selected high-risk offenders with high sensitivity. Expectedly, several of these risk characteristics pertain to the recidivism risk factor domains (i.e., the Central Eight) summarized by Andrews and Bonta (53): history of antisocial

behavior, antisocial personality pattern, substance abuse, poor family/marital relationships, and school/work problems. However, we were unable to systematically collect data on antisocial cognitions and associates, two of the four most predictive domains of criminal recidivism. The risk principle, one of three widely accepted principles for evidence-based, recidivism-reducing services (53) specifically prescribe that more extensive rehabilitative efforts should be directed toward offenders with more risk factors. Our findings suggest a need for continua of service for FPE examinees independently of their medico-legal status, that is, sentenced to inpatient FP treatment or not. Systematic reviews suggest high rates of psychiatric disorders also among prisoners (54), including substance misuse (55).

It may be tempting to interpret lower reoffending risk in treated vs. untreated FP examinees as an indication of a positive effect of FP care. However, causal conclusions should be avoided, first, because the weak to moderate differences in violent recidivism among treated FP patients as compared to non-treated FPE examinees became nonsignificant after statistical adjustment of well-known confounders (pre-index violence, education, and marital status). Second, FP examinees with 5+ admissions to a psychiatric hospital after the index conviction had almost twice the risk (adjusted HR = 1.95; 95% CI: 1.5-2.5) of violent recidivism compared to those with no hospital admissions. Similarly, this should not be interpreted to indicate that treatment increased violence risk. This finding may rather reflect additional unmeasured risk in those admitted more often, such as disorder severity and negative symptoms with or without concomitant medication non-adherence or substance abuse—both increasing the need for psychiatric care. To put differently, the distribution of subjects to FP treatment vs. ordinary non-FP sanctions is not randomized but purposefully sorted according to legislation and judicial practice. Hence, residual confounding cannot be excluded; that is, treated and non-treated FPE examinees likely differ in ways that were not possible to control for.

We also determined risk factors for violent re-offending among all FPE examinees, independently of a subsequent sentence to FP treatment or not. The analysis found male sex, younger age, previous violent crime, personality disorder (as compared to schizophrenia spectrum disorders and other psychiatric diagnoses), substance use disorder, and multiple psychiatric admissions to independently predict violent recidivism. These are all established criminogenic factors (14, 28, 29, 31, 35, 54, 56–58).

So far, there is uncertainty over the causes and the remaining heterogeneity found for the association between major mental disorder and violence. Variations across studies in age, SES, and comorbid substance use disorder or personality disorder might be the most plausible explanations of the mixed results (34). Studies aimed at identifying causal and potentially changeable risk factors specifically for FP patients are indeed needed.

Clinical Implications

First, although the ethics of violence risk assessment remains debated (59), substantial long-term violent reoffending among FP patients may motivate continued efforts to improve assessment and provision of evidence-based management of violence risk.

^aFollowing forensic psychiatric evaluation: examinees received either psychiatric care or ordinary (non-psychiatric) sanctions.

 $^{^{}b}N$ = 1,055, 7 subjects had data missing on one or more risk factor and were consequently excluded from the Cox regression.

[°]Interpretation: since age is a continuous variable, the hazard for recidivism decreases by 0.95 per one-year increase in age. This equals a $(1-0.95^{10})/100 = 40\%$ lower risk in individuals 10 years older than others at baseline, while accounting also for all other tested risk factors in the model.

Although structured risk assessments show higher reliability and predictive validity than unstructured clinical judgments, low risk-individuals are still more accurately identified than highrisk offenders (60). Prevention of reoffending requires addressing also dynamic risk factors and criminogenic needs, potentially amenable to intervention. So-called third and fourth generation risk assessment tools [e.g., Historical Clinical Risk-20 [HCR-20] V3; (61) Level of Service/Case Management Inventory (LS/CMI) (62)] aim at focusing a broader range of risk factors and integrate monitoring and intervention. However, such assessments are time-consuming and subsequently difficult to employ on a large scale in everyday clinical practice. Future research should examine how much added value to risk prevention more comprehensive risk assessments do indeed provide (63).

Limitations

First, historical data may be measured or documented inconsistently, which affects internal validity. Then again, we extracted baseline information from structured FPE protocols as documented 1980-1992 from accurate nationwide registers and followed the three cohorts until 2010. Second, we selected matched violent general offender controls from nationwide registers. Psychiatric disorders are common in prisoners worldwide (64), and controls might have suffered from psychiatric ill-health undetected in psychiatric registers. Third, detailed treatment data for FP patients and controls were neither available from registers nor possible to extract logistically and reliably from clinical records. This was the case for periods both before and after discharge from FP care and release from prison. However, throughout the long observation period, aftercare for discharged FP patients (and FP examinees who received non-FP sanctions) was generally provided by general adult psychiatry in the subject's respective district of residence. Regarding prisoners, we are not aware of systematic correctionsbased psychological treatments during the study period; thereby not excluding likely clinically motivated treatment. Fourth, data specifically on violent acts toward staff, and other patients during inpatient psychiatric care were not detectable unless reported to the police and registered in the Crime Register. Fifth, since data on criminal convictions were unavailable before 1980, the pre-index violence variable underestimated actual prevalence. It is, however, reasonable to assume that underestimation may be similar in the three cohorts and so should only affect estimate precision, not effect sizes. Sixth and finally, our study did not encompass also the large group of likely recidivism-prone offenders not referred for FPE, but who do suffer from mental disorders such as antisocial personality disorder and SUDs.

CONCLUSIONS

Our results suggest persisting violent reoffending during extended periods in FPE examinees; in treated followed by non-treated FPE examinees. FPE examinees also had a disproportionately high-violent reoffending risk and high risks of severe and recurrent violence. Violent recidivism was optimally predicted by established criminogenic factors rather than having a severe mental disorder. Our findings suggest a

need for continua of service for FPE examinees, independently of whether they are treated as FP inpatients or not. Management of violent reoffending risk in FP patients may need a longer-term perspective, as recidivistic violence occurred up until ca 20 years of follow-up. To guide the complex task to care clinically for FP patients, future outcome studies may benefit from finding and reducing the impact of causal, changeable risk factors to various facets of violent reoffending.

DATA AVAILABILITY STATEMENT

Requests for data can be made to Dr. Susanne Bengtson Pedersen. Such requests would be evaluated on a case by case basis as the dataset is being used for other studies. According to strict policies employed by data provider Statistics Denmark, requesting persons also have to be individually approved by this body.

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

SB and JL designed the study and collected the data. SB took the lead in writing the manuscript, although in close collaboration with and under supervision of NL. MI performed the statistical calculations. All authors provided critical feedback and helped shape design, analyses, interpretation and manuscript.

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A Qualitative Study of Mentally III Women Who Commit Filicide in Gauteng, South Africa

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contributor to child homicide rates. In order to prevent future homicides of this nature and aid in the rehabilitation of those mentally ill women who perpetrate these crimes, it is important to gain a better understanding of the dynamics that may result in filicide and the association of the mental illness with filicide. It is also important to explore how the rehabilitation processes are experienced and the impact they have had. The purpose of this study was to examine the perceptions of women regarding their offenses and their

perceptions about their treatment and rehabilitation in a South African context.

Introduction: Filicide is the deliberate act of a parent killing his/her own child and a major

Method: This was a qualitative study which followed a naturalistic paradigm. The data from the semistructured interviews conducted were analyzed using thematic analysis. The use of subjective experiences and descriptions by the participants aimed to give a representation of the participants' lived experience. This allowed the authors to explore the emerging themes, subthemes, and concepts and organize the most replicated information into a hierarchical assessment. The semistructured interviews were conducted with seven filicidal women with mental illness between July 2016 and April 2017 at Sterkfontein Hospital, Gauteng, South Africa.

Results: Most filicidal mothers were psychotic at the time of the offense and perceived trauma and remorse for their offenses. Support from the community and empathy and unconditional positive regard from the staff, notably psychologists, and occupational therapists were overwhelmingly present.

Conclusion: Filicide is tragic and largely understudied, particularly from the perpetrator's perspective. When perpetrators are mentally ill, rehabilitation within a nonjudgmental and empathetic environment is necessary.

Keywords: filicide, mentally ill women, lived experience, psychiatric rehabilitation, qualitative analysis

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INTRODUCTION

Filicide is the deliberate act of a parent killing his/her own child. Although not a frequent crime, it is a form of homicide that is considered an unthinkable act in most societies and one of the leading causes of death in children in developed countries (1).

It is estimated that the global rate of child homicide is 2.93 for boys and 1.92 in girls within the age group of 0-17 years old per 100,000 inhabitants (1).

Despite being a major contributor to child homicide rates, there is a paucity of literature with regards to the subject. Existing literature comprises mainly of quantitative studies, which focus on the categories of filicide, in terms of characteristics of perpetrators, as well as theoretical understandings of the offense. There is a dearth of literature regarding forensic rehabilitation and even less in the context of maternal filicide (1–4).

According to the World Health Organization, the highest rates of homicide in children under the age of 5 are in Sub-Saharan Africa and North America and the lowest in higher income countries of Europe and Asia (3).

The global statistics indicate that perpetrators of filicide are more likely to be female, which differs from the global gender statistics of other types of homicide where the more likely perpetrators are male than female. In a register-based study in Finland and Austria of all acts of filicide between 1995 and 2005, the gender distribution of filicide perpetrators in Finland was equal and Austria revealed a greater number of female perpetrators than male (5). Additionally, the rates of child homicide are considered to be underestimates due to the act often being concealed, underreporting, and inaccurate postmortem assessment (6).

The analysis of incidence rates is difficult, as many countries do not have an authority allocated to follow up on infant deaths, and therefore, infant deaths, possibly due to filicide, are often included in other types of death (7).

The most well-known classification system, that of Resnick, categorized filicide into: Altruistic Filicide, Acutely Psychotic Filicide, Unwanted Child Filicide, Accidental Filicide, Spouse Revenge Filicide, and Neonaticide (8). Almost half of filicidal acts reviewed by Resnick could be categorized as Altruistic Filicide. This category involves an altruistic motive for the act and is considered to be the most important distinguishing factor in filicide as compared to other homicides. There are two subgroups to Altruistic Filicide, and these are filicide associated with suicide, which includes parents who intend to commit suicide where the act of filicide is intended to prevent abandonment, and filicide committed to relieve suffering, where parents sought to ease their child's perceived suffering, whether it be real or imagined (9). Acutely Psychotic Filicide, often considered the weakest of Resnick's classifications, includes parents who seem to have committed the act due to the presence of hallucinations, delirium, and ictal phenomenon, and in those cases where no comprehensible motive could be determined (8). The category of the Unwanted Child is considered when a parent murders his or her child because he or she is no longer wanted by the parent. Reasons for this may include illegitimacy, parental intellectual developmental disorder, and financial and social burden (9).

In Accidental Filicide, the parent lacks homicidal intent; this category therefore extends to death of a child as a result of fatal maltreatment, violent outbursts, and excessive acts of discipline (9). Resnick described Spouse Revenge Filicide as those parents who commit filicide as a deliberate attempt to cause their spouse to suffer (8). The final category described by Resnick is Neonaticide. This is defined as the murder of a newborn within the first 24 h of life. Resnick described that these perpetrators were often women who were of a younger age than other offenders and often did not suffer from a mental illness. Many of these perpetrators are women who have concealed their pregnancy and where issues of illegitimacy are at the forefront (9).

While Resnick's classification is based on motive, subsequent models proposed by Scott and d'Orban categorize women who commit filicide according to the source of impulse behind the act. The six categories according to d'Orban include Battering Mothers, Mentally Ill Mothers, Neonaticides, Retaliating Mothers, Unwanted Children, and Mercy Killings (10).

In 1990, Bourget and Bradford put forward a classification system based on types of clinical situations; this included Pathological Filicide—including altruistic motives and extended homicide-suicide; Accidental Filicide—including battered child syndrome; Retaliating Filicide; Neonaticide—in particular the unwanted child; and Paternal Filicide (11).

The importance of such classification systems is to better understand the etiology of filicide so as to understand the motives and precipitating factors in the hope that preventative strategies can be developed.

Mentally ill women who committed filicide were found to frequently be diagnosed with psychosis, depression, or suicidality before the offense (12). Extended homicide-suicides, which fall into the category of Pathological Filicide, have a strong association with severely ill mothers (13).

There is an established association between mental illness and homicide, with a twofold increase in the relative risk of child homicide in relation to parental mental illness (14–16). Within the South African context, a recent large retrospective study of 573 accused female offenders referred for observation under the Criminal Procedures Act to six forensic mental health institutions showed that there were 175 crimes committed against children, and of those, 66% were biological children. Furthermore, it was found that 52% of these women had disclosed having a prior psychiatric illness, with 30% having committed filicide (17). In another unpublished study done at Sterkfontein Hospital, Gauteng, South Africa, 42% of referred cases of child homicide were found to have a history of psychiatric illness (18).

The approach to the prevention of filicide needs to be tailored to the woman's motivation. It is important that screening for mental illness begins in the antenatal period and continues postnatally. Women who are depressed and are at increased risk of suicide as well as filicidal ideation should be identified early and managed as high risk. Thoughts of harming their children should be taken seriously and explored at length. There should be a lower threshold for admission of women who are mentally ill and are mothers of young children due to the increase risk of extended homicide-suicides. In those women with psychotic illness or psychotic features, delusions and hallucinations

specific to their children should be explored while maintaining a nonjudgmental therapeutic relationship (19).

According to existing qualitative literature regarding women who commit filicide in the face of mental illness, it is difficult to identify risk and prevention strategies, as many women describe being committed caregivers towards their children and gave little or no warning of their filicidal urges (13, 19, 20). In the context of psychosis (most notably where delusions around the child were present), filicide was found to be ego-syntonic. However, once the psychosis had settled and the women had recovered, the offense was experienced as ego-dystonic and distressing (19).

A qualitative research study of mentally ill women, which focused on aspects of recovery postoffense, described that the women avoided thoughts around the offense and their memories were often described as patchy and horrifying in nature. The women described intense self-loathing and self-criticism. Support received from family, relationships with surviving children, and the support network provided by the treating multidisciplinary team were identified as important to the women's rehabilitation process and in the understanding of the role their mental illness had in committing the offense (20).

There is limited qualitative data with regards to mentally ill women and filicide in the South African context. The women included in this study were women who had committed filicide and were found not responsible for their offense due to the presence of severe mental illness and focused on the filicide within the context of mental illness (Resnick's classification as Acute Psychotic Filicide and Altruistic Filicide and under d'Orban's classification as Mentally Ill Mothers). In terms of South African law, they were not sentenced to prison but rather referred to a hospital for rehabilitation and psychiatric care.

The purpose of this study was to examine the perceptions of women regarding their offenses and their perceptions about their treatment and rehabilitation in a South African context in the hope of guiding clinical practice in a resource-limited health-care environment.

MATERIALS AND METHODS

This was a qualitative study that used a naturalistic paradigm (21). This study design emphasizes the use of subjective experiences and descriptions by the participants rather than objective explanations, which aimed to give a representation of the participants' lived experience and feelings towards the subject matter, thus adhering to constructivist epistemologies.

The semistructured interviews were analyzed using thematic analysis, which allowed the authors to explore the emerging themes and subthemes and organize the most replicated information into a hierarchical assessment (21).

The study was conducted at Sterkfontein Psychiatric Hospital in Krugersdorp (West of Johannesburg, South Africa) and the Leave of Absence Outpatient Clinics attached to Sterkfontein Hospital. The hospital is a specialized psychiatric referral hospital, providing forensic services by way of observation of awaiting-trial detainees and the subsequent management of State patients.

Sterkfontein Hospital offers services for 30-day forensic mental observation cases under Section 79(2) of the Criminal Procedures Act. The purpose of the 30-day forensic psychiatry observation is to determine whether the accused is suffering from a mental illness that would affect his/her fitness to stand trial and/or criminal responsibility. While undergoing the 30-day forensic psychiatric observation, the defendant is assessed by the multidisciplinary team including psychiatrists, psychologists, and occupational therapists (where applicable). Nursing observation and collateral information reports compiled by a social worker are also a part of the observation process. Under the Mental Health Care Act No. 17 of 2002 Section 42, if the forensic psychiatric observation finds the defendant of a major offense, such as filicide, not fit and/ or not responsible, the defendant is not sentenced to prison and may be declared by the court a State patient and referred back to a forensic hospital, such as Sterkfontein Hospital, for further inpatient treatment and rehabilitation. Additionally, there are leave of absence (LOA) clinics for those State patients who are outpatients, who then remain under the supervision of their families. The decision to grant a State patient leave is based on a variety of factors, including their current mental health status, the risk of recidivism, the degree of multidisciplinary rehabilitation received prior as an inpatient, the degree of supervision and psychosocial support that will be provided during the leave, and the level of insight of the patient and caregivers. Where a State patient is conditionally discharged in terms of Section 47(6) (d) of the Mental Health Care Act No. 17 of 2002, the order must specify the terms of the conditional discharge and the period of conditional discharge, and the mental health status of the State patient must be monitored. (22)

State patients referred for inpatient care might receive medication, psychotherapy (individual or group therapy), and occupational therapy in their rehabilitation process. Should the individual's mental state remain stable for an appreciable time, appropriate and adequate psychological and occupational therapy has been completed, show an improvement in insight and judgement, and is no longer deemed to be a threat to themselves or others in the community, they may be considered for a LOA. During the LOA period, these individuals are treated as outpatients with strict follow-up at the LOA clinics. Should the conditions of the LOA be adhered to and their mental state remain stable, after a period of extended leaves of absence (usually a period of 2 years), the individual may be considered for a conditional discharge from the Act pending judgement by the court.

Participants

The sample was drawn from female perpetrators who committed filicide and were suffering from a major mental disorder at the time of the offense between January 1996 and June 2017. The sample included those admitted as State patients at Sterkfontein Hospital, previously admitted for inpatient care at Sterkfontein, and those on LOA as an outpatient. Only individuals found to have a stable mental state and able to give written informed consent were included in the study.

In the period 1996-2010, there were 20 female perpetrators that were designated as State patients following a charge of

filicide (23). Eleven female perpetrators fulfilled the inclusion criteria and were approached to participate in the study. Only those subjects who were able to give written informed consent were recruited for the study. The characteristics of the study sample is summarized in **Tables 1–3**.

Procedures

The study was fully explained to the 11 participants at the time of invitation for participation and again before the interviewing process. Seven participants were identified as willing to participate in the study and met the inclusion criteria for participation. Written informed consent from each participant for participation in the study as well as informed consent for audiotaping was obtained before the interview process.

TABLE 1 | Demographic details of participants.

	N	%
Age (years)		
20–25		
26–30	1	14
31–35	3	43
36-40	2	29
41–45		
46–50		
51–55		
56–60	1	14
Race		
Black	5	72
White	1	14
Mixed race	1	14
Asian		
Other		
Highest Level of Education		
None		
Primary school level	2	29
High school level	4	57
Tertiary level	1	14
Employment		
Employed at the time of offense	2	29
Unemployed at the time of offense	5	71
Currently employed	1	14
Currently unemployed	6	86
Number of people currently living in their	r home	
0–3	2	29
4–7	4	57
8–10	1	14
>10		
Current Marital Status		
Single	2	29
Married	3	42
Divorced		
Separated	2	29
Widowed		
Number of surviving children		
0	2	29
1		
2	3	42
3	2	29

TABLE 2 | Psychiatric diagnosis.

	N	%
Psychiatric Diagnosis		
Psychotic disorder	3	42
Mood disorder	2	29
Substance-induced disorder		
Owing to another medical condition	2	29
Other		

TABLE 3 | Current classification under Section 42 of the MHCA.

	N	%
Current Classification		
Inpatient	2	29
Leave of absence	3	42
In the process of conditional Discharge application		
Conditionally discharged	2	29
Unconditionally discharged		

All participants were interviewed for 50–60 min by the lead author. The interviews were audiotaped and then transcribed. When obtaining informed consent, care was taken to reassure the participants of their anonymity and that their participation in the study had no impact on their classification as a State patient and subsequent leaves of absence or potential conditional discharges. Each participant was contacted 1 week postinterview to check if the interview process had caused any traumatic memories.

Data Collection

The use of a semistructured interview allowed for the in-depth interview of a participant by making use of open-ended questions (24). This allowed the participants the freedom to express their feelings and perceptions of events in their own terms. It is also a useful way of conducting interviews of participants who will only be interviewed once, i.e., where the optimum use of interview time is essential.

The semistructured interviews included, but were not limited to, exploring the participants' experience and memories of the time of the offense, as well as associated emotions with regards to this, their perceptions of the support they received, their experience of the rehabilitation process, their understanding of their mental illness, and their recovery since admission. Participants were encouraged to share as much as they were comfortable with regarding their experiences, associated emotions, and reflections.

Analysis

Data analysis was conducted by the repeated reading of transcripts and the categorizing of excerpts that were similar and adhered to the principles of thematic analysis. The process of data analysis was inductive, meaning that the process of coding was undertaken without trying to fit the data to into a preexisting frame or model (24, 25).

The interviews with the participants were audiotaped and transcribed with consent. The interviews were analyzed, guided by the concepts of consensual qualitative research described by Hill et al. (25). The process involves three general steps, which include the participants' responses in an interview consisting of open-ended questions. The core themes were constructed from the interviews of the participants. The core themes were then cross-analyzed. This involved the development of categories which described consistencies in the core themes (25).

Field notes were used during the analysis of the transcribed interviews. The seven interviews were labeled Participants 1–7. For each interview, the subjective answers were analyzed for emerging data. Each interview was completely analyzed, and repetitive answers (i.e., repeated data between interviews 1 and 7) were categorized into themes when information became saturated. If data were repeated within the themes, this was categorized into subthemes.

The process of coding was necessary to construct the themes and subthemes that emerged. The authors made use of openended coding, which involved coding the text paragraph by paragraph and in its entirety. These annotations and themes are attached to units of meaning which classify expression. This may be in the form of single words or short sentences of words (25).

The authors considered Guba's strategies of trustworthiness in the analysis of the data. These strategies include credibility, transferability, dependability, and conformability (26).

The process of triangulation assists with ensuring the validity of the research. This involved a second and third person to analyze the transcripts and draw their own themes, subthemes, and conclusions. The analysis of the transcripts was initially conducted independently by the author, the supervisor of the study, and a senior psychologist well versed in qualitative research, who does not work with female State patients. Following the initial analysis, the transcripts were analyzed collectively to increase the likelihood that as many key areas and themes were identified. The process of triangulation allowed for comparison and assisted in the validity and trustworthiness of the methodology used.

RESULTS

As the interview was informal, in which the individual participants could express themselves openly, honestly, and without being conformed to a specific format, the individual questions are not listed in the *Results* section but rather as themes and subthemes pertaining to concepts guided by prompt open-ended questions.

Themes and subthemes were drawn for the replicated responses as saturation was reached.

These superordinate themes, subthemes, and supporting participant quotations are summarized in **Table 4**.

Thematic analysis of the participants' responses yielded six superordinate themes: negative feelings about being a State patient, mental instability during the incident, remorse, closure, access to rehabilitation resources, and access to support.

NEGATIVE FEELINGS ABOUT BEING A STATE PATIENT

The first dominant theme from the seven interviews was the negative feelings towards being a State patient. The evident negative feelings were mainly anger and regret. Participants 1 (P1) and P2 stated that they felt angry for being State patients for a number of years. Two other participants indicated that their experiences of being State patients for a number of years was regretful. For instance, P3 stated that, "I just don't feel very good about what I did. And I really wish I could reverse it. If I could, I would." P4 also expressed regret in that her life had changed since the time of offense and being classified as a State patient, "My life—everything, I did it according to the way I wanted it to be. Now it's difficult." These negative feelings resulted from the perceived long length of stay in the hospital, lack of freedom, and loss of autonomy.

Long Duration Spent in Hospital

Two participants expressed their frustration with the long duration spent in the hospital after being classified as State patients. According to P5, being a State patient means that "...my time is being wasted and then I need to go out and look for a job so that I am able to look after my children." P4 also claimed that "...it's been difficult, the fact that you have to stay in hospital for a long time, away from my family and children."

Lack of Freedom

Another concern associated with being a State patient was the lack of freedom. All the participants expressed varying degrees of lack of freedom following being classified as State patients. This subtheme was replicated in all interviews and was expressed multiple times in the interview process. For example, P3 stated that being a State patient was "...not so great, because it's not easy to get out of it, you now. It's not easy to become a 'normal patient' and that is what I really want. I want to get out of this place now."

TABLE 4 | Results of Thematic Analysis.

Superordinate themes Subthemes

Negative feelings about being a state patient Mental instability during the incident Reflections postincident Closure Access to rehabilitation resources Access to support

Long duration spent in hospitalLack of freedomLoss of autonomy
PsychosisPerceived concern for children
RemorseInefficiency of outpatient clinics.
FaithDecision not to dwell on what happened
Occupational Therapy and Industrial TherapyNursing Staff and DoctorsPsychotherapy
Support from family and neighborsSupport from clinical staffSupport received as outpatients

P3 also had a similar description of being restricted stating that, "I didn't know in the beginning that it was something forever." P6 stated that being a State patient feels like they are "... locked up. Nobody likes being locked up. It's being cooped up in the ward all the time with anything to do." The same participant described that she felt "...like you've been buried alive, you can't breathe sometimes, like there is no freedom." P4 also claimed that, being a State patient, "...you feel as if you are being locked up."

Loss of Autonomy

A loss of autonomy was also identified as a significant subtheme in all the interviews. The participants expressed the inability to make decisions regarding personal freedoms. For instance, P6 said that "...the only time you go out is for OT and IT, you need to be granted parole and it's not simple." In addition, P4 claimed that:

Like you are not allowed to—when you go on LOA you are supposed to have somebody all the time to watch over you and you are not allowed to go anywhere and you just want to go and do the things you want to do.

P4 added that, "like you can't do your own things, you go according to routines: this is the time to sleep, this is the time to wake up, this is the time to eat." However, the participants who had the opportunity of LOA perceived this as a benefit of being made a State patient. According to P6:

Being on leave is wonderful. You get to spend time with your family. You get to go wherever you like, to malls, you know to buy yourself some ice-cream or have some KFC, go to Church. It's nice being normal.

P1 also alluded that being a State patient was better than being in prison because of the opportunity for LOA; "...you get a chance to go on LOA, in prison you don't get that." This statement was supported by P5 who claimed that, "...in hospital is where they are going to help me not like being on the other side in Sun City (prison)."

MENTAL INSTABILITY DURING THE INCIDENT

Based on the responses, the majority of the participants appeared to remember what had driven them to commit filicide. Six of the participants had a good recollection of the incident and the events that lead to the offense. The participants provided detailed descriptions of the events that led up to the filicidal incident. The participants indicated that they committed filicide while having an unstable mental state and described experiencing psychotic symptoms such as auditory hallucinations and delusions and as well as perceived concern for children to prevent them from suffering.

Psychosis

From the recollections of the incidents, many of the participants' expressed that their actions were influenced by factors that were

considered external to themselves such as auditory hallucinations. For instance, P4 claimed that hearing the voice of God speaking to her, she went on to explain "that week, like I was not myself, I was saying things that didn't make sense."

A participant claimed that her psychosis and unstable mental state eventually resulted in filicidal thoughts of sacrificing her child. P7 claimed that she could hear multiple voices in her mind during the act; "At the time I had 120 voices in my head, at that moment I didn't know which one I—I was just confused." According to P1:

I remember I woke up in the morning and everything was normal in the house. I did my cleaning and everything and then suddenly I went into my bedroom with my daughter, who was three months, and then when we got there I just started to have strange thoughts, like I don't know if it was voices or what, like I had to sacrifice my baby. That God wanted me to sacrifice my baby, Ja.

Similarly, another participant reported hearing voices that urged him to commit filicide after visiting a prophet. P3 explained that:

I was from a Prophet and then there was a voice and that told me that I must give my child methylated spirits to drink. I took the spirits and gave it to the child to drink and then I took the child to the hospital and when I reached the hospital they told me that the child is now dead and then from there I was arrested.

Perceived Concern for Children

For another participant, the burden of being a single mother and having an unfaithful and abusive husband contributed to her decision to commit filicide. P4 indicated that she decided to commit suicide and filicide to escape her problems and also prevent the children from suffering. As explained by P4:

I was doing laundry that day and a thought came to mind that, you know what, my husband has been cheating and I can't even provide for my children so that's what happened. Then I bought poison for me and my children, three of the children drank the poison. The second one passed away, only the first and third born were remaining ... all I kept on thinking about was how my husband wanted to take a second wife and I was against that. So, he'd come home and beat me up, so for that day, when I was busy doing the laundry, all I could think of was how I could get out of the situation and I couldn't leave my children with him. So the only thing was to take mine and all my children's life.

Despite not providing a fully comprehensible account, one participant committed filicide before attempting suicide. According to her recollection, P3 explained that:

I've killed my son on the 22nd January, I'm not sure about the date I think it was the 22nd, or anyway ja. And then, I killed my son and I wanted to take my life as well and I was admitted at hospital and then after being admitted at Baragwanath hospital I was sent to prison and then I stayed there a couple of months.

The participants' perceived concern for their surviving children was also evident during their rehabilitation process. One of the interesting findings that emerged from all the participants was concerning about their surviving children following stabilization of their mental state. Their frustrations towards being made State patients were related to being away from their surviving children. P4 spoke about the need to provide for their children and how being a State patient prevented this: "Ja it's difficult ... you have to stay in hospital for a long time, ja, away from my family and my children." P5 expressed that being in hospital meant that, "my time is being wasted and then I need to go out and look for a job so that I am able to look after my children."

REFLECTIONS POST-INCIDENT

All participants reflected on their experiences postincident. Much of what the participants shared was emotive, dealing with the emotions they experience following the offense. An interesting reflection made by some participants on LOA was that of frustration with the efficiency of the outpatient clinics and the impact that it had on their commitment to adherence.

Remorse

The participants shared the emotions they experienced after the incident and how they felt about themselves following the incident. The most replicated emotions were that of regret, guilt, loneliness, and faith, inferring remorse.

Most of the participants regretted their actions and avoided recollecting the events. One reported actively avoiding recalling the day of the offense. P4 explained that "Actually, I don't want to think about it too much because ... when I start thinking about it too much, it stresses me out." P3 also seemed to avoid speaking about the incident and only shared what occurred after the incident. The participant responded was that she had committed a crime and she did not want to share more about the incident. According to P3: "...umm, I don't remember it that well, I know I had a lawyer, and my dad paid for the lawyer for me and I explained the problem to him and then he put me in this place."

P4 explained that she came to terms with her actions in prison and deeply regretted and was remorseful for what she had done, "I started to get my mind straight when I was in prison, so after that I realized what had happened, I was so sad. It was traumatizing." P3 also demonstrated similar sentiments sharing that, "I just don't feel very good about what I did. And I really wish I could reverse it. If I could, I would." P3 added that, "Just feel regret, I wish I hadn't done that I did. Just regret." P5 reaffirmed the remorse expressed by all the participants explaining, "I was crying at the time thinking that my child would get up, will be better."

The participants expressed remorse because they perceived themselves as criminals for killing their children. P3 indicated that she was remorseful "...because I committed a crime, it's an inexcusable crime that I committed." P6 also claimed that, "Terrible, terrible. I called myself a murderer. I lost my appetite, I would cry overtime I saw a baby on TV, you know, it's a terrible emotion. I had terrible emotions."

Inefficiency of Outpatient Clinics

Those participants who were on longer LOAs as per Section 42 of the MHCA were required to follow up monthly at their local clinics and follow up every 6 months at Sterkfontein hospital. These participants expressed frustrations with the local outpatient clinic support. P7 claimed that "You see, to wake up early and then you just have to be there. Sometimes they don't have medication, that's what happens most of the time. They don't have medication." P7 added that "...the government knows that we should be supplied with medication, I mean why is there a shortage." In addition, P3 stated that "I had to phone them to get my medication to South Rand all the time, I don't mind that but you know, I wish I didn't have to phone them."

CLOSURE

The participants used various strategies to cope with and achieve a sense of closure after the offense. Most of the participants felt remorseful about their actions and turned to faith or religion. Some also decided to move on with their lives and stop dwelling on what had happened.

Faith

Despite one participant claiming that she had committed filicide after visiting a prophet, the majority used faith to cope with the aftermath following the offense. For example, the participants demonstrated a sense of hope linked to the importance of religion and faith. P7 stated that, "I've also learnt the part of forgiveness, making amends. I've learnt about a God of my understanding." P1 also claimed that she now turns to the Bible as opposed to crying, "I was crying, but there's the Bible." The participant added that prayer is a source of comfort for her, "I normally pray."

Decision Not to Dwell on What Happened

Some participants shared that they still thought about the day of offense, while other participants reported that they did not think about the day of the offense any longer. From those who reported that they still thought about the day of the offense, there was only one participant who seemed to have difficulty talking about the memories she experienced. This participant expressed that she really wished that she had not committed the offense and cried during this part of the interview.

Some of the participants believed that they were now in a better place. The participants stated that their actions were in the past and that they felt better. The reasons for this included treatment received as an inpatient and outpatient and religion.

One participant, who mentioned that she visited her child's grave often, reflected that this gave her a sense of closure and that through this she was still able to love her child.

P2 claimed that she decided to move on from the incident and now visits her child's grave for closure; "I felt bad at that time but now it has passed and I accepted what I did, I go to the graveside." In addition, P7 claimed that:

I feel much better, I'm much stronger. The pain is there, the pain will—you know, as time goes on, it will, you know, go away—it might never go away, but I'm much better now ... I understand it now.

P1, P7, P3, and P6 also indicated that they decided to forget what had happened and focus on rehabilitation. P1 claimed that it was better to forget what had happened and move on with life; "I forget it, it's the past." P7 claimed that she decided to avoid recollecting what had happened; "I don't think about what happened." In addition, P6 indicated that the best way to achieve closure is to shut the memories out; "I feel, ummm I let it be you know, I shut them out." P3 also stated that all she could do was move on with her life; "I just have to carry on, it's all I can do."

Another participant mentioned that she would hear the voice of her child crying and that this had improved and ceased after the doctor allowed her on a short LOA to put a gravestone at her child's grave. With regard to dealing with the memories the participants did have, one participant reported that she now allowed herself to remember and feel whatever it is she was feeling, and this appeared to be helpful to her. One participant reported that she used the coping techniques she had learned from psychotherapy to deal with her memories. From those participants who reported that they did not think about the day of offense, there was a sense that they had made a conscious decision to not to think about the incident. A participant reported that she believed it was senseless to think about what could have been as she would not be able to change what had occurred.

ACCESS TO REHABILITATION RESOURCES

The participants indicated that access to various resources including occupational and industrial therapy, nursing staff and doctors, and psychotherapy was essential in their recovery and rehabilitation process.

Occupational Therapy and Industrial Therapy

The activity that was most replicated by the participants as helpful towards their recovery was occupational and industrial therapy. The participants enjoyed cooking and baking because being involved in this kind of activity helped to distract them from their problems and that they were tasks that reminded them of being at home. In industrial therapy activities like knitting and making Christmas decorations gave the participants a sense of comfort and reminded them of their life outside the

hospital. According to P5, "OT is the one that helps me ... we are sewing, we are cooking, we are baking. That's the one." P7 also claimed that the therapist's involvement was very important in the recovery process, "The occupational therapist, when they get involved it also helps a lot." P3 was also happy that occupational therapy was helpful in her recovery; "I was quite cheerful because the OT was helping me." P4 explained that, "...the OT helps a lot because at least when you do something you tend to focus on that thing you are doing and not your problems and your stressors." Additionally, P6 supported this by adding that, "I loved IT, I enjoyed it a lot, being creative is my strong point."

Nursing Staff and Doctors

Many participants expressed that the care experienced from nursing staff and doctors, as well as the medical treatment, was helpful in their rehabilitation process. P7 stated that:

"The stigma is there yes, I was sitting one day with one of the sisters and we were talking about it, some people think you've just gone mad, after talking to her I realized that yes you do get some judgmental people but you do get people who understand too."

P3 also expressed that:

It calms patients down you know when they speak to a doctor. It enlightens you when you speak to a doctor, it always gives you hope. You know the doctor can help with that, it's nice to tell them your problems.

P4 added that nurses were nice and provided her with comfort; "The nurses were nice to me, they would comfort me." According to P7, "...there were three sisters that I've grown attached to—I could always go to them in an emergency and they were always there to listen."

Psychotherapy

Of the participants that were in individual therapy, most identified that the process of psychotherapy was beneficial to their rehabilitation. P4 claimed that, "The psychologist also, she helped a lot because at least she helps you talk about your experiences and all that stuff, ja, unresolved issues and stuff." P6 also indicated that, "...it was therapy all the way, I knew that every Tuesday I go to therapy, I talk about my emotions so that I can get better, Ja and look at me now (laughs)." However, P7 reported that she did not find psychotherapy to be beneficial or contribute positively to her rehabilitation process: "...it was compulsory oh, I shouted at them (laughs)...it was in the afternoon and I was dying to sleep, I told them that I don't like this and they were like—unfortunately, you just have to."

ACCESS TO SUPPORT

The participants indicated that support from family members, neighbors, nursing staff, and outpatient support services played an essential role in their recovery and rehabilitation.

Support From Family and Neighbors

The participants generally felt supported by their families, and some mentioned the importance of support from their neighbors. Most participants reported that the support they received during the time of the incident was sufficient and that they did not feel the need for more support. P4 claimed that, "I mean my husband was always there and we had a nanny around the house ... so they were supportive." P5 also stated that "the only support that I got was probably my mum and my neighbours, yes they went together with me." However, one participant expressed that she felt betrayed and abandoned by her brother at the time of the incident. She went on to explain she felt that her brother should not have left her alone with her child as she believed she was mentally unstable at the time of the incident and believed that her brother was aware of this. P6 stated that she felt betrayed because "...like my brother left me with the baby alone. He was supposed help me out with the baby." P6 indicated that visitation by family members played a major role in their rehabilitation process; "they would come and visit me and bring me things. Their support has made me strong. Just to think that there are some people out there who still care about you, you know, it makes you strong." According to P3, family members are important because they provide material support; "...they brought me things to get me through the week and that helped."

P7 highlighted the important of family support by stating that:

I was very lucky and I am grateful to have them because they are supporting me throughout - they were here like every weekend and if they didn't come they would phone me. I used to get whatever I want, they used to phone me, like every day. So I was very lucky.

P7 added that, "The support is great, my family is there for me, I grew since I got out of rehab and then I went back home ... our relationship is very good at this moment in time."

Support From Clinical Staff

The participants indicated that, in addition to care services, clinical staff were also supportive, thus improving their rehabilitation experiences. For instance, P4 claimed that "I feel good about it because they are trying their best, they are always there, they are always supportive and they always check up on us if everything is fine." P2 also stated that, "...as for the hospital staff, I felt grateful that there were people who would look after me." Support from clinical staff and doctors was also highlighted by P3 who expressed that "The support I had was good from the doctors concerned and OT and nurses ... I was appreciative ... the support system was quite good." In addition, P6 indicated the importance of the support from staff and the possibility of returning the favor in future; "The staff were supportive, eventually you know I will thank them some day.

Support Received as Outpatients

The participants shared their experience as outpatients, with regards to the support they received from the clinic, family, and community. Their experiences were similar to the experiences described as inpatients. They reported that they perceived the support as sufficient. Continued support from family was identified as having an important role in their recovery. The participants generally did not expect their communities to be supportive of them. They reported being pleasantly surprised by the perceived love and support they received from their communities. They reported that their recovery would have been made more difficult if they did not receive the support of their community.

Two participants indicated that the community was welcoming and provided them with support during their rehabilitation process. P6 stated that "...it was important for me, for my wellbeing, you know, they received me well," while P2 claimed that, "...right now it's overwhelming, because everyone seems to be caring for me." According to P6, the support provided by the community provided them with a sense of belonging; "I'm part of the community." P7 also reiterated this expressing; "I got to go home for Christmas, so many people came to my house, the whole community ... it was like 'wow' I didn't expect this." P2 also highlighted that "...the community have accepted me back and the love they have for me ... they still support me."

DISCUSSION

The demographic profile of the seven participants was in keeping with a recent review of 573 female offenders across six forensic mental health institutions in South Africa by Nagdee et al. (17). This study found that the majority of offenders were aged 21-50 years old, which is similar to this study where 86% of the participants fell within this age group. Seventy-one percent of participants in this study had a high school level of education or higher, which is higher than that of female offenders across the six South Africa forensic mental health centers. The contribution that socioeconomic stressors may have had was strengthened by 71% of the participants being unemployed at the time of the offense and the 86% who remained unemployed at the time of interview. Additionally, 71% of the participants had 4-10 people currently living in their home. Interestingly, 71% of the participants reported being married or in a common-law partnership at the time of the offense, and 42% were married at the time of the interviews, suggesting support offered by partners following an offense of this nature and strengthened by the importance of support structures highlighted in the qualitative findings of this study. The findings were in keeping with relatively high rates of serious mental illness among female offenders in the South African context (20). Severe psychopathology with psychotic disorders were most prevalent in these women, which suggests that more targeted screening of at-risk female offenders may indeed lead to earlier detection and prompt institution of treatment, which may prevent such offenses.

