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# Schema Therapy for Forensic Patients with Personality Disorders: Design and Preliminary Findings of a Multicenter Randomized Clinical Trial in the Netherlands

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According to Dutch Law, patients committing severe crimes justifying imprisonment of four years or more who cannot be held (fully) accountable for these acts can be sentenced to compulsory hospitalization in a specialized TBS hospital in the Netherlands. In the current paper, the effects of TBS treatment will be addressed in terms of recidivism numbers after termination of TBS treatment, as well as in behavioral changes that are observed during admission to TBS hospitals. Although these results offer some indirect support suggesting that TBS is effective, no randomized controlled trials had been conducted up until now that

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could confirm this. In the current study, preliminary results are reported from a multicenter randomized clinical trial on the effectiveness of Schema Therapy (ST) for hospitalized TBS patients with Antisocial, Borderline, Narcissistic, or Paranoid Personality Disorders, including those with high levels of psychopathy. Patients at seven TBS clinics were randomly assigned to receive three years of either ST or Treatment As Usual (TAU), and are being assessed on several outcome variables, such as recidivism risk (HCR-20, START), personality disorder symptoms (SIDP-IV, SNAP), and successful re-integration into the community. A three-year follow-up study will examine actual recidivism. One hundred and two patients are participating in the study. The preliminary findings from the first 30 patients to complete the three-year study suggest that ST is yielding better outcomes than TAU with regard to reducing recidivism risk and promoting re-entry into the community. These findings are not yet statistically significant, and thus need to be interpreted with caution until confirmed in our complete sample and follow up. However, they suggest that ST may be a promising treatment for offenders with personality disorders, including some psychopathic ones.

## INTRODUCTION

In most Western countries, individuals suffering from severe mental disorders are not held criminally responsible for committing a crime when this is done as a direct result from their illness (Spaans et al., 2011). Generally, this implies that offenders with, for instance, schizophrenia, are sentenced to undergo some form of intensive forensic psychiatric treatment, instead of having to serve time in a general prison. In many countries, the mere presence of a personality disorder, however, is not viewed as sufficient reason for criminal insanity and forensic treatment. In the Netherlands, however, offenders with personality disorders who committed severe crimes are relatively often judged to be 'diminished' or only partially responsible for their criminal acts, which can lead to a sentence that consists of both imprisonment as well as compulsory hospitalization in one of the twelve specialized so-called *TBS* institutions in the Netherlands, after having first served their sentence in jail.

In Dutch, TBS stands for 'TerBeschikkingStelling,' which may be translated as 'placed at the disposal' of the government in one of the specialized institutions for forensic psychiatric care (i.e., TBS hospitals). A TBS sentence can be imposed in cases of serious offenses punishable by imprisonment of at least four years, in offenders who are diagnosed with a mental disorder or developmental problems and are judged to have a high risk of recidivism. The main goal of the TBS order is to protect society from high risk offenders, directly through the mandatory admission of these offenders to secure forensic psychiatric hospitals and indirectly through treatment aimed at reducing violence risk. The TBS order is of indefinite duration; every one or two years, a judge decides on the continuation or termination of the TBS sentence on the basis of caregivers' reports about treatment progress and risk assessment.

TBS treatment is a multimodal, intensive approach to offender rehabilitation. Patients are given a range of psychological and other interventions, often including individual and group forms of psychotherapy; ancillary forms of therapy such as arts therapies (e.g., movement, drama, music, art); relapse prevention programs for addiction and aggression, pharmacological interventions, where indicated, vocational training, milieu therapy, and so forth. Nevertheless, in the absence of evidence-based treatments in the forensic field (e.g., Keulen-de Vos, Bernstein, & Duggan, 2012a, submitted), each of the 12 TBS clinics in the Netherlands has been given the latitude to implement the treatments of their own choosing. Thus, there is considerable variability within TBS institutions in terms of the treatments that are offered.

A very important aspect of TBS treatment is the gradual reintroduction of the patient into the community, a process known as "resocialization." Patients are assessed at regular intervals, usually on an annual basis, with standardized risk assessment instruments. When their risk levels diminish, they are given permission to go on leave, first for short periods of time under high supervision, and then later, for longer, unsupervised leave. This process can be reversed if patients begin to exhibit high-risk behaviors. All leave decisions are independently evaluated and advised on by an external body called the "Adviescollege Verloftoetsing TBS" [the "Leave Advisory Board"], or AVT in short, and need to be approved by the Dutch Ministry of Justice. Eventually, the resocialization phase, if successful, leads to the termination of the TBS sentence. The average length of stay in TBS has increased considerably in recent years, from about six years to nearly 10 years (Raad voor de Strafrechtstoepassing en Jeugdbescherming, 2011), a consequence of greater caution in releasing patients who may pose a high risk of recidivism.