The interview process was a specific experience of its own. Owing to the sensitivity of the subject, it was initially a tentative atmosphere, particularly with the first interview. The interviewer was aware of the emotionally sensitive and potentially traumatic nature of the content that the participants were being asked to share. At times, there was an overwhelming sense of regret and sadness. When recollecting memories of the offense,

many participants became emotional, often crying when expressing these details. However, the emotional content did not overwhelm the participants. Following the semistructured interview, participants were given an opportunity to express anything that they felt was not covered and if they wished to share or ask questions that they may have had. During this time, the participants expressed that the interview process had not been overwhelming, and some found it to have been beneficial in their healing. This feeling of the positive effect of having the opportunity to share their emotions was reiterated in the 1-week follow-up telephonic check-in with the participants.

Qualitative research allows for the exploration of the subjective experience of the participants. As noted by previous qualitative researchers, the process of the semistructured interviews can translate to a sense of validation and normalizing of their experience and be therapeutic for the participants (27). This appears to have been the case here.

Within the forensic setting, the understanding of the participants' feelings towards their mental disorder and the implications thereof can have important implications in terms of reducing the risk of recidivism (28).

Being a State Patient

The overall subjective experience of being classified as a State patient appeared to bring up negative feelings for the participants, with the evident feelings being that of remorse, anger, and regret. Participants described lacking freedom and being bound to rules and regulations of the facility, which included a long duration spent in the hospital. Despite being granted a LOA, there continued to be a general sense of anger and regret. One of the participants expressed that attending her mandatory LOA clinic visits were a reminder to her of her offense and caused the resurfacing of her emotions at that time. Additionally, participants expressed being unclear as to the process around being made a State patient, specifically around time frames and how this impacted on their experience of a lack of freedom and loss of autonomy. Most participants expressed that they would want to know more about the process. These sentiments are similar to the findings in Shepard et al. (29), which found that a lack of clarity around the participants' length of stay and the pathways out of care lead to a loss of hope and frustration (29).

Perceptions of Being a State Patient

Although most of the participants had little understanding of the nature and meaning of being classified as a State patient, there was a general sense of negativity towards this label and its consequences. This negativity centered around the participants' continued concern regarding the care of surviving children and family.

However, an overall sense of gratitude for the access to rehabilitation resources was also described. Participants felt that if they had been incarcerated, they would not have had the opportunity to be treated and rehabilitated effectively. Skeem et al. (30) described that the criminal justice system not only had a disproportionate representation of individuals

with serious mental illness but also that these individuals were disproportionately more likely to fail, with regards to recidivism, under correctional supervision. Furthermore, it was suggested that recidivism reduction is mediated by mental health services and symptom improvement, and this should play a larger role in managing the risk and long-term rehabilitation of these individuals (30).

Advocacy with regards to rehabilitation and treatment of criminal offenders who suffer from severe mental illness is imperative to decrease the risk of recidivism and stigma. This, however, must be balanced against the risk that these individuals may pose to themselves and society.

This serves to emphasize the importance of identifying psychiatric patients in the context of a forensic system. The illness itself needs to be holistically treated in order for an effective rehabilitative process to be expected.

State of Mind on the Day of the Offense

The participants' psychiatric illness caused symptoms that resulted in the act of filicide. Mental instability during the incident was highlighted as an important theme, with psychosis being the predominant subtheme. Most participants could remember the day's events and were able to give clear account of their psychiatric symptoms. This is similar to the findings of Stanton et al. (19). However, a few participants could not give a clear account of the day of the offense, with one participant avoiding the incident completely, instead describing what had happened after the act. Additionally, in this study, the experience of psychiatric symptoms was a main theme when exploring the event (19).

Memories of the Offense

Psychosis was the predominant finding; however, most of the participants did not acknowledge a psychiatric diagnosis before the offense, other than one participant who had diagnosed bipolar disorder. It appeared that, although most of the participants were aware of an altered state of mind and psychotic symptoms at the time of the offense, they had not received psychiatric care. This is in keeping with the literature, in that mothers are uneasy sharing filicidal thoughts with health-care professionals as they fear that their children may be removed from their care (31). It is well established that the postpartum period is a high-risk time for the emergence of psychiatric symptoms, which mothers may feel the need to conceal; therefore, there may be a need for more rigorous screening in this high-risk population.

The participants were concerned for the safety of their surviving children. There was a general feeling of concern that they were not able to provide for their surviving children as a result of the charge and being classified as a State patient. This emphasizes the ongoing sense of responsibility as a mother to surviving children. This seemed to be a significant stressor and directly affected their experiences. This has been replicated in the study by Stanton et al. (20), which explored the aspects of recovery as described by mentally ill perpetrators of maternal filicide, and the *role of the mother* was described as an important theme (20). Discussion around the participants' surviving

children must be incorporated into the psychotherapeutic process of participants who describe this specific concern, as this may aid with recovery and their experience of rehabilitation. The exploration of specific memories pertaining to the actual day of the offense assisted in describing greater detail of the subjective account of the participants' entire experience.

Those who had clear memories of the day of the offense could then describe both the traumatic nature of those memories as well as the ways they dealt with these memories.

The emotionality attached to the incident and the subsequent rehabilitation received at Sterkfontein Hospital allowed for participants to describe a sense of closure as well as a conscious decision not to ruminate on the past.

After the Incident

Emotions expressed were predominantly negative in nature. There was a great sense of remorse associated with the incident, with some participants describing a feeling of isolation, regret, guilt, and loneliness. Many participants noted that the interview process itself and being able to share and label these emotions were helpful to their healing. Addressing feelings of regret and guilt in the psychotherapeutic process may aid with healing from the aftermath of the offense as well as aid with the perception that these women may have of others towards them.

The role played by faith and religion in the grieving and rehabilitation process was found to be important to all the participants. Participants described being able to "heal from these difficult emotions" through a religious support structure. More qualitative research is needed to explore the role of religion and faith, which may be an important topic to explore in the rehabilitation process.

Helping in Recovery

The need for specific rehabilitation programs, namely, occupational therapy, industrial therapy, and psychotherapy, was emphasized by all participants. Many reported tasks performed in occupational therapy reminded them of tasks that they would be required to perform in their everyday lives, should they not be in a hospital. There was a general feeling that the familiarity of these tasks gave the participants a sense of hope and seemed to engender a sense of purpose. Additionally, performing such tasks seemed to distract participants from dwelling on the emotions of the offense and facilitate healing.

The ongoing support and physical presence of nursing staff was also highlighted as important in the recovery process.

Religion and the role of faith and spirituality were emphasized as being integral in the recovery process for these participants.

Support Received Around the Time of the Incident

Support, both from family and the close community where participants resided, appeared to be integral in recovery. Although this cannot be generalized to all families and communities, it was interesting to hear surprised descriptions of the forgiving, supportive, and inclusive nature of such persons,

despite the serious nature of the crime. Most participants felt that the support they received around the time of the incident was sufficient. Often, when relaying the support received, the participants seemed to experience the level of support as the antithesis of their expectations. This may reflect their perceptions of themselves at the time of the incident. In a study by Bourget and Bradford (11), mothers who commit filicide tended to report high levels of stress and lack of support. These women described multiple psychosocial stressors, were often the primary caregivers of their children, were unemployed with financial and relationship stressors, and lacked social support (11). Exploration as to why the support received was unexpected by the participants and what emerges around this may be a focus in further psychotherapeutic rehabilitation goals.

Support Received From Staff and Family as an Inpatient

The predominant impression was that of contentment with regards to the level of support that these participants experienced from staff while at Sterkfontein Hospital. However, one participant felt unsupported and "hurt" by the perceived "unwelcome" attitude of the staff during readmission following relapse. This is an anecdotal example of a subjective emotion of being an inpatient and would need further exploration, as training staff to be empathetic and nonjudgmental is imperative to a therapeutic and rehabilitative environment. Indeed, Shepard et al. (29) also emphasized safety and security in the forensic hospital environment as a necessary base in the recovery process. The clinical staff's ability to provide appropriate boundaries in the face of support and care for patients has been highlighted as important in the personal recovery of patients within the forensic setting (29).

All participants felt wholly supported by their families, which is particularly encouraging, as families are integral to the rehabilitation team. Engaging with the families, therefore, may prove to be a compelling resource in the rehabilitation process.

The experience of adequate support, whether it be at the time of the incident, as an inpatient or as an outpatient, was described as being unexpected but deeply valued by all participants. When this was explored with the participants, the reasons for not expecting the support that they received included a sense of regret and remorse around the incident and a fear of judgement by their families and community. Similarly, Resnick (32) also emphasized that parents who commit filicide often find it more difficult to forgive themselves than the society does. (32) During inpatient rehabilitation, it may therefore be useful to explore the role of being mentally unwell at the time of the offense in order to help process and manage feelings of being undeserving of support.

Support Received From Clinic, Family, and Community as Outpatients

The overarching experience by the participants was that of good support. This included support from their family and their community, which seemed to foster a sense of belonging; this was especially noted when on LOA. Initially, they anticipated and feared

judgment from their community. This underpins the importance of support structures as a protective factor for the participants living within the aftermath of filicide and is a promising finding and a positive predictor of outcomes for these individuals.

Two participants reported that the outpatient clinics were "inefficient" (specifically regarding the availability of medication and long delays that might have resulted in a return date as the specific clinic could not assist on her booked date). Attending the LOA clinics seemed to also remind the participants of their past offense. Although most participants had described a sense of closure in terms of their offense, attending the outpatient clinic seemed to be a reminder of the emotions at that time as well as reliving past trauma. One participant remarked that when she was at home and in her community, she did not think of her time as an inpatient State patient or the time of the offense, but when she was due to attend clinic, she would begin to "panic."

She reported: "You forget it, but when you come here..."
"Starting to panic, it's for a week before and a week afterwards"

(Participant 1)

The need for specialized clinic risk assessments in these individuals needs to be balanced against them being assessed in the community setting. Perhaps, the use of quantitative risk assessment forms may assist in decreasing the emotional retrauma that these visits may precipitate. Future studies, focusing on complicated grief and potential posttraumatic stress disorder would assist in developing and describing this concern and possibly assist with ways of intervention to improve this process.

Interviewer's Reflections

At the center of this qualitative research was the exploration of the lived experiences of mentally ill women who commit filicide. In capturing these stories, the lead author was aware of the nonverbal language and behavior of the participants. The interviews appeared to be an emotional experience for the participants. Initially, their body language suggested being anxious at the start of the interview, with many participants approaching the questions tentatively with a defensive body language. As the interviews progressed, however, they appeared to be more relaxed and open and to engage better. All the participants became emotional when recounting the events of the day of the offense and the emotions they experienced. When relaying their perceived support received as inpatients and outpatients, the participants' body language was open and more relaxed, and the mood in the interview appeared to lighten. The participants appeared to be more comfortable with the content of this part of the interview than when they relayed the events leading up to becoming a State patient. All participants reflected that speaking about the incident and their subsequent rehabilitation, although painful, was a positive experience to them. At the 1-week postinterview follow-up telephonic interview, all the participants reported that their emotional and mental states were stable; this was corroborated by collateral provided by family members, and none showed signs of requiring referral to the treating multidisciplinary team. One participant reported feeling a "sense of relief" from having the opportunity to express herself. On further inquiry around this, she reported that since completion of her multidisciplinary team rehabilitation, people do not inquire about the details of her experience or the incident itself. She reported that she felt more ready to talk about that time in her life and would want to talk about it as she felt it would help with her "healing." Another participant, who also verbalized that the interview was helpful, said that by talking about her experience, she realized "how far she had come" with regards to her mental rehabilitation.

CONCLUSIONS

Subsequent conversations and exploration of the lived experience of this specific population may be beneficial for their long-term rehabilitation and well-being and may be a future study interest. Indeed, Oberman (32) described that beginning to understand the lives of the women who commit this crime should be a key in the eliminating of maternal filicide (32).

It is suggested that further research into ethically thoughtprovoking issues of filicide in the context of forensic psychiatry might assist in preventing further acts of filicide and assist with a more evidence-based and individually sensitive rehabilitation process.

Limitations

The nature of qualitative research, especially a study of this nature with a very specific sample of participants, means that the sample size is small. For this reason, it is difficult to generalize the findings of this study to other populations. There is a dearth of qualitative studies in in the literature regarding maternal filicide committed in the context of mental illness; therefore, it was difficult to find data to support the findings of this study. Further study into this important topic is necessary to guide deeper understanding and clinical practice. The authors were aware of the potential for asymmetry in the power dynamics between the interviewer and the participants, as the interviewer is a medical practitioner who was training in Psychiatry at the time of the interviews. As a result, the participants may have been concerned that the details disclosed during the interview process may have had an influence on inpatient care, the opportunity for LOA or application for conditional discharge. Attempts were made to preempt and avail these concerns. Additionally, the interviewer was not part of the treating multidisciplinary team involved in the participants' care, and confidentiality would only be breached if the distress protocol was required.

The interviews were conducted in English, and the participants reported being comfortable with this. However, the nature of this qualitative research encouraged the participants to express their lived experience in their own words. As a result, the interviews not being conducted in some of the participants' home language may have neglected some nuances in their stories. Additionally, the author was from a different cultural background to some participants; it is possible that this may have influenced the

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interpretation of results. However, in the triangulation process, the interviews were analyzed by members of different cultural and linguistic backgrounds.

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 University of the Witwatersrand: Human Research Ethics Committee (medical). The patients/participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

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AUTHOR CONTRIBUTIONS

SM, US, and DH were responsible for the conception and design of work. SM was responsible for conducting the interviews and other data collection and the initial qualitative data analysis. SM, US, and DH were involved in the data interpretation. SM was responsible for drafting the article. US and DH were responsible for clinical revision and supervision of the research study and the article. SM, US, and DH provided critical feedback and helped shape the research, analysis, and manuscript and gave final approval of the version to be published.

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Focus on Brain Health to Improve Care, Treatment, and Rehabilitation in Forensic Psychiatry

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BACKGROUND

The aim of forensic psychiatric care is to care for, treat and rehabilitate patients back to independent life outside of hospital without recidivism into serious crime. Although the legal regulation of forensic psychiatric care differs from country to country, these patient groups are often distinguished by severe mental illness, a high risk of recidivism, complex rehabilitation and long hospital stays. Within Swedish forensic psychiatry (1) at any one time there are around 1,700 people sentenced to care. These forensic psychiatric patients often have a psychotic disorder, combined with substance use, and are receiving treatment with antipsychotics (2). Treatment often continues for several years (3) and there is a high risk of criminal recidivism after the end of treatment (4). A major problem is that forensic psychiatric care in general lacks evidence for the interventions that are used (5), although clinical guidelines for the treatment of mentally disordered offenders exist (6, 7). In this article we wish to raise the issue of whether forensic psychiatric care can be improved by reflecting on conditions potentially affecting the brain and the concept of brain health in the light of scientific findings concerning brain function, brain plasticity and clinical function in patients. Brain health may be regarded as a condition in which the brain can perform its functions in the best possible way. Recommended interventions for brain health are often associated with lifestyle changes, such as physical exercise (8), but can actually be assumed to apply to all interventions that aim to make it easier for the brain to function properly. We want to encourage forensic health professionals to perform interventions with potential for improving patients' brain health, and we want to inspire new research studying the effects of such interventions.

Impaired brain health in forensic psychiatric patients may have a number of different causes and result in different effects on the body, the psyche and on behavior. Some of the obvious causal factors that are often seen in patients include early and long-lasting, extensive substance use, and a psychotic disorder with persistent negative or cognitive symptoms. Many patients also have a background of repeated skull trauma, suspected brain damage due to alcohol misuse in the mother during pregnancy, birth injuries and neuropsychiatric problems that first appeared in childhood. In addition to this, there is a lifestyle of smoking, an unhealthy diet and low levels of physical activity, leading to physical illnesses such as diabetes and arteriosclerosis, which can affect cerebral blood flow. Most of these causal factors are general, but some can also be considered specific. How do we assess a possible influence on brain health in forensic psychiatric patients? One obvious way is the presence of any psychiatric diagnosis that includes cognitive effects. Although some forensic psychiatric patients have neurocognitive diagnoses (9), the number of unrecorded cases may be high, particularly for mild and marginal intellectual disability. In Sweden neuropsychological tests are often performed in connection

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Andiné P and Bergman H (2019) Focus on Brain Health to Improve Care, Treatment, and Rehabilitation in Forensic Psychiatry. Front. Psychiatry 10:840. doi: 10.3389/fpsyt.2019.00840 with a forensic psychiatric examination, while neurobiological examinations such as EEG, brain imaging, functional MRI or blood flow measurements are performed more rarely and then primarily if a tumour, bleed or dementia is suspected. We contend that there are great possibilities, based on existing knowledge and using current methodology, for increasing our knowledge of brain health in forensic psychiatric patients and thus introducing targeted measures for improving function, preventing further functional loss, and compensating for already existing functional loss. In the light of both old knowledge and new research, we would like here to provide a few examples of causes of impaired brain health and examples of interventions that can improve brain health in forensic psychiatric patients.

PSYCHOTIC DISORDERS

Fundamental to improving brain health among forensic psychiatric patients is to treat any psychotic disorder correctly. Forensic psychiatric patients with a psychotic disorder are often at an increased risk of aggressive behavior and treatment resistance to antipsychotics. For psychotic disorders a number of changes in the brain structure have been described, although these changes are small and varied, and are primarily demonstrated at group level. Individuals with schizophrenia and aggressive behavior, compared with individuals with schizophrenia but without aggression, have smaller volumes in several brain regions, such as the prefrontal cortex (10, 11), a region that plays a key role in cognitive impulse control (12). Treatment-resistant schizophrenia, a common clinical challenge in forensic psychiatry, is associated with even greater frontotemporal changes but perhaps also with specific brain changes (13). These brain changes may explain the greater severity of disorders with negative and cognitive symptoms, as seen in psychotic patients who are difficult to treat (14).

SUBSTANCE USE

The link between substance use, brain disorder, mental illness and violent crime is indisputable, and a large part of forensic psychiatric rehabilitation is based on offering a drug-free environment and preventing a relapse into substance use. Alcohol misuse produces brain damage (15) and affects cognitive functions (16), while narcotic preparations can produce brain damage in single doses (17). This itself is obvious, but clinically there is seldom more detailed knowledge of any brain damage and cognitive difficulties the patient may have. Although the patients are often deemed to be generally marked by previous severe substance use, a more detailed mapping of damage and functional difficulties using brain imaging and neuropsychological tests might provide guidance in forensic psychiatric rehabilitation.

TRAUMATIC BRAIN INJURY

The incidence of traumatic brain injuries increases the risk of violent crime (18), and produces an increased risk of violence

when forensic psychiatric patients are in institutional care (19). Some of the persistent problems of forensic psychiatric patients, after positive psychotic symptoms and drug withdrawal have been treated in the acute phase, consist of symptoms that to a certain extent may be likened to the mental fatigue that is seen after a traumatic brain injury, severe infections or cerebrovascular insults (20). Fatigue, lack of initiative, trouble concentrating, stress sensitivity, irritability and a great need for sleep may be understood from many different explanation models, for example, as negative and cognitive symptoms in cases of schizophrenia, reactions after prolonged substance use, institutionalisation, depressive reactions, or as effects of extensive pharmacological treatment. Future research may show if an explanation model based on mental fatigue after some form of condition influencing brain health could give an even more complete picture of the challenges of forensic psychiatric rehabilitation, and if biomarkers for traumatic brain injury (21) could be used for evaluation of the brain health of forensic psychiatric patients.

PHYSICAL HEALTH

The brain is affected in various ways by physical illnesses that can often be investigated and treated. The risk of developing diabetes (22), metabolic syndrome (23) and cardiovascular disease (24) is heightened with psychotic disorders, and patients with a psychotic disorder have an estimated reduced life expectancy of 10–20 years (23–25). Diabetes and metabolic syndrome, which predispose to cardiovascular disease, stroke and premature death, can be detected with simple measurements and blood tests that should be performed for all forensic psychiatric patients. Cardiovascular disease, diabetes and metabolic syndrome are all linked to poorer cognitive functions (26–28). Structured interventions for lifestyle changes, with targets such as the patient giving up smoking or losing weight, can have beneficial effects on physical and mental health (29).

COGNITIVE FUNCTION

Successful forensic psychiatric rehabilitation requires the patient to be able to use their cognitive abilities. Cognitive defects are a core symptom of schizophrenia that affect the patient's ability to make decisions and to manage independent living (30). Recently it was shown that attention problems in a group of forensic psychiatric patients correlated with future risk of violence and less rehabilitative engagement (31). Although there is currently no guaranteed effective treatment for cognitive symptoms, experimental treatment with transcranial magnetic stimulation has proven to be able to improve working memory in schizophrenia patients (32) and it has been suggested that pharmacotherapy for substance use could improve executive functions in misuse patients (33). Most interestingly, a randomized controlled trial of cognitive remediation training, a behaviorally based treatment for cognitive deficits in schizophrenia, showed promising effects on cognitive function in a cohort of forensic psychiatric patients with psychotic disorders (34).

DIET

Many forensic psychiatric patients have unhealthy dietary habits, with too high a calorie intake and an unbalanced diet. It is well known that alcohol misuse affects dietary intake and produces vitamin disturbances, but vitamin disturbances are also seen in psychotic disorder cases and vitamin B supplements could be a future supplementary treatment for schizophrenia in order to reduce symptoms (35). Vitamin D has also been suggested as supplement for psychosis treatment (36) and vitamin D deficiency has been demonstrated in forensic psychiatric patients (37).

PHYSICAL EXERCISE

Low oxygen uptake ability is an independent risk factor for cardiovascular disease and premature death (38). Low oxygen uptake ability has been demonstrated in patients with a psychotic disorder (39) and in patients in forensic psychiatric care (40). Aerobic exercise offers one possibility for improving patients' general health and their cognitive functions (8) possibly *via* activation of neurotrophic factors, such as BDNF (brain-derived neurotrophic factor), and brain repair (41) although the mechanism is not fully understood (42). In patients with schizophrenia, aerobic exercise has positive effects on psychotic symptoms, cognitive function, general functional outcomes and quality of life (43, 44). Aerobic exercise can also be expected to reduce the incidence of metabolic syndrome in forensic psychiatric patients and thereby reduce cardiovascular morbidity, diabetes and premature death (45).

COGNITIVE TRAINING

Cognitive training and other strategies for facilitating cognition (cognitive remediation) can improve cognitive function in cases of several different mental illnesses such as schizophrenia and substance use syndrome (46) and even in forensic psychiatric patients (34). Patients with schizophrenia who also have metabolic syndrome do not, however, get the same effect from cognitive training as schizophrenia patients without metabolic syndrome (47). Thus, to get an effect from cognitive training, psychosis patients should first be treated for their metabolic syndrome. A particularly interesting thought is therefore to combine various non-pharmacological interventions to achieve the best effect on brain health. In one pilot study, a combined treatment of aerobic exercise and cognitive training produced improved cognitive function in patients with schizophrenia (48).

PHARMACOTHERAPY

Pharmacotherapy is a staple of forensic psychiatric treatment, and most patients are given antipsychotics (2). Compliance with antipsychotic drug treatment is regarded on the one hand as perhaps the most important factor for avoiding recidivism into serious crime (49) along with freedom from misuse. On the other hand, antipsychotics have side effects that can have an adverse effect on cognition and physical health (50). Although at lower doses

antipsychotics are seen as being able to improve cognition in certain patients, the opposite effect can been seen at higher doses, particularly when there is a long treatment period, or when the patient is also taking anticholinergics to deal with extrapyramidal side effects. A structured and cautious reduction of the dose of antipsychotics in forensic psychiatric patients, in a stable clinical condition, can bring about improved cognition and functional outcomes (51). Atypical antipsychotics have been associated with metabolic side effects and the incidence of diabetes (52) and metabolic syndrome, but this is probably true of all types of antipsychotics to a certain extent (50). In one group of schizophrenia patients being treated with olanzapine, the incidence of metabolic syndrome was linked to lower blood levels of the neurotrophic factor BDNF (53). In addition, the future study of clozapine-treatment, a common antipsychotic in forensic psychiatry probably due to its effects on aggressive behavior and treatment-resistant schizophrenia (54), may be of great interest with regard to putatively positive effects on brain health.

CONCLUSIONS AND RECOMMENDATIONS

There is much to indicate that forensic psychiatric patients have various complex conditions, which vary from patient to patient, that may potentially affect brain health. These conditions may affect the whole brain either in a general way (relating to, for example, physical health, previous diffuse brain trauma or prolonged substance use) or in a specific way (relating to, for example, psychotic disorders, pharmacotherapy or localised brain injuries), although the dividing line between the two groups is vague. Here we put forward the hypothesis that interventions that improve brain health in forensic psychiatric patients should be able to result in lower degrees of psychiatric morbidity, improved cognitive functions, better physical health, shorter hospital stays, increased independence and a longer life. This approach and these interventions demand a broad range of expertise within the forensic psychiatric team, which in addition to psychiatric and psychological expertise also needs expertise in general medicine, physical exercise and diet management.

From a medical-psychiatric perspective, the patient should be investigated and treated for physical illnesses with particular focus on metabolic syndrome and other risk factors for cardiovascular disease and diabetes. Physical exercise here occupies a special position as a promising form of treatment. Pharmacotherapy should be planned so as to minimise it leading to metabolic and cognitive side effects. Particular focus should be placed on investigating and mapping any brain injuries and their effects. From a psychological perspective, the patient should undergo neuropsychological investigation with particular focus on cognitive functions. These functions should be followed over time and the patient offered cognitive training or targeted support measures. From a care perspective, the patient should be offered as much support as possible in making lifestyle changes concerning diet, exercise and stopping smoking. From a social perspective, forensic psychiatric patients heading towards outpatient care and at the end of care should be offered support, activities and housing suited to their functional level. From a risk assessment perspective, it may be added that one of the hardest challenges for forensic psychiatry is assessing the risk of recidivism

into serious crime and communicating that to the courts. Brain-related methods may become part of this risk assessment and risk communication (55–57) which means that forensic psychiatric methods for care, treatment and rehabilitation with a focus on brain health may also be significant for risk assessments and communication with the courts. Finally, we wish to encourage research concerning the mental and physical health of forensic psychiatric patients, with particular focus on conditions affecting brain health. Knowledge concerning longitudinal progress, brain health-related biomarkers and interventions to support brain health would be of particular importance.

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PA and HB contributed conception and design of the study. PA wrote the first draft of the manuscript. PA and HB contributed to manuscript revision, read and approved the submitted version.

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Measuring Psychological Change and Predicting Recidivism Following the Swedish One-to-One Program

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The One-to-One program aims to reduce criminal recidivism among prisoners shortly awaiting release, and among probationers. Of 1,484 program participants in Sweden, 776 contained adequate data for analysis. Pre- and post-program scores were available for the Alternative Thinking Test, Levenson's Locus of Control Scale, Skill Survey, Citizen Scale, and Problem Checklist, all areas addressed in the program. This study examined predictive properties of test scores and background characteristics regarding recidivism, as well as differences between sub-groups. All post-tests indicated pro-social changes. Older participants were more likely to complete the program. The most potent predictor for non-recidivism was program completion, with non-completers 64% more likely to re-offend. Significant associations occurred between recidivism and the tests measuring skill improvement over time, chance locus of control pre- and post-program, and attitudes and values (Citizen Scale), partly supporting the theory behind the program.

Keywords: recidivism, individual psychological intervention, psychological tests, prison, probation, criminal justice, naturalistic study

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INTRODUCTION

Criminal justice authorities have long been struggling to find effective ways to reduce recidivism in crime. The conviction that rehabilitation of individuals in the criminal justice system would not work was widespread following (1) negative evaluation of treatment programs from the 50s and 60s, leading to use of the term "nothing works." A slow return to belief in the value of rehabilitation came in the 1990s, when meta-analyses showed that some programs did work, particularly when they followed principles adapting content to participants' *risk* for reoffending, their specific offending-related problems or *needs*, and were built on *responsivity* to participants' learning styles (2). This development led to what amounted to a movement among policy makers and criminal justice staff, leading to intensive activity towards identifying "what works" and developing and implementing programs that would work. Among treatment programs that early on were shown to be effective in reducing criminal recidivism, 75% are based on cognitive behavioral theory (CBT) and are multifaceted (3). With a focus on criminogenic needs—cognitive deficits and offending-related attitudes and beliefs (4)—additional effective components include a sound conceptual model, attention to the responsivity principle, role playing/modeling, and social cognitive skills training (5).

The One-to-One (OTO) program was developed by Philip Priestley in Great Britain in 1993 with the aim of satisfying the above criteria for effective programs among probationers. In the OTO-program the focus lies on finding examples from daily life and on giving homework, which gives the

client an opportunity to practice actual execution of the problem solving skills (6). The format of this program is "one-to-one"; i.e., a counselor works individually with a client for up to twenty sessions over a period of several months. The OTO program is based on cognitive-behavioral principles and focuses on specific areas. Skills in areas such as interpersonal/social (cognitive) problem-solving, social skills, and self-control are trained. Work is also done in the areas of attitudes and values and thinking (as in cognitive restructuring). The main focus is on problem solving, and criminal behavior is regarded as a problem to be solved. The program integrates the above-mentioned concepts and measures changes in each specific area over time. The OTO program has been accredited for use by community probation services in England and Wales (7) and as a national program for use both in probation and prison settings in Norway (8). It has also been implemented on a small scale in Lithuania (9) and piloted in the Netherlands (10). A small scale study in the English West Mercia probation area reported a 24% reduction for 51 OTO completers in observed reconvictions, compared to those expected based on national statistics (7).

In an effort to ensure the quality of the programs offered, the Swedish Prison and Probation Service has adopted the "what works" initiative and consequently aims to implement only evidence-based programs, with 17 programs currently accredited (11). One of the programs accredited under this initiative is the OTO CBT program for addressing criminal behavior (12). The OTO program was the first program in Swedish criminal justice that was not conducted in a group format. A first evaluation in the Swedish context showed a 25% reduction in reoffending for 350 OTO program completers in prison and probation, compared to 7,280 non-participants, with incomplete participation associated with 28% higher risk of recidivism (13). A more recent Swedish evaluation reported that OTO program completion was associated with a 15% lower risk for reoffending compared to controls, whereas incomplete participation was associated with a 61% increased risk (14). An individual program might be more suitable for some participants, and logistic considerations as well as personal characteristics may be considered when choosing an individual format. Different delivery formats in terms of program length have been used (6), where the format used in Sweden consists of 20 one-hour sessions with the participant.

Most evaluations of offending behavior programs focus on one outcome measure only; i.e., either recidivism as a binomial variable, or psychological change of some kind (15). As the main aim of all these programs is to reduce re-offending, the recidivism view of outcome success is easily understood and adopted. However, it tells us nothing of the link between psychological change and change in recidivism, in terms of what actually happens within the program. As one of the characteristics associated with program success is that the program is based on a "sound conceptual model" (3), it is also important to see how this conceptual model holds up to scrutiny. This study examines post-program psychological changes as measured by the tests in this program and their associations with the outcome of recidivism, as well as pre-program test-based predictors of recidivism. This becomes an examination of

the theoretical basis for this program, and leads to the following aim and research questions.

We aim to explore whether background data or test data have predictive properties regarding completion and recidivism and whether test outcome scores differ significantly between completers/non-completers and recidivists/non-recidivists. The specific research questions were whether a) test scores differed significantly in the entire cohort over time; b) whether completers and non-completers differed in background data and pre-test scores and, where available, whether program completers differed from norm data c) whether recidivists and non-recidivists differed significantly in background data and test scores d) whether non-completion of the OTO program could be predicted by background data and pre-program scores; and e) whether recidivism rates could be predicted by background data, pre- and post-program scores, and/or change scores over time for pre-/post-tests.

MATERIALS AND METHODS

Sample

The data for this study were collected by the Swedish Prison and Probation Service. The original data set consisted of 1,484 participants who entered the program between 2000 and 2008. The program was formally accredited in 2003 and by 2008 it was offered in 27 of 60 probation units in Sweden and 11 of 55 prisons (13). Clients with a medium to high risk for recidivism were considered appropriate for the program. Prior to recruitment, an evaluation interview took place to assess motivation and suitability, and both client and interviewer discussed whether they thought the client would benefit from the program and if so, made a joint decision for the client to enter the program (H. Nyberg, personal communication, March 24, 2009).

Of the 1,484 cases included in the data set, 687 lacked preor post-test data and were excluded. Due to inconsistencies in the data, such as dates, number of sessions, completer/noncompleter status, and multiple registrations a further 21 cases were excluded. The final data set consisted of 776 cases (see **Figure 1**).

Participant characteristics were available regarding age, gender, program completion, and recidivism up to 5 years following program participation. When starting the program participants were 27.92 years old on average [standard deviation (sd) = 9.33]. Almost all participants were male (92.3%). Of the 776 participants, 483 were completers and 293 were non-completers (see **Table 1**). All participants were convicted individuals who had access to the program during their term in probation, prison, or electronic monitoring. Data on recidivism were obtained from Swedish Prison and Probation Service records from September 1, 2007 or after a maximum of 5 years following program completion. The mean follow-up time was 854.51 days (sd = 673.42; range 0–1,827 days).

Outcome Measures

The primary outcome measure was recidivism, defined as relapse into criminal behavior, which had been noted in the criminal justice system in terms of trial and reconviction

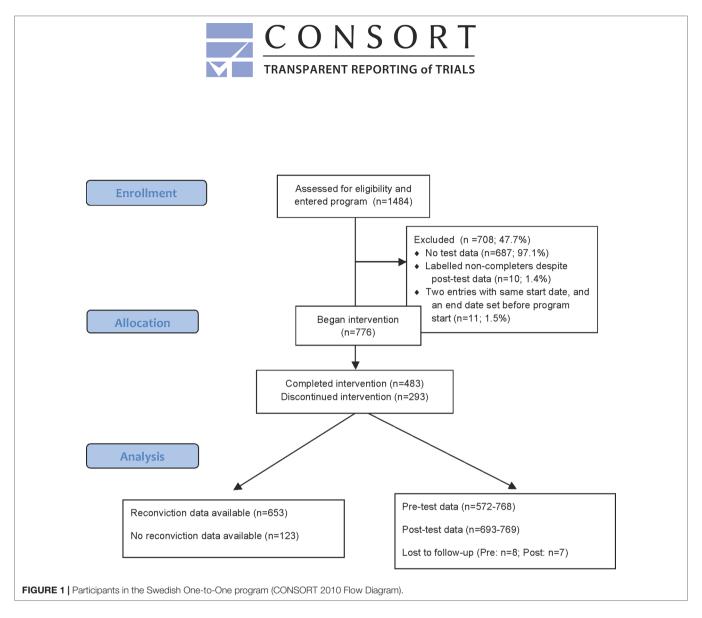


TABLE 1 | Sample characteristics for One-to-One program participants.

	N	n	%	Min.	Max.	Mean	Std. Dev.
Background characteristics							
Age at program start	771			15	66	27.92	9.33
Male	776	716	92.3%				
Female	776	60	7.7%				
Program participation No. of sessions	686			1	25	13.41	7.47
Completers	776	483	62.2%				
Non-completers	776	293	37.8%				
Pre-/post criminality No. of previous convictions	314			1	8	2.45	1.62
Recidivist	653	215	32.9%				
Non recidivist	653	438	67.1%				

during the follow-up period after the intervention. The terms recidivism, reconviction, and reoffense are used interchangeably.

Secondary outcome measures are scores on five different tests used within the OTO program as a basis for counselor-participant

discussions in the sessions. No psychometric data were available from Swedish samples on these tests, but they were retained to facilitate international comparability. **Table 2** shows the measures used in the study with information on number of items, the construct measured, and references.

TABLE 2 | Measures used in the study.

Measure	Items	Construct	References
Alternative Thinking Test (ATT)	4	Capacity to solve problems	Spivack, et al., (16)
Levenson's Locus of Control	24 (3 subscales)	Multi-dimensional locus of control.	Levenson (17)
Scale (LLOCS)		Subscales Internal, Powerful Others,	
		and Chance	
Skill Survey	20	Social skills. Questions taken from	Developed originally by Goldstein (18), 20 questions
		Goldstein's Prepare Curriculum	were selected for OTO program by Priestley (6)
Citizen Scale	4	Attitudes and values	Developed originally by Schneider (19), the Citizen
			Scale subscale was selected for OTO by Priestley (6)
Problem Checklist	110 (11 subscales)	A questionnaire regarding problems in	Constructed by James McGuire and adapted
		different areas of life	for the Swedish OTO by the Swedish Prison and
			Probation Service in Priestley (6)

Measures

Alternative Thinking Test

The Alternative Thinking Test (ATT) was developed as a means to measure the ability to generate solutions to problems, the *optional thinking* skill as defined by 16 The test consists of four different problems to which the test person generates as many solutions as possible. The number of alternative solutions is the test score. The test scores range from 0 with no upper limit, though scores on each item rarely exceed 12. This is the only test in OTO aiming to directly measure a skill rather than collecting participants' self-assessments. The ATT has been found to negatively correlate with self-harm in deliberate self-harm patients with no previous history of self-harm (20), verbal fluency, and attention in schizophrenic patients (21), and being a psychiatric patient (22). Pilot studies in Somerset and Cardiff have shown a significant increase in scores for OTO participants (6).

Levenson Locus of Control Scale

The Levenson Locus of Control Scale (LLOCS) is a well-researched test for measuring participants' views of their locus of control. The LLOCS scale consists of 24 items scored from -3 to +3, with 8 items in three subscales: Internal, Powerful Others, and Chance (IPC). The test is scored by adding 24 points to each subscale, yielding scores ranging from 0 to 48 for each subscale. As these scores are mutually independent, any combination of scores is possible. Norms based on an undergraduate U.S. student sample (n=161) with a mean age of 23.1 years yielded mean (sd) scores of 34.4 (5.4) on the Internal subscale, 24.4 (6.8) on the Powerful Others subscale, and 24.8 (6.1) on the Chance subscale (23). Conceptually, factor analysis has shown that the three dimensions of the LLOCS constitute different factors and the construct validity is satisfactory (24). Further support for the three-factor model emerged from a confirmatory factor analysis (25), and an analysis of three scales by Lindbloom & Faw (26). A pilot study found no significant changes over time in any of the subscales in pre- and post-program LLOCS scores for OTO participants (6); the test was therefore excluded in later versions of the program, after 2008.

Skill Survey

The Skill Survey measures strengths and weaknesses in the participant's social skill set. The survey consists of 20 items, selected from 50 items presented in the Prepare Curriculum (18). Each item requires the participant to rate how well they

use a certain skill, scored from 1 (not good) to 5 (very good), resulting in a score ranging from 20 to 100. In the OTO program, the survey is used to reflect changes in self-reported social skills levels. In pilot studies of OTO significant increases in skill levels have been reported for participants (6).

Citizen Scale

The Citizen Scale is a subset of a larger test designed by Anne Schneider (19), used in the OTO program under the name "The kind of person I am" to monitor changes in participants' views of themselves as being "good" citizens during the program. The test consists of four items, scored from 1 to 7 where each extreme represents the opposite of the other, for example "breaks rules" in contrast to "obeys rules"; the total score generated ranges between 4 and 28. Within the OTO program, the Citizen Scale score has demonstrated predictive power on the rate of reconviction, with higher scores linked to a lower reconviction rate (12).

Problem Checklist

The Problem Checklist (PCL) consists of 110 items used to assess the presence of criminogenic problems in the participant's life and divided into 11 subscales which reflect specific problem areas: work and unemployment, accommodation, money and financial pressures, alcohol, substance use, gambling, physical and mental health, social relationships, peer group pressure, family relationships, and family offending. Participants score each item from 0 to 10, where 0 means that the problem described in the item is not a problem for the participant, and 10 means that the problem is very serious; total scores including all subscales range from 0 to 110. The list was developed for the OTO program based on items generated by probation officers in Kent and thereafter modified and translated by the Swedish Prison and Probation Service. Within the program, the checklist is delivered in three parts during the first three sessions of the assessment part of the program. The checklist is also given in its entirety during session 19 as a post-test to see if there is any reduction in problem perception. Feedback regarding the division into subscales is revealed to the participant after the last module has been delivered. Within the OTO program, a pilot study showed that lower PCL scores at pre-test were associated with lower reconviction rates, and a later study showed significant positive post-program changes over time for all subscales on perceived problems (6).

The One-To-One Program

The structure of the One-To-One program is briefly outlined in **Table 3**. Each session follows a common structure throughout the program. Initially, any pressing issues that need to be handled are dealt with, followed by a review of homework tasks from the previous session. After this, the focus is on session-specific content, and the session ends with action plans for the time until the next session. Relapse prevention issues are continually addressed through discussion of the possibility of setbacks and of whether they really indicate failure.