In Dutch forensic psychiatric populations, offenders with personality disorders outnumber those with psychotic disorders (e.g., Emmerik, 2001; Nijman, Cima, & Merckelbach, 2003). For personality disordered offenders, however, no well-established pharmacological treatment options exist, and it has been questioned by many whether psychotherapeutic approaches can be beneficial in case of severe antisocial and psychopathic personality disorders (Rice, Harris, & Cormier, 1992). Nevertheless, the costly TBS system has been populated mostly by severely

personality disordered offenders since 1928. Yet, there is only limited evidence that TBS treatment is effective in reducing recidivism rates and psychiatric symptoms among personality disordered offenders.

## Outcomes of the TBS System

Although TBS is a costly treatment, published studies on the outcomes of TBS patients are scarce. Yet, quantitative information is available about the recidivism rates of TBS patients after discharge from the TBS system (e.g., Bregman & Wartna, 2010; Hildebrand et al., 2005), which can be contrasted with recidivism rates from Dutch offenders leaving general correctional institutions (Wartna et al., 2006). Although more indirect comparisons like that cannot be viewed as 'proof' for the effectiveness of TBS treatment, these recidivism statistics in general are favorable for the TBS system. Of the patients that were discharged from the TBS system in the years 1999 to 2003, 22.9% had relapsed into any form of crime (i.e., light to severe offenses) within two years after termination of the TBS measure. Although a substantial recidivism rate, it is considerably lower than the recidivism numbers from ex-prisoners (prisoners who did not receive the specialized TBS treatment). The recidivism rates of ex-prisoners who were released from prison in the years 1999–2003, for instance, fluctuated from 54.0% to 58.8% within two years after release (Wartna et al., 2006). Also, when comparing recidivism in severe crimes only, or comparing recidivism rates over longer follow-up periods, the relapse rates among ex-TBS patients are lower than those found among ex-prisoners. For example, of the TBS patients for whom the TBS measure was terminated in the years 1999–2003, 32.1% had recidivated to a serious crime (i.e., a crime for which a prison sentence of at least four years or more can be given; Bregman & Wartna, 2010) within five years. In comparison, 57.1% of the prisoners who were released in 2000 recidivated to a serious crime within five years (Wartna, et al., 2006). Furthermore, the most recent report on recidivism figures of TBS patients after termination of their TBS measure (Bregman & Wartna, 2011) points out that the recidivism rates steadily have gone down over a substantial period of time. To illustrate this, the proportion of patients relapsing into a serious crime (see definition above) in the cohort of patients that left the TBS system in 2004–2008 was half of that of the patients who left the TBS system 25 years ago (i.e., in 1984–1988; percentages currently being 17.0% versus 36,4%, respectively).

A few studies have addressed changes in psychiatric symptoms and risk factors during TBS treatment (e.g., de Jonge, Lammers & Nijman, 2009; Nijman, van Nieuwenhuizen & de Kruyk, 2004). The largest of these studies, as far as we know, was based on 984 (repeated) measurements with the Historisch Klinisch Toekomst-30 (HKT-30) performed in three Dutch TBS hospitals (de Jonge et al., 2009). The HKT-30 is a validated (Hildebrand et al., 2005) Dutch risk assessment scale, which resembles, and follows, the three-subscale structure of the HCR-20. It was found that more than half the scores for dynamic risk factors, as well as the HKT-30 total score, declined significantly as TBS treatment progressed, but the differences were small in absolute terms (see de Jonge et al., 2009). Also, in this large-scale study, no waitlist condition or control group condition was used, which leaves all kinds of alternative explanations for the observed decline in risk indicators as reported by the caregivers from the participating TBS hospitals on the HKT-30.

To summarize, some empirical data exist that support the notion that TBS treatment can benefit some forensic psychiatric patients, and may be superior in reducing recidivism risks over imprisonment without specialized treatment. However, no randomized clinical trials have been conducted to confirm this. Such studies would require random assignment to TBS clinics or prisons, a research design which, for judicial and ethical reasons, might not be feasible to implement. Moreover, although TBS does appear to be more effective than incarceration, there is little evidence about which elements of TBS treatment might account for this. For example, it might be that the treatment milieu itself is more benign in TBS clinics than in prisons, and this alone accounts for TBS's greater effectiveness. Thus, we don't know whether the specialized interventions offered in TBS clinics contribute to its success. This problem is compounded by the limited evidence base over the effectiveness of forensic treatments in general. For example, a recent review of the literature found that there were no published studies of randomized clinical trials testing the effectiveness of specific interventions for forensic patients with personality disorders (Keulen-de Vos et al., 2012a, submitted). Thus, there are many unanswered questions about TBS treatment: whether it works, for whom it works, and how it works?