Ethical Considerations

Written informed consent was given by the participants for the use of data for research purposes, according to a routine established by the Swedish Prison and Probation Service. Data were provided by agreement between the Service and author PP, in a file where personal identifiers such as civic registration number and name had been removed. For research purposes, data such as age, gender, time of attending the program, and classification of the offense were retained in the data file.

Statistical Analyses

The statistical analyses were performed using statistical package SPSS 16.0 for Mac. For baseline comparisons between included and excluded participants, chi-square tests were used for non-parametric data and independent samples t-tests for parametric data. For comparisons between pre- and post-program scores, paired samples t-tests were used, as well as within-group effect sizes according to Cohen's d (27). For comparisons of pre-program scores between program completers and

TABLE 3 | One-to-One program content.

Module	Sessions	Significant aspects
Pre-program motivational session	Pre-prog.	The counselor and the participant get to know each other. The participant is introduced to the program, and the program leader elicits statements about the participant's motivation for joining the program and reinforces them. Practice exercises are introduced.
Assessment	1–5	Assessment tests are completed by the participant. The counselor conducts a behavioral analysis focusing on antecedents, behavior, and consequences of the participant's offending behavior, and also proposes a personalized theory of the participant's offending.
Skills training	6–13	The participant works with applied training on problem solving, social skills, cognitive restructuring, moral training, goal setting, and self-management.
Application	14–20	Problem solving and social skills training are further practiced. The counselor also chooses areas from the skills training part deemed beneficial for the participant for further practice. This part ends with completion of post-tests, after which the participant formally exits the program.

non-completers, and comparisons of pre- and post-program scores between recidivists and non-recidivists, independent samples t-tests were used. In order to control for the effects of mass significance, increasing the probability of type I errors, a Bonferroni-corrected probability of p = 0.05/76 = 0.0007 was used. According to Lazerle & Mulaik (28), this is an unnecessarily conservative measure that may increase the risk for type II errors (false negatives). Therefore, in this study, results are reported according to a multi-stage method suggested by Lazerle & Mulaik (28), where the p-value was corrected to (0.05/[76-27] = 0.001), where 76 refers to the total number of significance tests carried out and the 27 refers to the number of significant results according to the first Bonferroni correction (p-value 0.0007). To assess predictive factors for program completion and recidivism, respectively, logistic regression was used.

Missing Data

Complete data for 776 cases were available for gender, and data for number of previous convictions were available for 314 cases (missing for 462). For pre-program tests, data for 5–204 cases were missing and for post-program tests 7–83 cases were missing (see **Figure 1**). Since data were collected by the Prison and Probation Service, the reasons for missing data are unknown. In the case of the LLOCS pre-test, the difference in missing values between this test and for example the PCL may mainly be due to the fact that the later version of the manual does not include the LLOCS. The large number of missing values in the number of previous convictions variable may be due to the possibility that some of these missing values were intended to mean zero previous convictions and were not actually missing values. No imputation procedures were applied.

Comparisons Between Included and Excluded Participants

Comparisons between the 687 excluded cases and the 776 cases that remained available for further analysis (see **Figure 1**) were made for gender, age, recidivism, and number of sessions, showing no significant differences (gender, $\chi 2 = 2.29$, df = 1, p = 0.130; age, t = -0.645, df = 1,324, p = 0.159; recidivism $\chi 2 = 1.558$, df = 1, p = 0.212). However, exclusion from analysis within this study was significantly related to the number of pre-program sessions, with the excluded group having fewer sessions (t = -9.190, df = 1,232, p < 0.001). Data were missing in the excluded group for 13 participants regarding gender, 129 for age, 3 for recidivism, and 158 for number of sessions; in the included group data were missing for 26 regarding gender, 123 regarding recidivism, and 89 regarding number of sessions.

RESULTS

Paired t-Tests Comparing Pre- and Post-Test Data

All paired t-tests comparing pre- and post-program scores over time yielded significant differences, using the multistage Bonferroni corrected p-value of 0.001 (**Table 4**).

TABLE 4 | Comparisons over time of results on pre- and post-program tests

Measure (pre-; post-n)	Pre-program mean (sd)	Post-program mean (sd)	t	Degrees of freedom (df)	р	Pre-/post- program difference (sd)	Cohen's d
Alternative Thinking Test (n = 760; n = 758)	12.27 (4.36)	15.23 (5.78)	-12.20	464	<0.001	-3.06 (5.40)	0.58
LLOCS (n = 572; n = 693)							
Internal	37.17 (4.76)	38.41 (4.61)	-5.19	396	< 0.001	-1.24 (4.78)	0.26
Powerful Others	22.86 (7.11)	21.50 (6.99)	4.13	396	<0.001	1.36 (6.58)	0.19
Chance	25.12 (6.51)	22.72 (7.36)	7.91	396	<0.001	2.40 (6.06)	0.35
Skill Survey (n = 729; n = 767)	69.22 (12.00)	75.19 (12.38)	-11.51	471	<0.001	-5.97 (11.27)	0.49
Citizen Scale (n = 768; n = 768)	19.76 (4.02)	22.27 (3.88)	-14.02	474	<0.001	-2.50 (3.89)	0.64
Problem checklist (PCL) ^a							
(n = 765; n = 769)							
Work and unemployment	29.11 (18.72)	20.29 (17.30)	12.41	470	<0.001	8.82 (15,29)	0.49
Money and financial pressures	26.76 (20.28)	18.20 (18.50)	12.07	470	<0.001	8.56 (15.39)	0.44
Alcohol	14.54 (16.18)	9.26 (12.98)	9.50	470	<0.001	5.28 (12.06)	0.36
Substance use	11.96 (16.84)	6.18 (12.83)	10.18	470	<0.001	5.78 (12.32)	0.39
Gambling	5.52 (13.42)	3.23 (9.44)	5.55	470	<0.001	2.29 (8.95)	0.20
Physical and mental health	19,96 (16.31)	11,56 (12.84)	13.74	470	<0.001	8.40 (13.27)	0.57
Social relationships	16,02 (14.40)	9,38 (11.31)	12.70	470	<0.001	6.64 (11.35)	0.51
Peer group pressure	21.05 (15.56)	12.39 (12.27)	14.78	470	<0.001	8.66 (12.72)	0.61
Family relationships	14.55 (14.24)	9.01 (12.04)	10.69	470	<0.001	5.54 (11.24)	0.42
Family offending	5.34 (8.21)	2.63 (7.33)	5.92	470	<0.001	1.70 (6.25)	0.35

^aIn the Swedish version of the PCL the subscale on accommodation was exchanged for a subscale on violence that was considered more relevant to the Swedish setting. However, the data available included both PCL versions, although not identified as to which version was used, so results on the accommodation or violence subscales could not presented.

Completers Compared to Dropouts

Only age at program end showed a significant difference between program completers and dropouts (t = -3.76, df = 748, p < 0.001), where program completers were on average 2.96 years older than non-completers.

Recidivist Completers Compared to Non-Recidivist Completers

Comparisons of pre- and post-program scores for program completers who were later reconvicted (recidivists) with non-recidivist program completers showed significant differences for the Levenson Chance subscale and the Citizen Scale pre- and post-program tests and for number of previous convictions. Recidivists scored higher on the LLOCS Chance subscale pre- and post-program tests and lower on both pre- and post-program tests for the Citizen Scale. Recidivists also had a significantly higher number of previous convictions (see **Table 5**).

Completers' Locus of Control Compared to Student Sample

Comparison of pre- and post-program scores on the three LLOCS sub-scales for program completers with cross-sectional student test means (23) showed that completers differed significantly on all scores except for the Chance pre-program test. Before and after the program, program completers had higher scores than students on the Internal sub-scale as well as lower scores on the Powerful Others sub-scale; after the program, completers had lower scores on the Chance sub-scale (see **Table 6**).

Predictors of Program Completion and Recidivism

Predictor variables were initially evaluated to identify whether any association existed with the dependent variables (DVs) of program completion and recidivism. For gender, no association was identified, neither for program completion ($\chi^2 = 1.03$, df = 1, p = 0.311) nor for

TABLE 5 | Significant differences in pre- and post-program means between recidivists and non-recidivists.

Test	Pre-/post- program tests	Recidivist Mean (SD)	Non-recidivist Mean (SD)	t	df	Sig. (two-tailed)
LLOCS Chance	Pre-program	23.50	22.05	-3.95	488	.000
		(7.09)	(7.00)			
	Post-program	22.96	20.63	-3.43	366	.001
		(6.98)	(6.89)			
Citizen Scale	Pre-program	18.77	19.95	3.43	647	.001
		(4.25)	(4.05)			
	Post-program	15.56	15.08	3.50	441	.001
		(6.04)	(5.74)			
Number of previous convictions	Pre-program	3.26	2.11	-3.62	61.64	.000
		(1.88)	(1.36)			

TABLE 6 | Comparison of program completers' locus of control to norm data.

Test	Pre-/Post-test	Student test mean (SD)	OTO test mean (SD)	t-value	df	Sig. (two-tailed)
LLOCS Internal	Pre-test	34.4	37,06	13.18	571	.000
		(5,4)	(4,83)			
	Post-test	"	38,38	17.06	399	.000
			(4,66)			
LLOCS Powerful Others	Pre-test	24.4	23,01	-4.64	571	.000
		(6,8)	(7,18)			
	Post-test	"	21,48	-8.37	399	.000
			(6,98)			
LLOCS Chance	Pre-test	24.8	25,42	2.19	571	.029
		(6,1)	(6,76)			
	Post-test	"	22,76	-5.54	399	.000
			(7,36)			

recidivism (χ^2 = 1.38, df = 1, p = 0.279). Gender was therefore not included as a predictor in the logistic regression analyses below. The predictor variables retained were age and all pre-program tests.

For program completion, a total of 554 cases were included in the analysis, and the full model was significant (χ^2 = 64.94, p < 0.001), accounting for between 11.1 and 15.9% of the variance. Overall, 73.8% of the predictions of completion status were correct, with 95.7 of the completers correctly predicted, but only 18.5% of the dropouts. Only the age variable was significant for predicting non-completion, both age at the beginning of the program (B = 0.40) and at the end (B = 2.57), meaning that for every increase of 1 year in age at the end of the program, the chance for completion increased by a factor of 2.57.

For recidivism among program completers, predictor variables consisted of pre- and post-program scores, the difference between pre- and post-program scores, and the categorical variables

of program completion and age as predictor variables. As the predictor variables were as many as 50, a forward conditional analysis was used in order to find the model best predicting the DV. The best-fit model included age at the end of the program, the pre-program LLOCS Chance subscale, the post-program PCL money and financial problems subscale, and the difference over time between pre- and post-program Skill Survey scores. An enter method logistic regression including only these four variables was performed in order to include a maximum of cases with valid data. A total of 365 cases were analyzed and the full model was significant $(\chi^2 = 33.73, df = 4, p < 0.0001)$. This model accounted for between 8.8 and 12.5% of the variance, with 94.5% of non-recidivists successfully predicted but only 17.9% of recidivists accurately predicted. Overall, 71.0% of the predictions were accurate. Table 7 shows that older completers were less likely to be reconvicted, with an odds ratio (B) of.96; having more post-program financial

TABLE 7 | Predictors of recidivism among program completers (n = 365).

	Variables in the equation	В	S.E.	Wald	df	Sig.	Exp(B)
Step 1	LLOCS Chance pre-test	.03	.02	3.13	1	.077	1.04
Change score Skill Survey	03	.01	5.71	1	.017	.97	
Age at end of program	04	.01	7.57	1	.006	.96	
Problem Checklist money and financial pressures post-test	.02	.01	11.72	1	.001	1.02	
Constant	87	.67	1.67	1	.196	.42	

problems was also associated with being reconvicted, with an odds ratio (B) of 1.02. A larger change over time on the Skill Survey score was also associated with not being reconvicted (B = 0.97).

A second logistic regression analysis was carried out with recidivism as the DV among program completers as well as non-completers (for whom post-program data were lacking) using pre-program data, age and program completion status as predictor variables. A total of 554 cases were analyzed and the full model was significant (χ^2 = 64.93, df = 18, p < 0.0001). This model accounted for between 11.1 and 15.9% of the variance, with 95.7% of non-recidivists successfully predicted but only 18.5% of recidivists accurately predicted. Overall, 73.8% of the predictions were accurate. The significant variables were: the PCL preprogram money and financial pressures and physical and mental health subscales, the LLOCS pre-program Chance subscale, and completion status¹. A higher level of perceived financial problems was associated with being reconvicted (odds ratio 1.02), whereas a higher level of perceived health problems was associated with not being reconvicted (odds ratio 1.02). Higher scores on the LLOCS Chance subscale were associated with being reconvicted (odds ratio 1.05), and program completers were less than half as likely to be reconvicted (odds ratio 0.36; see Table 8).

DISCUSSION

How to maximize reduction of criminal recidivism has been the main focus of criminal justice activities in Sweden for about 25 years, through the introduction of "what works" concepts and empirical findings (29). Numerous CBT programs have been introduced during this time, and evaluations of recidivism as an outcome have shown that the programs are associated with lower recidivism rates, including the OTO program, with its 15% lower risk of recidivism for program completers, and a much higher risk of 61% for non-completers (14). In this study, our aim has been to elucidate possible associations between psychological changes measured within the OTO program, and recidivism or its absence.

The most important variable protecting against recidivism in OTO-program participants was program completion, with non-completers 64% more likely to re-offend. Numerically, 25.7% of the OTO program completers re-offended compared to 49% of non-completers; the average rate of recidivism for the entire criminal justice population in Sweden varied during this time between about 40% in the year 2000 and declined to about 33% in 2008 (30). Older participants were more likely to complete the program, and they were also less likely to re-offend. Among program completers, all test results improved in a pro-social direction, with most effect sizes in the medium range. Regarding specific test results, social skills tended to improve over time among completers who did not re-offend, compared to recidivists. Locus of control tests indicated that program completers believed more in internal control and less in chance determination compared to student norms. However,

all program participants at baseline perceived a higher internal control over events while ascribing less control to other powerful people compared to student norms. Furthermore, participants at baseline believed in chance as a determinant of life events about equally to norm data. In summary, program completion, being older and improving skills over time seemed to be primary factors associated with non-recidivism, recidivists, whether or not they completed the program, had more prior convictions than non-recidivists. All measures of change over time for program completers indicated positive, pro-social development, with effect sizes varying between 0.19 on Powerful Others locus of control and 0.64 on the Citizen Scale. Nonetheless, aside from a pre-program perception of worse health, only changes in social skills over time were clearly associated with absence of recidivism. Recidivism was associated with perception of greater perceived financial problems and Chance locus of control. We focus our discussion on background and program-related factors found to be associated with recidivism, and aspects of psychological change identified as significant predictors of recidivism or its absence.

Higher age protected from recidivism and was associated with program completion, in line with previous extensive literature (e.g., 31). One possible consequence of this finding could be that an older population should be directed to OTO, whereas a different program, better suited for younger age groups, should be offered them. Recidivists had more previous convictions than non-recidivists, a finding also congruent with previous findings indicating that the number of previous convictions is one of the most important risk factors related to criminality (32, 33). The program completion variable was the most potent in predicting absence of recidivism. In view of the exclusion from analysis of the variable on the number of previous convictions due to missing data, the potency of program completion as a predictor for non-recidivism may have spuriously increased in the logistic regression model. The clear difference in recidivism between completers and non-completers, however, was expected based on prior research.

Notwithstanding these issues, the comparison of OTO participants to matched non-participant controls showed a program effect for reducing recidivism (14) as well as similar findings from other studies comparing CBT program participants to matched controls (e.g., 31) indicating that the program can be ascribed an effect beyond static predictors of recidivism such as age and number of previous convictions. Worth noting, however, is that non-completion of such programs is associated with a higher risk of recidivism compared to matched individuals who did not participate in programs, suggesting that the fact of non-completion can carry a heightened risk (34). Individuals identified as high-risk are more likely to drop out of a program (35). A study of sexual offense cases showed that the largest predictor of dropout from treatment was previous convictions for non-sexual offences. Also, fathers' unemployment is a variable that has shown discriminating properties between completers and non-completers (36). Another study of dropout found that cannabis dependence, criminal history (in terms of previous lifetime arrests), as well as hostility during treatment are factors that independently predict dropout, whereas employment

¹The number of previous offenses could not be included because there were only 144 valid cases for this variable.

TABLE 8 | Predictors of recidivism among program completers and non-completers (n = 554).

	Predictor variables ^a	В	S.E.	Wald	df	Sig.	Exp(B)
Step 1	Alternative Thinking Test	01	.02	.06	1	.799	.99
	LLOCS-Internal	.03	.02	.02	1	.144	1.03
	LLOCS—Powerful Others	.01	.02	.02	1	.418	1.01
	LLOCS-Chance ^b	.05	.02	.02	1	.016	1.05
	Skill Survey	.00	.01	.01	1	.588	1.00
	Citizen Scale	04	.03	.03	1	.192	.96
	PCL work and unemployment	00	.01	.01	1	.724	1.00
	PCL money and financial pressures	.02	.01	.01	1	.004	1.02
	PCL alcohol	01	.01	.01	1	.337	.99
	PCL substance use	.00	.01	.01	1	.691	1.00
	PCL gambling	01	.01	.01	1	.290	.99
	PCL physical and mental health	02	.01	.01	1	.040	.98
	PCL social relationships	.02	.01	.01	1	.098	1.02
	PCL peer group pressure	00	.01	.01	1	.816	1.00
	PCL family relationships	01	.01	.01	1	.228	.99
	PCL family offending	.02	.01	.01	1	.119	1.02
	Program completion status	-1.03	.24	.24	1	.000	.36
	Age at program start	.14	.14	.14	1	.290	1.16
	Age at program end	17	.14	.14	1	.210	.84
	Constant	-1.42	1.26	1.26	1	.261	.24

^aAll test variables are from the pre-program testing time point.

predicts staying in treatment (37). A qualitative study found no difference in motivation to change between completers and non-completers (38), although Wormith & Olver (35) found motivation (not clearly defined) to be a predictor of dropout. A study on differences between dropouts and completers in a court-mandated treatment for spouse abusers found that dropouts were more likely to be younger, not married and more likely to have previous convictions, but also less likely to be depressed when starting the program (39).

In terms of measures of psychological change during the program, improving social skills during the program was found to be a factor protecting from recidivism. The aim of the Skill Survey is to identify strengths and weaknesses in the participant's social skill set, and each of the skills associated with the test items is the focus of modules in the OTO program. An increase in social skills according to the Skill Survey could reflect participant success in utilizing social skills training within OTO, yielding an effect on the targeted outcome of recidivism. The finding that perceived pre-program worse health appeared to protect against recidivism might be interpreted to mean that the criminal lifestyle is challenging and that a person leading that kind of life has to have some measure of good health to persevere in it. Since the PCL physical and mental health subscale does not distinguish between physical and mental it is not clear, however, what this finding might stand for. It is also important to remember that this finding concerns only the pre-program test and showed a relatively large within-group effect size of 0.57 over time.

The finding that post-program perception of financial problems predicted recidivism for program completers might be related to the fact that work with financial problems and vocational status is not included in OTO, although problem-solving is a major component of the program. This finding suggests that money and financial problems are an important issue to address within the program, for example as in the Community Reinforcement

Approach (CRA; 40), where the therapist acts as a coach for job searching skills, including how to speak to persons at relevant authorities, for instance in order to restructure the participant's debts. In CRA participants are also encouraged to form job searching clubs, yielding more opportunities for exercising and practicing these skills. Whether this could be feasible in within the prison and probation setting as well as a good fit for the OTO program needs to be further explored.

Program completers who were reconvicted had a higher belief in Chance locus of control than non-recidivists, in line with previous studies (41, 42) as well as the previous finding that the Chance subscale correlates with sociopathy (43). Interestingly, only the Chance subscale was of importance in relation to re-offending, while Internal or Powerful Others loci of control were not problematic. During the cognitive restructuring parts of the OTO program, the participant's locus of control is addressed in terms of whether the participant externalizes control; it might be wise to consider addressing Chance locus of control specifically instead of working with External locus of control as a uniform concept. In terms of comparison with normative data on Chance locus of control, program completers did not differ from US student norms pre- or post-program, in line with (44) findings in a study of prisoners. However, it should be noted that the norms used might not necessarily be valid in Sweden and as a population mean. It may also be the case that those with criminal convictions need to believe in a Chance locus of control in order to motivate them to take the risks involved, but that the mean does not necessarily differ from the normal population.

Strengths and Limitations

This study had several strengths. The evaluation of pre- and post-program test data in a national population of OTO participants between 2000 and 2008 was the first in Sweden as

^bVariables marked in bold were significant predictors of recidivism (not subject to Bonferroni correction).

well as internationally. The associations with background and reconviction data give meaning to the findings, particularly in relation to the later effect study comparing OTO participants to matched controls (14). Nonetheless, the current study was limited by the lack of psychometric data and norms on the tests used, the lack of any control group, and missing data common to naturalistic studies in prison settings; an additional limitation was the lack of data on staff qualifications as well as the lack of fidelity measures for program adherence. Specific comments on the strengths and limitations of the tests used follow below.

The tests used for measures to assess progress in the program are not readily available. Only the LLOCS test was found to be previously validated, with some US norm data available but none in a Swedish population. Although each test has a clear source (see Table 2), the source for the PCL was not readily available. Nonetheless, the tests used in OTO appear to have good face validity. For example, the concept of locus of control is explicitly addressed in OTO in relation to problem-solving, and an association between locus of control and perceived problemsolving skills has been found in male university students (45). The Skill Survey asks about the participant's perceived skillfulness in specific areas that are worked with in OTO, and as such has merit in identifying where there have been changes. The Citizen Scale measures participants' perceptions of how they rate themselves on attitudes to laws, following rules, cooperation, and honesty, and the focus of sessions on cognitive restructuring, morals, and role rotating tasks might influence the participant's attitudes in a way that can be measured by this test. In this study, no checks were conducted for social desirability for these tests, and this is a factor that may affect how individuals report data. Since no normative studies have been conducted in a more readily comparable population, it is difficult to infer anything meaningful about the magnitude or clinical significance of any reported changes in scores. Nonetheless, the results of this study could be of use to counselors in building a personalized theory of the participant's offending. Since our findings show that some test results relate to re-offending, if norms should become available then deviations from norms for convicted and general populations might be of special interest both to counselors and participants in the assessment part of the program.

CONCLUSIONS

The theory behind offending behavior programs in general and the OTO-program in particular, is that various aspects of psychological change mediate program outcome in terms of recidivism (46). In OTO, the psychological focus lies in the areas of problem-solving, values, motivation, social skills, and certain problem areas, and addressing these areas within the program is assumed to mediate a lower rate of recidivism. Although this study identified pro-social changes over time in the program target areas, in the absence of a control group no causal effects for the program can be ascertained. Regarding the problems associated with recidivism, mainly financial problems stand out. This aspect is not clearly linked to the theory behind the OTO program and not directly addressed within the program, but is measured

pre- and post-delivery and could be addressed in tailored versions of the program. Based on the theory behind the program it was surprising that the internal-external locus of control dimension had no significance; still, our finding that Chance locus of control predicted recidivism lends some support to the idea that locus of control is meaningful to address within OTO.

The basis for the OTO-program is problem-solving and the test used to measure this aspect, the ATT, did not discriminate between recidivists and non-recidivists, and had no predictive properties. No evidence was found for the assumption that improved problem-solving ability mediated reduced recidivism. We suggest that the ATT is not the most adequate test to measure changes in problem-solving. One alternative could be the Means-Ends Problem Solving Test (MEPS), which has been used in adult populations (e.g., 47) and has shown differentiating properties for maladjustment; this test is based on the same theoretical foundation as the ATT, and was developed by the same researchers, but aims at another aspect of problem-solving, namely meansends problem solving thinking. Another approach would be to consider the recommendations of D'Zurilla and Maydeau-Olivares (48) for using the IDEA (Inventory of Decisions, Evaluations, and Actions) as an outcome measure, or the SPSI-R (Social Problem-Solving Inventory-Revised) as a process measure of social problem solving. We do recognize, however, that one advantage of the ATT is that it is easy to administer and score and that it measures an actual skill, reducing bias, and social desirability.

The concept of psychological change leading to reduced recidivism is not new, but empirical findings are scarce on mechanisms driving such change and its translation to desistance from criminal recidivism. Much of the literature on the concept derives from theory on the Psychology of Criminal Conduct (PCC) originally described by Andrews and Bonta in several editions of their seminal book with this name (e.g., 5). A recent in-depth discussion on the PCC suggested that although dynamic risk factors have good predictive validity, the way in which psychological changes in these criminogenic needs convert to empirical outcomes has not been explored sufficiently (46). While this study focuses specifically on change in these dynamic risk factors in relation to reconviction, information on the nature of the mediating path between psychological change and reduced criminal behavior has not been part of the data set. Thus, although we identified findings that partly support the existence of a relationship between psychological changes that take place during the program and recidivism, this relationship is far from clear or unambiguous and it is important to note that no support for the theory of problem-solving deficits as related to offending was found in this study, perhaps due to the fact that the test used to measure problem-solving within OTO is not well-suited. Although we cannot draw any far-reaching conclusions based on the results of this study, they are sufficiently interesting to warrant further examination of the program with a stronger research design, particularly one that illuminates the path between in-program changes and later desistance from criminal behavior. Future studies should include tests validated with the target population and, if possible, population norms from general population and convicted samples. The problem-solving test should also include a wider range of problem solving aspects. Data collection within the prison

and probation setting should prioritize high data input, possibly by using online forms centrally coordinated rather than relying on program counselors to collect data. In order to strengthen the design and allow for causal conclusions, pragmatic clinical trial design should be used (49), as well as single-case studies to closely study the path between psychological change and later behavior (50). A valuable aspect of this study could be a focus on mapping changes in emotions as addressed in relation to childhood schemas (46). Finally, from a practical point of view, it could be expedient to evaluate age-appropriate interventions in comparison to OTO participation, to investigate whether younger people might show greater retention and success in reducing criminal behaviors compared with OTO in its current version. Practical interventions to reduce financial problems at the end of the program could also be added to OTO as an additional session focusing, for example, on job searching clubs and debt restructuring. The OTO program has been shown successful in reducing recidivism. It has long been offered in several criminal justice services internationally. This well-founded program could be further improved if the recommendations from this study are followed.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this manuscript will be made available by the authors to any qualified researcher.

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AUTHOR CONTRIBUTIONS

Authors PP and AB conceived the study design, and PM and MG carried out the analyses within their thesis work for the MSc degree in Clinical Psychology, under AB's supervision. This manuscript, based on the thesis originally written by PM and MG, was revised and edited by AB with input from PP, PM, and MG. All authors approved the final manuscript and are accountable for its contents.

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Conflict of Interest: PP is the author of the One-to-One program, and trained criminal justice staff (1990 – 2003) to deliver it in the UK, Sweden, and Norway. He has no current involvement with the program in any of those locations.

The remaining 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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A Clinical Feasibility Study of the Forensic Psychiatry and Violence Oxford (FoVOx) Tool

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Background: Risk assessment informs decisions around admission to and discharge from secure psychiatric hospital and contributes to treatment and supervision. There are advantages to using brief, scalable, free online tools with similar accuracy to instruments currently used. We undertook a study of one such risk assessment, the Forensic Psychiatry and Violence Oxford (FoVOx) tool, examining its acceptability, feasibility, and practicality.

Methods: We completed the FoVOx tool on all discharges from six secure psychiatric hospitals in one region in England over two years. We interviewed 11 senior forensic psychiatrists regarding each discharge using a standardized questionnaire. Their patient's FoVOx score was compared to clinical risk assessment, and the senior clinicians were asked if they considered FoVOx scores accurate and useful. A modified thematic analysis was conducted, and clinicians were surveyed about current risk assessment practice on discharge.

Results: Of 90 consecutive discharges, 84 were included in the final analysis. The median FoVOx probability score was 11% risk of violent recidivism in two years after discharge. We estimated that 12 (14%) individuals reoffended since discharge; all were in the medium or high risk FoVOx categories. Clinical assessment of risk agreed with the FoVOx categories in around half the cases. Clinicians were more likely to provide lower risk categories compared with FoVOx ones. FoVOx was considered to be an accurate representation of risk in 67% of cases; clinicians revised their view on some patient's risk assessment after being informed of their FoVOx scores. Completing FoVOx was reported to be helpful in the majority of cases. Reasons included improved communication with other agencies, reassurance to clinical teams, and identifying additional factors not fully considered. 10 of the 11 respondents reported that FoVOx was practical, and seven of 11 reported that they would use it in the future, highlighting its brevity and speed of use compared to existing risk assessment tools.

Conclusions: Senior clinicians in this regional forensic psychiatric service found the FoVOx risk assessment tool feasible, practical, and easy to use. Its use addressed a lack of consistency around risk assessment at the point of discharge and, if used routinely, could assist in clinical decision-making.

Keywords: FoVOx, risk assessment, feasibility, recidivism, secure hospital, forensic psychiatry

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INTRODUCTION

After discharge from forensic psychiatric hospital, rates of violent reoffending are reported to range from 2% to 8% per year in high income countries, and one cohort study based on around half of the forensic hospitals in England reported that 1 in 8 men and 1 in 16 women were convicted of serious offences over a mean follow-up of 6 years (1). Thus, risk assessment has become an integral part of forensic mental health in order to inform decisions about admission, management, and discharge (2). Further, professionals working in forensic mental health regularly advise court proceedings, which can involve considerations of future risk.

If accurately done, risk assessment should identify those patients presenting with the highest risk, reduce length of stay, and assist in treatment allocation. Structured violence risk assessment is broadly split into two approaches: actuarial tools, which use statistical methods to give a population-based percentage chance of reoffending, and structured professional judgment tools, which attempt to guide mental health professionals by identifying some risk factors. Structured professional judgment tools are more frequently used in clinical settings. In the UK, for example, 90% of medium secure units report using them in one survey (3), and their completion is used as a key performance indicator (4). However, there are important problems with using them (5). Structured professional judgment tools take a long time to complete, for example 15 person-hours to complete an initial HCR-20 (6). They often have low to moderate validity in field studies (7), have often been developed in prison, rather than hospital, settings, and using methods to derive them which are dated. Further, there have been low standards in reporting, including few performance measures, authorship bias (8), wide variations in what constitutes 'high' risk (9), and their underlying risk factors are based on heterogeneous samples and do not incorporate new evidence on risk (10). In the case of the commonly-used HCR-20 and PCL-R, for example, it has been found that most of the factors are not predictive (11). One new approach has been to use solely dynamic risk factors, but this may lead to harsher penalties for minority groups by conflating risk with rehabilitative needs (12) and also poor accuracy as strong risk factors for reoffending including sex, age, and criminal history are omitted. Thus, the potential use of high-quality actuarial tools needs reconsideration in forensic mental health (13).

One such tool is the Forensic Violence Oxford (FoVOx) tool (14), which was developed using all forensic psychiatric patients in Sweden and based on the largest forensic psychiatric sample to date. When reported, the FoVOx study was novel in that it incorporated independent risk factors tested in a large sample, reported calibration (observed vs. expected probabilities) and published a study protocol. The FoVOx tool also has the advantage of using routinely available data, which are less liable to bias than interview-based measures (e.g. of a personality trait). The 12 items within the FoVOx tool are sex, age, previous violent crime, previous serious violent crime, primary discharge diagnosis, drug use disorder at point of hospitalization or discharge, any lifetime drug use disorder, alcohol use disorder at point of hospitalization or discharge, personality disorder at discharge, employment at admission, five or more prior inpatient episodes, and whether current length of stay has exceeded one year. The FoVOx tool is scalable, quick, free to use and available online. All the model coefficients are reported, meeting a key concern of using clinical prediction models that they should be transparent. In the derivation sample, the AUC was 0.77, which makes it as accurate in terms of discrimination as existing tools (15). Its use could enable clinicians to provide a reasonably accurate risk assessment in a brief and cost-effective way, and free up time to focus on clinical care and risk management rather than risk assessment. Possible limitations of the FoVOx tool are that it does not specifically predict serious (as opposed to any) violent reoffending and has not been externally validated to date.

In addition to external validation, prior to introducing any new risk assessment into a clinical setting, information about potential users and their decision-making is necessary (16). Clinical impact should be assessed, including where it could sit in the clinical pathway and the consequences of its use. Attitudes towards any tool should be sought, and any preconceptions about risk prediction models identified. Therefore, we undertook a feasibility study of the FoVOx tool, assessing its acceptability to professionals, demand for its use, and its practicality in one regional English forensic psychiatric service.

METHODS

The study protocol used a mixed methods approach by identifying discharged patients and scoring them using the FoVOx tool at the point of their discharge, which was followed up by qualitative work assessing clinician views about the use of the FoVOx tool.

Sample

Patients

We identified all consecutive patients discharged from the Thames Valley Forensic Mental Health Services between March 2016 and March 2018, covering three counties (Oxfordshire, Buckinghamshire and Berkshire) across different levels of security (medium and low security, and a pre-discharge unit). All patients, both male and female, were included in the study irrespective of diagnosis or any other individual factor. All were over the age of 18. If any patients were discharged more than once from the service during that time, the most recent discharge was selected.

Clinicians

We interviewed all the senior clinicians ('Responsible Clinicians') in the service, made up of eight men and three women. In England and Wales, Responsible Clinicians are the legally considered the lead professionals involved in the care of detained forensic mental health patients. All Responsible Clinicians in the service were consultant (i.e. certified on the General Medical Council Specialist Register) forensic psychiatrists.

Measures

FoVOx

Two members of the study team (AL and OP) accessed the electronic healthcare record ('Care Notes') of the discharged patients to obtain the information required to calculate their

FoVOx score at the point of the most recent discharge, using an online calculator available at https://oxrisk.com/fovox/.

Questionnaire

A standardized tool was developed to collect views and information from senior clinicians (**Appendix 1**). Each clinician underwent an in-depth interview by one of the study team (RC, OP, or AL) regarding each discharge. The standardized tool contained no patient identifiable information. The anonymized discharge number was the only identifier. During the interviews, patients' identities and discharge location were shared in order to collect the clinician view on risk assessment of their own patients.

The clinician was asked to provide their estimate of the 2-year risk of a violent conviction (meaning any interpersonal violent or sexual offence) at the point of their most recent discharge. They were asked to provide a high, medium or low risk rating in line with pre-specified FoVOx categories): Low (< 5% chance of violent offending within two years of discharge), Medium (5–20%), High (> 20%) or state if they could not recall this. They were then asked if, according to their knowledge, their patient had committed a violent offence since that period of discharge.

After this, the patient's FoVOx score (both probability and categorical) at the time of discharge was shared with the Responsible Clinician. Cohen's Kappa was calculated for agreement between clinical categorical risk assessment and FoVOx category. The clinician was then asked if they considered this to be a fair representation of their risk and if not, why. Participants were also asked whether it would have been of benefit to know the FoVOx probability and categorical score at the point of discharge, for example by altering clinical management at that point. Reasons were again given for each case. Answers to the two questions about whether FoVOx was accurate and useful were recorded, using the interviewee's wording and with an opportunity for the clinician interviewed to confirm that the transcribed notes represented their stated reasons. One researcher (RC) analyzed these records, creating individual response codes, noting how often these were each stated and thematically grouped them. The transcripts were then read by a second researcher (OC), who re-analyzed according to themes independently, before the two researchers met to agree a consensus about the principal themes.

The clinician was next asked whether they routinely use a risk assessment tool at discharge in order to check whether they were already using the FoVOx tool and to determine whether they were using other tools they consider effective.

The unpopulated FoVOx tool was then shown to the clinician. They were asked their views on its practicality, ease of use, and future plans for risk assessment. Participants were asked to give specific reasons as to whether they thought FoVOx was practical to use, and whether they would use FoVOx in the future. Again, these responses were recorded and coded and grouped into themes by two researchers (RC and OC).

Ethics

The project was approved by the Oxford Health NHS Foundation Trust Clinical Governance Committee in March 2018 and by the Clinical Lead for Forensic Services as a Service Evaluation project. Therefore, individual informed consent was not deemed necessary. No data beyond that collated in routine clinical care was used, and the management of patients was not impacted by the study. To identify patients, existing discharge data being collected by the Trust for audit purposes was used. All Responsible Clinicians participated in the study voluntarily, and patient data was anonymized other than for the 'unblinding' during the Responsible Clinician interviews.

RESULTS

Sample

Ninety discharges from forensic psychiatric hospitals were identified from May 2016 to May 2018. Six patients were excluded from analysis (two had been transferred to another secure psychiatric setting, one deported abroad and three were aged over 65 years). Thus, 84 patients were included in the study (**Figure 1**). Of these, 11 were female (13%). One transgender patient had their assigned gender used for FoVOx scoring (17). The mean age of patients was 39.2 years, SD 10.7, range 21–60.

The number of discharged patients per clinician was 2 to 18. The median number of days from discharge to study interview was 485 (interquartile range 339–643). Sample characteristics and FoVOx scores are included in **Table 1**. 9 of the 11 clinicians (82%) reported that they routinely completed a risk assessment process around the time of discharge. These included a multi-disciplinary clinical risk assessment, a description of risk in a Mental Health Review Tribunal Report, the patient's latest HCR-20, and HoNOS (Health of the Nation Outcome Scales). One respondent reported regularly using a structured risk assessment specifically at the point of discharge.

FoVOx Scores

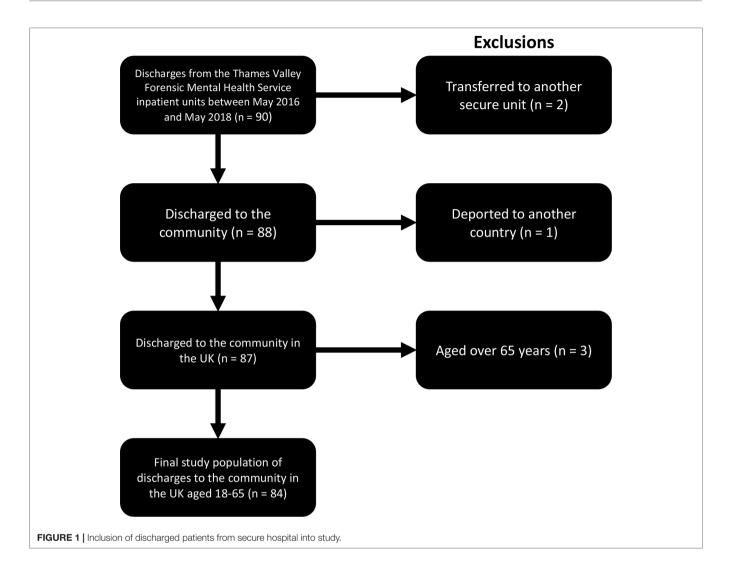
FoVOx scores were calculated from clinical records and took no more than 15 minutes per case. The median FoVOx probability score was a 11% chance of violent recidivism in 2 years (interquartile range 6–19%, range 2–49%). In terms of categories, 12 (14%) were low risk, 55 (66%) medium risk and 17 (20%) high risk. Some individual items were missing for 15 patients, and for these a FoVOx risk score range was generated (as per the online calculator). Of these, four ranges crossed low-medium or medium-high categories. In these cases, the higher risk rating was presented to the clinician.

Recidivism

Of the 84 patients included, five were lost to follow up. Of the remaining 79 who were still in contact with mental health services, 12 (14%) were reported to have committed a violent offence since discharge based on information known to the Responsible Clinicians. Of these, eight had FoVOx scores in the medium category and four were in the high category.

Concordance Between FoVOx Scores and Clinical Judgment (Case by Case)

There was agreement for risk assessment based on three categories (i.e. low/medium/high) between the clinical unstructured



judgment and the FoVOx score in 49% of cases (41 out of 84; $\kappa = 0.20$ [95% CI, 0.06–0.35]). Where there was disagreement, clinicians were more likely to score patients in a lower risk category compared with their FoVOx score (in 36 of the 43 cases). When considering two risk categories: low and medium/high, there was agreement between clinical unstructured judgment and the FoVOx score in 63% of cases (53 out of 84; $\kappa = 0.22$ [95% CI, 0.06–0.38]). For most cases (56 out of 84, 67%), the FoVOx score (combined categorical and probability) was felt by the clinician to be an accurate representation of the violence risk at discharge. In the 28 cases (33%) where it was not, the clinician was asked to give reasons. Two main themes were identified. The first was that clinicians viewed certain risk factors as dynamic and modifiable by treatment, such as substance abuse and the response to medication and psychological treatment; "The dynamic risk factors have been modified in hospital, there was no alcohol or drug use on discharge and these were relevant for previous offending" and "The risk is too high, it doesn't take into account any completed therapeutic intervention." These were thought to contribute to risk in both directions; if the patient had responded to treatment the FoVOx score was felt to be an overestimate, and vice versa. The second theme was that clinicians felt that there were

additional factors which influenced risk which were not measured by the FoVOx tool. These included the recency of offending and violence, and the nature of supervision in the community, as well as cases in which the patient was only felt to pose a risk in a specific set of circumstances: "Risk is over-represented as there has not been any violence for the past 15 years", "The estimated risk is too high; the patient has engaged very well with treatment and supervision in the community" and "This tool underestimates risk as relationship instability is a risk factor". These themes are summarized in Table 2.