## Rationale

In this article, we describe a multicenter randomized clinical trial that is being conducted in the Netherlands to address these questions for the largest group of offenders in TBS clinics: those with personality disorders. This study, which began in 2007, was undertaken in response to a Dutch parliamentary investigation (Tweede Kamer der Staten Generaal, 2005/2006) into some highly publicized cases in which TBS patients escaped and committed violent offenses while on leave from their institutions. The committee made a number of recommendations, including making risk assessments mandatory whenever patients requested leave. Furthermore, the committee recommended that Dutch universities and forensic institutions collaborate on research, including clinical trials, to improve the effectiveness of TBS treatment. The project described in this article is the largest and most sustained effort in response to the committee's recommendations.

The study is a three-year randomized clinical trial and three-year follow-up comparing the effectiveness of Schema Therapy (ST) to treatment as usual for male forensic patients with Antisocial, Borderline, Narcissistic, or Paranoid Personality Disorders (PDs) at seven TBS clinics. We chose an intensive, longer-term form of psychotherapy, ST, because it has shown evidence of effectiveness in (non-forensic) patients with Borderline PD (Farrell, Shaw, & Webber, 2009; Giesen-Bloo et al., 2006; Nadort et al., 2009), and could be successfully adapted to forensic patients with personality disorders (Bernstein, Arntz, & de Vos, 2007). In a previous study (Giesen-Bloo et al., 2006), patients receiving ST showed substantial reductions in PD symptoms, with 50% judged to be in remission from their Borderline PD symptoms, and 70% showing clinically significant improvement, after three years of therapy plus a one-year follow-up. Given the high rates of recidivism in forensic patients with personality disorders, compared to other mentally ill offenders (Coid, Hickey, & Yang, 2007; Jamieson & Taylor, 2004; Steels et al., 1998), we felt that an intensive, longer-term form of treatment was needed to achieve reductions in personality disorder symptoms and recidivism risk in these patients.

## SCHEMA THERAPY

ST is an integrative therapy for personality disorders (PDs) combining cognitive, behavioral, psychodynamic object relations, and humanistic/experiential approaches (Rafaeli, Bernstein, & Young, 2011; Young, Klosko, & Weishaar, 2003). ST is an intensive form of individual psychotherapy that is usually delivered twice a week in forensic inpatients with severe PDs. Treatment usually lasts from two to three years, with frequency often reduced in the third year of treatment. Group forms of ST have also been developed (e.g., Farrell et al., 2009), including for use in the forensic field (Beckley & Gordon, 2009), but these are usually intended as ancillary treatments in forensic patients who are also undergoing individual ST.

ST has a number of features that make it innovative. First, the ST therapist uses "limited reparenting"—a focus on providing for the patient's early unmet developmental needs, within appropriate limits and boundaries—to foster a secure attachment. Second, in addition to cognitive and behavioral techniques, ST incorporates experiential, emotion-focused techniques, such role playing and imagery rescripting, to access and reprocess emotions, including those stemming from traumatic experiences. Third, ST incorporates specific techniques for confronting and setting limits on patients' inadequate coping behaviors (e.g., aggression direct towards self or others), and teaching more adaptive coping skills. Finally, ST focuses on modifying emotional states, known as "schema modes," which are considered to play a central role in severe personality disorders (e.g., Antisocial, Borderline, and Narcissistic PDs), such as those often seen in forensic patients (Rafaeli et al., 2011; Young et al., 2003).

Bernstein and Arntz's adaptation of ST for forensic patients (Bernstein et al., 2007) focuses on the emotional states ("schema modes") that are most common in forensic patients with PDs and are hypothesized to play a role in violence and criminality. Schema modes are fluctuating emotional states that dominate the patient's thoughts, feelings, and behaviors at a given moment. Bernstein and colleagues (2007) expanded the schema mode model to include the modes that are most characteristic of antisocial and psychopathic patients. These include states of dominance, arrogance, and superiority ("Self-Aggrandizer" mode); the use of threats and aggression to intimate others or defend oneself against perceived threats ("Bully and Attack" mode); manipulative attempts to achieve a goal by playing a deceptive role ("Conning Manipulative" mode); a hypervigilent focus on uncovering hidden threats ("Paranoid Overcontroller" mode); and cold ruthless aggression to eliminate a threat, enemy, or an obstacle to a goal ("Predator" mode). Recent research supports the schema mode concept in patients with Antisocial and Borderline PDs (Lobbestael et al., 2009), including hypothesized relationships between maladaptive schema modes, crimes, and violence (Keulen-de Vos, Bernstein, Vanstipelen, et al., 2012, submitted). The goal of forensic ST is to reduce the patient's reliance on maladaptive coping modes; break through the patient's emotional detachment to access and heal his vulnerable side ("Vulnerable Child" mode), including early wounds caused by traumatic experiences; teach the patient more modulated and constructive ways of expressing anger; enhance frustration tolerance and lessen impulsivity; and enhance reliance on more healthy forms of coping ("Healthy Adult" mode).