Views on Utility At the Point of Discharge (Case by Case)

Responsible Clinicians reported that it would have been helpful to know FoVOx scores at the point of discharge in 49 (58%) cases, and not that helpful in 35 (42%) cases. Qualitative feedback is summarized in **Table 3**. The most frequent reasons given for why FoVOx would be helpful were related to its concordance with existing clinical risk assessment, including supporting and providing further evidence of the clinical categorization of risk if it aligned with the FoVOx score; "(It) can offer confirmation of

TABLE 1 | Sample characteristics and FoVOx scores.

Demographics		
	Male:female Age at discharge (SD) Median days since discharge (IQR) Median FoVOx score (range)	73:11 39.2 (10.7) 485 (334–643) 11% (2%–49%)
-Low -Medium -High	All included patients 12 (14%) 55 (66%) 17 (20%)	Violent recidivists (based on clinician recall) 0 8 (67%) 4 (33%)
Responsible clinician view on FoVOx -Accurate? -Helpful?	Yes 56 (67%) 49 (58%)	No 28 (33%) 35 (42%)

informal risk assessment". Improved information sharing with other agencies was repeatedly noted, including being used as an additional source of evidence; "this was a high-profile case and the Tribunal was reluctant to discharge, perhaps the clinical view over-estimated risk and it would have been helpful to have the FoVOx score". It was also reported, for 14 cases, that using FoVOx would identify risk factors which had not been fully considered by clinicians, suggesting that it could impact on risk management in addition to risk assessment; "Can confirm risk assessment and help identify and consider other risk factors" and "Identifies outstanding areas of risk". In cases where FoVOx was considered not useful, the most common reason given was clinicians not attributing value to any actuarial tool; "Won't add value to clinical practice and is unlikely to add to discharge planning. Doesn't use any clinical risk factors, such as insight". Other comments included that it might lead to unintended consequences. For example, FoVOx could increase anxiety if it rated patients at higher risk than clinical assessment. It was also reported that sharing the FoVOx score could lead to delays in liaison with other agencies, for example if they refused or delayed housing or support on discharge on the basis of high risk; "Can increase anxiety and delay discharge planning, induce self-doubt in clinical decision-making, make other teams reluctant to take over care."

Overall Opinion of Practicality and Future Use

After reviewing individual discharges, 10 (90%) clinicians reported that the FoVOx tool is practical to use and that it could be completed without reference to medical notes. All respondents could complete FoVOx scoring in under 1 minute for their most recent discharged patient.

Seven of 11 (64%) respondents reported that they would use FoVOx in the future for a number of reasons (**Table 4**). In addition to improved information sharing and possible impact on management, there were a range of positive comments about the FoVOx tool specifically. These included the ease with which information could be found, and the speed with which it could be completed. Criticisms included the emphasis on static, historical factors, inability to specifically predict serious (as opposed to any) violence, and a preference to see validation studies in a UK forensic sample before local adoption.

Finally, clinicians were asked if they had any other comments regarding the FoVOx tool. Its potential use at an earlier stage, either at gatekeeping or to screen referrals, was noted twice. The benefits of its brevity and speed of use over existing actuarial tools were repeatedly noted, even among clinicians who felt that actuarial risk assessment tools were of little value: "If we have to use an actuarial tool then I would use this" and "Straightforward, reassuring, also helpful/interesting to consider cases where there is discrepancy. Nothing to lose, why wouldn't you?". Three respondents stated that the low/medium/high risk categories were unnecessary. There were also some specific queries about individual cases, including whether those in full-time education at the time of their index offence should be considered as employed, and classifying some UK offences as serious or aggravated/otherwise.

DISCUSSION

We examined the use of a novel violence risk assessment tool (FoVOx) on 84 consecutive discharges from secure (forensic) psychiatric hospitals within one region of England over 2 years to assess its feasibility and acceptability. As part of this, individual interviews were conducted with senior clinicians regarding each discharge to assess the potential impact of the FoVOx tool on risk assessment and management.

TABLE 2 | Qualitative feedback on challenges with FoVOx scoring.

Theme	Sub theme	FoVOx score is too high	FoVOx score is too low
Dynamic Risk Factors	Primary discharge diagnosis— medical treatment	Good response to medication	Poor response to medication
	Personality disorder diagnosis— psychological treatment	Successful (increased insight, specific work on offence)	Unsuccessful (non-engagement, untreated personality disorder)
Risk factors not identified by FoVOx	Substance misuse diagnosis Supervision	No longer using substances Engaged with community mental health support, use of statutory supervision	High risk of substance misuse after discharge Uncooperative with supervision
FOVOX	Chronicity of violence Psychosocial support	No violence in hospital Improved relationships with family, good psychosocial functioning, lifestyle change	Frequent violence in hospital Relationship instability
	Specific circumstances to index offence	No forensic history prior to index offence, long period of time since index offence, offending could only occur in a specific context	Lengthy past forensic history, unpredictability

TABLE 3 | Qualitative feedback on the usefulness of FoVOx scoring

Theme	Sub Theme	Helpful	Unhelpful
Used as evidence to support decision-making	As part of discharge planning	Other agencies more likely to support discharge, e.g. Mental Health Review Tribunals, Parole Board	Could lead the same agencies less likely to discharge, FoVOx score is less relevant if patient is discharged due to circumstances other than a reduction in risk
	In liaison with third parties	Improved information sharing with accommodation providers, non-forensic mental health services, probation and MAPPA	Negative responses such as not accepting patient for housing.
Risk assessment	Reassurance	Reassurance if agrees with clinical assessment, reducing anxiety if FoVOx rates risk lower than clinician	No added value if FoVOx and clinician assessment agree, increasing anxiety and leading to review if FoVOx rates risk higher than clinician
	Changing patient management	Identification of unaddressed risk factors and informing management decisions such as threshold to recall	Over or under-estimates risk due to reliance on historical factors
	Existing perceptions of risk assessment	Highlights over-reliance on clinical factors as being predictive of recidivism	Skepticism about the value of any actuarial tool
	Need to differentiate between serious and less serious offending		Inability of FoVOx to predict serious, as opposed to any, violent recidivism
	Discharge due to factors other than risk reduction		Discharge was dictated by factors other than a reduction in risk.

TABLE 4 | Qualitative feedback on whether clinicians would use FoVOx in the future.

	Reasons for using	Reasons for not using
FoVOx specific	Information is easy to find	Based on static, historical risk factors No actuarial tool is of value
	Information can be found	May narrow thinking about
	quickly	risk assessment
	Useful adjunct to existing risk assessment	Not wishing to add another tool to existing metrics Lack of sensitive clinical risk factors (e.g. insight, response to medication)
	Has construct validity	Not yet validated in a UK forensic population Inability to predict serious, as opposed to any violence
Information	Information sharing with	
sharing	other agencies Resolves disagreements about risk	
Impact on management	Reassurance when agrees with clinical opinion	No added value if agrees with existing risk assessment May provide false reassurance
	Helpful challenge when disagrees with clinical opinion Guides community management (e.g. level of supervision)	

We found that the data required to complete the FoVOx tool was routinely collected, and there was no need to seek additional sources of information other than the patient's electronic healthcare record. Furthermore, in 82% of forensic psychiatric patients included in this study, all the information required to complete FoVOx could be extracted from the individual's clinical record by a mental health professional unfamiliar with their case within 15

minutes. When one or more pieces of data were unknown, FoVOx generated a range of probability scores. For the lead clinician, FoVOx could be completed in around 1 minute for their most recent discharge and without recourse to clinical notes. Therefore, we conclude that FoVOx is feasible for clinicians familiar with a case; it is practical to use, requires no additional training, and minimal resource allocation. The brevity of the tool was repeatedly considered a strength in the qualitative clinician interviews.

We found a lack of any agreed practice around risk assessment at the point of discharge in this sample of UK forensic psychiatrists. Although these clinicians reported that they did complete a risk assessment, its nature varied. Some used existing tools completed within the prior 6 months, others a clinical assessment comprising a descriptive account in a psychiatric report, and some a multi-disciplinary discussion of risk.

The qualitative part of this investigation found that completing FoVOx was helpful to most clinicians. Benefits included improved information sharing with other agencies, reassurance for the clinical team, and identification of unaddressed or underweighted risk factors. FoVOx also assisted in guiding community management after discharge. In the future, 7 of the 11 clinicians reported that they would use FoVOx as part of their clinical practice. Benefits over existing tools used included its brevity, the ease with which information can be found, and how it clearly and transparently outlined a particular patient's risk to other agencies who are less likely to be familiar with more detailed structured professional judgment tools currently used in forensic mental health settings. Clinicians who said that they would not use it in future provided mostly neutral feedback including that it did not provide any additional value. Specific criticisms were not unexpected, including the lack of dynamic factors, and the view that clinical risk assessment is more accurate than actuarial tools. Some of the themes identified when clinicians thought FoVOx was inaccurate may actually be indirectly measured by the tool. For example, close supervision was felt to reduce risk of recidivism. The FoVOx item regarding stay of over a

year also lowers risk scores; patients with a longer inpatient stay are more likely to be in receipt of statutory supervision after discharge.

Overall, FoVOx scores were thought to be accurate in around two-thirds of the cases and, for some patients, clinicians revised their view of the risk of future violent re-offending to a higher level after being informed of the FoVOx scores, suggesting that probability-based FoVOx scores could assist clinical decisionmaking. Clinicians were more likely to underestimate risk compared to FoVOx scores. Reasons identified included FoVOx emphasizing risk factors underweighted by clinicians. Understandably, clinicians are most likely to focus on clinical factors which can be addressed, such as response to medical treatment, engagement in psychological therapy, and abstinence from substances abuse in the supported environment of hospital. Being informed of FoVOx scores thus may enable clinicians to rebalance the relative importance of these hospital-based clinical factors against static ones that are independently predictive of violent recidivism. Thus, using FoVOx routinely would prompt clinicians to keep these factors in mind, suggesting that FoVOx could be useful as an adjunct to clinical decision-making. However, local external validation is required to know the accuracy of FoVOx compared to clinician judgment. Without this, placing more weight on FoVOx scores would be unwarranted and clinical decision-making should take precedence. At the same time, awareness of the factors that might lead clinical teams to underestimate risk needs careful consideration-from weighting more recent factors, and structural (such as the need to maintain sustainable lengths of stay in secure services) and therapeutic factors.

One useful aspect of this feasibility work was to elicit views about the timing of FoVOx. As most factors are static and will not change during hospitalization, this provides some flexibility as to when it can be administered. At the point of discharge, patients are well-known to their clinical teams, and a more individualized and detailed risk formulation is likely to be available. FoVOx may be of more value if completed earlier in a patient's pathway through the secure hospital system, possibly at the point of referral or gatekeeping into secure psychiatric care, or early in their admission. Completing the FoVOx tool at an earlier stage would allow for patient's future risk to be stratified sooner, assist to guide their pathway through the secure hospital system and inform allocation of treatment resources.

One of the clinical implications of this study would be to integrate the FoVOx tool into patient care, for example by including it as part of their electronic patient healthcare record. Future work could compare FoVOx to other current risk assessment tools to compare acceptability and feasibility including the time taken to complete them, clinician satisfaction, and impact on patient care.

LIMITATIONS

External validation was not conducted, which is a considerable challenge in forensic psychiatry due to patient numbers and event rates. If one assumes around 20% violent reoffending over 2 years, then around 500 forensic psychiatric discharges would be recommended for a validation study (18). This would likely

require a large multi-centre study across different regions and/ or nations. One limitation of the current investigation is that the outcome was based on clinical knowledge, and future work could triangulate this information with criminal records. When the available information was incomplete to complete FoVOx scoring, and a range of risk generated, we chose the higher value. An alternative would be to give an average value to missing variables to avoid potential over-estimation of risk.

A high proportion of cases (66%) reviewed were assigned to the medium risk category. If the majority of the patients are all assigned to the same risk class, this may reduce the clinical utility of the tool. Three of eleven clinicians felt that the low/medium/high categorization was unnecessary. In future research, solely using the probability score of reoffending can be examined.

Another limitation is that there may have been a positive bias to the qualitative data as the tool was developed by researchers locally, including one of the interview team. The study was also limited to forensic psychiatrists, and the views of other clinicians are necessary in further work.

Overall, the clinician views on FoVOx were consistently positive in many respects from informing decision-making to assisting risk communication. The novel features of FoVOx, including its brevity, online platform, and ease of use suggest that it can improve the risk assessment process in individuals detained in forensic psychiatric hospital.

DATA AVAILABILITY STATEMENT

Anonymized completed interview questionnaires and Service Evaluation proposal are available on request.

AUTHOR CONTRIBUTIONS

SF, RC, and AL designed the study. AL developed the standardized tool (**Appendix 1**). AL and OP completed FoVOx scoring of patients. RC, AL, and OP conducted clinician interviews. RC and OC completed thematic analysis. SF, RC, OP, SM, and AL wrote the paper.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2019.00901/full#supplementary-material

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Conflict of Interest: SF and RC are authors on the original FoVOx paper.

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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Pharmacological Treatment in Forensic Psychiatry—A Systematic Review

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Howner K, Andiné P, Engberg G, Ekström EH, Lindström E, Nilsson M, Radovic S and Hultcrantz M (2020) Pharmacological Treatment in Forensic Psychiatry—A Systematic Review. Front. Psychiatry 10:963. doi: 10.3389/fpsyt.2019.00963 **Background:** Pharmacological treatment is of great importance in forensic psychiatry, and the vast majority of patients are treated with antipsychotic agents. There are several systematic differences between general and forensic psychiatric patients, e.g. severe violent behavior, the amount of comorbidity, such as personality disorders and/or substance abuse. Based on that, it is reasonable to suspect that effects of pharmacological treatments also may differ. The objective of this systematic review was to investigate the effects of pharmacological interventions for patients within forensic psychiatry.

Methods: The systematic review protocol was pre-registered in PROSPERO (CRD42017075308). Six databases were used for literature search on January 11, 2018. Controlled trials from forensic psychiatric care reporting on the effects of antipsychotic agents, mood stabilizers, benzodiazepines, antidepressants, as well as pharmacological agents used for the treatment of addiction or ADHD, were included. Two authors independently reviewed the studies, evaluated risk of bias and assessed certainty of evidence using Grading of Recommendations Assessment, Development and Evaluation (GRADE).

Results: The literature search resulted in 1783 records (titles and abstracts) out of which 10 studies were included. Most of the studies included were retrospective and non-randomized. Five of them focused on treatment with clozapine and the remaining five on other antipsychotics or mood stabilizers. Five studies with a high risk of bias indicated positive effects of clozapine on time from treatment start to discharge, crime-free time, time from discharge to readmission, improved clinical functioning, and reduction in aggressive behavior. Psychotic symptoms after treatment were more pronounced in

the clozapine group. Mainly due to the high risk of bias the reliability of the evidence for all outcomes was assessed as very low.

Conclusion: This systematic review highlights the shortage of knowledge on the effectiveness of pharmacological treatment within forensic psychiatry. Due to very few studies being available in this setting, as well as limitations in their execution and reporting, it is challenging to overview the outcomes of pharmacological interventions in this context. The frequent use of antipsychotics, sometimes in combination with other pharmacological agents, in this complex and heterogeneous patient group, calls for high-quality studies performed in this specific setting.

Keywords: forensic psychiatric care, mentally disordered offenders, pharmacological treatment, systematic review, antipsychotics

INTRODUCTION

Rationale

In most jurisdictions mentally disordered offenders are given special treatment within the legal system. A criminal offender who due to a mental disorder is judged as not accountable (or legally insane) is generally considered as not responsible for his offence and hence not sentenced to a criminal sanction. In most cases such a person is, if the crime is severe and there is a great need for psychiatric care, transferred to compulsory psychiatric care (1, 2). Sweden, is one of a few exceptions, here all criminal offenders are considered responsible for their actions and forensic psychiatric care is a criminal sanction. Regardless of criminal law regulations, compulsory psychiatric care for mentally disordered offenders is often given in special forensic psychiatric institutions. Most patients have committed violent offences, leading to a potentially high risk of aggression and violent behavior within the care institution. As a result, the staffing levels in forensic wards are high compared to general psychiatric in-patient care. These circumstances result in high care costs, and forensic psychiatry often represents a large part of the overall psychiatry budget, while the population is rather small in terms of the number of patients (3).

There are a number of systematic differences between the forensic psychiatric patients and the general psychiatric patients. Firstly, forensic patients are not only patients but also offenders, in many cases offenders of severe violence (4). Even though violent behavior in an acute non-forensic setting is frequently occurring, in the forensic setting many patients have a history of more severe violence and disruptive behavior (5). Therefore, managing aggression and violent behavior are of special concerns here. The responsible clinician must not only consider the patients' well-being, but also bear in mind the protection of society from potentially violent mentally disordered offenders (6). Secondly, in the forensic setting, all patients are involuntarily admitted and under compulsory treatment which could affect the process of shared decision making and compliance with treatment over time. Even if compulsory care also appears in general psychiatry, the majority of the psychiatric patients is under voluntary treatment. A third difference is the length of inpatient care, since in forensic psychiatric care the duration

often lasts years compared to the general psychiatric care, in which the duration of inpatient care mainly is days to months. Another difference is that the proportion of comorbidity is higher compared to general psychiatry (7, 8). Psychotic disorders are the most frequent primary diagnosis in this population, but comorbidity such as personality disorders, substance abuse and neuropsychological disorders, are more common here, compared to in general psychiatry. In the light of these differences it is plausible that effects of pharmacological treatments could differ between the forensic and the general psychiatric setting.

The vast majority of patients in forensic psychiatry are treated with pharmacological agents (9). Psychotic disorders are well represented within the forensic psychiatric population, and pharmacological treatment with antipsychotics is crucial in this regard (10, 11). When comparing the use of traditional versus atypical antipsychotics in Sweden, we found that it was more common to use traditional antipsychotics in the forensic setting and also that combinations of several antipsychotic agents were more frequent (12). A few systematic reviews relevant to the field have been published. A recent review (13) emphasizes the value of clozapine in the treatment of violent and aggressive behaviors also in a forensic population. Another recent study (14) identified two previously published systematic reviews, which in part addressed the effects of pharmacological interventions within forensic psychiatry (15, 16), showing that only a few primary studies had been published, all of which were assessed as being at high risk of bias. However, the reports had methodological limitations and could potentially have resulted in relevant records having been overlooked. Also, and more importantly, as the last literature searches were performed in 2010 (16) and 2012 (15) respectively, an update is needed to ensure that research published over the previous six years is included.

Based on the fact that the general and forensic psychiatric populations differ in many respects, it is reasonable to suspect that effects of pharmacological treatments also may differ. Since there may be relevant studies from the forensic setting published since the latest systematic reviews in the field, we aimed to perform an updated systematic review, searching for pharmacological intervention studies in the specific forensic psychiatric setting.

Objective

The aim of this systematic review was to investigate therapeutic effects and side effects of pharmacological treatment within forensic psychiatry, with a focus on outcomes important to patients as well as society. When searching for relevant literature we chose to focus specifically on forensic psychiatric patients with psychotic disorders, personality disorders, autism spectrum disorders and substance use disorders, as these are the most common diagnoses in this setting.

MATERIALS AND METHODS

Protocol and Registration

This systematic review was conducted at The Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU), and a Swedish version was submitted to the Swedish Ministry of Social Affairs (www.sbu.se/258) in June 2018. A peer-reviewed protocol, including pre-specified objectives, was registered in PROSPERO (http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017075308). The systematic review process follows the general concepts covered by PRISMA (17).

Eligibility Criteria

We included studies of adult offenders (over 15 years of age, since that is the cut off for criminal responsibility in Sweden) with severe mental disorder, including psychotic disorders, autism spectrum disorders or personality disorders, in forensic psychiatric care. The interventions were antipsychotic agents, mood stabilizers, benzodiazepines and benzodiazepins-like agents, pharmacological addiction treatment, pharmacological ADHD-treatment, and antidepressants. All primary studies with a control group were included without restrictions as to study type. We tried to include a wide range of different outcomes: symptoms of psychosis (clinical functioning), aggression and violent behavior, adverse events, mortality, reoffending (both violent acts and non-violent offences), mental and physical health, time outside the hospital before readmission, quality of life, and long-term compliance to treatment.

Search Strategy

The literature search was performed by an information specialist and included the databases Cinahl, Cochrane, EMBASE, PsycINFO, PubMed, and Scopus. The search covered studies published in English, Swedish, Norwegian or Danish up to January 11, 2018. In addition, references from narrative reviews and articles published in international journals, not identified in the main search, were also included. This by going through reference list from the articles found in the main search. Grey literature, such as conference abstracts or dissertations, were excluded. Electronic searches were conducted using Medical Subject Headings (MeSH) and relevant text word terms. The detailed search strategy can be found in Supplementary Material.

Study Selection

Two reviewers independently screened the titles and abstracts identified by the search strategy. All studies of potential relevance according to the inclusion criteria were obtained in full text and two reviewers independently assessed them for inclusion. Any disagreement was resolved by discussions, with involvement of a third review author, when necessary.

Risk of Bias in Individual Studies

Two reviewers independently assessed the risk of bias with the use of tools developed for randomized and non-randomized controlled trials, including signaling questions to address selection bias, performance bias, detection bias, reporting bias and bias due to conflicts of interest. The tools for assessing risk of bias in individual studies were developed at SBU (18) and focus on the same aspects that are included in international guidelines for reporting standards (19, 20). Before starting the assessments, the questions were thoroughly discussed so that all reviewers had a common understanding as to how these criteria could affect the results in this specific research area. Each study was rated as having a low, moderate or high risk of bias.

Data Collection Process

From each included study data were extracted and inserted into tables by one reviewer, followed by auditing of the data extraction by another reviewer. Any disagreement was resolved by discussion. Information concerning study design, setting, population, intervention, control group, outcome and results were extracted from each included study.

Data Analysis

We anticipated that there would be limited scope for metaanalysis because of the range of different outcomes measured across the small number of existing trials. However, if studies would have used the same type of intervention and comparator, with equal outcome measures, we would have pooled the results using a random-effects meta-analysis. The certainty of the evidence for each outcome was assessed using Grading of Recommendations Assessment, Development and Evaluation (GRADE) (21) and we followed the suggested criteria for using GRADE presented on the GRADE working group website (www. gradeworkinggroup.org).

RESULTS

Study Selection and Characteristics

The systematic literature search resulted in 1783 records (titles and abstracts), out of which 10 studies fulfilled the inclusion criteria. The primary reasons for exclusion of studies were that the studied populations were not treated within a forensic setting or the studies did not evaluate the effect of an intervention (list of excluded full-text studies with reasons for exclusion are available on request). All 10 included studies (22–31) were assessed as having a high risk of bias, primarily due to selection bias. The

review process and number of reviewed articles are summarized in the flow diagram in **Figure 1**.

Synthesized Findings

The 10 included studies, which are further described in **Table 1**, were conducted in the United Kingdom (24, 25, 30, 31), USA (23, 29), and Canada (22, 26–28). Seven of the studies were retrospective. The study populations were exclusively from high security hospitals. One study followed the patients from in- to outpatient care (28). Half of the studies investigated the specific anti-psychotic clozapine with regard to effect on aggressive behavior, psychotic symptoms, time of treatment inside the hospital before release and time outside the hospital before readmission (22, 25, 28–30).

In **Table 2** we present the different outcomes according to GRADE. Some of our defined outcomes, survival, compliance to treatment and quality of life, were not present in any of the selected studies. The outcomes that we did find in the included studies were psychotic symptoms, side-effects of pharmacological treatment, reoffending, time outside the hospital before readmission, clinical functioning, aggressive behavior and length of stay in hospital. When measuring psychotic symptoms after treatment, the clozapine group showed more psychotic symptoms compared to the control

group (22), while there were no differences between groups studying ad-on treatment with lithium (24) or quetiapine versus olanzapine (26). In one study there were three groups with mood stabilizers, which found reduction on psychotic symptoms in the group with valproate and the combination valproate and topiramate after treatment (27). When studying crime-free time and time in the community between discharge from hospital to reoffending or readmission, two studies showed valuable effects in the clozapine group (28, 29) compared to other antipsychotics. Regarding measures of time spent in hospital after the start of treatment, two studies showed positive effects of clozapine (29, 30), while a third study did not find any differences between clozapine and other antipsychotics (25). Two studies found improvement in clinical functioning in the clozapine group compared to other antipsychotics (22, 29), while a study comparing risperidone compared to traditional antipsychotics did not find any differences (23). We found two studies showing positive effects of clozapine on aggressive episodes (22, 28), while there were no group differences when comparing risperidone with traditional antipsychotic (23), quetiapine with olanzapine (26) or topiramate with valproate (27). The only study comparing high with standard doses of antipsychotics showed more pronounced psychotic symptoms and more side effects in the high dose-group after the treatment period (31).

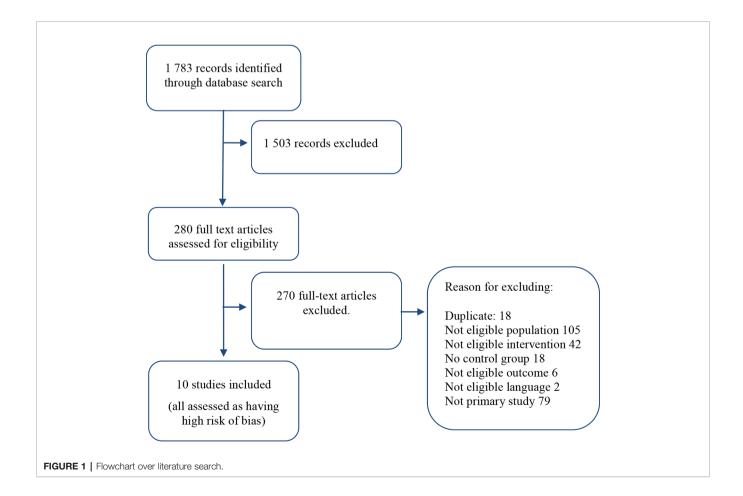


TABLE 1 | Characteristics of included studies.

Study	Country and settings	Type of study	Population	Intervention	Control	Outcome	Results	Strenghts and limitations
Balbuena, et al. (22).	Canada Forensic psychiatric hospital, dedicated to high-risk, high-need, federally sentenced (2 years or more) mentally disordered offenders.	Retrospective study	Clozapine group: n = 65, mean age 34 (63 male, 2 female). Control group: n = 33, mean age 37 (31 male, 2 female). All patients and controls had psychosis or related disorders according to DSM-IV. No information on co-morbidity.	Clozapine treatment for 6 months. Dose or administration form is not given.	Treatment with traditional antipsychotics at the same hospital for 6 months	Frequency of noncompliant incidence, change in BPRS total score. Institutional pay was recorded as a measure of good behavior, presumably reflecting clinical functioning.	Clozapine-group: Mean pay increase: 38/65 got increased pay level Mean BPRS score: 38.5 Mean number of post-treatment offences during 12 months: 0.62 Control group: Mean pay increase: 10/33 got increased pay level Mean BPRS score: 30.4 Mean number of post-treatment offences during 12 months: 1.37	High risk of bias Comment: Non-randomized. risk of selection bias. The effect of clozapine may be under-estimated because of negative selection (all patients in the clozapine group were non-responders to traditional antipsychotics). Lack of compliance analysis in the clozapine group in contrast to the control group. Number of interactions were not recorder during the six-month period after. Unclear whether patients during the latter six-month period were on clozapine or other antipsychotics.
Beck et al. (23)	USA Three forensic treatment wards at state mental hospital.	Retrospective study	Risperidone group: n = 10, mean age 39 (all male). Controls: n = 10, mean age 40 (all male). All patients and controls had schizophrenia or schizoaffective disorders according to DSM-IV. No information on co-morbidity.	Risperidone treatment for 6 + 6 months, 6 mg/day, administration form not given.	Treatment with traditional antipsychotics (equivalent with 2,000 units of chlorpromazine) at the same hospital for 6 + 6 months.	Scores on TSBC, reflecting clinical functioning. Frequency counts of aggressive behaviour and bizarre motor behaviours were recorded.	No difference between risperidone patients and controls with regard to overall clinical functioning or aggressive behaviour.	High risk of bias Comment: Non-randomized and risk of bias since patients were recruited from 3 different wards. Lack of information in the control group. Only the frequency of aggressive behaviour was recorded. In the control group only chlorpromazine equivalents were given instead of a detailed description of what antipsychotics used.
Collins et al. (24)	UK High security hospital	Randomized single-blind trial	Lithium add-on: n = 21, mean age 39 (all male). Controls: n = 22, mean age 38 (all male). All patients and controls had schizophrenia or related disorders according to DSM-III. No information on co-morbidity.	Addition of lithium carbonate to traditional antipsychotics 400 mg twice daily	Treatment with various antipsychotics throughout the treatment period.	Psychiatric conditions according to the Manchester Scale (modified to separate flattening and incongruity of affect) and SANS Scale.	Lithium add-on showed no improvement in psychiatric condition	High risk of bias Comment: High drop-off in the treatment group. Individua antipsychotic treatment was not reported.
Dalal et al. (25)	UK High security hospital	Retrospective study.	Clozapine group: n = 50 (44 male, 6 female). Information on age not given, unless that mean age at first psychiatric contact was 20 years. Control	Clozapine treatment baseline before, after 6 months, after 1 year, after 2 years. No specific doses of clozapine is given, only, in	No control group, effects were compared with baseline values. 50 non- clozapine patients from the same hospital were	Frequency of violence and self harm. Discharge rate from the hospital Positive symptoms according to Health of the	50% of patients showed a reduction in positive symptoms and aggressive behaviour after 2 years of treatment. Significant	High risk of bias Comment: Non-randomized. No internationally accepted rating scales were used. Negative symptoms were not recorded. Thus, unclear patient population. Missing information of the control group.

(Continued)

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TABLE 1 | Continued

Study	Country and settings	Type of study	Population	Intervention	Control	Outcome	Results	Strenghts and limitations
			group: n = 50 Schizophrenia or schizoaffective disorder. Local rating scales of positive symptoms were used.	some cases, chlorpromazine- equivalent doses.	used as controls, but for the comparison of discharge rate only.	Nation Outcome Scales	increase in discharge rate in patients that continued treatment compared to those that discontinued clozapine. However, this discharge rate was not higher compared to the controls.	
Gobbi et al. (26)	Canada High security	Randomized open-label study.	Quetiapine group: n = 8, mean age 43 (7 male, 1 female). Olanzapine group: n = 7, mean age 38 (all male). Patients were diagnosed with schizophrenia, schizoaffective disorder, or paranoid disorder (DSM-IV)	Comparison between Quetiapine treatment (10 weeks, mean dose 475 mg/ day) and Olanzapine treatment (10 weeks, mean dose 15 mg/ day)	Comparison between quetiapine and olanzapine Two different treatment groups.	Impulsive and aggressive behaviour according to "Modified Overt Aggression Scale" and "Impulsivity Rating Scale" Psychotic symptoms according to BPRS, PANSS, and CGI.	Both drugs decreased impulsivity and psychotic symptoms. No significant difference between the drugs were observed. Quetiapine was better than olanzapine in improving depression symptoms.	High risk of bias. Comment: Sponsored study High quality of the study, although very small sample size. Vague information on medication at baseline (day 0 prior to treatment).
Gobbi et al. (27)	Canada High security	Retrospective study	Topiramate group: n = 16, mean age 37 (34 male, 3 female). Valproate group: n = 16, mean age 39 (all male). Combination group: n = 13, mean age 41 (12 male, 1 female) Patients were diagnosed with schizophrenia, schizoaffective disorder, any subtype of delusional disorder, or bipolar disorder	Add-on treatment (8-12 weeks) to traditional antipsychotics with topiramate (mean dose 250 mg/day), valproate (dose corresponding to plasma concentration of 700 µM), or a combination of both drug.	Three different treatment groups.	Aggression (Overt Aggression Scale), agitation (Agitation- Calmness Evaluation Scale), psychotic episodes (BPRS), number of therapeutic isolation and surveillance interventions.	All groups showed a reduction in agitation, aggressive behaviour. Valproate group and the combination of topiramate and valproate showed a reduction in psychotic episodes.	High risk of bias Comment: Non-randomized. Only part of the data was analysed in a blind manner. A selection of patients was mac - only patients being able to tolerate topiramate/valproate were chosen. Greater loss of patients in topiramate-group.
Mela and Depiang (28)	Canada Open care patients from Regional Psychiatric Center	Retrospective study	Clozapine treatment: n = 41, Non-clozapine: n = 21 Age or gender not given. Offenders with mental disorders	Clozapine treatment more than 6 weeks in open care, dose titrated to therapeutic relevance. 2- years follow up.	Treatment with antipsychotics other than clozapine	Number of reoffending behavior (nonviolent, violent, and sexual). Time from release to the first offence. Crime-free time.	The clozapine group had a lower, although non-significant, incidence of all of the categories of reoffending, except sexual Time from release to first offence longer in the	High risk of bias Comment: Compliance not accounted for during the 2 years of follow-up. Contact with the health professionals may vary between the groups Diagnosis not specified. No randomization. In the comparison group various antipsychotics were used. The effect of clozapine may be

(Continued)

TABLE 1 | Continued

Study	Country and settings	Type of study	Population	Intervention	Control	Outcome	Results	Strenghts and limitations
							clozapine group. Crime-free time longer in the clozapine group.	underestimated because of a negative selection (all patients in the clozapine group were non-responders to traditional antipsychotics).
Stoner et al. (29)	USA Psychiatric Rehabilitation Center Patients hospitalized due to forensic court commitment, security level unclear.	Retrospective study	Haloperidol treatment: n = 78 Clozapine treatment n = 21 Total sample: 69 male and 15 women Patients were diagnosed with schizophrenia or substance abuse.	Clozapine treatment Haloperidol treatment (either orally, mean dose 15.5 mg/day, or intramuscularly mean dose 206 mg every 4 th week).	Two treatment groups: comparison between clozapine and haloperidol	Psychiatric symptoms according to GAF Conditional release Revoked conditional release	Haloperidol group: 59% showed improved GAF scores. 33% successfully obtained conditional release. Clozapine group: 86% showed improved GAF scores. 38% successfully obtained conditional release. Periods of conditional release before revocation were longer in the clozapine group	High risk of bias Comment: Non-randomized. Various diagnosis, including both schizophrenia and drug abuse - groups were not homogenous. Some patients were treated by a combinatio of haloperidol and clozapine. Haloperidol was given either orally every day or intramuscularly every 4 weeks The effect of clozapine may b underestimated because of a negative selection (all patients in the clozapine group were non-responders to traditional antipsychotics).
Swinton and Haddock (30)	UK High security hospital	Retrospective case-control study	Clozapine group: n = 106, mean age 29 (73 male, 33 female). Non- clozapine group: n = 106, mean age 30 (73 male, 33 female). Diagnosis: mainly schizophrenia.	Clozapine treatment	Treatment with antipsychotics other than clozapine at the same hospital for	Evaluation of discharge rates	Clozapine group achieved increased rates of discharge when compared with non-clozapine group. It took more than one year until this effect was obtained	High risk of bias Comment: relatively high drop-out. Some female cases in the study may not have had a diagnosis of schizophrenia. No information on the treatment of the non-clozapin group.
Tavernor et al. (31).	UK High security hospital	Retrospective case-control study	High-dose group: n = 32, mean age 39 Control group: n = 32, mean age 38 No information on gender. Diagnosis of schizophrenia (62) or schizoaffective disorder (2)	High doses of traditional antipsychotic drugs	Patients with standard doses of antipsychotic drugs	Psychiatric symptoms evaluated by BPRS, GAS, SDAS, and NOSIE	Cases had higher BPRS total score than controls, as well as neurological side-effects. Cases were rated as more aggressive than controls. Conclusion: little benefit for the use of high-dose antipsychotics.	High risk of bias Comment: Selection bias where cases had worse psychiatric symptoms and may have been prescribed a high-dose antipsychotic drug Many patients received a combination of antipsychotic drugs and doses of antipsychotics were only give in equivalents of chlorpromazine. The antipsychotic drugs used are not specified. It is unclear whether each case received the same antipsychotic drug as the matched control.

Risk of Bias

All outcomes were assessed as very low certainty due to a severe or critical risk of bias, imprecision and/or indirectness and inconsistency. There were problems with selection bias in all the included studies. As all the studies were conducted in clinical settings and only a few had randomization (24, 26), there were potential differences between comparison groups of patients. In many studies there was also a lack of transparency as to how the patients were selected (23, 27) and a lack of information about essential characteristics of the groups, such as comorbidity and

TABLE 2 | Summary of findings according to GRADE.