ST begins with an assessment and case conceptualization phase that lasts for several sessions or more. During this phase, the therapist teaches the patient the "language" of schema modes, and working together with the patient, develops an individualized case conceptualization, using the mode concept. This mode conceptualization becomes the "road map" that guides the treatment in the schema change phase of therapy, which can last for two to three years. Because motivation is so often problematic in forensic patients, ST addresses motivational issues throughout the course of therapy. ST views the patient's motivation as dynamic and fluctuating, rather than static. It conceptualizes obstacles to motivation in terms of schema modes which block the therapy's progress. By using the mode model to identify stuck points in treatment, the therapist addresses motivational issues whenever they occur, choosing interventions that target the specific modes in question.

### Population

Patients with Antisocial, Borderline, Narcissistic, or Paranoid PDs were chosen for treatment as they represent the most prevalent diagnostic group in TBS clinics (Blackburn et al.,

2003; Lindsay et al., 2006; Timmerman & Emmelkamp, 2005; Nijman et al., 2003), and are considered among the most challenging to treat. Research indicates that patients with these personality disorders are at higher risk for recidivism, and account for higher rates of institutional violence and other infractions (Coid et al., 2007; Jamieson & Taylor, 2004), than other forensic patients.

Patients with high levels of psychopathy are at very high risk for recidivism, about two to four times as likely to commit future offenses within one to three years following discharge, compared to other forensic patients (Hemphill, Hare, & Wong, 1998; Salekin, Rogers, & Sewell, 1996). Psychopathic patients have traditionally been considered very difficult, if not impossible to treat (Rice et al., 1992). However, there is little empirical support for this view (D'Silva, Duggan, & McCarthy, 2004). We therefore chose to include psychopathic patients in our study.

In this report, we describe the rationale for our randomized clinical trial; its methodology; progress; and some preliminary results of clinical outcomes in the first cohort of 30 patients to complete the three-year study. This study represents, to our knowledge, the only large-scale randomized clinical trial conducted so far to examine the effect of a specific intervention for forensic patients with personality disorders, either in the Netherlands or internationally. Moreover, it is the only study of its kind that includes a high proportion of psychopathic patients; approximately 50% of the patients have a Psychopathy Checklist-Revised (PCL-R; Hare, 1991) total score of 25 or higher, and about 30% have a score of 30 or higher. Thus, the study will enable us to test the effectiveness of ST for some of the most intransigent psychopathology in forensic settings, including patients who are highly psychopathic. Although one previous randomized controlled study investigated the effectiveness of ST in patients at a British high-security hospital (Tarrier et al., 2010), it was marred by serious methodological problems. These problems included high attrition; poor statistical power; self-reports as the main outcome measures; an insufficient frequency of ST; a version of ST that did not incorporate schema modes; and the provision of ST by only two therapists, neither of whom was able to demonstrate competency in ST, even after the end of the two-year treatment. Thus, while this study failed to find differences between ST and treatment as usual, it is difficult to draw conclusions from it.

The aim of the present clinical trial is to determine whether ST can lower recidivism risks and associated personality disorders compared to treatment as usual in TBS clinics. Our multicenter, randomized design (see below) enabled us to compare ST to treatment as usual at a broad and representative number of clinics (seven of the 12 TBS clinics in the Netherlands are participating), encompassing approximately 30 therapists in each treatment condition, 102 patients, and diverse interventions representing "treatment as usual." Thus, our design is capable of determining whether ST is an effective specific intervention for forensic patients with Antisocial, Borderline, Narcissistic, or Paranoid PDs, compared to treatment as usual that is offered in TBS clinics.

## Methods

### *Implementation*

The project is a joint undertaking between the seven participating TBS clinics, the Expertise Center for Forensic Psychiatry (EFP), and Maastricht University's Faculty of Psychology and Neuroscience. The project is led by the first author of this article (D.P.B.), who also serves as chair of the project's research committee, which consists of the representatives from all of the clinics, and makes decisions about the study's design and implementation. Each clinic has a project team, consisting of a project leader (usually the head of the research department or a clinical manager), research assistant, therapists, and other personnel (e.g., diagnostic staff). The EFP is also supporting this project, by providing a national coordinator, L. Bouts, and a database manager, L. de Geus. In all, over 100 people are working on this project.