Reference	Pharmacological treatsment	Outcome (Variable)	Studydesign Number of studies (Par- ticipants)	Results	GRADE assessment	Comments
Balbuena et al. (22)	Clozapine vs other antipsychotics	Symptoms of psychoses (measured with BPRS)	Non- randomized retrospective study 1 (98)	More psychotic symptoms assessed with BPRS in the clozapine group compared to other antipsychotics.	Very low certainty We are uncertain about the effect of clozapine on psychotic symptoms compared to other antipsychotic treatments	-3 risk for bias (Selection bias: non- randomized study, unclear if the two groups were comparable at onset of study)
Mela and Depiang (28)	Clozapine vs traditional antipsychotics	Crime free time (number of months from release to reoffending)	Non- randomized retrospective study 1 (62)	Time from release to reoffending was on average 52 months longer in the clozapine group	Very low certainty We are uncertain about the effect of clozapine on the length of "crime free time" compared to traditional antipsychotics	-3 risk for bias (Selection bias: non- randomized study, unclear if the two groups were comparable at onset of study) Unclear if treatment continued during time after release, the so called "crime free time"
Dalal et al. (25) Swinton and Haddock (31) Stoner et al. (29)	Clozapine vs traditional antipsychotics	In-patient time (Measured as time from treatment start until release from ward)	Non- randomized retrospective studies 3 (n = 411)	Subjects in the clozapine-group were released faster compared with subjects in traditional antipsychotic group (29, 31) In-patient time did not differ between clozapine group and other antipsychotics-group. Drop outs in the clozapine group had significant longer in-patient time. (25)	Very low certainty We are uncertain about the effect of clozapine on in-patient time before discharge compared to traditional antipsychotics	-3 risk for bias (Selections bias: non- randomized studies, unclear if the two groups were comparable at onset of study) -1 inconsistency
Stoner et al. (29) Mela and Depiang (28)	Clozapine vs other antipsychotics	Time in freedom (time on conditional release before readmission or reoffending)	Non- randomized retrospective studies 2 (n = 161)	Patients treated with clozapine had longer time in freedom before readmission compared to patients on haloperidol (29) Time from release to reoffending was 52 month longer in the clozapine group (28)	Very low certainty We are uncertain about the effect of clozapine on time on conditional release before readmission or reoffending compared to traditional antipsychotics	-3 risk for bias (Selections bias: non- randomized study, unclear if the two groups were comparable at onset of study)
Balbuena et al. (22) Mela and Depiang (28)	Clozapine vs other antipsychotics	Aggressive behavior (Aggressive episodes reported by staff or police, intensity of aggressive behavior under treatment, and time from release to first aggressive episode)	Non- randomized retrospective studies 2 (n = 160)	Patients on clozapine had fewer episodes of aggressive behavior compared to the group with other antipsychotics. (22, 28) Longer time from release to first aggressive episode in clozapine group compared to other antipsychotics (28)	Very low certainty We are uncertain about the effect of clozapine on aggressive behavior compared to traditional antipsychotics	-3 for bias (Selections bias: non-randomized studies, unclear if the groups were comparable at onset) -1 indirectness (indirect measures for aggressive behavior)
Balbuena et al. (22) Stoner et al. (29)	Clozapine vs other antipsychotics	Clinical functioning (measured with Global assessment of functioning, GAF and a reward system at the ward)	Non- randomized retrospective studies 2 (n = 197)	Rewards for good behavior were higher in clozapine group (38/65 compared to control group (10/33) (22) Improvement in GAF-scores in 86% of clozapine group compared to 59% in haloperidol group (29)	Very low certainty We are uncertain about the effect of clozapine on clinical functioning compared to traditional antipsychotics	-3 for bias (Selections bias: non-randomized study, unclear if the two groups were comparable at onset of study)
Beck et al. (23)	Risperidon vs traditional antipsychotics	Clinical functioning	Non- randomized retrospective study 1 (n = 20)	No difference in clinical functioning between risperidone and traditional antipsychotics.	Very low certainty We are uncertain about the effect of risperidone on clinical functioning, compared to traditional antipsychotics.	-3 bias (Selections bias: non-randomized study, unclear if the two groups were comparable at onset of study) -1 imprecision (non-significant results with low number of participants)

(Continued)

TABLE 2 | Continued

Reference	Pharmacological treatsment	Outcome (Variable)	Studydesign Number of studies (Par- ticipants)	Results	GRADE assessment	Comments
Beck et al. (23)	Risperidon vs traditional antipsychotics	Aggressive behavior (number of aggressive episodes)	Non- randomized retrospective study 1 (n = 20)	No difference in aggressive behavior between the group with risperidone and traditional antipsychotics	Very low certainty We are uncertain about the effect of risperidone on aggressive behavior compared to traditional antipsychotics	-3 bias (Selections bias: non-randomized study, unclear if the two groups were comparable at onset of study) -1 imprecision (non-significant results with low number of participants)
Collins et al. (24)	Mood stabilizer (lithium) as ad-on treatment to antipsychotics	Psychotic symptoms (measured with "Manchester Scale")	Randomized controlled study (RCT) 1 (n = 43)	No differences in psychotic symptoms between the group receiving only antipsychotic or lithium as ad on treatment	Very low certainty We are uncertain about the effect of ad on treatment with lithium on psychotic symptoms	-2 risk for bias (treatment bias due to lack of blinding, the antipsychotic treatment was different between study groups) -1 imprecision (non-significant results with low number of participants)
Tavernor et al. (31)	High-dose vs. normal dose with traditional antipsychotic	Psychotic symptoms (measured with BPRS)	Retrospective case - control study 1 (n = 64)	Patients treated with high-dose antipsychotic showed more psychotic symptoms compared to patients in the group treated with normal dose of antipsychotics	Very low certainty We are uncertain about the effect of high dose antipsychotic on psychotic symptoms compared to standard dose	-3 risk for bias (Selection bias: non-randomized study, unclear if the two groups were comparable at onset of study)
Gobbi et al. (26)	Quetiapin vs Olanzapin	Psychotic symptoms (measured by BPRS, PANSS, CGI)	RCT 1 (n = 15)	Both quetiapin and olanzapine reduced psychotic symptoms, no difference between groups	Very low certainty We are uncertain about the comparative effects of Quetiaptin and Olanzapin. on psychotic symptoms	-2 risk for bias -1 imprecision (non-significant results with low number of participants)
Gobbi et al. (27)	Topiramate vs. Valproat vs. Combination of Topiramate & Valproat	Psychotic episodes (measured by BPRS)	Non- randomized retrospective study 1 (n = 45)	Valproat group and the combination group showed reduction in psychotic episodes	Very low certainty We are uncertain about the comparative effects of Topiramate, Valproat or a combination of both, on psychotic episodes	-3 risk for bias (Selections bias: non-randomized study, unclear if the two groups were comparable at onset of study) -1 imprecision (low number of participants)
Gobbi et al. (26)	Quetiapin vs Olanzapin	Aggressive behavior (measured with modified "Overt Aggression Scale" and "Impulsivity Rating Scale")	RCT 1 (n = 15)	Both quetiapin and olanzapine reduced aggressive behavior, no difference between groups	Very low certainty We are uncertain about the comparative effects of Quetiaptin and Olanzapine on aggressive behavior	-2 risk for bias -1 imprecision (non-significant results with low number of participants)
Gobbi et al. (27)	Topiramate vs. Valproat vs. Combination of Topiramate & Valproat	Aggressive behavior (measured with modified "Overt Aggression Scale" and "Impulsivity Rating Scale")	Non- randomized retrospective study 1 (n = 45)	All groups did show reduced aggressive behavior, no difference between groups	Very low certainty We are uncertain about the comparative effects of Topiramate, Valproat or a combination of both, on aggressive behavior	-3 risk for bias (Selections bias: non-randomized study, unclear if the two groups were comparable at onset of study) -1 imprecision (low number of participants)
Tavernor et al. (31)	High-dose vs. normal dose with traditional antipsychotic	Side effects (neurological and autonomic measures with side effect scale)	Retrospective case – control study 1 (n = 64)	High-dose treatment resulted in higher frequency of neurological and autonomic side effects compared to normal dose treatment	Very low certainty We are uncertain about the effect of high dose antipsychotic on side effects compared to standard dose	-3 risk for bias (Selection bias: non-randomized study, unclear if the two groups were comparable at onset of study)

substance abuse (22–24, 28, 30). Due to the non-randomized study design, as well as severe additional concerns about selection bias, the certainty of the evidence was assessed as very low.

DISCUSSION

The limited findings from this systematic review reveal a knowledge gap in pharmacological treatment within forensic psychiatric care. Even though the use of pharmacological agents is high in forensic psychiatric settings, these patients are seldom included in pharmacological trials. As in the two previous systematic reviews we did not find any primary studies of high quality (15, 16). Rather, all selected studies had a high risk of bias. Compared to these two previous reviews, we included four primary studies which had not previously been included. One study compared the effect of add-on treatment with lithium (24) and another compared clozapine to haloperidol (29). Two studies were published later than both of these reviews; one compared treatment with quetiapine versus clozapine (26), the other followed inpatients through to outpatient care comparing clozapine with other antipsychotics (28).

Most of the studies found were retrospective (22, 23, 25, 27–31) and performed in a clinical context, which resulted in a high risk of selection bias. Only two of them were prospective (24, 26). Half of the studies analyzed the therapeutic effects of clozapine (22, 25, 28–30). As clozapine is a third-hand choice in guidelines for treatment of psychotic disorders, all the patients receiving clozapine were non-responders to traditional antipsychotics. Potentially these patients could have been suffering from more severe psychotic symptoms, or other kinds of symptoms, resistant to traditional antipsychotics. For example, psychotic symptoms before treatment have been more pronounced in the clozapine group, indicating a selection bias (22).

Guidelines for forensic psychiatric treatment have been proposed, although, the authors found that the evidence base for forensic-psychiatric practice is weak (32). In another study presenting guidelines for aggressive psychiatric patients in California, these guidelines were developed from a collection of prescribing recommendations, clinical trial results, and years of clinical experience in treating patients who are persistently violent or aggressive in the California Department of State Hospital System, and included recommendations provided offlabel prescribing of pharmacological agents (33).

We think that the specific circumstances within the forensic psychiatric care; forensic patients in general being suffering more often suffer from comorbidity as well as aggression and violent behavior and the fact that one objective of the care is coetail protection may influence the outcome of pharmacological treatment. Therefore, we maintain that there is an urgent need for studies performed in this unique context. Randomized prospective studies in forensic psychiatric samples should be prioritized. Forensic populations ought to be studied with higher precision, with regard to their particular context. Also, there are specific outcomes of special interest to forensic settings compared to the general psychiatry, such as reoffending and

violent behavior. Clearly, any pharmacological treatment with a potential effect on offending and violent behavior would be of great interest not only for the patients but also society at large. Since most forensic patients are treated involuntarily for a long time period, which entails a major infringement of several human rights, interventions shortening the length of stay in hospital would also be of great ethical value. It would also be of great interest from a health economic point of view, as the cost of pharmacological treatment is almost negligible in comparison to all other costs of forensic psychiatric care.

Limitations

This systematic review only included studies produced within the specific setting of forensic psychiatry. However, there could be studies produced in other settings, such as in general psychiatry or in correctional samples, that could have added evidence, for example those focusing on pharmacological effects on patients with comorbid conditions. Our study selection was also limited to studies written in English, Swedish, Norwegian or Danish language, and we did not include gray literature. Therefore, there is always a potential that studies only published as reports etc., or in other languages were missed. Studies which may have been published after the original literature search in January 2018 were not included in this review.

CONCLUSIONS

This systematic review highlights the scarcity of knowledge on the effectiveness of pharmacological treatment within a forensic psychiatric population. Thus, due to the very few studies available in this setting, as well as limitations in their execution and reporting, it is challenging to overview the outcomes of pharmacological interventions in this regard. The frequent use of antipsychotics, with or without a combination of other pharmacological agents, in this complex and heterogeneous patient group, calls for high-quality studies performed in specific settings. Such strategies are also highly warranted from an ethical as well as health economics standpoint.

AUTHOR CONTRIBUTIONS

KH, PA, EL, GE, MH, and MN defined PICO, assessed relevance of abstracts and full text articles, extracted data, assessed the risk of bias in individual studies, analyzed and interpreted the results, and wrote the manuscript. EE and SR defined PICO, analyzed and interpreted the results, and wrote the manuscript.

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SUPPLEMENTARY MATERIAL

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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 potential conflicts of interest.

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Are There Any Biomarkers for Pedophilia and Sexual Child Abuse? A Review

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Jordan K, Wild TSN, Fromberger P, Müller I and Müller JL (2020) Are There Any Biomarkers for Pedophilia and Sexual Child Abuse? A Review. Front. Psychiatry 10:940. doi: 10.3389/fpsyt.2019.00940 The use of biomarkers in medicine is a common and valuable approach in several clinical fields. Understanding the relationship between measurable biological processes and clinical outcomes not only is indispensable in the face of understanding physiological processes in healthy as well as in diseased organisms but also for understanding and evaluating treatment effects. Therefore, also in the context of forensic psychiatry, biomarkers and their potentially beneficial effects are of growing interest. The objective of this review is to examine if there are biomarkers that may serve as a tool to support diagnostic process, treatment evaluation, and risk assessment of pedophilic individuals and child sexual offenders. In the first part, we present an overview of the current neurobiological, as well as physiological and psychophysiological approaches to characterize pedophilia and child sexual offending. Secondly, we discuss and evaluate the impact of these approaches on the development of biomarkers for diagnosis, therapy, and risk assessment in pedophilic subjects and child sexual offenders. We conclude that a lot of research has already enhanced our neurobiological knowledge about pedophilia and child sexual offending. Although there surely exist promising parameters and approaches, in our view currently none of these is ready yet to serve as a clinically applicable diagnostic, response, or predictive biomarker for pedophilia and child sexual offending. Therefore, further work remains to be done. The development of a composite diagnostic biomarker to assess deviant sexual interest, combining several measures like functional magnetic resonance imaging, electroencephalogram, eye tracking, and behavioral approaches seems to be most promising. A valid and reliable measurement of deviant sexual interest, insensitive to manipulations could significantly support clinical diagnostic process. Similarly, regarding therapy evaluation and risk assessment, a composite biomarker to assess inhibitory control functions seems to be promising. Furthermore, the application of the Research Domain Criteria-approach, a new approach for investigating and classifying mental disorders, offers the possibility to take research to a new level.

Keywords: pedophilia, child abuse, biomarker, etiology, diagnostics, treatment evaluation, risk assessment

BIOMARKERS IN PSYCHIATRY

The Biomarkers Definitions Working Group of the National Institute of Health defined biomarkers as "a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes or pharmacological responses to a therapeutic intervention" (1, 2). Biomarkers already play a crucial role in many (bio-)medical fields as they can be used for a deeper understanding of normal, healthy physiology and the relationship between measurable biological processes and clinical outcomes (3). Therefore, the use of biomarkers opens the opportunity not only to improve the accuracy of a diagnose but can also be vital for monitoring the success of a treatment. Ideally, biomarkers should serve as clinical "tests" that diagnose the disorder or predict outcome (4). Nowadays, biomarkers do not only include molecular, blood, genetic, or neurotransmitter biomarkers but also epigenetic, and structural and functional imaging parameters. Additionally, there also exist psychophysiological, behavioral, and digital behavioral biomarkers, such as neural patterns associated with working memory, which are disrupted in patients with schizophrenia (5, 6), eye tracking measures of social attention as an indicator for autism (7), behavioral movement biomarkers to predict later motor and cognitive dysfunctions in young highrisk infants (8), or physical activity assessed with mobile technologies (9).

Before any biomarker can be used in medical settings, it needs to be validated in large-scale clinical trials. Biomarkers only are valid if a number of preconditions are satisfied: i) there must exist a statistically significant relationship between the biomarker and a defined clinical endpoint, ii) the biomarker and the defined clinical endpoint must be causally or mechanistically related, iii) sensitivity and specificity must be sufficient to distinguish between false positives, false negatives, true negatives, and true positives, and iv) the method should be reproducible across all clinically relevant fields (4). In addition, other authors recommend that biomarkers should preferably be minimally invasive, and acceptable to the patient (10).

Prata et al. (4) simplified a sophisticated scheme to evaluate biomarkers proposed by Lassere (11) and adapted it for use in the psychiatric field; a two-dimensional scale assessing quality of evidence (similarly to phase I–IV of clinical drug trials) and effect size. Thus, a biomarker is considered to be validated if it shows a positive result in a study (p < .05, corrected for multiple comparisons). Furthermore, this study should i) demonstrate large effect sizes, ii) be controlled for relevant extraneous variables, iii) be performed with an explicit *a priori* intent to discover a precisely defined biomarker, and with adequate power informed by previous positive studies of the same biomarker (i.e., replication in at least two studies in a larger cohort) (4). However, even valid, applicable biomarkers are not useful until shown to provide a meaningful advantage when incorporated into decision-making or clinical care (1, 4).

In contrast to other medical disciplines, the development of biomarkers is a particular challenge for the field of psychiatry, as diagnoses are solely based on a descriptive collection of behaviors without the availability of any objective test to stratify patients (i.e., DSM/ICD) (5). The use of biomarkers in psychiatry provides an opportunity to enrich the subjective descriptive classification with objective and tangible measures in order to improve diagnosis, treatment, and prognosis. Since the 1980's, a large amount of research has led to remarkable progress in biological research and a critical insight into the pathogenesis of various psychiatric disorders, considering also associations between genes, brain, and social behavior [e.g. (12) for an overview see: (13)]. However, as pointed out by several authors, clinically translatable biomarkers in psychiatry are yet to be identified [e.g. (12, 14)]. In a large systematic and quantitative review, Prata and colleagues analyzed over 3,200 articles investigating psychosis-related biomarkers (4). Out of these, fewer than 200 studies investigated biomarkers longitudinally, and assessed their predictive utility with regard to course of disease and treatment response. According to the evaluation scheme developed by Prata and colleagues (see above), only one biomarker passed the a priori threshold for clinical applicability (4, 15). Venkatasubramanian & Keshavan identified some possible reasons for this failure: i) as mentioned above, current classificatory and diagnostic systems in psychiatry are primarily symptom-based, ii) methodological limits of the existing studies on biological abnormalities in psychiatry, iii) lack of valid "in-vitro" models for psychiatric disorders, iv) issues related to conceptualizations of pathogenetic paradigms for psychiatric disorders (14). Due to the complexity of psychiatric disorders, Lozupone et al. claim not to use single biomarkers, but a combination of diverse biomarker types (12). This could lead to an improvement of diagnosis, treatment, and prognosis of psychiatric patients on a personalized level.

As compared to general psychiatry, the field of forensic psychiatry is rather small. Nevertheless, a substantial amount of research has been conducted in order to identify biological underpinnings of forensically relevant disorders. In accordance with this research, the Integrated Theory of Sexual Offending (ITSO), as one theoretical approach to explain sexual offending, provides a framework including an interaction between neurobiological and ecological factors (16). With respect to pedophilia, Tenbergen et al. proposed a conceptual neurodevelopmental framework, with pedophilia as a complex and multifactorial phenomenon, in which the influences of genetics, stressful life events, specific learning processes, as well as structural brain changes may generate the specific phenotype of child sexual preference (17). In our review, however, we will solely concentrate on biological parameters. Obviously, we are aware of the significance of other, highly relevant factors, e.g., environmental, parental, social, and cultural factors. Nevertheless, those factors are outside the scope of this review. Furthermore, due to the low prevalence of pedophilia in women and the low level knowledge regarding pedophilic women (18, 19), we will only discuss research focusing on men.

At this point we would like to emphasize that obviously research on biomarkers has a different aim than research on the pathoetiology of pedophilia. Studies focusing on biomarkers are interested in biological markers, which could classify between groups, e.g., for diagnostic purpose. In contrast, studies interested in the underlying neurobiological pathoetiology of

pedophilia want to understand the causes of pedophilia or at least underlying neurobiological processes. Currently, there are no studies explicitly intending to develop biomarkers for pedophilia and child sexual abuse. One exception might be approaches aiming to classify subjects with respect to their sexual interest in order to support the diagnostic process. Therefore, in the following, we will first summarize the current neurobiological, as well as physiological and psychophysiological approaches to characterize pedophilia and child sexual offending. Secondly, we discuss and evaluate the impact of these approaches on the development of biomarkers for diagnosis, therapy, and risk assessment in pedophilic subjects and child sexual offenders. If available, criteria of psychometric quality, such as discrimination accuracy and validity are described.

BIOLOGICAL UNDERPINNINGS OF PEDOPHILIA AND CHILD SEXUAL OFFENDING—THE CURRENT KNOWLEDGE

Sexual child abuse is one of the most destructive events for child development. On behalf of the victims of child sexual abuse and for the general public, research on the underpinnings of pedophilia and child sexual offending is of great importance. In the public in general, pedophilia and child sexual offending are often used synonymously. However, pedophilia neither is a necessary nor a sufficient precondition for child sexual abuse. According to Seto (18) about half of child sexual offenders fulfill diagnostic criteria of pedophilia (20).

Pedophilia belongs to disorders of sexual preference (ICD-10), and paraphilic disorders (DSM-5) respectively. According to the ICD-10 (21) "pedophilia" (F65.4) is defined as a "persistent or dominating sexual preference for prepubescent children" with a duration of at least 6 months. A person being diagnosed with pedophilia has to be at least 16 years old and at least 5 years older than the child/the children. Furthermore, the person has to act upon his sexual preference or is suffering from his deviant sexual preference. The DSM-5-criteria of the so called "pedophilic disorder" (302.2) are very similar, namely "recurrent, intense sexually arousing fantasies, sexual urges, or behaviors involving sexual activity with prepubescent child or children over a period of at least 6 months, which causes marked distress or interpersonal difficulty or the individual has acted on these sexual urges." However, "if persons report an absence of feelings of guilt, shame, or anxiety about these impulses and are not functionally limited by their paraphilic impulses, and their self-reported and legally recorded histories indicate that they have never acted on their impulses, then these individuals have a pedophilic sexual orientation but not a pedophilic disorder" (22). Currently, most published (neurobiological) research does not differentiate between pedophilic disorder and pedophilic sexual orientation according to DSM-5. Furthermore, some studies did not apply diagnostic criteria as defined in ICD-10 or DSM-4/DSM-5 due to unavailability of data, while others used different kinds of criteria and methods for grouping (e.g.,

victim age, responses in penile plethysmography). Therefore, to enhance readability, in the following, the term "pedophilia" will be used for subjects with a sexual orientation toward children, independently of the diagnostic system or method that was used. If available, details will be given about offense status.

In recent years, some research groups have focused on the differentiation between pedophilia and child sexual offending. Interestingly, as will be shown below, some neurobiological parameters seem to belong to pedophilia, while others seem to be associated with sexual offending. Accordingly, it can be assumed that biomarkers for pedophilic offenders differ from biomarkers for pedophilic non-offenders and non-pedophilic offenders. Hence, if possible, we describe these differentiations.

Genetic and Prenatal Factors Genetic Factors

Brain development is a complex organization of processes under genetic, epigenetic, hormonal, environmental, and immune regulation, and consequently is vulnerable to a variety of disturbances (23). Pre- and perinatal factors are therefore, among others, important predictors of many later life outcomes, including but not limited to criminality and psychopathology. Also for pedophilia, a neurodevelopmental basis has been suggested [e.g., (17)]. Even though several biological parameters supporting this hypothesis have been identified, more research is needed to strengthen existing empirical evidence and to clarify specificity. In a group of healthy male twins and their siblings (N = 3,967), Alanko et al., for instance, found a small amount of variance (14.6%) attributable to nonadditive genetic influences (heritability) for self-reported sexual interest in children (24). Later, the same group reported small genetic effects for male pedophilia: several SNPs (single-nucleotide polymorphisms) linked to androgen, estrogen, prolactin, corticotropin, serotonin, and oxytocin were associated with self-reported sexual interest in children in a community sample, but only before controlling for multiple testing (25). Examining paraphilic sexual offenders and nonoffending controls, Jakubczyk et al. failed to find an association between a history of a sexual offense and the distribution of genotypes or alleles in several analyzed polymorphisms, linked to dopamine, serotonin, monoamine oxidase A, and the brainderived neurotrophic factor (26).

Minor Physical Anomalies and Congenital Malformations

Minor physical anomalies (MPAs), superficial deviations from typical morphological development, such as malformed ears or toes, or fine electric hair, develop prenatally. MPAs might be external markers of abnormal brain development, as both the central nervous system and the skin derived from the same ectodermal tissue *in utero*. They are supposed to develop during the first and/or early second trimester of gestation (27–29). Even though the exact mechanism remains elusive, there are some indications that besides genetic factors, also environmental perturbations (e.g., hypoxic events) during early embryonic period may determine the extent and nature of malformations (27, 30). Research supports the hypothesis of an association

between MPAs and several neuropsychiatric disorders, such as autism and schizophrenia (31, 32). Pedophilic individuals seem to exhibit a greater number of MPAs relative to samples of individuals with schizophrenia as well as healthy controls: Dyshniku and colleagues found that MPA indices were positively associated with multiple indicators of pedophilia, including phallometric responses to sexual stimuli, number of child but not adult victims, and possession of child sexual exploitation material (30). There is also a relationship between adult men's height and pre- and perinatal factors, such as genetic predisposition or conditions in utero (33). Fazio and colleagues found a reduced measured height and reduced leg length in pedophiles as compared with teleiophiles. The magnitude of this difference was similar to the difference found in other biologically based neurodevelopmental disorders (33). Using a large data-set from Swedish populationbased registers (13,773 sex offenders, 135,953 violent non-sexual offenders, 680,120 matched controls), Babchishin and colleagues found that two perinatal factors, being small for gestational age, and a small head circumference were both associated with risk of sexual, and non-sexual violent offenses (adjusted odds ratios between 1.12 and 1.51) (34). Furthermore, any congenital malformation (according to ICD10: P00-P99) had a small effect on sexual offending against children [adjusted odds-ratio: 1.15, CI (1.02-1.30)], but not against adults. However, this association reached level of significance also for non-sexual violent offenses [adjusted odds ratio: 0.91, CI (0.88–0.94)] (34), which raises the question of whether those parameters are rather biomarkers for violent offending than for child sexual offending or pedophilia. In a subsequent study, Babchishin et al. compared a subset of 655 child sexual exploitation material offenders (CSEM), individuals who had additionally conducted contact sexual offenses against children, as well as with 3,928 matched controls (35). Any congenital malformation remained the only pregnancy-related independent risk marker for mixed offenders [CSEM and contact offenses, adjusted odds ratio: 1.7, CI (1.2-2.4)], but not for CSEM-exclusive offenders (35).

Handedness and Androgens

There is evidence that the fetus exhibits lateralized behavior from as early as 10 weeks of gestation, as soon as it independently moves its arms. This can be seen as a precursor of lateralized postnatal behavior (36). In the general population, about 90% are right-handed. Left- and mixed handedness has been reported in up to 60% of individuals suffering from several neuropsychiatric and developmental disorders, such as autism spectrum disorders, attention deficit hyperactivity disorder, schizophrenia, and different forms of addiction (37). Research has further linked left- and mixed handedness to deviant sexual interest, pedophilia, and sexual offending against children, supporting the view of a neurodevelopmental origin of paraphilic sexual preference (38). Analyzing a large sample (N = 1,857), Fazio et al., for instance, described higher rates of non-right handedness (sinistrality) in pedophilic sex offenders (14.6%), and increased ambiguous handedness in offenders with a sexual preference for pubescent children (12.4%) compared to teleiophilic offenders [7.4% resp. 8.8%; $\chi^2(1, N = 1,712) =$ 13.62, p < .001]. Interestingly, the laterality quotient also was significantly associated with the subjects' pedophilic phallometric index score (39).

Considering the ontogenesis of handedness, recent research on molecular epigenetic mechanisms suggests that instead of single genetic factors, particular asymmetries in DNA methylation might affect asymmetric gene expression in the brain that, in turn, mediates handedness (40). In line with this, Schmitz and colleagues showed that birth stress (e.g., premature birth, breathing difficulty at birth) might be a factor that affects DNA-methylation in the promotor region of the NEUROD6 candidate gene, which could be associated with left-handedness (40). NEUROD6 is leftward asymmetrically expressed in the fetal brain, and acts as a differentiation factor for neural precursor cells in the developing brain. The absence of NEUROD6 is associated with reduced glutamatergic network activity and disruption of neocortical projections of the corpus callosum and other commissural fibers (40–42).

Regarding sexual preference, hormonal factors, such as prenatal testosterone levels, are of special interest. The earliest known effects of androgens during the prenatal phase, the so called "organizational effects," do not only lead to sexual differentiation of the periphery in mammals but also to sexually dimorphic brains, with testosterone exposure resulting in male-typical development (masculinization), and the relative absence of testosterone resulting in female-typical development (feminization) (43-45). Interestingly, testosterone and its androgen receptor (AR) do not appear to be directly responsible for the perinatal masculinization of the brain. It is rather the local aromatase-dependent conversion of testosterone to estradiol that accounts for these effects (46, 47). The ratio between the second and the fourth digit (2D:4D ratio) has been considered as a potential marker for prenatal testosterone exposure. However, due to ethical reasons, prenatal testosterone levels cannot be manipulated in humans and causal relationships cannot be derived. Although it is still being debated, research indicates a negative association of the 2D:4D ratio and prenatal testosterone levels. In other words, a lower 2D:4D might indicate a higher prenatal testosterone (stronger masculinization). On average, the 2D:4D is smaller in males than in females [for an overview see: (48)]. A higher 2D:4D ratio in the left compared to the right hand might be associated with a tendency toward left-handedness, but this effect was not consistently reported (37). In a community sample of 200 heterosexual men, for instance, Rahman et al. found that men with stronger paraphilic sexual interests had a higher right-hand 2D:4D ratio and a trend for a lower Edinburgh Handedness Inventory scores (i.e., less right-handed) compared to men with lower paraphilic sexual interests (49).

Regarding underlying neurobiological mechanisms, not only classical genomic actions at the transcription level might play a role (modulating synapse growth, changing neurotransmitter production etc.), but also the receptor binding capacity of the AR. A particular polymorphism on the AR gene, the CAG (cytosine-adenine-guanine) repeat polymorphism is of functional importance, with shorter CAG repeats being related

to a greater expression of AR protein (i.e., larger number of AR receptors) and increased transcriptional activity of AR. As a result, men with shorter CAG repeats appear to convert the same concentration of androgen into larger physiological effects than do men with longer repeats [for an overview see: (43, 50, 51)]. Although there does not seem to be a clear correlation between violent criminal activity and AR repeat polymorphism, some studies found that violent criminals, rapists, and murderers had shorter CAG repeat length than non-violent controls (52, 53).

In a recent study with 194 subjects, 2D:4D ratios were inversely associated with the total number of child sexual offenses, but not with pedophilia itself, supporting the role of prenatal testosterone in the development of delinquent behavior (54). The authors did not find a main effect for the CAG repeat length, but in the non-offending group, shorter CAG repeats were linked with higher percentage of AR-receptor methylation. They interpreted this as an indicator for a regulatory mechanism to maintain normal functioning system, i.e., the higher the AR receptor functionality (shorter CAG repeats), the less ARs are synthesized (high methylation level). Most interestingly, this regulatory mechanism was not seen in the offending population (independently of diagnosis of pedophilia), which was interpreted as an impaired regulatory mechanism between genetic and epigenetic factors in the androgen system (54). Unfortunately, the authors did not report any data about handedness. The question of whether or not there is an association between handedness and the length of CAGrepeats was nevertheless examined by another research group. Analyzing a large sample of healthy adults (N = 1,057), Arning et al. found that longer CAG-repeats were related to a higher incidence of non-right handedness (i.e., less lateralization). As mentioned above, longer CAG-repeats are linked to less efficient AR-function. The authors therefore concluded that differences in AR-functioning in the developing brain could be one of the factors that determine individual differences in brain lateralization (55).

Structural and Functional Imaging

Magnetic resonance imaging and electrophysiological studies constitute another interesting biological source of information to characterize pedophilia and child sexual offending.

Structural Imaging

So far, three neurobiological theories for pedophilia have been proposed (50, 56). The frontal-dysexecutive theory was put forward by Graber et al. (57) and assumes that structural and functional damage to the frontal lobe might lead to behavioral disinhibition, which favors pedophilic behavior. The temporal-limbic theory, on the other hand, posits that the temporal and limbic brain regions play a major role in sexual functions. Especially, lesions of the temporal lobe are associated with hypersexual behavior (58). The dual-dysfunctional theory connects the former theories, assuming dysfunctions in both temporal and frontal brain areas. According to the latter theory, hypersexual behavior caused by temporal deficits—together with behavioral disinhibition caused by frontal deficits—leads to

pedophilic behavior. However, these theories might explain hypersexual and disinhibited behavior, but not a pedophilic sexual interest itself. Furthermore, hypersexual and disinhibited behavior could also be related with other mental disorders, such as other paraphilias/paraphilic disorders, hypersexuality itself, and neurodegenerative disorders (59).

Regarding pedophilia, early pioneer studies found volume reductions in sexually relevant brain regions, such as the amygdala, hypothalamus, limbic gyri, orbitofrontal cortex, ventral striatum, and insula in pedophilic compared to nonpedophilic subjects [e.g., (56, 60, 61)]. However, these earlier studies did not distinguish between pedophilia and child sexual abuse. Recent reviews and meta-analyses investigating differences between individuals sexually oriented toward children and individuals sexually oriented toward adults revealed that their brain structures are very similar in nature (17, 62, 63). As indicated by two recent studies, aberrant neuroanatomy might rather be associated with child sexual abuse than with pedophilia (64, 65). Applying voxel based morphometry (VBM) in 219 individuals, Schiffer et al. failed to find group differences in the relative gray matter volume specifically associated with pedophilia (64). However, nonoffending pedophiles (n = 60) exhibited larger gray matter volume in the right temporal pole than offending pedophiles (n = 58) or non-pedophilic controls without any history of child sexual offending (n = 101). The gray matter volume in the right temporal pole was negatively associated with self-focused sexual behavior in offending pedophiles but also in healthy controls. Interestingly, the risk of re-offending [assessed with the SSPI-2, Screening Scale of Pedophilic Interest 2nd version, (66)] was associated with lower local gray matter volume in the right dorsomedial prefrontal cortex/anterior cingulate cortex. This finding might be related to research results on deficient inhibitory control in offending pedophiles (see below) (64). In a large sample of 283 individuals, Lett et al. could further demonstrate with moderate effect sizes that as compared to non-offending pedophiles (n = 77) and healthy controls (n =133), pedophiles with child sexual offenses (n = 73) showed lower IQ-performance, reduced cortical thickness in the right motor cortex, reduced cortical surface area comprising bilateral frontal, temporal, cingulate, and insular regions, and reduced white matter fractal anisotropy particularly in the corpus callosum (65).

Functional Imaging – Functional Magnetic Resonance Imaging

Similarly, functional imaging studies examining neural underpinnings of child sexual offending revealed that a diminished fronto-limbic functional connectivity at resting state is rather linked to child sexual offending than to pedophilia (67, 68). According to the authors, these findings may support the theory of disturbed fronto-limbic functioning as a possible causal factor for child sexual offending regardless of pedophilia. Interestingly, a reduced fronto-limbic functional connectivity (as a response to provocations) has also been shown for violent and psychopathic offenders (69, 70). From

studies with healthy subjects, it is known that there is a strong top-down inhibitory control of prefrontal over limbic structures (especially amygdala), mediating responses to provocations [for review see: (71)]. Hence, a diminished fronto-limbic functional connectivity could be seen as a neurobiological correlate for an (general) impaired ability to assert inhibitory control on behavior.

Another large amount of functional imaging research has been conducted in order to understand the neural underpinnings of child sexual interest, and to develop an "objective" instrument, a biomarker, which could support the diagnostic process of identifying pedophilia itself. A deviant sexual preference is one of the strongest single predictors for sexual-offense recidivism (72). Currently, the Western European standard for the assessment of sexual interest are self-reports. However, it is known that self-reports and questionnaires are susceptible to denial or faking (73), which is of special relevance in the forensic context. Avoiding this problem, functional imaging approaches use hemodynamic brain responses to sexual stimuli to gather information about the participant. This idea is based on the assumption that sexually relevant features of stimuli are preferentially processed, i.e., preattentively selected, and automatically trigger focal attention to these sexual aspects (74). These attentional processes can be measured at behavioral but also at neural level. With the four-component model of sexual arousal, Redoute and colleagues proposed four excitatory (cognitive, motivational, emotional, autonomic) and one inhibitory component to describe the processing of sexual stimuli at behavioral and neural level (75, 76). Early pioneer studies reported differences in several sexually relevant brain regions when comparing pedophilic child sexual offenders and healthy subjects [e.g., (77-79)]. Recent studies yielded evidence that pedophilic subjects exhibit similar brain activations as healthy subjects while watching their preferred sexual stimulus, indicating that the four-component model of sexual arousal does not only hold true for healthy individuals but also for individuals with a sexual preference for children [for review see: (17, 62, 63, 76, 80)]. Supporting these results, Polisois-Keating and colleagues did not find significant differences between the groups in a meta-analysis with 123 subjects (80). Current research also confirms this view, and adds the idea that the right inferior temporal gyrus might be a possible candidate region mediating sexual arousal in patients with pedophilic disorder (81). Comparing responses in pedophilic outpatients (n = 15) and healthy controls (n = 15) to the presentation of sexually preferred and non-preferred stimuli, two areas in the right temporal gyrus showed increased (BA37) and decreased responses (BA20) in pedophiles. According to the authors, these areas could play an opposite role, i.e., an activating and inhibiting role in sexual arousal (81).

The typical experimental designs in this type of research, i.e., passive viewing of sexual stimuli, are, however, susceptible to manipulation. As a consequence, researchers have started to develop alternative means for the assessment of sexual interest. For instance, Jordan and colleagues have used an active cognitive task to capture healthy subjects' attention while they were

simultaneously presented with task-irrelevant sexual stimuli. Results indicated that such tasks can indeed be used to measure sexual interest in healthy subjects (N = 22) (82). Another stimulation design, useful for avoiding possible manipulations by the subjects, seems to be the subliminal presentation of visual sexual stimuli (83, 84). Subliminal stimuli are shown with a presentation time of 50 ms at the most. The threshold of 50 ms ensures that the stimuli are, in most instances, not consciously perceived by the subjects, which decreases the possibility of manipulation of the subjective reaction (85). Applying a promising automatic pattern classification algorithm of brain responses, Ponseti and colleagues demonstrated that pedophilic out-patients (n = 24, 50% with sexual offenses) and non-pedophilic healthy controls (n = 32) could be classified with high sensitivity and specificity according to their responses not only to supraliminally presented, preferred, and non-preferred sexual stimuli (sensitivity 88%, specificity 100%) but also to face stimuli (sensitivity 95%, specificity 91%) (86, 87).

In a large sample (N=104), Cantor et al. (88) further demonstrated a wide-ranging increased functional connectivity in the default mode network, with regional increases and decreases in the frontoparietal network in pedophilic sex offenders (n=37) compared to non-sexual offenders (n=28) and non-offenders (n=39). Interestingly, most of these regions are known to respond to sexually relevant stimuli, again supporting the four-component model of sexual arousal for pedophiles (88). Based also on previous studies, which showed differences in structural connectivity (voxel based morphometry, diffusion tensor imaging), Cantor et al. proposed a pattern of *dys*connectivity rather than *dis*connectivity as a neuroanatomic substrate of pedophilia (56, 88, 89).

Functional imaging has not only been applied to assess sexual interest, but also to characterize cognitive aspects in pedophilic subjects and sexual child offenders, such as inhibitory control abilities. As one of the first research groups, Habermeyer et al. (90) examined a small sample of pedophilic sex offenders (n =11) applying a go/no-go task to measure response inhibition behavior. In comparison to non-offending healthy controls (n = 7), pedophilic offenders exhibited slower reaction times and a less accurate visual target discrimination, which was accompanied by attenuated deactivation of brain areas belonging to the default mode network. Based on these results, Habermeyer et al. assumed a higher degree of inattention and increased self-referential processes in their pedophilic sex offenders while performing the no-go task (90). Applying a similar task with larger groups, Kärgel et al. (91) could differentiate offending (n = 40) and non-offending pedophiles (n = 37). While no general group differences were found between pedophilic subjects and non-offending healthy controls (n = 40), non-offending pedophiles exhibited superior inhibitory control behavior compared to offending pedophiles. Furthermore, an increased inhibition related activity in left posterior cingulate and left superior frontal cortex, areas associated with effective cognitive functioning, was found in non-offending pedophiles. According to Kärgel et al., these data indicate a better inhibitory

control in pedophiles who successfully avoid committing handson sexual offenses against children (91).

Supporting functional magnetic resonance imaging (fMRI) and EEG studies (see below), neuropsychological research has shown executive dysfunctions in child sexual offenders (92). Interestingly, a recent neuropsychological study supports the results by Kärgel et al. (91) in so far as executive dysfunctions (worsened response inhibition abilities) are related to offense status rather than pedophilic preference (93).

Functional Imaging-Electroencephalogram

In contrast to fMRI, the application of electroencephalography (EEG) stands out for its high temporal resolution (1 ms) and therefore allows for the detection of very early and fast brain responses to perceived stimuli. To our knowledge, besides a few older studies [e.g., (94)], only two recent studies have investigated the application of EEG in pedophilic individuals and child sexual offenders. Knott and colleagues (95) used eventrelated brain potentials (ERP) to investigate the time course of the explicit processing of adult erotic, emotional, and neutral pictures in 22 pedophilic sex offenders and 22 healthy controls. In general, the ERPs elicited by emotional stimuli were similar in pedophilic sex offenders and controls, but an early positive component (P2) was significantly attenuated and slower in pedophilic individuals compared to controls. The authors interpreted the results in terms of a failure of rapid attentional capture by adult erotic stimuli, which could reflect the relatively diminished sexual interest in adults (95). Based on the knowledge of impaired response inhibition in child sexual offenders, Rosburg et al. (96) investigated these processes by means of a go/nogo task in a sample of 21 pedophilic contact child sexual offenders (CSOs), 19 non-contact CSOs (child sexual exploitation material offenders, pedophilic status not accessed), and 21 healthy controls. Results revealed that response inhibition, processing of stop-signals, and error detection were not necessarily impaired in CSOs. However, the amplitudes of a positive response-related component, reflecting error evaluation and error awareness, were strongly diminished in CSOs, even more in contact CSOs. The authors interpreted that CSOs may allocate less cognitive resources to the evaluation of committed errors, which might reflect a reduced sense of responsibility (96).

Hormones and Neurotransmitters

The question of whether levels of the male sex hormone testosterone (T) are altered in pedophilic individuals and (child) sex offenders is rather old. This idea derived from the fact that testosterone plays a key role in all aspects of male sexuality, including sexual interest, thoughts, motivation, desire, arousal, spermatogenesis, erection, and ejaculation [for review see: (43)]. Despite this clear association between T and sexual function, the nature of this relationship remains complex, also in healthy men. One reason might be that the physiological range of testosterone levels (3–12 ng/ml or 11–40 nmol/L) is considerably higher than required for maintaining normal sexual functions. Research has also concentrated on the forensically relevant relationship between testosterone and aggression. However, as

pointed out by Carré et al. (97, 98), studies on humans from as early as the seventies revealed, if at all, only weak associations between testosterone and aggression. The testosterone-behavior relationship is rather thought to be subject to individual differences and contextual variables, i.e., testosterone influences aggression especially in high dominance men, in those men with low cortisol levels, and it can affect both aggression and prosocial behavior (97, 98). In line with this, Volman et al. (70) found that psychopathic offenders exhibited less control-related anterior prefrontal activity and anterior prefrontal-amygdala coupling in a task requiring control of emotional actions, when compared with healthy control subjects. This pattern was pronounced in psychopathic individuals with high endogenous testosterone levels (70). Nowadays, it is known that, contrary to the general belief, sex offenders do not have higher testosterone concentrations than non-offenders. Recently, Wong and Gravel (99) published a carefully conducted meta-analysis, examining seven studies with a total sample size of 325 sex offenders and 196 comparison participants. They did not find a significant association between testosterone and sexual offending (99). In a current study, Kruger et al. even reported lower, but nevertheless normal testosterone levels in CSOs compared to non-offenders, which was independent of a potential pedophilic preference (54).