### *Therapist Training, Competency, and Therapy Adherence*

ST is delivered according to the procedures described in Young et al. (2003), *Schema Therapy: A Practitioner's Guide*, which has been adapted for forensic patients, as described in Bernstein et al. (2007), and elsewhere (e.g., Bernstein et al., 2012). Therapists participating in the multicenter clinical trial receive extensive training in ST, which includes completing an eight-day training program in ST for forensic patients, developed by D. Bernstein and T. Kersten, and given annually through the Expertise Center for Forensic Psychiatry (EFP) and the Dutch Cognitive-Behavioral Therapy Association (VGCt); working with a practice patient, giving the therapist the opportunity to practice ST skills; and participating in twice monthly supervision groups at each site. Therapists' sessions with practice patients are videotaped and scored for therapist competence by an independent expert. Therapists are required to meet competency standards established by the International Society for Schema Therapy (isst-online.com) to see patients for the study. Therapists' tapes are also rated three times (early, mid-, and late-therapy) for adherence to the therapy protocol. Approximately 60 therapists (psychologists and psychotherapists) are participating in this project, approximately half in the SFT condition and half in the TAU condition.

### *Recruitment, Sites, and Inclusion/Exclusion Criteria*

Recruitment began in 2007 at three clinics: de Rooyse Wissel (Venray), van der Hoeven (Utrecht), and Oostvaarders (Almere). Five additional clinics (see below) joined the study in 2009–2011. Recruitment was completed in July, 2012. There are 102 patients enrolled in the study. The final sample size was slightly lower than the projected enrollment of 114

patients, based on a power analysis which indicated an *N* of 114 needed for power = .80 to detect a 25% difference in the proportion of patients with successful outcome, a medium effect size comparable to that in a previous study of ST in patients with Borderline PD (Giesen-Bloo et al., 2006). The lower than expected enrollment was caused by a reduced rate of patient referrals to the TBS system in the past three years, as a result of the increasing length of stay (see above). The first 30 patients who entered the study in 2007 have already completed the three-year treatment (see below for preliminary results). The entire sample will complete the three-year treatment study by mid-2015. The three-year follow-up study will be completed by mid-2018.

Male patients with Antisocial, Borderline, Narcissistic PD or Paranoid PD are being recruited at seven TBS clinics: de Rooyse Wissel (Venray and Maastricht locations), van der Hoeven (Utrecht), Oostvaarders (Almere), Kijvelanden (Portugaal), Mesdag (Groningen), Veldzicht (Balkbrug), and FPK Assen (Assen). Only male patients were included, as they are far more prevalent than female patients in the TBS population. Other personality disorders (e.g., Histrionic PD) were not included in the study because they are less prevalent in forensic populations and there is less evidence that they are associated with recidivism (Hiscoke et al., 2003). On the other hand, patients with a diagnosis of Personality Disorder-Not Otherwise Specified (PDNOS) were included in the study if they had at least five Cluster B PD symptoms and no other Axis II PD diagnosis. Thus, the study included some patients with significant Cluster B PD traits who did not meet diagnostic thresholds for a Cluster B PD diagnosis, to create a broad and representative sample of patients with Cluster B PD characteristics that are typical of patients found in TBS institutions. Exclusion criteria are (1) the presence of a current psychotic symptoms, (2) schizophrenia or bipolar disorder, (3) current drug or alcohol dependence (but not abuse), (4) low intelligence (i.e., Full Scale IQ < 80), (5) serious neurological impairment (e.g., dementia), 6) an autistic spectrum disorder (e.g., Autism, Asperger's Disorder), and (7) pedophilia (i.e., a fixated sexual preference for children). Addictive disorders are not an exclusionary criterion, as 80% or more of these patients have drug or alcohol problems. Exclusive pedophiles (i.e., those with a fixated preference for children) were excluded from the clinical trial, because they were considered to represent a different subpopulation of patients (e.g., Biddey & Beech, 2003; Groth & Birnbaum, 1978) that required a further adaptation of SFT methods that went beyond the scope of this study. However, pedophilic patients who did not exhibit a fixated pattern were included in the study.

### *Participants*

Thirty five patients were approached initially at the three clinics that began the study in 2007. One patient declined to participate before randomization and another declined shortly after being randomized, but before he received his first therapy session. A third participant had to be excluded because he met one of the exclusion criteria, leaving 33 patients to start the therapy. Of these 33 patients, 30 patients (ST, $N = 16$, TAU, $N = 14$) completed the three-year trial in time to be included in the analyses reported below. Of the first 30 patients to complete the three-year randomized clinical trial, 86.7% ($N = 26$) had a DSM-IV diagnosis of Antisocial PD, 30% ($N = 9$) of Borderline PD, 33.3% ($N = 10$) of Narcissistic PD, and 3.3% ($N = 1$) of Paranoid PD. None of the patients had a diagnosis of Cluster B PD NOS. Thirty seven percent ($N = 11$) of the patients were diagnosed solely with Antisocial PD, 10% ($N = 3$) solely with Borderline PD and 3.3% ($N = 1$) solely with Narcissistic PD. Fifteen of the patients had more than one personality disorder diagnosis. Twenty percent ($N = 6$) of the patients were diagnosed with both Antisocial PD and Borderline PD, 26.7% ($N = 8$) with Antisocial PD and Narcissistic PD, and 3.3% ($N = 1$) with Antisocial PD and Paranoid PD. Patients had a mean age of 41.3 years ($SD = 8.5$ years), mean full scale WAIS IQ of 93.3 ($SD = 12.2$), and mean PCL-R total score of 25.4 ($SD = 6.9$). Eight patients (26.7%) had PCL-R scores of 30 or greater. When using a cut-off of 25, 18 of the 30 patients (60%) had a high PCL-R score.

By chance, in this small, preliminary sample, patients assigned to the ST condition were more psychopathic, though not significantly so, than patients in the TAU condition. The ST condition contained more highly psychopathic patients (PCL-R total score of 30 or greater), compared to the TAU condition ($N = 6$, 37.5%, versus $N = 2$, 14.3%, respectively), though this difference was not statistically significant ($\chi^2(1, N = 30) = 2.01$, $p = .15$). When using a cutoff of 25, again the ST condition included more high-scoring psychopaths ($N = 11$, 68.8%) than the TAU condition ($N = 7$, 50%; $\chi^2(1, N = 30) = 1.09$, $p = .3$). The ST group had a (non-significantly) higher mean PCL-R total score than the TAU group (mean ST = 26.8, $SD = 7.5$ versus mean TAU = 23.8, $SD = 6.0$; $t(28) = -1.16$, $p = .26$). Twenty-seven out of 30 patients (90%) had received TBS sentences for committing violent offenses, including sexual offenses ($N = 6$, 20%) and non-sexual offenses ($N = 21$, 70%). The vast majority of patients were of Dutch origin ($N = 27$, 90%), with the rest from Morocco ($N = 1$), Surinam ($N = 1$), or other European Union countries ($N = 1$).

### *Research Design*

Patients at each clinic are randomly assigned to receive either ST or treatment as usual ('TAU'). Random assignment is accomplished using an "adapted biased urn procedure" (Schouten, 1995), which randomly assigns patients to treatment conditions at each site using an algorithm that assures that the overall proportion of patients in the experimental and control condition will be in equal balance. Patients are

assigned by a central research assistant who is blind to any information about the patient.

### *Treatment as Usual*

TAU is the treatment as usual that patients receive at each clinic, which is usually another (non-ST) form of individual psychotherapy, such as cognitive-behavior therapy, psychodynamic therapy, or client-centered therapy. The clinics are free to choose the type of therapy that they provide to patients. Although cognitive-behavior therapy is the most common form of "treatment as usual" offered in TBS clinics, practices vary considerably. Thus, "treatment as usual" in this study enabled us to compare ST to a broad and representative assortment of the treatments offered in these institutions. ST patients receive twice per week individual therapy sessions, as this is the 'dose' of ST that is usually recommended for severe PDs (Young et al., 2003), and was effective in non-forensic patients with Borderline PD (Giesen-Bloo et al., 2006); TAU is delivered once per week, as this is usual practice in TBS clinics. Patients in both treatment conditions also receive a number of ancillary treatments, such as group therapy (e.g., Aggression Replacement Therapy; Hornsveld, Nijman, & Kraaimaat, 2008), and Arts Therapies (van den Broek, Keulen-de Vos, & Bernstein, 2011), that are common in TBS clinics. Treatment lasts for three years. In the third year of treatment, patients in the ST condition often reduce their frequency of sessions to once per week, especially once they enter into the resocialization phase of treatment. The duration of treatments in the TAU condition varies considerably, with therapy often being reduced in frequency or terminated when treatment goals are considered to have been met. In some cases, termination of patients in the ST and TAU conditions occurred prior to three years, for example, when treatment goals had been achieved, patients dropped out of therapy, or patients were transferred to other institutions. In some of these cases, patients continued to receive other treatments, or were offered different ones.