Even though sex offenders do not have altered testosterone concentrations, testosterone lowering treatment (TLT) has been used for 30 years to treat paraphilic patients and sex offenders. TLT leads to a profound decrease of testosterone levels, which should result in a reduction of sexual drive and, in consequence, a reduced risk of recidivism (50, 100). Typically, outcome measures comprise hormonal parameters, self-reports about sexual activity and interest or recidivism. Yet again, self-reports are susceptible to denial or faking. Hence, methods using biomarkers as "objective" measures could support treatment evaluation. To examine the effect of TLT by means of fMRI, three case studies with similar experimental designs were conducted, in which sexually relevant stimuli were presented at a supraliminal level to measure sexual interest. Based on the results of these three case studies, it can be assumed that TLT leads to a decreased activation in brain regions linked with sexual functions, especially with regard to the autonomic, the emotional, and the motivational component of sexual arousal (101-103). Results of an additional fMRI case study, in which visual sexual stimuli were presented subliminally further indicate that even at an unconscious level, TLT can lead to changes in the processing of sexually relevant stimuli, supposedly reflecting changes in cognitive and perceptive automatic processes (104). Next to fMRI, also eye tracking can be used to depict TLT induced changes. In an eye movement study with a single pedophilic CSO who was presented with pedophilic stimuli, it was found that controlled attentional processes could change under TLT whereas automatic processes remained mostly stable (104). Obviously, case studies can only provide anecdotal evidence for the usability of potential biomarkers. Nevertheless, using fMRI, EEG, or eye tracking to assess TLT induced changes in responses to sexual stimuli seems to be a promising approach for the identification of biomarkers.

According to the monoamine hypothesis, monoaminergic neuroregulatory dysfunctions are involved in the pathophysiology of paraphilic disorders (105, 106). Evidence for this comes from several sources of data. The monoamine neurotransmitters dopamine and serotonin and also norepinephrine are involved in the regulation of autonomic, motivational, and emotional sexual functions. Furthermore, they appear to modulate dimensions of human and animal psychopathology, including impulsivity, anxiety, depression, compulsivity, and pro-/antisocial behavior-dimensions that are disturbed in many paraphilic patients (106). Side effects of antidepressant (e.g., SSRIs), psychostimulant, and neuroleptic drugs in humans suggest that alterations of central monoamine neurotransmission can have substantial effects on human sexual functioning. Even though we do not fully understand the complex picture, few earlier studies indeed indicate that monoamine systems might be disturbed in paraphilic disorders [for review see: (50)]. To our knowledge, only one recent study investigated alterations in neurotransmitter levels in pedophilic sex offenders (107). By means of magnetic resonance spectroscopy, Ristow and colleagues found reduced gammaaminobutyric acid (GABA)/Cr concentrations (γ-aminobutyric acid/creatinine) in the dorsal anterior cingulate cortex in pedophilic sex offenders (n = 13) compared to non-offending healthy controls (n = 13), which was associated with selfreported lower self-control in patients. As GABA is an inhibitory neurotransmitter, the authors interpreted the reduced GABA/cr ratio as neuronal correlate of inhibition and behavioral control in the group of pedophilic sex offenders (107).

Penile Plethysmography

In north America, penile plethysmography (PPG) is considered the golden standard for assessing pedophilic interest. By utilizing this device, changes in penile circumference or volume in response to sexual stimuli of different ages and sexes can be assessed. A current large meta-analysis (N = 6,785 subjects) suggests that several phallometric testing procedures are valid indicators of pedohebephilic interest (i.e., prepubescent and pubescent children) with small to large effect sizes. Moreover, phallometric tests were able to predict sexual reoffending with moderate effect sizes (N = 2,709 subjects) (108). A recent large study (N = 1,136) showed that most sex offenders against children (83%) were unable to successfully suppress their sexual arousal to pictures depicting children when instructed to do so. Moreover, the ability to suppress sexual arousal was not associated with recidivism (109). Nevertheless, phallometric testing has been criticized for its intrusiveness, the high proportion of non-responders (probably 20-25% of all subjects), and its discriminant validity and selectivity (110). In the above mentioned study conducted by Babchishin et al., phallometric testing could only moderately discriminate between sex offenders against children and non-offending men {area under the ROC Curve (AUC) = 64.96%, [CI:.59-.69]}, a finding that did not significantly change during the suppression condition (109). However, it is likely that improving the quality of stimulus material could increase classification accuracy [up to 84.95%, (111)]. Nevertheless, PPG is recommended in DSM-5 as

an additional, diagnostic marker for pedophilia (22) (see also *Ethical Considerations*).

Eye Tracking

The earliest eye trackers were built in the late 1800s, but their relevance for sexuality has only been discovered quite recently (112). The measurement of eye movements provides the opportunity to directly explore attentional processes. Humans' ability to identify fine details is limited to two degrees of central vision, the foveal region of the retina. This limitation of acuity of the human visual system makes it possible to identify the features most interesting to the viewing subject by eye movements (113). Using eye movements, several variables can be measured, such as saccades, fixations, or pupil size [for review see: (114)]. Renaud et al. were the first to demonstrate the potential of eye tracking (and virtual-reality technology) in the assessment of deviant sexual preferences. Although there were no significant differences between pedophilic sex offenders (n = 8) and non-deviant controls (n = 8) in classical eye-movement parameters, the study provides initial indications of the potential of using eye movements in assessing pedophilic interests (115). In a later study, the same group showed in 20 healthy male subjects that eye movements can be used to assess erectile inhibition during PPG measurement (116).

Our group measured eye movements in two groups of forensic inpatients (22 pedophilic child sex offenders, 8 non-pedophilic adult sex offenders) and 52 healthy controls while they were simultaneously presented with the image of a child and an adult. Pedophiles demonstrated significantly shorter fixation latencies and significantly longer relative fixation times for child stimuli than either of the control groups. Pedophilic and non-pedophilic individuals could be classified with high sensitivity (86.4%) and specificity (90%) (117, 118). Concerning susceptibility to manipulations, a first study demonstrated that healthy hetero- and homosexual subjects (N=32) could be discriminated with moderate sensitivity (77%) and specificity (86%), even though they had to mask their sexual orientation, while viewing sexual stimuli (119).

In another experimental setting, a sexual distractor task, the same subjects had to solve a cognitive task while simultaneously being presented with an image of a sexual stimulus [child or adult stimulus (120)]. Hence, this task requires attentional control in the presence of sexual stimuli. Pedophilic subjects showed significantly lower attentional control, as indicated by eve movements, than both non-pedophilic control groups. They could be discriminated with high accuracy (sensitivity: 90.9%, specificity: 84.9%). We assumed that the measured attentional control represents inhibitory executive functions, specifically interference control. Further studies will have to examine, if attentional control to sexual distractors could be linked to clinically important aspects of controllability, the capacity of self-control, and the severity of a paraphilic disorder (120). Applying the same cognitive task, outpatients with a selfreported sexual interest in children (and self-reported sexual offenses) differed from pedophilic forensic inpatients with respect to attentional control but not with regard to sexual interest (121). They demonstrated significantly better

attentional control than pedophilic forensic inpatients in the face of adult sexual stimuli, but not with respect to child sexual stimuli. This might reflect a higher capacity for self-control and self-regulation in these patients. Nevertheless, child stimuli remain highly distracting for them (121).

Behavioral Approaches

Behavioral approaches do rather not belong to the classical biomarkers. However, as biomarkers are defined as "a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes or pharmacological responses to a therapeutic intervention" (1, 2), they may nevertheless be considered as such. Recently, Loth and Evans proposed the term "bio-behavioral" to refer to tests which measure fundamental social, cognitive, emotional, and motivational processes with a neurobiological basis (122). With respect to neurodevelopmental disorders, Loth and Evans discuss a possible conversion of those tests into clinically useful bio-behavioral markers. They argue that those tests can be relatively brief, cost-effective, easy to administer and interpret, and have only few risks/side effects. Furthermore, Loth and Evans argue that with respect to autism research more sophisticated biological measures [e.g., structural magnetic resonance imaging (sMRI), fMRI, EEG] do not show better discrimination accuracy between groups than cognitive/behavioral tests (e.g., emotion recognition) (122).

Like functional imaging, electrophysiological and eye tracking studies, most of the behavioral approaches aim to "objectively" assess deviant sexual interest. Similar to these measures, behavioral approaches are "i) inherently less transparent than self-report measures due to the indirect character of the measurement procedure, and ii) able to tap into automatic attitudes and behavioral dispositions, because of the implicitness of the constructs to be measured" (123). Instead of relying on self-report measures, behavioral approaches use different parameters and methods to gather information about the participant. These parameters and methods include, but are not limited to, reaction times, measurement of accuracy in a cognitive task, or evaluations of stimulus' valence and arousal. A variety of tasks are used to measure subject's responses to the presentation of sexual stimuli, e.g., evaluate valence and arousal of sexual stimuli, locate a dot on a sexually preferred or nonpreferred stimulus, or name the color of a sexually preferred or non-preferred stimulus (please see below). If those approaches use response latencies during tasks to measure sexual interest, they often are called "latency-based" measures (123). Most behavioral approaches have been developed in order to assess child sexual interest, and to develop an "objective" instrument, a biomarker, which could support the diagnostic process of identifying pedophilia itself. In contrast to classical biological measures (e.g., sMRI, fMRI, EEG, hormones, neurotransmitters), behavioral approaches often have already been tested with respect to discrimination accuracy, effect sizes etc.

The viewing time (VT) approach is the most established measure of sexual interest and is based on the observation that subjects spent a larger amount of time looking at erotic than at non-erotic stimuli (124, 125). According to Schmidt and

colleagues (125), VT effects can be described as prolonged decision latencies for attractiveness ratings of sexual targets. In consequence, only if participants actually followed the instructions to rate the sexual target's attractiveness, then the measure would be valid (125). Recently, Schmidt et al. conducted a large meta-analysis of VT-measures of sexual interest in children (N = 2,705 subjects). They concluded that VTmeasures demonstrate overall moderate discriminant validity for distinguishing between sexual offenders against children and sexual offenders against adults or non-sexual offenders [d = .60, CI (.51-.69)], and significant, small to moderate convergent validity with self-reports, PPG, the Implicit Association Test (please see below), and sexual offense history measures [r ranging from r = .18 to r = .38 (125)]. Similarly to PPG, VT is recommended in DSM-5 as an additional diagnostic marker for pedophilia (22) (but see Ethical Considerations).

The Choice Reaction Time Task [CRT, (126)], and the pictorial modified Stroop task (127) rely on the concept of limited attention capacity during controlled information processing (128). Following this concept, the sexual contentinduced delay (SCID), which was first proposed by Geer and Bellard (129), occurs when a salient sexual stimulus triggers attentional processes, interfering with or limiting attention to other tasks. The CRT requires the subject to locate a dot as quickly as possible while viewing sexual stimuli. According to the SCID, reaction times should be longer if dots are superimposed on images of sexually preferred stimuli compared to sexually non-preferred stimuli. In a large sample of child sex offenders and non-offenders (N = 233), Dombert and colleagues (130) found an overall poor to moderate effect size for the CRT (AUC values between .59 and .69). Additional comparisons of pedophilic and non-pedophilic sex offenders did not significantly improve the results. Interestingly, convergent validity was seen with the child sexual fantasy scale of the MSI [Multiphasic Sex Inventory (131)] (130). The pictorial modified Stroop task asks participants to name the color of stimuli while ignoring their sexual content and allows to discriminate between heterosexual and homosexual subjects (127). This notwithstanding, the task did not prove usable for distinguishing between CSOs and nonoffenders. Originally developed to identify implicit racist attitudes, the Implicit Association Test [IAT (132) was adapted to measure implicit child-sex associations to discriminate pedophiles from non-pedophiles]. In a meta-analysis Babchishin et al. (133) analyzed 12 distinct samples of child sex offenders and different control groups (N = 707), in order to examine discriminant and convergent validity of IAT-measures to assess sexual interest in children. They found that IAT measures were able to distinguish between CSOs and nonoffenders with large effect size [mean weighted d = .96, CI (.67-1.24)]. Effect sizes decreased when comparison groups were non-sex offenders or rapists (d = .58 resp. d = .48). Convergent validity was supported by correlations with VTmeasures in few studies, self-report, and sexual offense history variables (r ranging from r = .27 to r = .30) (133). In an adapted IAT, the go/no-go association task (GNAT, a combination of the IAT and the go/no-go response inhibition task) Bartels and colleagues (134) could distinguish between individuals with a

history of exclusive extrafamilial sexual offenses against children and those with exclusive intrafamilial offenses or offenses against both children and adults (N=70) with good discrimination accuracy (AUC=.71, p < .007). However, only partial support was found for convergent validity between the GNAT and questionnaires on sexual thoughts and fantasies (134).

Those single measures of sexual interest are promising, but effect sizes are only small to moderate. Therefore, multimodal approaches have been proposed in order to develop a clinically applicable tool for the assessment of sexual interest with high reliability and validity. Banse and colleagues (135), for instance, introduced the Explicit and Implicit Sexual Interest Profile (EISIP), which combines direct self-report and indirect latencybased measures, i.e., IAT and VT. In a first study, the EISIP demonstrated an overall high discriminative validity (AUC = .95, p < .001) between child sex offenders and controls (non-sex offenders, non-offenders, whole sample size N = 113 subjects) (135). In a similar study Babchishin et al. could partially replicate these results, with significant differences between the groups regarding VT and self-report but not with respect to an IAT (136). The authors argued that besides the relatively small sample size (N = 56), a gender-related IAT probably would yield better results than the neutral one that they had used in the study. Recently, several latency-based measures of sexual interest (VT measures, CRT, pictorial modified Stroop task, modified IAT) were combined with psychophysiological measures, i.e., pupillary responses, and sexual fantasy questionnaires, in order to assess sexual interest in 102 community men (137). Correlations between measures were positive, albeit effect sizes varied from small to large. Additionally, convergent and concurrent validity was shown for latency-based measures and pupil-dilation. Combined indices of sexual preference for adult stimuli predicted 75% of the variance in self-reported sexual interest in adults (137).

Applying a completely different approach, Fromberger et al. conducted a pilot study to test if behavioral monitoring of CSOs in high-immersive virtual risk situations provides additional information for risk management (138). Six pedophilic CSOs and seven non-offender controls walked through three virtual risk situations (supermarket), where they were confronted with a virtual child character. In 89% of cases, CSOs showed behaviors not in line with their own beliefs about adequate behavior in comparable risk situations. Although this was only a pilot study, results suggest that virtual risk scenarios could provide practitioners with the opportunity to monitor the behavior of CSOs, and to test their decisions on unsupervised privileges without endangering the community. This may provide additional information for therapy progress (138).

ARE THERE ANY BIOMARKERS FOR PEDOPHILIA AND CHILD SEXUAL ABUSE?

In the following, we will discuss and evaluate the above described biological, psychophysiological, and behavioral findings with respect to their usefulness as clinically important biomarkers for pedophilia and/or child sexual offending (see **Figure 1**). Thereby, if possible, we will refer to the scheme proposed by Prata et al. to evaluate biomarkers in psychiatry [see above, (4)]. According to these authors, valid biomarkers fulfill the following criteria: i) their relationship to a certain clinical endpoint is reliable (statistical significant), ii) plausible (causally or mechanistically understandable), iii) accurate (sensitive and specific), and iv) reproducible across clinically relevant settings. Moreover, even valid, clinically applicable biomarkers have to provide a meaningful advantage into decision-making or clinical care.

Potential Diagnostic Biomarkers to Assess Sexual Interest in Children

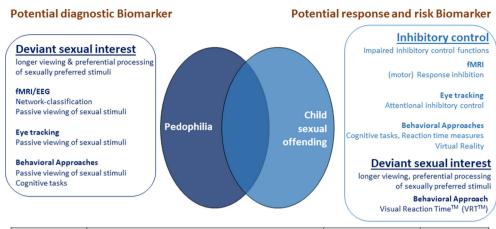
According to Califf (139), diagnostic biomarkers detect or confirm the presence of a disease or condition of interest, or identify an individual with a subtype of the disease. Susceptibility/risk biomarkers, on the other hand, can indicate the potential for developing a disease or medical condition in an individual who does not currently have the clinically apparent disease or medical condition [for more details see: (1, 2, 139)].

Functional Magnetic Resonance Imaging, Penile Plethysmography, Eye Tracking, and Behavioral Approaches to Assess Sexual Preference

As seen above, the assessment of deviant sexual interest using fMRI, PPG, eye tracking, or behavioral approaches has a long tradition in the forensic research context (see *Structural and Functional Imaging, Penile Plethysmography, Eye Tracking, Behavioral Approaches*). In comparison to other parameters, these approaches are most likely to fulfill criteria for a validated and clinically meaningful diagnostic biomarker to assess sexual interest in children (see **Figure 1**).

Applying fMRI, pedophilic and non-pedophilic subjects could be classified with high sensitivity and specificity while viewing sexually preferred stimuli (86, 87). Even though independent replication studies examining reliability and validity in a sample of non-admitting subjects are necessary, this approach is a promising tool to support the assessment of deviant sexual interest in the diagnostic process. Furthermore, susceptibility to manipulation has to be examined.

Also, PPG seems to be a valid indicator for pedohebephilic interest, and is able to predict sexual recidivism (108). However, discrimination accuracy is only moderate, the number of non-responders seems to be high, and ethical issues regarding the intrusiveness of this measure should not be underestimated (109, 110). The measurement of eye movements while being presented with sexually relevant and sexually non-relevant stimuli seems to be a promising, potential tool to discriminate between pedophilic sex offenders and non-pedophilic controls (offenders and non-offenders) with high accuracy (117). However, independent replication studies are necessary and reliability and validity remain to be assessed. Furthermore, susceptibility to manipulations has to be examined with the target groups. Besides PPG, also behavioral measures of sexual interest are well studied, especially with respect to psychometric criteria such



Diagnostic Biomarker Sexual Interest	Selected criteria for a validated biomarker	Response/Risk Biomarker Inhibitory Control	Risk Biomarker Sexual interest
(+)	Statistically significant relationship, causally or mechanistically, between biomarker and a defined clinical endpoint	-	(+)
+	Statistically significant difference between target groups, with large effect sizes (p <.05, corrected)	+	+
+	Appropriate sensitivity and specificity	(+)	+
(+)	Reproducibility	-	-
+	Minimally invasive	+	+
(+)	Manipulability	-	(+)

FIGURE 1 | Suggested potential composite diagnostic, response and risk biomarkers for pedophilia and child sexual offending. The table summarizes the evaluation of these potential biomarkers according to selected criteria for validated biomarkers. +: fulfills the criterion, (+): fulfills the criterion with restrictions, -: does not fulfill the criterion.

as reliability, validity, and discrimination accuracy. They show small to moderate discrimination accuracy between pedophilic and non-pedophilic subjects, and between CSOs and controls. However, as aforementioned, convergent validity was not always tested, and effects were small. Multimodal approaches have shown that combining self-reports, latency-based measures, and psychophysiological measures could enhance reliability, validity, and discrimination accuracy (135-137). Although those multimodal approaches have to be replicated and tested for susceptibility to manipulation in large groups of pedophilic and non-pedophilic men with and without sexual offenses as well as healthy controls, they provide a first step in the development of the aforementioned "composite biomarkers," i.e., composite measures of several parameters. Recently, Demidowa and colleagues recommended a more intensive international collaboration of sexual behavior assessment labs in order to establish the most effective methods for the assessment of sexual interest, and to facilitate standardization and evaluation procedures (140). It would be of interest, if the combination of different approaches (e.g., ESIP, eye tracking-, and fMRImeasures) will carry forward the development of a composite biomarker to assess deviant sexual interest.

Considering the aforementioned criteria for a validated biomarker, one critical point remains: the relationship between this potential diagnostic biomarker and a defined clinical endpoint. A "sexual interest biomarker" can assess sexual

interest at that moment. However this measured sexual interest in children obviously should not be equated with a diagnosis of pedophilic sexual orientation according to DSM-5, because it does not deliver any information on the continuity of this preference, or any fantasies and sexual urges. Furthermore, a clinical diagnosis of pedophilia according to ICD-10, and pedophilic disorder according to DSM-5 requires feelings of guilt, shame, or anxiety about these impulses or interpersonal difficulty or behaviors involving sexual activity (21, 22). Hence, a "sexual interest biomarker" could provide clinicians with supportive information on a sexual interest in children, especially with regard to social desirability, denial, or faking attempts. It has a significant relationship to the clinical endpoint (i.e. a diagnose). This notwithstanding, in our view, a "sexual interest biomarker" cannot be equated with a diagnosis of pedophilia/pedophilic sexual orientation or pedophilic disorder.

Potential Biomarkers for Therapy Response and Risk Assessment

To evaluate therapy or assess risk of recidivism, several types of biomarkers can be used. Generally, pharmacodynamic/response biomarkers change in response to exposure to a medical product or an environmental agent. Changes in or the presence of predictive biomarkers predict that an individual or a group of individuals is more likely to experience a favorable or unfavorable effect from exposure to a medical product or

environmental agent. Prognostic biomarkers, on the other hand, identify the likelihood of a clinical event, disease recurrence, or disease progression in patients with a disease or medical condition of interest [for more details see: 1, 2, 139)]. In the following, we will therefore discuss the usability of the methods and findings discussed above as biomarkers in therapy and risk assessment.

Functional Magnetic Resonance Imaging, Eye Tracking, and Behavioral Approaches to Assess Inhibitory Control in Therapy and Risk Assessment

In addition to the assessment of deviant sexual interest, fMRI, eye tracking, and behavioral methods have been used to characterize cognitive functioning in pedophilic subjects and CSOs (see Structural and Functional Imaging, Eye Tracking, Behavioral Approaches). Inhibitory control functions are of special interest with respect to therapy and risk assessment in those groups. Sex offender treatment programs rely on cognitive or behavioral interventions to reduce the risk of recidivism. Cognitive behavioral therapies are intended to change internal processes—thoughts, beliefs, emotions, physiological arousal alongside changing overt behavior, such as social skills or coping behavior (141). Control functions, as a part of executive functions, are of importance for those behaviors. In treatment, offenders learn to monitor and control thoughts, feelings, and behaviors associated with offending, in order to adopt alternative ways of coping with deviant sexual thoughts and desires. Moreover, general self-regulation problems belong to psychologically meaningful risk factors of sexual recidivism (142).

Results of fMRI, and neuropsychological studies found impaired (motor) response inhibition functions in sexual offenders against children (90, 92). Recent studies revealed that a worsened response inhibition ability is related to offense status rather than pedophilic preference (91, 93).

Supporting these results, functional imaging studies have shown that a diminished fronto-limbic functional connectivity at resting state is rather linked to child sexual offending than to pedophilia (67, 68). As discussed in *Structural and Functional Imaging*, a diminished fronto-limbic functional connectivity could be seen as a neurobiological correlate for an (generally) impaired ability to exert inhibitory control over behavior, which seems to be associated with child sexual offending. Furthermore, pedophilic CSOs also seem to have lower attentional control capacities than non-pedophilic controls, as was shown in a sexual distractor task with high discrimination accuary while measuring eye movements (120). Finally, the application of virtual reality approaches could be promising to examine a more realistic, inhibitory control behavior; for instance when confronting participants with children in a virtual supermarket (138).

In conclusion, these studies suggest that inhibitory control functions at simple motoric, attentional, as well as at complex behavioral level could be related to (pedophilic) child sexual offending. According to the above mentioned significance of inhibitory control functions in therapy, they potentially also might be of interest in therapy evaluation. Hence, the assessment of inhibitory control functions seems to be an

interesting potential biomarker for therapy and risk assessment. However, currently none of the above discussed approaches are tested for reliability, validity, and susceptibility for manipulation. Furthermore, it is not clear if these parameters are specific for child sexual offending. A diminished functional fronto-limbic connectivity, for instance, is also seen in violent and psychopathic offenders. Therefore, it might be a potential biomarker within the groups of subjects with a sexual interest in children, to "indicate" the risk of offending, but not a general "screening" biomarker. Additionally, the four structural and functional imaging studies derive from the same research collaboration (NeMUP, www.nemup.de), hence they will have to be replicated by independent research groups.

Behavioral Approaches for Risk Assessment

To the best of our knowledge, Gray and colleagues published the only study applying a behavioral approach to predict sexual recidivism in CSOs (143). They investigated the applicability of the so called Visual Reaction TimeTM (VRTTM), a version of the aforementioned viewing time (VT) approach. Gray and colleagues were interested to measure sexual interest in children in order to predict sexual recidivism among men who sexually abused children and men with other sexually deviant behaviors (N = 621). VRTTM to children was significantly related to sexual recidivism over a 15-year period, and independent of the specific deviant sexual interest. The VRTTM showed a moderate to large effect size for differentiation between reoffenders and non-re-offenders (Cohen's d = .71). When dividing participants into three groups based on their VRTTM, the 97 participants with a VRTTM lower than one standard deviation (SD) below mean had not relapsed. Relapse rates in the 432 subjects with a mean VRTTM and the 92 participants with a VRTTM higher than one *SD* above the mean, on the other hand, were higher and amounted to 7 and 27%, respectively (143). An important limitation of this study was that only 22 out of the 621 subjects were registered as re-offenders. The VRTTM is a promising approach to become a risk biomarker, however, replication studies with larger samples of child sexual abusers are necessary to confirm the results. The authors also proposed to evaluate, if VRTTM scores can be used to monitor treatment progress. That is, it should be examined if treatment can lower an abuser's VRTTM to children and if this reduction correlates with risk of recidivism. If VRTTM indeed allows conclusions about treatment progress and recidivism risk, it could further be incorporated into existing actuarial recidivism indices (143).

Neurobiological Findings for Pedophilia and Sexual Offending—Currently Not Suitable to Serve as Potential Biomarkers

In our view, the findings summarized below are useful to characterize pedophilia and child sexual offending and enhance our knowledge about neurobiological underpinnings. Potentially, they could help to better discriminate between pedophilia and child sexual offending. However, at this point in time, we believe that it is still unclear if they could provide potentially clinically applicable biomarkers.

Prenatal Factors

The above discussed research (see: Genetic and Prenatal Factors) indicates that genetic and prenatal factors, such as birth stress, epigenetic modifications, or prenatal testosterone, potentially leading to MPAs, congenital malformations and non-right handedness, are small but relevant risk factors for the development of pedophilia and/or the occurrence of child sexual offending. Sample sizes in the reported studies are large, and effect sizes vary from small to moderate. However, up to date, we do not certainly know if those factors are rather associated with pedophilia, child sexual offending, or any sexual, or non-sexual offending. One approach to get more clarification could be to split groups more sophisticatedly regarding sexual orientation, that is, to include variables such as preferred gender and age, and also offense status in the analyses (54, 144). Additionally, genetic effects are small, and did not survive corrections for multiple testing (25). Furthermore, it is known that most of the MPAs are not unique to pedophilia, autism, schizophrenia, attention deficit hyperactivity disorder, or any other psychiatric disorder (145). To our knowledge, the question of which circumstances may result in which specific psychopathological signs is still under debate. Moreover, the frequency of the pre- and perinatal anomalies examined is rather low. Babchishin et al., for instance, reported any congenital malformation in 47 out of 654 offenders (7.2%) (35). Fazio et al. pointed out that, even though they found a significant relationship between handedness and pedophilia, handedness accounted for only about 0.2% of the variance in pedophilia (39). However, one has to keep in mind that, considering the low base rate of pre- and perinatal anomalies, their explanatory power is rather limited.

Hormones and Neurotransmitters

Based on the current knowledge (see *Hormones and Neurotransmitters*), the actual basal testosterone concentration could probably not serve as a biomarker for child sexual offending or pedophilia. Regarding the complex relationship between testosterone, sexuality, aggression, and also individual and context characteristics, a multimodal assessment could help to disentangle this network [for instance see: (70)]. If fMRI-approaches are suitable to evaluate TLT, has to be shown in the future.

Furthermore, up to date, we do not fully understand the complex picture with respect to neurotransmitter changes in pedophilia and child sexual offending [for a review see: (50)]. Besides the study by Ristow et al. (107), further studies connecting directly measured neurotransmitters with other biological, behavioral, or criminological parameters remain to be conducted.

Structural Imaging

As mentioned in *Structural and Functional Imaging*, altered brain structures might rather be associated with child sexual offending than with pedophilia (64, 65). Nevertheless, structural brain alterations are well known for several psychiatric diseases. Although the effects in offending pedophiles seem to be specific, reliability and validity has not yet been evaluated. Classification

analyses to discriminate different patient groups, an approach that is already being used in the case of other psychiatric disorders, are necessary. For instance, there is evidence that it is possible to distinguish cortical abnormalities in bipolar disorder from schizophrenia by means of machine learning (13). Future research will have to examine if approaches like this could also prove useful in the classification of CSOs.

Functional Imaging - Electroencephalography

Even though the two EEG-studies examining sexual interest and response inhibition respectively yielded interesting results, they have to be replicated with larger, well-defined groups. Discrimination accuracy has to be shown, as well as reliability and validity (95, 96).

Ethical Considerations

Public, clinical, and scientific expectations regarding biomarkers are particularly high. Hence, it is possible that any clinical application of biomarkers would be quickly implemented, without time for reflections on social and ethical issues (146).

The worldwide accepted principles of biomedical ethics by Beauchamp and Childress comprise i) respect for autonomy (a norm of respecting and supporting autonomous decisions), ii) nonmaleficence (a norm of avoiding the causation of harm), iii) beneficence (a group of norms pertaining to relieving, lessening, or preventing harm and providing benefits and balancing benefits against risk and costs), and iv) justice [a group of norms for fairly distributing benefits, risks, and cost (147)]. These principles should be equally applied in biomarker research and application. With respect to the topic of this review, the distinction between a measured sexual interest in children (e.g., using a biomarker) and a diagnose of pedophilia/ pedophilic disorder is of great significance. It is a common public misconception that all people with pedophilia/pedophilic disorder have, or will sexually abuse a child (148). Hence, pedophilia/pedophilic disorder is among the disorders that lead to serious stigmatization and social rejection (149, 150). Bearing this in mind, a "sexual interest biomarker" potentially could be considered as a "biomarker for pedophilia" by the general public, and may raise the expectation of an "objective, infallible" screening marker for pedophilia and child sexual abuse. Therefore, we should be careful regarding the significance of a "biomarker to assess sexual interest in children." Similarly, the VRTTM approach to asses sexual recidivism should be applied with precaution, and obviously only as an additional tool, potentially supporting established risk assessment instruments and clinical evaluation. Labeling a person with a strong pedophilic VRTTM score as a person of high risk of relapse based only on this score is a serious stigmatization. The same holds true for a potential response and risk biomarker which assesses inhibitory control functions. To classify a person with poor inhibitory control functions as a person with high recidivism risk and low therapeutic success, based solely on this marker, clearly is stigmatizing and unethical.

These short considerations point to special ethical challenges which arise with the development of potential biomarkers for pedophilia and child sexual abuse.

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CONCLUSION

The objective of this review was to examine the literature regarding potential biomarkers of pedophilia and child sexual offending and to describe their usefulness with respect to the diagnostic process, treatment evaluation, and risk assessment. First we presented an overview of the current neurobiological knowledge, as well as physiological and psychophysiological approaches to characterize pedophilia and child sexual offending. Secondly, we discussed and evaluated the impact of this knowledge on the development of biomarkers for diagnosis, therapy response, and risk assessment in pedophilic subjects and CSOs.

The development of a composite diagnostic biomarker to assess deviant sexual interest, combining several measures like fMRI, eye tracking, and behavioral approaches (including VR) seems to be most promising. Probably, characterizing sexual interest at different information processing levels (electrophysiological and hemodynamic responses, behavioral, and attentional processes) could lead to synergetic effects, thereby enhancing discrimination accuracy. A valid and reliable measurement of deviant sexual interest, insensitive to manipulations, could significantly support the clinical diagnostic process. With respect to pedophilia, such a biomarker would be a specific instrument, as it would aim to measure one of the core signs of pedophilia, that is, a sexual interest in children. Nevertheless, the underlying principles of this method, i.e., the measurement of attentional processes toward individually salient stimuli/objects, is not specifically bounded to the assessment of a deviant sexual interest. Rather, it could also be transferred to other diagnostic settings. Similarly, regarding therapy evaluation and risk assessment, a composite biomarker to assess inhibitory control functions seems to be promising. This should be accomplished at different information processing levels, but also with respect to different inhibitory control functions, such as simple (motor) response inhibition, cognitive inhibitory control, and complex behavioral control functions. In contrast to the biomarker of sexual interest, this potential biomarker would not be a specific marker for pedophilia and/or sexual child abuse. As mentioned above, impaired inhibitory control functions are known also for violent and psychopathic offenders, and their improvement is a central part of offender treatment in general.

In conclusion, a lot of research has enhanced our neurobiological knowledge about pedophilia and child sexual

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offending. However, in our view, according the criteria by Prata and colleagues (4), currently none of the above discussed parameters and approaches is ready to serve as a clinically applicable diagnostic, response, or predictive biomarker for pedophilia and child sexual offending. Therefore, further work remains to be done in order to identify the most useful biomarkers.

The application of the so called Research Domain Criteria (RDoC), a research initiative for new approaches to investigating and classifying mental disorders, made an approach to carry forward the research (accessed 18th June 2019, https://www. nimh.nih.gov/research/research-funded-by-nimh/rdoc/index. shtml). Abi-Dargham et al. suggested that this approach is directly relevant to the search for biomarkers because it aims to identify valid elements, such as genes, molecules, cells, circuits, physiological measures, or behavior, that are associated with specific cognitive constructs across different systems (5). Altered inhibitory control functions, for instance, are a common deficit in several mental disorders, and not limited to any DSMcategory or child sexual offending in particular. The RDoC approach contains a domain "cognitive systems" including the construct "cognitive control" (accessed 18th June 2019, https:// www.nimh.nih.gov/research/research-funded-by-nimh/rdoc/ constructs/cognitive-systems.shtml). Bringing together research results about impaired cognitive control, independent of any diagnosis, would enhance our knowledge about this construct and alterations in mental disorders, and hence facilitate the development of appropriate biomarkers.

AUTHOR CONTRIBUTIONS

KJ conducted literature searches and wrote the first draft of the manuscript. TW gave substantial linguistic support. TW, PF, IM and JM were involved in an intensive drafting and revision of the manuscript. All authors have read and approved the final manuscript.

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A "Necessary Evil": Staff Perspectives of Soft Restraint Kit Use in a High-Security Hospital

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Introduction: Forensic mental health nurses working at the forefront of services can intermittently face enduring and somewhat harrowing or stressful situations. Enclosed is an example of the use of mechanical restraints (Soft Restraint Kit) for a two month period. Staff experience of working under such circumstances is an under reported area.

Methods: The experience of nursing a patient under extreme conditions was captured through use of a qualitative study, using semi structured interviews with a purposive sample of (n = 10) staff nurses and nursing assistants in a high-security hospital.

Results: Thematic analysis was undertaken generating four themes: sense of responsibility, aptitude, enablers/inhibitors, and consequence. Conclusions suggest that Soft Restraint Kits provide a useful method of containment, although prolonged use presents considerable challenges for staff. The importance of preparation and training cannot be underestimated and continued support and supervision are absolutely essential

Keywords: mechanical restraints, emergency response belts, forensic mental health, soft restraint kit, high secure hospital, seclusion and restraint

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INTRODUCTION

Nurses need to ensure they are actively involved in discussions relating to the management of violence, because staff safety is a primary concern in forensic mental health facilities (1). It is widely reported that high secure hospitals across the UK experience a high number of violent and aggressive incidents (2). Different strategies and approaches are used to deal with violent and threatening behaviour (3). In secure settings, physical, relational and procedural security measures are implemented in order that care can be safely delivered whilst at the same time risk can be managed (4). Due to the complexity of violence as a phenomenon it is perhaps best dealt with using a multi-professional approach (5).

Conflict and containment, for example, seclusion and manual restraint are important matters for hospital management and nursing practice (6). Extreme measures, such as those highlighted, are most commonly used when there is a risk of harm to others (7). It is the increasing emphasis on the use of restrictive practices that is a concern and seclusion is becoming a contentious practice (8). The challenge to clinicians, especially nurses, is to provide a safe environment while dealing with volatile patients and they may have little alternative to seclusion, having exhausted all other

interventions (8). Nursing perspectives on the subject of reducing and eliminating containment methods, such as seclusion and mechanical restraint, have recently been captured through a large scale survey undertaken in Australia (9). Respondents viewed these containment methods as last resorts to maintain staff and patient safety.

Precipitants for seclusion are usually impending bodily harm to the patient or others and suicidal behaviour (5, 10); although NICE guidelines (2015) (11) never recommend seclusion for self harm or suicidal behaviour. The highest seclusion rates tend to be found in patients with diagnoses of psychosis, mania, personality disorder and intellectual disability (12).

A number of challenges emerge when patients demonstrate extreme violence repeatedly, especially when they require prolonged use of physical restraint. In such circumstances the use of mechanical constraints is usually considered. The rationale for this is linked to the risks to a person's life from positional asphyxia. This can be brought on by many factors including a prolonged struggle and restraining of a person for extended periods of time in the prone (face down) position, especially if weight is applied to their back. People who are obese, on highdose anti-psychotics or have pre-existing cardiac or respiratory conditions are particularly high risk in this position. Chan et al. (13) directly measured the restrictions on breathing during physical restraint and observed a 10% reduction in the supine (face up) position compared with a 15% reduction in the prone position. As a consequence of this risk to life, exploration regarding other restraint devices, which may allow a greater degree of control over prolonged violent persons, has been conducted within the research realm, and in the year 2000 led some organisations to adopt the use of a mechanical restraint called Emergency Response Belts (ERB's). The name was changed to Soft Restraint Kits (SRK) around 2017, these two terms will be used interchangeably throughout, because ERBs was the term used when the research was carried out in 2016.

Use of Soft Restraint Kits (SRK) in high secure hospitals

SRKs are used in a number of different situations, primarily to enable safe movement or transportation of a patient, or to temporarily immobilise the patient to enable treatment to be administered. SRKs are used in situations where the patient is violent, highly resistive or extremely volatile and unpredictable and where, without the use of SRKs, such interventions would present significant risks to the safety of staff, the general public or the patient.

Within the Mechanical Restraint System policy of the Scottish high secure hospital, the use of SRKs must be a reasonable and proportionate response to the risk presented by the patient. The decision to apply mechanical restraint is a clinical decision and must be underpinned by a clear clinical rationale and treatment plan that details the clinical monitoring regime, the reporting regime, and the review procedures associated with the intervention.

There are three patients currently prescribed SRKs within the Scottish high secure hospital. Governance of their use is stringent. The prescription of use is for instances of extreme prolonged violence, serious self-harm and for treatment or medical attention, obtain blood samples and the relocation in the event of a fire evacuation. Their use requires approval from two Directors from the Senior Management Team and from the Mental Welfare Commission (an external governing body). Prior to the current research project the use of SRKs had been brief and limited to the transportation for medical intervention to a general hospital; they had never been used for prolonged periods such as the situation under scrutiny. This was quite a unique situation, worthy of evaluation.

Effects on the Nursing Role and Relationship

Although ward based nurses within forensic mental health, settings have many important roles, including maintaining a safe and secure environment, a priority is to establish the caring nurse-patient relationship (14). It is this priority that creates the difficulty when the patient is in seclusion, extended time-out or using SRKs. Patients who display significant challenging or dangerous behaviours may require a tailored care plan enabling them to be cared for in isolation from their peers. In these exceptional circumstances, there may be a need to modify their environment and at times have their own nursing care team, separate from the ward. In the most extreme cases, seclusion and/or extended time-out may last for prolonged periods of the day, sometimes months and years.

The role of a nurse and the relationship and interactions between a nurse and patient within forensic psychiatric care has received increased interest over the past few decades (15-19). Some of the literature associated with seclusion reflects a negative view of caring for in-patients within psychiatric care. The focus is predominantly on decision-making and management procedures (20, 21), nurses and patients attitudes (22–24) and the satisfaction of service users expectations of mental health care (25, 26). There seems to be a dearth of literature exploring the role and relationship of the nurse and the extreme cases of patients detained within high secure forensic services with tailored nursing care plans when cared for in seclusion and self-isolation including patients using SRK's (27). A more recent review suggests, that many clinicians support the use of seclusion as a safe, and even therapeutic, intervention (28). Perhaps these positive attitudes towards seclusion would diminish if it was used less frequently.

Aim

The aim of this study is to explore the perceptions of staff nursing a patient in Soft Restraint Kits over a sustained period of time.

Methodology

In order to achieve the aim and address the research questions a qualitative method was adopted. The greatest strength of qualitative design is that it enables the researcher to study phenomena which would otherwise be unachievable (29). It also allows the researcher to acquire a more in-depth understanding of the phenomena (30) and enables participant's thoughts, feelings and experiences to be heard (31). As this study sought to explore participant's perceptions

which are likely to include thoughts feelings and experiences directly relating to the use of SRKs, then this design was deemed suitable.

METHOD

Case study

This article is based on the experience of managing one particular case, personal details are restricted in order to maintain anonymity. Mr E was admitted to the high secure hospital following a serious offence. He presented with florid psychotic symptoms, was unresponsive to medication and was unmanageable within the main ward. The level of violence towards himself and others escalated over a period of weeks and was so extreme and of sufficient intensity that a decision was made by the Senior Management Team to use mechanical restraint - SRK - as part of his ongoing care and treatment programme. The patient was isolated from the main ward and nursed in the Modified Strong Room (MSR), more commonly used for seclusion. Initially three belts were used with soft cuffs, one on the chest, abdomen and knees. The patient was lying in a supine position on the floor. The belts were on twenty four hours a day. Gradually, one by one the belts were loosened then removed entirely.

Research questions

- What is the role of the nurse in caring for patients using SRK's?
- What are the factors that influence and inhibit the role of the nurse in caring for patients using SRK's?
- What skills are required to assess, plan and record interventions related to caring for patients using SRK's?

Sample

A purposive sample of ten registered and unregistered female and male staff drawn from wards across the high secure hospital were selected for interview by the Principal Investigator (PI); the PI was a Consultant Nurse who had worked in forensic services for nearly twenty years. Demographic details of the sample were limited once again to protect the anonymity of participants. Braun and Clarke (32) maintain that sample size of 15 - 30 participants is typical of a qualitative study; however these numbers can vary depending on what information is being sought. This size of sample is perhaps small but acceptable for the purpose of gathering useful information on this specialist subject, and did include 50% of the staff trained in the use of SRKs at the time. The sample was identified through discussion with Lead Nurses within the hospital. This particular group had been directly involved in the care and treatment of the patient during the two month period the patient was restrained using SRKs and were thus in an ideal position to reflect on their experience. They were all very experience members of staff, having worked in the hospital for many years; part of a small group of twenty who had received specialist (one day) training in the use of ERBs prior to implementation.

Interview

Rather than use structured interview whereby the information gathered could have been restricted, semi-structured interviews were undertaken allowing participants the flexibility to explain their own experiences in detail without being restricted to a tight framework (33). The main questions forming the basis of the interview guide were: 1) what are the skills and roles of the nurse? 2) is there anything that inhibits/enhances the way that you work? 3) what qualities are required to be able to work with people in ERBs? 4) what do you think about the training that was provided? 5) how would you describe the nurse patient relationship in these circumstances?

Ethical considerations

All participants were approached by the PI and given an information leaflet offering details of the study. They were advised they had seven days to consider their involvement, but were under no obligation to do so. Following the seven day period they were re-approached by the PI and asked to sign a consent form prior to participation. Participants were assured that as far as possible their anonymity would be preserved when reporting. All participants were issued a unique identifier (P1–P10). The confidential data they provided was stored in a locked cabinet in the PIs office, where only researchers have access. Due to changes in legislation in 2012 in the United Kingdom staff interviews no longer require ethical approval from the Integrated Research Application Service (IRAS). The proposal was still subject to scrutiny through the local Research Committee.

Data analysis

Thematic analysis (TA) was used to analyse the data generated from the semi-structured interviews carried out by the first author. TA was selected over Interpretive Phenomenological Analysis (IPA) for pragmatic reasons. There were ten people available for interview (n=10) and the interviews were likely to be shorter using TA, thus less time would be used for transcription; this was part of a wider study which had a restricted time-frame. Thematic analysis is a method for identifying and interpreting themes from the data (34). The advantages of this type of analysis are that it is a flexible and useful research tool, which can provide a rich and detailed account of the data (35). Analysis begins with reading and familiarising of the data. Initial codes are then made which involved organising the data into meaningful groups. The data is then read and reread with the aim of identifying repeated patterns and how different codes may combine to form a theme. The data analysis includes multiple levels of interpretation to detect inconsistencies, contradictions and researcher bias (35). Finally, once the themes are generated the validity of the themes in relation to the data set are considered. This ensures that the themes reflect an accurate representation of the data that is transparent to the reader.

Rigour

Both authors were from a nursing background and had significant research experience, thus had credibility with the participants because they were able to relate to them. The first

author no longer works in the organisation so there was no personal connection and this prevented any perceived and undue pressure on participants, in addition to reducing the chance of biased responses. Interviews were undertaken, transcribed and analysed by the co-authors. Following transcription the scripts were returned to each participant to check for accuracy. This process of respondent validation is well recognised as a strategy used to ensure the strength and credibility of the research (36, 37). Both researchers (HW and LT) reviewed each transcript against their original audio file. The content of the interviews was compared and contrasted in order to ensure saturation had been reached. The views expressed represent a comprehensive review of staff experiences. The underlying patterns and notions that emerged into themes were based on the reflections of the co-authors and quotes to match each theme were selected by mutual agreement.

RESULTS

Four major themes were identified from the transcripts: sense of responsibility, aptitude, inhibitors and enablers and consequence. All of these themes (in bold) were further subdivided based on the analysis (in italics) see **Box 1** for a summary of all themes.

Sense of Responsibility

There was an overwhelming 'Sense of Responsibility' voice by the nurses, making this the first super-ordinate theme. The strength of emotion stafffelt was palpable and this clearly affected the role they assumed. The tensions between what they thought they ought to do as a nurse and what was being asked of them in this dynamic situation was evident. Their thoughts were firstly for the patient and secondly for themselves and this sense of professionalism was

BOX 1 | Summary of super-ordinate and sub-ordinate themes emerging from interviews.

Sub-тнеме	
Changes over time	
Compassion Patient Safety	
Staff Safety	
Dignity	
Maintaining hope	
Observation skills – recording/monitoring Physical skills - attending to needs Relational skills - maintaining therapeutic relationship	
Restricted movement	
Acts of violence	
Patient's Mental State	
Training Feeling valued	
Withdrawal	
Intensity	
Pressure	
Anxiety Burnout	

admirable. Sub-ordinate themes included changes over time, compassion, patient safety, staff safety and dignity.

Changes Over Time

In relation to the role and the skills used, there was a suggestion that the role changes over time.

'It changes minute to minute, day to day, you have to adapt your role to meet the patient's needs at that time' (P2).

For some participants changes over time intimated a more positive attitude towards the ERBs.

'Initially I was taken aback a wee bit, the patient was cuffed up and strapped, lying down on the ground and I thoughthow did we get to this stage? How are we going to feed him and get him to the toilet? Once we got used to the process it seemed easier as time went onI did wonder if he was ever going to get better.... there is a kind of release on the nursing staff though because once you get someone into the belts there's less chance that the patient can assault them, so they don't feel under threat anymore – but on the other side the patient's anxiety increases' (P10).

Not everyone shared this view, one participant was more reticent.

'I'm not sure if peoples' attitudes do change over time, people seem to get their head around it and think it can be acceptable in the short term, but it's definitely not ideal for long term use.....the waters are muddied a bit on this one' (P1).

Compassion

Compassion was expressed when reflecting on the situation under which the patient was being nursed.

'It had to be done, although it was not a pleasant experience, it's not nice, I felt terrible having to do it. I felt bad because I've never seen a patient so stressed....it was kind of sad, when it gets to that stage that someone's mental health has deteriorate so much that they are so violent, but they are in total crisis, that this is what it's come to – that you're having to use mechanical restraints' (P4).

Patient Safety

Patient Safety was at the forefront of participants' minds and a pragmatic focus was evident.

'Right from the start when you're putting them (the belts) on, you are making sure they are safe and secure ... they (the patient) are very dependent on you ... if you're not there they're going to injure themselves'(P1).

'I think it's very effective....the fact that you're keeping the patient safe is good, there's nothing worse than seeing somebody mentally unwell slapping themselves off walls and things like that, so the fact you're keeping them safe is good'....it's very hard to beat' (P2).

Others questioned the approach to patient safety and wondered if something else could be done.

'I know the reasons why we're having to use it, but it still goes against the grain of what you've been taught, I'm talking about de-escalation, least restrictive and this is at the end really' (P4).

Staff Safety

Staff safety was also highlighted and participants commented on how the use of ERBs reduced the risk for everyone involved.

'From a purely security point of view and keeping the staff and other patients safe then it's good, but not ideal ... it's like a necessary evil' (P1).

It allows us to administer treatment safely, to protect the patient and other people. I do think there are lots of benefits from the ERBs as long as it is safely governed, that is vital ... they have worked wonders for some of our patients.... I've only ever seen them used in extreme cases where there was absolutely no other way we would have been able to administer medicine....I wouldn't like to see them used regularly; it worked for this patient – thankfully- it allowed him to get medicated and recover' (P3).

Dignity

The issue of dignity evoked a strong response and divided opinion, around half the participants felt the ERBs helped maintain dignity.

'When used for emergency treatment it preserves patient's dignity because they can be put in a wheelchair with a blanket over them (when taken to a general hospital)', this maybe reduces the stigma rather than in handcuffs or holds with three members of staff (P3).

'I think it's more dignified, it's less restrictive and it does give patient that space, so you don't need three people on top of the person....in that respect it's more acceptable' (P6).

The other half were more dismissive, commenting on the fact it could be degrading and limits independence.

'From a nursing point of view I'm not sure it's as dignified as it could be for the patients, if I'm honest.... the patient is totally powerless at the end of the day' (P1).

Maintaining Hope

The resilience demonstrated by staff was remarkable and it seemed to be drawn from their need to maintain hope.

'You'd come in each day and count the belts and sometimes your heart would just sink because there was one more than yesterday, but it was great when it worked the other way round' (P5).

'Amidst torrid abuse 'there were spells of times when the patient was humorous and showed a likeable side to him..... that kept us going' (P6).

Aptitude

The wider role of the nurse was captured under the second super-ordinate theme 'Aptitude'. This is where the competence of nurses emerged and both practical and relational elements were highlighted. Sub-ordinate themes included observation skills, physical skills and relational skills.

Observation Skills

All staff were of the impression that monitoring was done in keeping with the policy, yet their reporting on the frequency of checks was variable.

'Checks need to be done a minimum of 4 hourly, but you would be constantly checking, when applied the belts are checked for tightness anyway but you would check to see they (the patient) are breathing ok'. 'You also need to check the colour in their fingers'. Routine monitoring of the physical stuff is done. There should be an up to date care plan that includes why we've put them on, what the objectives are and we need to make sure that it is reviewed regularly'(P3).

There also seemed to be inconsistency in views relating to recording and reporting.

'There's nothing formal in regard to what you put in the nursing report, unless just a brief sum up of the checks and stuff you have been doing. Normally we would just write about how the patient's been and present a story of what's happened in the last 2 hours or so - notes were entered into the electronic patient recording system RIO....a bit of structure would be good so that things don't get missed'(P4).

'We put a formal process in place for recording as we didn't have a proper policy, because we hadn't used the process before and we thought it better to record too much rather than not enough' 'physical observations had to be carried out and recorded, they were checked, I think every 2 or 4 hours. I think we were a bit cautious and we maybe didn't need to do the observations quite as much'(P6).

Physical Skills

Attending to physical needs was much more of an issue than participants originally anticipated, and it created quite a strength of feeing.

'We did what we had to do – it was like caring for the elderly....we had to do everything for him, feed him toilet him, wash him – there's no dignity in that' (P10). 'Because you were feeding him, giving him fluids, cleaning him and so on, that in itself puts a certain amount of dependency on you. He was defecating and urinating in the belts deliberately – that was behavioural – it seemed to be the only way he could get back at us..... what else could he do' (P6).

Relational Skills

There were mixed views in relation to people's ability to develop and maintain a therapeutic relationship with the patient. One or two participants were quite adamant that...

'It's much easier to nurse people in ERBs when you know them' (P7).'The opportunity to develop a therapeutic relationship was there because you were spending so much time with him; it didn't seem much different to working with any other patient. I don't think the ERBs changed it in any way, shape or form at all, the good thing was that the guy was seeing the same people everyday...but from a personal view you just get on with it' (P6).

Normalising the experience was important to staff.

'You need to make sure you are still treating them (the patient) as you normally would, whether nine times out of ten they are there because they have been assaultive, you need to make sure you're not being judgemental, that you are trying to maintain a normal relationship with them' (P4).

Others thought perhaps the patients understanding of why ERBs were applied might have affected the relationship.

'Because his behaviour was mostly mental health driven at least we still had a bit of a good relationship with the guy and as his mental health started to improve the relationship started to build itself back up. There was no him and us sort of thing, it was just a case of keep going to get through to him' (P2).

Arguably, close proximity helps to maintain a therapeutic relationship

'You could say it didn't hinder the relationship because you were with one person instead of 12 in a ward, so you're closer with him and engaging with him' (P2).

Inhibitors and Enablers

The third theme outlines some of the more positive and negative aspects of working with patients in ERBs, entitled: Inhibitors and Enablers'; This was broken down into five sub-ordinate themes—the first three were inhibitors and the last two enablers: restricted movement, acts of violence, patient's mental state, training, and feeling valued.

There were clear challenges due to the circumstances and things that got in the way of good practice, these were identified as 'Inhibitors'.

Restricted Movement

Staff struggled with the restrictions of the environment.

'It's hard though because of the position he's in, belted up and you have very limited movement, they don't want to engage with you ... when dealing with this guy he just wanted to get out so he could hit you' (P2). 'You can't use touch – if you know the patient well you can use a certain level of touch to reassure them, but you don't in this situation, you kind of stand back and observe the patient – it acts like a barrier between you and the patient – physically and the way you relate.....their social interactions are completely different' (P10).

Acts of Violence

The violence continued, despite the use of the ERBs and staff needed to react quickly on many occasions.

'The level of aggression was so intense...at one point he was going to throw a cup of tea over me, but we were close enough that we were able to intervene quickly'(P8). 'He tended to get angry. It was behaviours, he would describe it as 'night dreams', and if he woke up from a 'night dream' he would be frightened - that could kick the behaviour off....I think he was genuinely frightened of being killed ... the behaviour would go on for a long time. I think he was happy for the staff to be in close proximity still having to hold him. Even though he was in the mechanical restraint the staff still had to hold his arms to prevent him thrashing himself about, he could still do himself a lot of damage if not held. This may be why he was spitting and urinating, because of his frustrations linked to us preventing him hurting himself (P6).

Patient's Mental State

The struggle to comprehend what was driving the behaviours was unclear and staff wanted to believe it was due to the patient's mental state rather than it being deliberate and calculated.

'He was so unwell it was hard to know what he was taking in and he needed a lot of reassurance to make him believe we were actually trying to help him....his

$\ensuremath{\mathsf{BOX}}\xspace 2$ | Qualities of the forensic nurse identified by ward staff involved in using ERBs/SRKs.

'You need a 'long attention span'....you're stuck there and you can't go there or get anything if there's only two of you trained in ERBs, you can't even get to the toilet.

'You've got to be 'thick skinned' I think you've got to be like that to work in this type of area anyway because the abuse is going to come at you regardless of the ERBs. You deal with that kind of stuff in clinical supervision' (P1).

'You can't be a shrinking violet and you've **got to be able to take the abuse and not personalise it.** I certainly wouldn't put a new staff nurse into that situationI think it would finish a lot of people off. I think you're looking for **experienced** people that have been here a relative length of time so they are able to adapt to situations' (P7).

'You tend to be working with a high profile patient and you are more open to scrutiny, that's why it's better to be experienced, 'be good at building rapport quite quickly with a patient' (P6).

'You really need to be resilient' (P5).

'Be tolerant – especially when you are repeatedly being insulted, the insults were quite bad (sexually explicit, racist) which seemed deliberate. If bored he'd comment on something that would maybe get a reaction, for example, something homophobic, although staff tried not to react, if they did, he'd continue to press the buttons; **you need to know when you need to take a break**' (P10).

'Be very patient, understanding and be able to relate to the patient' (P9).

Be calm, objective, feel confident in the job they are doing ... people have to feel confident using the equipment and they have to feel supported ... they also have to be effective communicators and be very observant and have good negotiating skills'. When people are put into a situation where they use something that they don't use all the time, that can be very anxiety provoking for them. I think the adrenalin could be surging and sometimes it's trying to get hings done as fast as you can, possibly just because you want done....that's where others can help and can slow it down a bit, you're not just working on your own, it's about being part of a team and being a team player' (P8).

mental state was very poor, he had a fixed belief that he was here to be harmed and to be murdered, he seemed to be fighting for his life......' (P10)

Participants were able to identify things that helped the role, identified here as 'Enablers'; also see **Box 2**.

Training

Staff were provided with one day training in the use of ERBs.

'It was important that they knew about the governance of their use, the legislation and when it was appropriate to remove them immediately if there were physical problems. They also needed an underpinning knowledge of the risk factors. Staff needed to know what was expected of them whilst nursing a patient in ERBs, and the associated benefits of their use. They need to know they should never work outwith their capabilities, and they should never make decisions alone – they are a team' (P3).

Training did prepare you.

'The one day training is great, you feel really confident at the end of the day. If you are using ERBs regularly, but if you have one day training 7 or 8 months before you use it then that's different. When you're doing the training you are having the ERBs applied to yourself and it gives you a sense of how it feels, it does really feel weird and it doesn't feel good to be honest, but it gives you an idea of what it's like' (P4).

Some reported feeling less ready.

'I didn't feel adequately prepared or confident about the task being asked" Felt shocked, worried, what if something goes wrong?, what are the repercussions if something bad happens?' (P9).

Feeling Valued

The whole process was protracted, extending across a few months. Staff simply wanted their continued efforts to be acknowledged, because of the huge amount of pressure they were under to get this right; given it was the first use of ERBs for an extended period.

'You really want support from your line managers as well ... you want some recognition of you know ... you are coming in here day in day out, dealing with a really challenging patient, you're using equipment that is predominantly unfamiliar to you, you're being exposed to a whole array of stuff, verbal abuse, potential assaults, patients trying to self harm which can be quite distressing. So I think the recognition for the staff would be good and an acknowledgement of the difficulties people face'(P8).

Consequence

The fourth and final theme was 'Consequence'. In any new situation where there is a test of change there is chance there will be a mixed response. Nursing assistants seemed very able to cope and shut off from the abuse, perhaps this is due to the fact they are with patients most of their working shift. There was a tendency for more registered staff withdrawing.

Withdrawal

Involvement in the use of ERBs was voluntary initially and despite wanting to continue a small number dropped out of the delivery team.

'Reasons for withdrawal – not doing what was agreed at the outset, 'veering from the agreed plan', rules and methods seemed to be changing and it was frightening' (P4).

Intensity

The staff who were on the ward where the patient was in ERBs were more likely to be involved regularly and felt the brunt of the intervention. There was an acknowledgement from all participants that it could be difficult and perhaps challenging if it was regular practice.

'It was hard physically, because at first you were bent over and on your knees most of the shift and it becomes really uncomfortable. The patient is very dependent on you, you can't leave their side, you are there for total care. You're knackered at the end of a shift, cause it can be really tense, if he's unsettled and you're medicating then restraining, by the end of the night shift you just want to go home' (P1).

Pressure

Pressure affected some more than others:

'There's a lot of pressure on you because we feel that this guy ... the state that this guy is in he could actually die in these belts quite easy because they are quite restrictive and that's what they're designed for.to cut down the amount of injuries to him and us. You would go home physically knackered and mentally drained.... it's harder than the usual work' (P2).

'You need to be able to soak up the pressure a wee bit in these situations ... you feel a sense of responsibility to do it too.... the reason I did it was because I was the key worker for the patient and I didn't want to let my patient down. It didn't really get to me' (P7).

Anxiety

Anxiety was evident amongst some but not all participants.

'You never quite know if the ERB's are going to work and everything's going to be quite safe when patients are in them – which you would kind of anticipate – but people are still getting hurt whilst they are in them so you're constantly on edge' (P3).

'I wasn't that anxious, but I could understand people being a bit anxious because of the threat' (P6).

Burnout

Burnout.... was it inevitable?

'It could very easily be an area where staff cold burnout ... there's a high risk of that....I know there are people who have been involved then asked to get moved away

and then decided not to update their training.....it was because they found it very difficult' (P6).

'There was a horrible feeling of dread coming into work in the morning.... I avoided answering the phone at night ... I didn't want another shift' (P9).

DISCUSSION

Despite the controversy over the use of seclusion and restraint, they are commonly used to treat and manage disruptive and violent behaviour (5). The more limited literature on the subject of mechanical restraints (27) makes it quite difficult to generate comparisons with findings from this current study. There certainly seems to be a move towards reducing the use of seclusion and restraint (7, 38, 39).

One large scale quantitative Australian study, reported on 512 nursing perceptions of reducing containment methods such as seclusion and mechanical restraint (9). A number of questionnaires were used to elicit responses and results do resonate with the findings from our small sample, especially in relation to nurses using their clinical skills to maintain safety.

This report focuses on a relatively unique situation for nursing staff where individual experiences were quite discrete and varied. The role of the nurse has been highlighted and many examples offered. Staff all understood the rationale for use of the SRKs and were willing participants, because they realised this was the safest option for that particular patient at that point in time. One body of literature suggests that the more professionals are personally involved in these processes the more positive they evaluate them (40, 41) and we would tend to agree with this based on the feedback from our sample; despite the difficulties incurred along the way. The necessity of restraint and use of various containment methods is supported in the context of dangerous situations, albeit as a last resort to protect both patients and staff alike (42). There is evidence to support the use of SRKs here, some staff attitudes changed over time becoming less anxious and more accepting as time progressed, however, this does not apply to everyone.

Factors that influence and inhibit the role centred around the importance of being prepared through training and feeling valued by management. Benefits of training and preparedness generally reduce anxiety even in highly tense situations such as this, indeed it should be considered an essential component of any new initiative. Through brief discussion with one member of Senior Management, from their perspective, they felt they were wholly supportive of staff.

There still appears to be a conflict in staff views with regard to the use of mechanical restraint as a method of containment, which is also reflected in the literature. Over the past decade seclusion with or without restraint has been considered therapeutic (43, 44), others have viewed it as a control measure (45). Recent reports from Gerace and Muir-

cochrane (9) consider these extreme measures to be deleterious to relationships with patients. Our sample were predominantly positive about the need for SRKs but this initial experience was clearly difficult for them on a number of different levels; they were torn on the issue of therapeutic value. For this reason a small number (two) of the original group of twenty were allowed to withdraw from participation.

It would be of real interest if there was more literature on the subject, extending beyond staff perspectives, to include patients' views; this might enable others to benefit from the learned few. A recent example of eight forensic patients' perspectives was reported by Askola et al. (46), in this study patients' narratives contained different themes telling different things. The suggestion was that patient's experiences of their treatment could potentially improve the quality of patient centred care.

The Hospital involved in this study did learn from the experience and a decision was made to make training in the use of SRKs mandatory for all registered nurses, in order to minimise and hopefully eradicate burnout. Several mentioned that it might have been easier if they could have shared the load with a wider group of people and that may have served to reduced the intensity of the experience.

Two years on the patient was functioning well and was enjoying grounds access. His parents were delighted with the outcome and praised the Senior Management Team for the extreme steps they took to care for their son, because they were struggling to see any resolution to the situation.

STRENGTHS/LIMITATIONS

This study offered an excellent opportunity to capture the perspectives of nurses working under extremely difficult circumstances, necessitating the use of mechanical restraints with a very disturbed and distressed patient. This was a small scale study on a single site and views of the limited number of participants may not necessarily be representative of the wider forensic nursing population. There is also the likelihood of recall bias since the study was undertaken more than six months after the staff had been actively involved in the use of SRKs. This may also account for the discrepancies in reporting on procedures for recording and reporting. If future research could capture the patients' perspective this would be of real interest to clinicians. To repeat the research in the same organisation now that all nursing staff are trained in the use of SRKs would also be of interest.

CONCLUSIONS

This was a small scale study undertaken to capture the views of staff nursing a patient for an extended period using SRKs. The sampling techniques, data collection and analysis selected reflect the research approach used to enhance the credibility, trustworthiness and dependability of findings. Use of SRKs as a containment method generated a mixed response, perhaps best summarised as 'a necessary evil, but a last resort'. In some sense, the patients who are deemed to require use of SRK test the limits of therapeutic relationships and relational security. Four clear themes were generated from discussions held with nursing staff. The first related to a clear 'sense of responsibility', with a tendency for opinion to change over time. Staff felt compassion towards the patient empathising with the situation he was in and made every effort to maintain some level of dignity. Patient and staff safety were of paramount importance, but maintaining hope was just as crucial to the success of the care plan. The second theme related to 'aptitude' employed whilst caring for a patient in SRKs. The necessity for good observations skills and an aptitude to record are report accurately was highlighted. The dawning realisation that all needs had to be attended to was something that staff had perhaps given less thought to during their preparation, but the stark reality of the situation meant they had to find ways to effectively deal with each issue as it emerged. Developing and maintaining a therapeutic relationship was more difficult for some than others and the SRKs seemed to instantly provide a barrier to engagement. A number of inhibitors and enables were identified through interview, generating the third theme. The constant extremes of verbal abuse and violent behaviour presented challenges and staff had to use their clinical skills to deal with this. Yet the patient's poor mental state, which most believed was driving the behaviour, was the thing that staff focussed on more. Training did make the role easier, but feeling valued was even more important. The final theme was 'consequence'. It became apparent that the pressure and intensity of managing this violent patient weighed heavily on the staff creating increased anxiety and a degree of burnout. It is crucial that staff are supported and protected from the potential unwelcome impact.

Implications for practice

Situations such as that reported here are somewhat unconventional, even for forensic mental health care, but much has been learnt from these early experiences in an NHS facility:

- the use of SRKs can offer an effective method of managing extremely violent behaviour in a relatively safe and contained manner;
- preparation and planning for SRK use is essential and until people are placed in a live situation they are quite unaware of the impact it can have;
- the training could include something on the potential psychological emotional impact on staff and brief refreshers once a year should be considered;.
- support and supervision of staff is recommended during a sustained period of practice using mechanical restraints, reflective practice groups could be particularly beneficial.

DATA AVAILABILITY STATEMENT

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

ETHICS STATEMENT

Ethics approval was not required as per local legislation and guidelines. The patients/participants provided their written informed consent to participate in this study.

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Both authors contributed to the design and delivery of the study in addition to the write up of the article.

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Highly Structured Treatment Programs for Addicted Offenders: Comparing the Effects of the Reasoning & Rehabilitation Program and DBT-F

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Background: When treating addicted offenders in a forensic psychiatric setting, a primary concern is to decrease antisocial cognitions and behaviors. The cognitive style of offenders is often characterized by impulsiveness, egocentricity, irrational thinking, and rigidity. We examined the relative efficacy of Reasoning and Rehabilitation Program (R&R) and Dialectical Behavioral Therapy– Forensic (DBT-F) on the domains of underlying psychological constructs (e.g., mental flexibility, planning, and problem-solving).

Materials and Methods: The R&R and DBT-F were introduced in a forensic-psychiatric hospital for offenders with substance addictions in Germany. We compared pre- and post-tests to measure the cognitive skills of addicted offenders having undergone R&R (N = 47), DBT-F (N = 34), or Treatment as Usual (TAU; N = 28). Participants' skills (cognitive flexibility, ability to inhibit cognitive interference, cognitive performance/mental speed, divergent and convergent reasoning/problem solving) were assessed using neuropsychological instruments. Analyses of variance were conducted to investigate whether there were significant improvements within groups and whether these differences were significant between groups. To examine the predictive power of treatment-program on outcomes, and diagnosis of personality disorder, a hierarchical regression model was used.

Results: Both programs were associated with improvements in nearly all of the measured constructs. The only construct on which the R&R and DBT-F groups differed significantly was word fluency, with those receiving R&R improving more than those receiving DBT-F. A regression model showed no predictive power for age, IQ, or diagnosis of personality disorder. Treatment group explained 13.8% of variance in cognitive flexibility but did not predict variance in other outcomes.

Conclusion: Surprisingly, we did not find superiority for one intervention over TAU or differential effects between the two programs. Future research should use larger samples

and additional outcomes, including recidivism, to identify possible effects of treatment programs. Additionally, qualitative methods might inform us about these programs are implemented as well as which outcomes may be relevant.

Keywords: forensic psychiatry, addicted offenders, substance misuse, Reasoning and Rehabilitation Program, Dialectical Behavioral Therapy- Forensic, cognitive skills, § 64 StGB

INTRODUCTION

Under § 64 Strafgesetzbuch [StGB (German Criminal Code); (1)], courts can order individuals convicted of an offense to undergo addiction treatment if they suffer from a substance use disorder linked to their offense. Furthermore, "such order is only to be made if there is a sufficiently reasonable prospect that the person can be cured [...] by way of placement in an addiction treatment facility or that a relapse into addictive behavior and the commission of serious unlawful acts caused by that proclivity can be prevented for a substantial period of time." [\$64 StGB; (1)]. The maximum length of stay is related to the prison sentence given at the same time, specifically it cannot be longer than two years plus two thirds of this prison sentence but is usually much shorter than that. The average length of stay is two years (2).

Mentally disordered offenders (mostly diagnosed with psychotic disorders, severe intellectual disabilities, or disorders of sexual preference) are treated in forensic-psychiatric hospitals according § 63 StGB on the condition that they have committed an offense in a state of criminal irresponsibility or of diminished responsibility. In addition, the person must represent a danger to the general public due to the risk of committing a serious offense in the future.

In 2013 (latest official figures), there were over 3,600 persons in forensic-psychiatric hospitals detained under § 64 StGB (3). In 2009—the starting point of our project—a survey identified that the §64-population is mostly male (almost 95%) and has an average age of 33.4 years. The patients had on average 8.5 offenses prior to admission, almost 40% were addicted to alcohol or psychotropic medication and 60% to illegal drugs (4). Seventy percent of the population was not diagnosed with a personality disorder (PD), about 13% had an antisocial PD (ASPD), about 4% an emotionally unstable PD, and almost 10% combined PD. The most common index offense was bodily harm (about 32.5%), sex offenses (about 28%), and drug offenses (about 22%). Information on criminal responsibility was not collected at that time.

More recent data from the same longitudinal study indicated that this population is still characterized by male gender (95.2%), an average age of 34.46 years, but that the largest group of index offenses are now drug-offenses (about 33%), followed by bodily harm (26%), and robbery (21%) (5). Individuals had an average of 9.61 previous convictions. Thirty nine percent were diagnosed with polytoxicomania, 19% had an alcohol related disorder, about 13% were addicted to cannabinoids, 10% to opioids, 9% to cocaine, 8% to stimulants, and less than 1% were addicted to sedatives or hypnotics. About 24% of the male forensic inpatients had an ASPD, 9% an emotionally unstable PD, 18% a combined

PD, and around 66% had no PD. About 64% of the 2018-population were fully criminally responsible. In sum, the patients have gotten older, have a greater number of previous convictions, are less addicted to alcohol, but increasingly polytoxicomanic and/or addicted to illegal substances. The vast majority is criminally responsible and has no psychiatric co-morbidity.

The recidivism rates of these offenders are up to 50%, 3 years after discharge from inpatient treatment (6-9), considerably higher than those of forensic inpatients with other mental disorders (around 5% after three years in § 63 population). Seifert et al. (10) examined recidivism rates of § 63 offenders for a follow-up period of 16.5 years on average (N = 321). They observed re-offenses in about one third of released forensic patients (35.2%), severe criminal acts (violent crimes or sexual offenses) were committed by 12.8%, and 15.6% were detained in a forensic setting again. The authors observed that the risk for recidivism decreased in patients with schizophrenic disorders but only marginally in those with PD (especially for those who committed sexual offenses). Seifert et al. (10) concluded that it is necessary to identify these "high-risk groups", provide them with more intense follow up, and evaluate the effectiveness of treatment methods and outcomes after release.

A "high-risk group" in the \$64-population are patients with premature termination of treatment because of a low prospect of success (under German law, these patients can be referred back to prison). Recidivism rates for these patients amount to 48% within the first year and 73% after 3 years after discharge from prison (9). The severity of offenses is also much higher compared to regularly discharged patients (9).

Alongside treating the substance use disorder, one of the primary concerns is to decrease criminogenic cognitions and behaviors. Numerous studies have examined the relationship between neuropsychological factors and the onset, development, persistence, and desistance of antisocial behavior (11–15), in which executive functions play a significant role. Executive functions comprise diverse cognitive processes and behavioral capabilities. These functions enable individuals to initiate, plan, regulate, sequence, and achieve complex goal-oriented behavior and thought (16–19). Executive functions are conceptualized as higher-order brain functions (of attention, information organization, forward planning, and self-control) which regulate lower level cognitive processes to performance complex tasks (20, 21).

An overview of the relationship between executive functions and antisocial behavior is presented in the meta-analysis of Ogilvie et al. (22), which demonstrates a strong association. Both individuals with psychopathy and with externalizing traits show distinct cognitive-affective dysfunctions (23–25). Affective

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and inhibitory deficits can materialize or dissipate in individuals with psychopathy depending on whether affective or inhibitory information is congruent with their goal (26–30). Combined, these studies show that persons with externalizing traits display deficits in executive functions and over-react to emotional information (31–34). They are prone to over-allocate cognitive resources to stimuli in situations that are subjectively motivationally significant. This over-allocation reduces the capacity for other executive functions such as inhibition, shifting, and control (35). A lack of problem-solving skills is also associated with executive functioning difficulties (36).

The relationship between social problem-solving and criminal behavior has been thoroughly examined in the literature (37-41). Poor social problem-solving abilities have been hypothesized to lead to criminal behaviors as maladaptive attempts to solve personal or interpersonal problems (40). There is evidence of a relationship between poor executive functioning and negative treatment outcomes such as increased treatment dropout rates and disruptive behavior during treatment (42). These findings have implications for the treatment of addicted offenders. About 50-70% are discharged without completing treatment (43-47). Most of these studies focus on misdirection of the court. Recent findings indicate that some of these risk factors could be taken into consideration for treatment planning to help reduce premature discharge and recidivism (48). These include executive functions, hyperactivity/impulsivity (49) and aggressiveness/irritability (49, 50).

In the last few decades, in line with the evidence, mentally disordered offenders (incl. addicted offenders) have primarily been treated with cognitive-behavioral therapy interventions (CBT), ranging from psychoeducation to multi-professional and multimodal treatment programs. Barnao and Ward (51) distinguish between treatments targeting mental illness and other psychological issues, interventions based on the principles of the Risk-Need-Responsivity model [RNR; (52, 53)], and strength-based models. All interventions have in common the aim to reduce recidivism. According to Müller et al. (54), Dialectical Behavioral Therapy-Forensic [DBT-F; (55, 56)], Mentalization-Based Therapy [MBT; (57-61)], Schema therapy (62, 63), and Transference Focused Psychotherapy [TFP; (64-66)] are the most commonly applied treatment approaches in forensic psychiatry in Germany. However, evidence for their effectiveness in these settings is largely absent.

DBT is a well-known therapy-approach, which is effective for patients with problems in emotion-regulation. For further description see section "the treatment programs".

MBT is based on the psychodynamic concept of "mentalization". Bateman & Fonagy (57) developed this psychotherapeutic approach for the treatment of Borderline-PD. Storebø et al. (67) demonstrated the effectiveness of MBT in BPD in a systematic review, although findings were based on a small number of studies of mainly female patients in nonforensic settings. MBT was more effective in reducing self-harm with a Risk Ratio (RR) of 0.62 [95% CI (0.49, 0.80); 3 trials, 252 participants], suicidality at end of treatment [RR 0.10, 95% CI (0.04, 0.30), 3 trials, 218 participants], and depression

[SMD -0.58, 95% CI (-1.22, 0.05), 4 trials, 333 participants], compared with TAU. Findings in relation to interpersonal problems, attrition, and adverse effects were inconsistent. An adapted version of MBT has been developed for patients with ASPD (58) and is currently being examined in a multicenter randomized trial (68).

Schema therapy is an evidence-based treatment for Borderline PD (69-71) and for Cluster C PDs (72, 73). It is an integrative approach adapting CBT and psychodynamic elements, concepts of attachment theory, humanistic psychology, and other psychological approaches. Bernstein et al. (74) adapted Schema therapy for forensic patients with antisocial, narcissistic, borderline, or paranoid PDs and examined the effectiveness in seven forensic hospitals in the Netherlands (75). Male patients (N = 103) with the aforementioned PDs were randomly allocated to Schema therapy or TAU for 3 years of treatment. Over two-thirds had significant levels of psychopathy; nearly all of them were violent offenders. Results showed that the experimental group had significantly better outcomes than the TAU group on a range of variables [lower risk for recidivism, improved strengths and protective factors, decreased PD symptoms, reduced early maladaptive schemas, and facilitated reintegration into the community; (75)]. Due to these findings, Schema therapy has officially been recognized as the first evidence-based treatment for forensic patients with PD in the Netherlands (76). Additional indications for forensic populations are also reported by other research teams (77-79). Current research examines whether schema modes are central to the change process (80).

TFP is a manualized, psychoanalytic treatment program, which has evidence for Borderline and other severe PDs (66, 81, 82). Fontao et al. (83) monitored the application of TFP in forensic setting in a pilot study. Therapeutic process was assessed over 18 months. TFP participants (N=12) showed positive changes in personality dimension scores and global psychopathological indices. Based on the small sample size the generalizability of the study results is reduced.

Beside these therapeutic approaches, there exist a number of other offender rehabilitation programs [e.g., Reasoning & Rehabilitation [R&R; (84)]; Enhanced Thinking Skills [ETS; (85)] and treatment programs on aggression, anger and violence (86–90). ETS appears to improve attitudes regarding aggression and violence in patients with a primary diagnosis of PD (89). Doyle et al. (91) found significant improvements in antisocial attitudes, anger regulation and social problem-solving skills in a prisoner group diagnosed with ASPD compared to TAU. Interventions targeting anger and aggression specifically have yielded inconsistent results (86–88). The long-term effect remains unclear however (90).

The Treatment Programs The R&R Program

R&R is an evidence-based, manualized cognitive-behavioral program. It is recommended as best practice in the S2-guidelines for the treatment of ASPD of the German Association for Psychiatry, Psychotherapy and Psychosomatics

[DGPPN; (92)] and the guidelines of the National Institute for Health and Care Excellence [NICE; (93)].

The R&R Program is a special training for criminal offenders, which targets cognitive skills, enabling them to develop and apply more prosocial behavioral alternatives. In summary, R&R focuses on "modifying the impulsive, egocentric, illogical, and rigid thinking of the offenders and teaching them to stop and think before acting, to consider the consequences of their behavior, to conceptualize alternative ways of responding to interpersonal problems and to consider the impact of their behavior on other people, particularly their victims" [(94), p.31]. R&R was conceived for antisociality-related cognitive problems, not for specific problems such as substance abuse related thinking and behavior. It consists of 36 two-hour sessions, which include role-playing, thinking games, learning exercises, dilemma puzzles, and problem solving (95). The training has nine components: problem solving, social skills, negotiation skills, management of emotions, creative thinking, values enhancement, critical reasoning, skills in review, and cognitive exercises [(84); Institut für forensische Psychiatrie Haina e.V. (IFPH), (96)]. This intervention was originally targeted at medium-to high-risk offenders with an IQ above 70 (because participants have to have adequate verbal skills to understand the content), with a lack of cognitive skills (because their antisocial behavior has to be caused by cognitive deficits) and without issues related to major mental illnesses (95). More recently, the Cognitive Centre of Canada [CCC; (97)] has developed new, adapted, specialized and shorter programs that target the needs of specific groups: R&R2 for Antisocial Adults, R&R2 for Antisocial Youths, R&R2 for individuals with ADHD, R&R2 for Girls and Young Women, R&R2 for those with Mental Health Problems, R&R2 for Families and Support Persons, and R&R2 for Antisocial Drivers (see CCC-website).

The evidence is based on a broad base [for an overview see (98)]. A meta-analysis by Tong & Farrington (99), which included 16 evaluations (involving 26 separate comparisons) from 3 countries (USA, Canada, and UK), showed a significant 14% decrease in recidivism for R&R participants compared to controls. The weighted mean effect size (ES) was 1.16 [95% CI (1.09, 1.27); p < 0.0001], based on rearrests or reconvictions. The period of time at risk varied from 3 to 24 months. R&R groups were less likely to reoffend compared to control-groups (for reconviction/rearrests: 20 OR were greater than 1.0, two were exactly 1.0 and three were less than 1.0). Controls had a 16% increase in recidivism compared to R&R participants, both groups did not differ significantly in revocations, violations, and in return to prison. R&R has been shown to be effective in community [11 trials; ES = 1.27 (p <.017)] and institutional settings [15 trials; ES = 1.16 (p < .0005)], and for both low- and high-risk offenders [8 trials; ES = 1.28 (p < .005) vs. ES = 1.12], judged by recidivism rates. There were also no major differences in reductions in reoffending by R&R participants in all three countries. Furthermore, comparisons between programs delivered to those volunteering for treatment and compulsory programs did not reveal differences (voluntary: OR = 1.17; p < .0001; non-voluntary: OR = 1.20; p < .057).