### *Outcome Variables*

The main outcome variables (Figure 1), which are assessed every six months, are recidivism risk, as measured by standard risk assessment instruments (i.e., *Historical, Clinical and Risk management scheme* (HCR-20; Douglas & Webster, 1999), the *Sexual Violence Risk Assessment-20* (SVR-20; De Vogel, 2005; De Vogel et al., 2004), and the *Short Term Assessment of Risk and Treatability* (START; Webster et al., 2004; Webster et al., 2009); PD symptoms (i.e., *Structured Interview for DSM-IV Personality Disorders* (SIDP-IV; Pfohl, Blum, & Zimmerman, 1995), patient and the informant versions of the *Schedule for Nonadaptive and Adaptive Personality* (SNAP-I; Clark, 1993; Keulen-de Vos et al., 2011); resocialization (i.e., supervised and

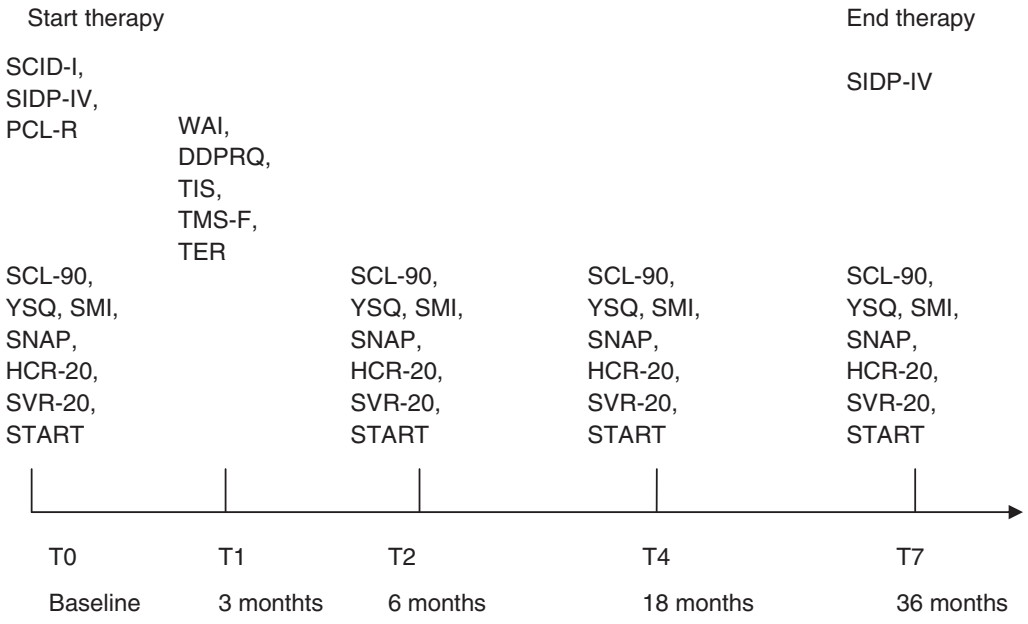


FIGURE 1 Schematic of assessments administered over the 3-year course of the study

*Note:* T3, T5, and T6 measures, which are not depicted, are the same as at T2 and T4. T1 measures are repeated at T4 and T7. Recidivism to be measured at 3-year post-treatment follow-up. *Abbreviations: SCID-I-Structured Clinical Interview for DSM-IV Axis 1 disorders; SIDP-IV - Structured Interview for DSM-IV Personality Disorders; PCL-R – Psychopathy Checklist-Revised; SCL-90 – Symptom Checklist-90; SNAP - Schedule for Nonadaptive and Adaptive Personality – Patient and Informant Versions; YSQ – Young Schema Questionnaire-Research Version; SMI – Schema Mode Inventory; HCR - Historical, Clinical and Risk Assessment; SVR - Sexual Violence Risk Assessment-20; WAI - Working Alliance Inventory; DDPRQ - Difficult Doctor-Patient Relationship Questionnaire – Ten item version; TIS – Therapy Integrity Scale; TMS-F - Treatment Motivation Scales for Forensic Outpatient Treatment; TER - The Treatment Engagement Rating Scale for Forensic Outpatient Treatment.*

unsupervised leave); early maladaptive schemas and schema modes (*Young Schema Questionnaire – Short Version,* Young, 1998; *Schema Mode Inventory*, Lobbestael et al., 2010); institutional violence (i.e., aggression and other incidents) and general psychopathology (*Symptom Checklist-90* (SCL-90, Derogatis, Lipman, & Covli, 1973).