In 2008, a meta-analysis with a larger pool of 19 evaluations, involving 32 separate comparisons, was published (100). Findings only partially confirmed those reported in 2006. The authors found a weighted mean OR of 1.16 [95% CI (1.04, 1.31); p=.011] in recidivism for controls compared with R&R participants. Program effects for low risk offenders were not statistically significant [10 trials; OR=1.18 (n.s.)], but they were for high-risk-offenders [10 trials; OR=1.12 (p=.011)]. Crosscountry comparisons revealed some differences: R&R was effective in Canada and the United Kingdom but not in the United States. As before, the program was effective in community [12 trials; ES=1.22 (p=.023)] and institutional settings [21 trials; ES=1.15 (p=.064)], whether or not it was given on a voluntary basis.

DBT-F

DBT has been shown to be the most effective evidence-based intervention in treating individuals with BPD (101, 102). The adapted DBT-F is a multi-professional and multimodal CBT-based program involving individual and group therapy, skills training, a mindfulness group, and patient meetings without professionals [for detailed information see (103)].

In the S2-guidelines for personality disorders (92) and the NICE-guidelines (104) DBT is recommended as best practice in treating BPD but NICE limited the recommendation to women. In recent decades, DBT has been developed and adapted for individuals with other mental illnesses or other clientele [e.g., for forensic patients, adolescents, individuals with substance use disorders, ADHS, etc.; for an overview see (105)].

The most recent systematic review comparing treatment effects in individuals with BPD comprised 75 randomized controlled trials with 4,507 participants, predominantly females (67). More than 16 different kinds of psychotherapy were included. The most commonly applied psychotherapeutic treatments were DBT and MBT (MBT effects were described above), which were compared with TAU, waiting list, and other treatments. Treatment duration varied from one to 36 months. In sum, authors found beneficial effects on all primary outcomes for BPD-tailored psychotherapy compared with TAU. They observed effects of DBT (compared with TAU) for BPD severity with a standardized mean difference (SMD) of -0.60 [95% CI (-1.05, -0.14); 3 trials, 149 participants], self-harm [SMD -0.28, 95% CI (-0.48, -0.07); 7 trials, 376 participants] and psychosocial functioning [SMD -0.36, 95% CI (-0.69, -0.03); 6 trials, 225 participants]. Secondary outcomes showed mixed findings for anger, affective instability, and chronic feelings of emptiness, impulsivity, attrition, interpersonal problems, and adverse effects. Authors summarized, however, these effects were all based on low-quality evidence and could therefore not be considered robust.

RATIONALE

In 2009, we started to implement and evaluate two psychological interventions in our forensic clinic: R&R and DBT-F.

Our research project at that time ("The Treatment of antisocial addicted offenders") was funded by the Ministry for Labor, Social Affairs, Health, and Family of the State of Mecklenburg-Western Pomerania in Germany. The research was designed to add to the What Works literature by looking at a subgroup of criminal offenders detained under § 64 of the German Criminal Code. Preliminary results focusing on the effects of R&R in comparison with TAU were published reporting on changes in cognitive style, impulsiveness, and social cognitions (106–108). These findings indicated that mental flexibility, planning and problem-solving could be improved in the R&R-group compared to controls. Now, we present additional data that includes a DBT arm.

We hypothesized that both R&R and DBT-F would show greater improvements compared to TAU on cognitive skills such as problem-solving and reasoning. We further hypothesized that R&R would show better effects than DBT-F. There have been no direct comparisons of the two approaches as far as we are aware. We hypothesize that R&R would show greater effects on cognitive skills compared to DBT.

MATERIALS AND METHODS

Design

A longitudinal, prospective, quasi- experimental design was used. We compared pre- and post-tests regarding cognitive skills of individuals either having undergone R&R, DBT-F, or TAU.

Participants

Participants were male inpatients, recruited from a forensic-psychiatric hospital. All participants received treatment for substance addiction according to § 64 StGB. During the time period of the study (2009–2019) more patients were treated in these programs, but due to the voluntary nature of research participation and our inclusion- and exclusion criteria, not all patients could be included in the research.

Our inclusion criteria were: male gender, completed detoxication, completed diagnostic process, and completed preand post-measures. We excluded women because of the low number (N=7) and the associated statistical problems. All study-participants had gave informed their consent.

Our exclusion criteria were: diagnosis of schizophrenia or organic disorder, an IQ of less than 80 (Intelligence Quotient according to the Hamburg-Wechsler-Intelligence test for adults [(HAWIE-R; (109)], Wechsler-Intelligenz-Test für Erwachsene [WIE; (110)] or Wechsler Adult Intelligence Scale [WAIS-IV; (111)]. All mental disorders were diagnosed according the International Classification of Diseases 10 [ICD-10; (112)].

Treatment Allocation

The study run on three wards: One of the three therapy-wards implemented DBT-F, one R&R, and one ward served as the TAU ward, not having implemented either of these two interventions. Patients were assigned to these therapy wards on the basis of clinical indication: impulsive antisocial inpatients to DBT-F,

those with significant antisocial cognitions and behavior to R&R. Those with no such issues were allocated to the TAU ward.

Our clinic offers a wide range of interventions to all patients. Therefore, TAU consisted of weekly psychotherapeutic individual and group therapy sessions for the entire treatment period. In addition, patients took part in psychology led psychoeducational groups (drug and alcohol dependency) and anti-aggression training when appropriate. Treatment was delivered by certified clinical psychologists or advanced trainee psychologists working towards this qualification according to the German therapeutics law (PsychThG). Each inpatient was allocated a primary psychologist as well as two primary nurses. In addition to the psychology run treatment groups there are nurse-lead reflection groups. In addition, a social skills group, led by social workers, is offered. Each inpatient is involved in occupational therapy and sport sessions.

DBT-F was implemented in 2009. According to guidance, it involved individual and group therapy sessions once a week with the psychologist, skills-training, and a mindfulness group. The group skills training involved teaching skills in four domains (mindfulness, distress tolerance, emotional regulation, and interpersonal effectiveness). Nurses leaded the skills training with a frequency of 90 min sessions two times a week. Mindfulness skills were practiced weekly in an extra group, leaded by a psychiatrist. In addition, patients met without professionals formally once a week to manage group activities. The adapted version DBT-F includes a "delict analysis", which has to worked out in individual therapy sessions together with the psychologist. During a long process, patients shall understand their index delict including underlying processes, risk factors and behaviors, and obvious consequences. The final analysis was presented in the rounds. The DBT treatment (including four skills modules mentioned above) lasted about 12 months.

The R&R program was implemented into routine care in 2009. It involved two sessions of 2 h [recommended by IFPH; (96)] with a group of eight to ten inpatients for about 18 weeks. Two certified trainers (psychologists; certified by IFPH) implemented the manualized sessions. To facilitate transfer into daily life, social workers, nurses, and psychologists were trained on R&R in a two-day workshop, led by the R&R Trainers. In addition, staff are informed as part of routine care about the group topics and possible problems of the individual R&R participants.

Outcome Measures

We implemented pre- (T1) and post- (T2) measurements immediately before and within two to three months after interventions. T1 and T2 for controls were in line with the time points of the assessment of the R&R participants. We collected pre- and post-data on groups run over a period of ten years. We also collected sociodemographic, clinical, and criminogenic data, namely age, school graduation, professional qualification, IQ, length of stay, previous convictions, index offense, diagnosed substance dependence or harmful use, and diagnosed PD.

To compare the changes in different psychological constructs between groups, a psychometric test battery for executive functions was used, including tests for cognitive flexibility, the ability to inhibit cognitive interference, divergent reasoning, and planning. We selected commonly used [overview in (113)] psychometric instruments for assessing these constructs: the Trail Making Test [TMT-B; (114)], Farbe-Wort-Interferenz-Test [FWIT (Stroop-Test); (115)], Turm von London [Tower of London, TL-D; (116)], and Regensburger Wortflüssigkeits-Test [a word fluency test, RWT; (117)]. Mental speed, as the basis of all intellectual performances, was assessed using the Zahlen-Verbindungs-Test [a number-connection test, ZVT; (118)]. For further information see **Table 1**.

TMT-B

The TMT is used for assessing set-switching (defined as the ability to flexibly switch attention between competing task-set representations). In the TMT-B, the participants have to draw lines to connect numbers and letters in a numeric and alphabetic sequence (i.e., 1-A-2-B, etc.) as fast and accurately as possible. The time to completion is typically used as an index for performance (119). A series of studies have validated the TMT-B on healthy and individuals with brain injuries [(120, 121); for an extensive overview see (122)].

FWIT

Performing the FWIT, participants are required to read three different tables as fast as possible. The first two tables represent the "congruent condition" in which participants have to read the names of colors, printed in black ink and name different color patches. In the third table color-words are printed in an inconsistent color ink ("incongruent condition") and participants are required to name the color of the ink instead of reading the word. They therefore have to perform a less automated task while inhibiting the interference arising from a more automated task [Stroop effect; (123)]. We assessed, in line with the literature, the ability to inhibit cognitive interference indexed by time to completion and errors, depicted as T-norms. Numerous studies have found the FWIT to be a reliable assessment tool [e.g., (124); overview in (125, 126)], including in forensic populations (127).

TL-D

The Tower of London is one of the most commonly uses measures of planning and problem-solving [e.g., (128–134)]. The test contains a board with three vertical pegs of different heights and three different colored balls. The pegs can hold a maximum of three, two, or one ball. Participants have to convert

an initial configuration into a goal configuration by moving the balls among the pegs according to a set of rules (e.g., you can only move one ball at a time, touching one ball counts as a move). The test outcome most commonly used is the number of moves to achieve the goal (unless it is too high in which case it is considered an error). Percentile values are used for analysis.

RWT

The RWT is an education-adjusted word fluency test, which has been validated in neurological and psychiatric patient populations, including patients with alcohol dependency; interrater reliability for all subtests is very strong (r = .99), test-retest reliability ranges between r_{tt} = .72 and r_{tt} = .89 (117). The test involves formal lexical and semantic streams. The RWT contains parallel tests, which were used in our study (first form at T1, second form at T2). Four subtests are conducted per measure. Participants have to name as many different words as they can in a period of 2 min per subtest. In the formal lexical subtest, subjects have to name words with a given first letter; in the subtest "formal lexically with shifting", they are required to name words alternating between two given first letters. In the semantic subtest, participants have to name words fitting to a given category (e.g., food), again there is a shifting-form with two given categories (e.g., clothes or flowers). The number of correct answers is transferred to percentile values.

ZVT

The ZVT is a mental speed test with very strong reliability (test-retest reliability between $r_{tt}=.84$ and $r_{tt}=.97$; parallel test reliability between r=.95 and r=.98) and a validity of between r=.40 and r=.83 [correlations with various intelligence tests; (135)]. Participants have to draw lines to connect the numbers 1 to 90 in a numeric sequence four times as fast and accurately as possible. The time to completion gives an indication of IQ.

Statistical Analysis

All analyses were performed with SPSS software Version 24.0 (136). The (at least) ordinal scaled data (data were non-parametric, tested by Shapiro-Wilk) were analyzed by Kruskal-Wallis Test. School education, professional qualification, diagnosis, PD, and index offence were analyzed using chi-square tests. If expected cell frequencies were below five, the Likelihood-quotient was used. Continuous parameters are shown as means and standard deviations, categorical parameters as percentages.

To examine interaction effects between treatment groups, we used a mixed ANOVA-Model. Because the mixed ANOVA is relatively robust regarding breaches of normal distribution, no

TABLE 1 | Assessment information.

Psychological construct	Operationalization	Category
cognitive flexibility	Trail Making Test Part B [TMT-B; (114)]	time of performance in sec.
ability to inhibit cognitive interference	Farb-Wort-Interferenztest ["Stroop"-Test, FWIT; (115)]	T-value of interference
cognitive performance/mental speed	Zahlen-Verbindungs-Test [ZVT; (118)]	ZVT-IQ
divergent reasoning	Regensburger Wortflüssigkeits-Test [RWT; (117)]	Percentile of word fluency
problem solving, convergent reasoning, planning	Tower of London [TL-D; (116)]	Percentile of solved problems

corrections were made. We tested the homogeneity of covariance by Box's test (137, 138). As we only had two points of measurement, sphericity was given. Error variances were examined with Levene's test.

We examined a possible relationship between patient characteristics and the results of the tests with a multiple regression model. Hierarchical regressions enable analyzing possible confounders. Known possible predictors should be entered into the model first in order of their importance for outcomes, new possible predictors can be added (139). We chose, besides treatment-group (Model 2), age at T1, IQ, and personality disorder (Model 1), as possible predictors/ confounders. We chose IQ because the IQ, measured by instruments mentioned above, includes-amongst other constructs—reasoning, and education-adjusted factors. Because we examined cognitive performances, age could also have had an effect as cognitive performance, like mental speed or reasoning, etc. decrease with age. Personality structure (BPD and ASPD especially) is sometimes also characterized by typical cognitive dysfunctions (see Introduction) depending on severity of PD. We included any diagnosed PD as a possible confounder in the analysis.

All chosen predictors fulfilled criteria for multiple linear regressions (no multicollinearity, etc.).

Ethical Approvals

The study was approved by the ethics committee of Rostock University Medical Center. All participants gave written informed consent in accordance with the Declaration of Helsinki (140).

RESULTS

Sample Characteristics

One hundred and forty-one patients were initially included in the study, 32 were drop-outs ("non-completers").

The Drop-Out-Group

The 32 drop-outs including patients with premature termination of their hospital treatment (N = 6), 17 subjects with uncompleted

measures, one patient, who was discharged before postmeasurement, 2 patients that were referred back to prison due to court decisions, and 6 unclear drop-out-cases.

Of the six patients who dropped out because of referral back to prison due to low prospect of success, five had started with R&R and one with DBT-F. Four patients were between 23 and 25 years old, one 33, and one was 48 years old. Their IQ ranges from 84 to 102 (missing data: N = 1). Five had completed school, one had a professional qualification. Regarding substance dependence or harmful use, the distribution was equal across the whole sample: two patients had problems with alcohol (addiction or harmful use), two with illegal substances (addiction or harmful use), and two with a combination thereof. Three patients had no PD; the number of previous offenses was also high in this group: only one patient had one previous conviction, the other five had between 6 and 15. Two patients of that group had committed violent offenses (e.g., robbery, assault) as index-delict; one manslaughter; two property offenses; one drug offense. The length of stay (before T1) varied between 5 and 12 months (missing data: N = 1).

The Examined Sample

We examined 109 male forensic inpatients. The DBT group comprised 34, the R&R group 47 and the control group 28 males (see **Table 2**). Only those who completed the whole program once were included. Sociodemographic and treatment characteristics are shown in **Table 2**. Most of the participants were around 30 years old. The *average age* was 29.71 years (SD = 7.35). There was no statistically significant difference in age between the groups (**Table 2**). The average IQ across all patients was 94.97 (SD = 10.67) with a range from 80 to 122. IQ did not differ between groups.

The average *lengths of stay (at T1)* of DBT-F-patients was significantly shorter than in the other groups (DBT-F versus R&R p = .014; versus TAU p = .048), but there was no difference between the R&R and the DBT-F group. The number of months at T1 varied from 2 (DBT-F group) to 18 (DBT-F and TAU) months, outliers (38, 26, and 23 months) were removed.

We found no significant differences in *education* and *professional qualification* (see **Table 2**), but a larger proportion of the inpatients of the TAU group had graduated from school

TABLE 2 | Descriptive information.

Descriptive	Category	TAU (N = 28)	R&R (N = 47)	DBT-F (N = 34)	Total	Ch ²
Mean age (at T1)	Years (SD)	M = 28.54 (7.38)	M = 29.98 (7.87)	M = 30.29 (6.65)	29.71 (7.35)	$\chi^2(2) = 2.21, p = .331$
IQ	Points (SD)	M = 97.07 (11.98)	$M = 94.36 (9.24)^a$	M = 94.03 (11.33)	94.97 (10.67)	$\chi^2(2) = 1.30, p = .523$
School graduation	completed	92%*	75%	62%*	77. %	$\chi^2(2) = 8.53$, p = .014
Professional qualification	completed	48% ^b	46% ^c	18%*	37%	$\chi^2(2) = 8.01$, p = .018
Length of stay (before T1)	Month (SD)	$M = 8.73 (3.90)^d$	$M = 9.09 (5.30)^{e}$	M = 6.79 (6.29)*	8.18 (5.55)	$\chi^2(2) = 8.08, p = .018$

p < .05

TAU, Treatment as usual; R&R, Reasoning & Rehabilitation Program; DBT, Dialectical Behavioral Therapy-Forensic; M, Mean; SD, Standard Deviation; IQ, Intelligence Quotient according HAWIE- R (109); WIE (110), WAIS-IV - Fourth Edition (111).

 $^{^{}a}n = 44.$

 $^{^{}b}n = 25.$

 $^{^{}c}n = 46.$

 $^{^{}d}n = 15.$ $^{e}n = 43$

 $e_n = 43.$

than statistically expected, whereas the DBT group comprised fewer than expected. Regarding school dropouts, data are the other way round.

Only 18% of the DBT group and a little less than half of the TAU and R&R participants had a *professional qualification*. This difference was statistically significant.

Offending and diagnostic characteristics are reported in **Table 3**. The majority (55%) of the study participants' main *offenses* were violent offenses (e.g., robbery, assault), followed by property (13.76%), drug offenses (11.93%), and homicide [11.01% (murder, manslaughter and grievous bodily harm resulting in death)]. Sex offenses were rare. The variable *other offenses* included arson and traffic offenses. Groups did not differ significantly.

In all three groups, the number of *previous offenses* was high. On average, patients in the DBT-group had more than ten (M = 10.47; SD = 6.89) previous convictions, the R&R patients more than nine (M = 9.17; SD = 6.00), and those in the control group greater than seven previous convictions (M = 7.64; SD = 4.85). Previous convictions ranged from 0 to 32. There was no difference between the groups in offending data.

Regarding *substance dependence or harmful use* were no differences between the three groups observed. Approximately one third of each sub-sample was addicted to alcohol, illegal drugs, or a combination thereof (**Table 3**).

Differences in PD *comorbidity* had a non-significant medium effect size (V = 0.27). Half (50.46%) of the patients did not have any PD. The largest group of personality disorders was ASPD and other Cluster B PDs [Diagnostic and Statistical Manual of Mental Disorders; DSM-IV, (141)], followed by a combined PD. More inpatients of the DBT group had a Cluster B PD, and fewer had no PD, than statistically expected. TAU participants

frequently had no PD and were less likely to be diagnosed with Cluster B PD. Because of a single inpatient in the R&R group observed data in Cluster C PD was more than expected.

Comparison of TAU, R&R, and DBT-F Groups on Cognitive Skills

First, we analyzed differences between the three groups in assessed cognitive skills at T1. There were no significant differences in any of the dependent variables (see **Table 4**). At T2, the three groups also did not differ significantly on any of the outcomes assessed. With the exception of ZVT-IQ, the performances (at T1 and T2) were on average within normal ranges in all three groups. In all three groups, ZVT-IQs were below average (at T1 and T2).

Within-Group Comparisons

Table 5 shows the within-group differences between pre- and post-measurement. The TAU group showed significant increases in *cognitive flexibility* with an ES of r = .39; *ability to inhibit cognitive interference* (r = .41); *cognitive performance/mental speed* (r = .33); and *problem-solving/convergent reasoning* (ro = .31).

The DBT-F group showed significant increases in *cognitive* flexibility (ES: r = .48); ability to inhibit cognitive interference (ES: r = .39); cognitive performance/mental speed (ES: r = .23); and problem-solving/convergent reasoning (ES: r = .39). Patients in the DBT-F group also demonstrated significant decreases in three of the four subtests of the RWT (formal lexically with shifting; semantic; semantic with shifting).

The R&R-group showed significant increases in the following variables: *cognitive flexibility* (ES: r = .25); *ability to inhibit*

TABLE 3 | Clinical and Criminogenic Characteristics.

Descriptive	Category	TAU (N = 28)	R&R (N = 47)	DBT-F (N = 34)	Total	Ch ²
Previous Convictions	Mean of number (SD)	M = 7.64 (4.85)	M = 9.17 (6.00)	M = 10.47 (6.89)	9.18 (6.07)	$\chi^2(2) = 2.78,$ $p = .250$
Index offense (frequencies and percentage)	homicide	3 (10.71%)	7 (14.89%)	2 (5.88%)	11.01%	$\chi^2(10) = 8.24,$ $p = .606$
	other violent offenses	15 (53.57%)	24 (51.06%)	21 (61.76%)	55.05%	
	property offenses	2 (7.14%)	8 (17.02%)	5 (14.71%)	13.76%	
	drug offenses	5 (17.86%)	4 (8.51%)	4 (11.76%)	11.93%	
	sex offenses	2 (7.14%)	1 (2.13%)	0	2.75%	
	other offenses	1 (3.57%)	3 (6.38%)	2 (5.88%)	5.50%	
Substance dependence or harmful use (frequencies and percentage)	Alcohol	10 (35.71%)	16 (34.04%)	12 (35.29%)	34.86%	$\chi^2(8) = 4.37,$ $p = .822$
	Illegal drugs	11 (39.29%)	16 (34.04%)	11 (32.35%)	34.86%	
	Alcohol and illegal drugs	7 (25%)	15 (31.91%)	11 (32.35%)	30.28%	
Personality Disorder or distinctive Personality-Style	no	20 (71.43%)	24 (51.06%)	11 (32.36%)	50.46%	$\chi^2(10) = 20.95,$ $p = .021^*$
	Cluster A	1 (3.57%)	1 (2.13%)	0	1.83%	
	Cluster B	4 (14.29%)	18 (38.30%)	19 (55.88%)	37.61%	
	Cluster C	0	1 (2.13%)	0	0.92%	
	combined	3 (10.71%)	3 (6.38%)	4 (11.76%)	9.17%	

^{*}A chi-square test was used to compare the variables Personality Disorder (DSM-IV) or distinctive Personality-Style and Treatment group. 61.1% of cells of expected frequencies were below 5, so Likelihood-Quotient was used. Results show a significant between Personality Disorder (DSM-IV) or distinctive Personality-Style and Treatment group, $\chi^2(10) = 16.18$, p = .021, $\varphi = 0.39$.

TAU, Treatment as usual; R&R, Reasoning & Rehabilitation Program; DBT, Dialectical Behavioral Therapy-Forensic; M, Mean; SD, Standard Deviation. Disorders due to psychoactive substance use were diagnosed according ICD-10 (112), personality disorders according DSM-IV (141).

TABLE 4 | Between-group Differences at T1 and T2: Kruskal-Wallis-Test.

Instrument		Ch ²			
		at T1	at T2		
TMT-B: cognitive flexibility FWIT: ability to inhibit cognitive interference		$\chi^{2}(2) = .09, p = .956^{a}$ $\chi^{2}(2) = .46, p = .796^{b}$	$\chi^{2}(2) = 3.17, p = .205^{e}$ $\chi^{2}(2) = .22, p = .894^{f}$		
ZVT : cognitive performance / mental speed		$\chi^{2}(2) = .51, p = .774^{\circ}$	$\chi^2(2) = .01$, p = .994°		
RWT: divergent reasoning	formal-lexically	$\chi^2(2) = 2.45, p = .294^d$	$\chi^2(2) = .46, p = .793^9$		
	forma-lexically with shifting	$\chi^2(2) = 1.93, p = .382^a$	$\chi^2(2) = .12, p = .940^h$		
	semantic	$\chi^2(2) = 3.13, p = .209^a$	$\chi^2(2) = 1.36, p = .506^f$		
	semantic with shifting	$\chi^2(2) = .65, p = .721^a$	$\chi^2(2) = .97, p = .614^f$		
TL-D: problem solving, convergent reasoning, planning		$\chi^2(2) = 1.58, p = .453^{\circ}$	$\chi^2(2) = .19, p = .906^h$		

TMT, Trail Making Test Part B [TMT-B; (114)]; FWIT, Farb-Wort-Interferenztest ["Stroop"-Test, FWIT; (115)]; ZVT, Zahlen-Verbindungs-Test [ZVT; (118)]; RWT, Regensburger Wortflüssigkeits-Test [RWT; (117)]; TL-D, Tower of London [TL-D; (116)].

cognitive interference (ES: r = .26); cognitive performance/mental speed (ES: r = .28); problem-solving/convergent reasoning (ES: r = .43) and in three of the subtests of the RWT with medium effect sizes: formal lexical (ES: r = .21); formal lexical with shifting (ES: r = .23) and semantic (ES: r = .24). Only in one subtest the T2-results were lower than the T1-outcome (semantic with shifting: ES: r = .26).

Between-Group-Comparison

There were significant main effects for cognitive flexibility (TMT-B), problem solving/convergent reasoning (TL-D), and the ability to inhibit cognitive interference (FWIT), but no statistically significant interaction between these performances and treatment-groups (see **Table 6**). This means average scores were higher post compared to pre-treatment though independent of group membership.

We did not find any indication for a significant main or interaction effect for *cognitive performance/mental speed* (ZVT) though the within-group-analysis (see below) revealed improvements in all three groups.

The effects of the subtests of RWT (divergent reasoning) were heterogeneous. Whereas performance in the formal lexical subtest did not change significantly in any of the three groups (no main and no interaction effect), the performance in the semantic test with shifting showed a main, but no interaction, effect with the different kinds of interventions. The main effect of the semantic test with shifting suggests that all groups demonstrated a decrease in performance.

The only test performances that were dependent on group membership were the RWT subtests formal lexical with shifting test and semantic. There were statistically significant decreases between T1 and T2 for the DBT-F-participants in formal lexical with shifting test and the semantic subtest. The scores of the R&R group increased between T1 and T2 (see **Table 6**).

Multiple Regression

Our results revealed main effects for some test performances, but no statistically significant interaction effect between these performances and treatment groups. We found within-group improvements for all assessed cognitive skills, especially for the

 $\textbf{TABLE 5} \ | \ \text{Within-group Differences in pre- and post-measurements of TAU, R\&R, and DBT-F: Wilcoxon-Test.}$

Instrument		TAU(n = 21)Z	р	DBT-F(n = 29)Z	р	R&R(n = 45)Z	р
TMT: cognitive flexibility		- 2.56	.011*	- 3.71	.000**	- 2.37	.018*
FWIT: ability to inhibit cognitive interference		- 2.65	.008**	- 3.08	.002**	- 2.49	.013*
ZVT : cognitive performance / mental speed		- 2.04	.041*	- 1.82	.069*a	- 2.67	.008**
RWT: divergent reasoning/ word fluency	formal-lexically	09	.931	06	.951	- 1.95	.051*a
	forma-lexically with shifting	- 1.17	.242	- 2.37	.018*	- 2.16	.031*
	semantic	- 1.43	.153	- 2.06	.040*	- 2.26	.024*
	semantic with shifting	86	.389	- 2.84	.005**	- 2.47	.014*
TL-D: problem solving, convergent reasoning, planning		- 2.04	.041*	- 3.14	.002**	- 3.91	.000**

^{*}p < .05.

TMT, Trail Making Test Part B [TMT-B; (114)]; FWIT, Farb-Wort-Interferenztest ["Stroop"-Test, FWIT; (115)]; ZVT, Zahlen-Verbindungs-Test [ZVT; (118)]; RWT, Regensburger Wortflüssigkeits-Test [RWT; (117)]; TL-D, Tower of London [TL-D; (116)]; TAU, Treatment as usual; R&R, Reasoning & Rehabilitation Program; DBT, Dialectical Behavioral Therapy-Forensic.

ap has to halve and compare with alpha, because a one-sided effect (induced increasing by treatment) was expected.

 $^{^{}a}n = 106.$

 $^{^{}b}n = 108.$

 $^{^{}c}n = 104.$

 $^{^{}d}n = 107.$

 $e_n = 97.$

 $^{^{}f}n = 98$

 $^{^{}g}n = 99.$

 $^{^{}h}n = 100.$

^{**}p < .01.

TABLE 6 | Results of the mixed ANOVA-Model.

Instrument		main effect	р	interaction effect with group	р
TMT: cognitive flexibility		F(1,92) = 24.11	<.001**	F(2,92) = 1.88	.158
FWIT: ability to inhibit cognitive interference		F(1,94) = 6.37	.013*	F(2,94) = .44	.648
ZVT : cognitive performance/mental speed		F(1,89) = 2.87	.094	F(2,89) = .74	.482
RWT: divergent reasoning/ word fluency	formal-lexically	F(1,94) = .05	.822	F(2, 94) = 1.16	.317
	formal-lexically with shifting	F(1,94) = .36	.552	DBT: F(1,29) = 6.84	.014*
				R&R: $F(1,44) = 4.58$.038*
	semantic	F(1,89) = 2.87	.094	DBT: F(1,28) = 4.86	.036*
	semantic with shifting	F(1,93) = 12.06	.001**	F (2, 93) = 1.52	.223
TL-D: problem solving, convergent reasoning, planning	· ·	F(1,92) = 33.33	<.001**	F(2, 92) = 1.00	.370

^{*}p < .05.

TMT, Trail Making Test Part B [TMT-B; (114)]; FWIT, Farb-Wort-Interferenztest ["Stroop"-Test, FWIT; (115)]; ZVT, Zahlen-Verbindungs-Test [ZVT; (118)]; RWT, Regensburger Wortflüssigkeits-Test [RWT; (117)]; TL-D, Tower of London [TL-D; (116)]; DBT, Dialectical Behavioral Therapy-Forensic; R & R, Reasoning & Rehabilitation Program.

R&R group. In order to explore the relationships between the assessed cognitive skills and treatment and/or patient characteristics as predictor variables we used a multiple regression analysis (**Table 7**).

For Model 1, we chose the following patient characteristics: age at T1, IQ, and diagnosed personality disorder. Model 1 did not explain variance of any of the dependent variables (cognitive flexibility, ability to inhibit cognitive interference, cognitive performance/mental speed, divergent reasoning, and problem solving/convergent reasoning).

Model 2 (treatment group) explained 13.8% of the variance of *cognitive flexibility* (TMT). The R^2 for the second model was.24 (adjusted $R^2 = .14$) for *cognitive flexibility* (TMT), indicative of a medium goodness-of-fit according to Cohen (142). This model did not explain any variance in the other test-results.

DISCUSSION

The study compared CBT-based treatments, which were developed and validated for criminal offenders. We examined the outcome of two evidence-based programs (R&R and DBT-F) in an addicted offender population in direct comparison with controls (TAU). Using neuropsychological instruments, participants' cognitive skills were assessed in a pre- and post-measurement design. The measured constructs were cognitive

flexibility, ability to inhibit cognitive interference, cognitive performance/mental speed, divergent reasoning, and problem solving/convergent reasoning. Results demonstrated that none of the treatment groups improved significantly more than the others across the measured outcomes. All three groups improved their performances in nearly all of the applied instruments. The only outcome on which patient improvements were distinguishable between the DBT-F and R&R groups was divergent reasoning. Age, IQ, and diagnosed PD did not confound findings.

Our results were unexpected as we hypothesized that both interventions would be more effective than TAU and that R&R participants would improve more compared to the DBT-F group. Our previous research also indicated that mental flexibility, planning and problem-solving improved more in the R&R compared to the control group (106-108).

The most important finding of this study was the absence of a difference between the treatment groups (DBT-F and R&R). All groups, including TAU, differed from baseline values after treatment. There are several important considerations when interpreting this finding. One interpretation could be that all these treatments, which are based on CBT principles (including TAU) worked in our difficult to treat patient group of addicted offenders. Our method of assigning patients to appropriate treatments according to each patient's clinical profile seemed to work and resulted in improvements. Patients that needed extra help received this within their assigned treatment program

TABLE 7 | Results of Multiple Regression.

Instruments		Model I: Age at T1, IQ, PD	р	Model II: Treatment group	р
TMT: cognitive flexibility		F(7,78) = 1.56	.161	F(9,78) = 2.39	.020*
FWIT: ability to inhibit cognitive interference		F(7,78) = 1.15	.345	F(9,78) = .87	.557
ZVT : cognitive performance/mental speed		F(7,74) = .88	.527	F(9,74) = .92	.515
RWT: divergent reasoning/ word fluency	formal-lexically	F(7,77) = .42	.889	F(9,77) = .73	.680
	formal-lexically with shifting	F(7,77) = .13	.996	F(9,77) = 1.31	.250
	semantic	F(7,75) = 1.17	.333	F(9,75) = 1.52	.161
	semantic with shifting	F (7,76) = 1.19	.376	F(9,76) = .92	.513
TL-D: problem solving, convergent reasoning, planning	_	F(7,76) = .46	.862	F(9,76) = .42	.920

^{*}p < .05

TMT, Trail Making Test Part B [TMT-B; (114)]; FWIT, Farb-Wort-Interferenztest ["Stroop"-Test, FWIT; (115)]; ZVT, Zahlen-Verbindungs-Test [ZVT; (118)]; RWT, Regensburger Wortflüssigkeits-Test [RWT; (117)]; TL-D, Tower of London [TL-D; (116)].

^{**}p < .01.

and therefore the mean value changes between the groups ends up similar. Our results could indicate that patients were assigned to the appropriate treatment.

Further, we comment on differences between our current findings and previous findings from our own group which identified improvements in cognitive skills in an R&R-group using data up to 2015. Maybe this study reflects the changes in the \$64 clientele in the last years. As mentioned more recently this population has gotten older, has had more previous convictions, and has used more varied and multiple substances. It is conceivable that the change in the population led to a less significant treatment effect compared to previous findings.

Our offenders were more similar to a prison population than a population of mentally ill offenders—they were all criminally responsible (at least partly) and functioned at a reasonable level as indicated by the fact that with the exception of one test all tests were within the normal range. Therefore, it is possible that we did not detect changes due to ceiling effects.

Within this group of patients with good cognitive abilities, TAU participants differed from DBT-F patients in that participants from the DBT-F group were older, had a lower IQ, were less educated and qualified, and had more previous convictions. A greater number of patients in that group had a diagnosis of Cluster B PD. Therefore, TAU participants were less severely disordered, had better cognitive abilities and were perhaps better placed to benefit from psychological treatment. As patients were allocated to treatment groups on the basis of clinical need, not randomly, the TAU patients would have been judged clinically to not need additional interventions as would have been demanded by the RNR principle (52, 53). This means on the one hand that the TAU group is expected to benefit from treatment without additional groups such as DBT-F or R&R. On the other hand, one could argue that the DBT-F treatment was effective simply because a more complex patient group still improved with the treatment.

Another possible explanation for the lack of significant differences between the groups could be that all patients in our hospital receive significant therapeutic input, including longterm individual (eclectic) psychotherapy. Therefore, common factors of psychotherapy as the main cause of therapeutic change, such as problem activation, resource activation, coping, motivational clarification, and therapeutic relationship (143-145) are likely to have impacted significantly on the change process. The additional effects of specific interventions might therefore be marginal, but this would not rule out significant treatment effects of such interventions in settings where TAU is less intense. The results highlight the difficulties in evaluating single treatment programs in clinical practice, especially in forensic hospitals. There are many potential confounders when evaluating treatment programs, which could not be controlled [e.g., program characteristics, context effects, evaluation, and participant characteristics; (146)].

We compared two intervention types, which are based more or less on cognitive-behavioral approaches. Our TAU is also oriented, in line with the evidence, towards this. It is possible that we could not detect any differences due to the similarity in theoretical basis and methods used. The results could also indicate that DBT-F and R&R are less suited to treat the special population of addicted offenders. Neither of these two interventions had specific modules for substance misuse.

The findings could also represent the importance of correct program implementation and maintaining fidelity to manualized treatment regimes. Correct R&R implementation is easier to control than DBT-F implementation. Each R&R session is manualized, and the trainers validate each other, even during the session; after each session participants and trainers evaluate it. DBT-F is a multi-professional approach with its own theoretical background and methods. Implementation is expected on the ward as a whole systems approach but we cannot rule out slippage in adherence to DBT principles in clinical practice.

Finally, it is plausible that that the instruments used in the present study did not assess the psychological constructs we attempted to measure, thus reflecting a problem of construct validity.

It is notable that there were significant results of the fourth RWT subtest across the three groups. The subtest semantically with shifting assessed the number of words participants can produce over two minutes for given categories. On close inspection of the content of the task, we hypothesized that an effect was shown, which is more associated with creativity, learning strategies, and school success (147, 148). At T1 the inpatients had to produce words according the categories "sports" and "fruits", at T2 the categories were "clothing" and "flowers". With the category "flowers", the male participants scored lower than the pre-measurement. It is possible these results were unrelated to treatment modality. This outcome seems to be more an educational effect, because names of flowers might not be everyday knowledge for this patient group. This effect might have been particularly relevant in the DBT-F group, because these patients were less likely to have achieved educationally (school education and professional qualification) than the other patients.

In contrast to the literature, we did not find distinct executive dysfunctions at baseline, which is normally associated with antisocial behavior [e.g., (22)]. These findings were independent from diagnosed substance abuse or PD, sociodemographic, and criminogenic data. Our results are unexpected in this respect, especially given a lack of problemsolving skills is related to criminal behavior (37-41). R&R was developed to focus—amongst other skills—on these maladaptive problem solution processes. It is possible that our examined population did not benefit from interventions based on these principles. Their deficits and maladaptive resources seem to be different. The evidence of R&R is primarily based on lower recidivism rates after discharge (98-100). This study examined possible changes in executive functions, thus we cannot yet give statements as to long-term effects in our § 64-population. In contrast to R&R, the evidence of DBT is primarily based on reducing symptoms (often in female populations), like BPD severity, self-harm, and psychosocial functioning (67, 149-151). So, research into the efficacy of DBT, particularly DBT-F or DBT-S in male forensic populations (especially in male addicted forensic populations) is still in its infancy.

Limitations

We examined a relatively small sample of inpatients in one forensic hospital in Germany, so generalizations of our results to the whole population of treated offenders cannot be made. However, our sample was similar to the profile of patients described in Berthold & Riedemann (5), suggesting they were fairly typical of individuals detained under §64 StGB. Another limitation is the allocation to clinical need, so our study was not an RCT. The implementation of DBT-F and R&R was not examined. The investigated measures were purely cognitive measures within a highly structured context, which makes generalization to real world problem-solving difficult, particularly a ceiling effect was suspected. We examined underlying psychological constructs, not "objective criteria" of recidivism and substance-relapse, so we cannot give statements to long-term effects of the treatment-approaches. Outside these points, the results highlight the difficulties of clinical research, particularly the influence of many potential confounders, which could not be controlled.

Clinical and Research Implications

In sum, the current results indicate that not all of the special group of addicted offenders benefitted from R&R and DBT-F in relation to cognitive skills. Maybe this special clientele would benefit more from DBT-S (DBT for addicted persons), especially the addicted offenders with no personality disorder. It would also be conceivable to combine DBT-F modules with DBT-S modules or extend the duration of treatment for both R&R and DBT with booster-sessions. From our experience, the transfer from theory to practice is particularly difficult for patients, especially in a closed psychiatric setting. This transfer should be more supported by requesting and practicing treated topics and skills in every-day life on wards. It also seems to be very important to pay attention to indication. Therefore, only medium- to high-risk offenders with an IQ above 70, with impairments in cognitive skills and without major mental illnesses (95) should participate in R&R, and only patients with severe impulsivity in DBT-F. Structured and supervised implementation is fundamental to maintain treatment integrity.

Future research should adopt a RCT design to measure differences in outcomes for these groups. However, adopting an RCT design is not easy within forensic inpatient settings given the ethical concerns regarding the randomization of treatments offered under conditions of deprived liberty. Where RCTs are not appropriate, further quasi-experimental or retrospective studies should be conducted. CBT-based programs should be compared with other kinds of evidence-based treatments such as psychodynamically-oriented programs (e.g. MBT group programs or individual therapy), pharmacological interventions, or substance use disorder-specific treatments.

The implementation process of treatment programs should be evaluated. We also suggest the use of different outcome measures to avoid ceiling effects. To verify our findings, it would be important to compare the results with other samples, e.g. a matched sample of imprisoned offenders or individuals with substance abuse problems only. In addition, future research should include the outcomes of criminal recidivism and substance-relapse. We plan to conduct a qualitative study to explore the findings of the present study in more

detail. Patients and staff will be asked for their interpretations of the results and the lack of meaningful differences between the treatment groups.

CONCLUSION

Overall, our evidence suggests that that there is clinical utility associated with implementing R&R and DBT in forensic treatment settings. R&R seems to be effective in reducing reoffending, DBT in reducing problems with emotion regulation. We did not find evidence attesting to the superiority of one treatment program over another for addicted offenders. All supplied treatments (TAU, R&R, and DBT-F) resulted in improvements. We could derive some clinical and research implications. Additional research is needed to examine the effectiveness of these programs for male addicted offenders. To further investigate the results, we will continue to examine offender treatment, focusing on using different outcome measures without ceiling effects, and explore issues of implementation.

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 Ethics committee of Rostock University Medical Center. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

AW and DS conceived the study and planned data collection and analysis. AW supervised data collection and data entry, analyzed the date, and wrote the first draft of the manuscript. BV supervised the data analysis and the writing process and critically revised the manuscript. All authors contributed to the article and approved the submitted version.

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