In general, we attempted to use multiple measures of all main outcome variables, and incorporate measures that are not dependent on patients' self-report, to avoid well-known response biases in forensic patients (Keulen-de Vos et al., 2011). The assessments that did not depend on patients' self-reports were the risk assessment measures (i.e., HCR-20, SVR-20, and START); the informant version of the SNAP personality disorder questionnaire, which was completed by staff members in frequent contact with the patients; the registry of patient incidents; the data on approval of leave applications; and the data on actual recidivism. In addition, the diagnostic interviews that were conducted (e.g., SIDP-IV, PCL-R) were rated based on a combination of patient's self-report and file information. Diagnostic interviews (e.g., SIDP-IV, PCL-R) and risk assessment procedures (e.g., HCR-20, SVR-20, START) were administered by the diagnostic teams at the clinics or by research assistants who were trained to give these instruments.

Raters were not kept blind to treatment condition, as this was not feasible in a three-year study in clinical settings. However, raters who were blind to patients' treatment condition status double-scored a subset of these risk assessments; results indicated good inter-rater agreement for blind and non-blind ratings, suggesting that raters' knowledge of patients' treatment condition had little effect on risk assessment scores. In a sub-sample of 16 patients, the interrater reliability (intra-class correlation (ICC) for the average of two raters) for the HCR-20 overall judgment of the risk level within the hospital was .81; there was perfect agreement for ratings of risk level outside of the hospital (ICC = 1.0). The interrater reliability for the PCL-R total score was ICC = .88; ratings were also internally consistent (Cronbach's alpha = .80). The interrater reliabilities for the four PD diagnoses in our study, based on the SIDP-IV, were ICCs = .80 for Antisocial PD, .83 for Borderline PD, .92 for Narcissistic PD, and .90 for Paranoid PD. The percent agreement between raters was perfect (100% agreement) for all SCID Axis I diagnoses in a sub-sample of 6 patients.

We classified outcome globally as positive, neutral, or negative. Positive outcomes were defined as successfully completing treatment; neutral as prematurely terminating treatment for reasons not related to poor outcomes; and negative as events such as dropping out of therapy, recidivism, or being transferred to another TBS facility due to a poor treatment response.

After treatment is completed, a three-year follow-up study will be conducted to assess actual recidivism, using Ministry of Justice records. A number of possible moderators of outcome will also be examined, including patients' PCL-R scores assessed at baseline, and the therapy alliance and patients' motivation for treatment (rated by patients and therapists at 3, 18, and 36 months). This research protocol was approved by the Medical Ethical Committee of Maastricht University (D. Bernstein, Principal Investigator). All patients in the study gave their informed, written consent.

### *Statistical Analyses*

For our preliminary analyses of clinical outcomes, we used Fisher's exact test to compare proportions of patients in the two treatment conditions receiving supervised and unsupervised leave, and Cox regression survival analysis with PCL-R scores as a covariate to analyze the number of days needed to obtain permission for supervised and unsupervised leave. We analyzed differences in percentage of patients with negative global outcomes using Fisher's exact test. We did not use intention-to-treat analysis, as there were no missing data for these analyses. We used repeated measures ANOVA to analyze the effect of ST versus TAU on HCR-20 scores over the course of treatment, using centered PCL-R scores as a covariate. We used the HCR-20 estimate of patients' risk if they were to leave the hospital (as opposed to their risk if they were to stay in the hospital), because this gave us the best indication of their likelihood of recidivating on release. Six patients were missing data at one or more time points for the HCR-20, and were dropped from these analyses. We did not analyze other outcome variables, or examine interactions of treatment condition with PCL-R scores, because of the low statistical power in this preliminary sample of 30 patients.

## Preliminary Results

A higher proportion of ST patients received supervised and unsupervised leave at each time point across the course of the study than patients in the TAU condition (Figure 2), though these differences did not reach statistical significance. After two years of treatment, 62.5% of ST patients ($N = 10$) had received supervised leave, but only 35.7% of the TAU patients ($N = 5$) (Fisher's Exact Test, $p = .27$); during the same period, 31.3% ($N = 5$) of the ST patients received unsupervised leave, but just 7.1% ($N = 1$) of the TAU patients (Fisher's Exact Test, $p = .18$). These differences diminished over the last year of treatment, as the ST patients neared a possible ceiling, and the TAU patients "caught up." By the end of the three-year study, 81.3% ($N = 13$) of the ST patients had received supervised leave, compared to 78.6% (N = 11) of the TAU patients (Fisher's Exact Test, $p = 1.0$); 62.5% ($N = 10$) of the ST patients had received unsupervised leave, compared to 57.1% ($N = 8$) of the TAU patients (Fisher's Exact Test, $p = 1.0$).

We used Cox regression survival analysis to compare the two treatment conditions with respect to the number of days required to obtain permission for supervised leave and unsupervised leave, respectively. PCL-R scores were included as a covariate in order to increase the power of the analyses. In

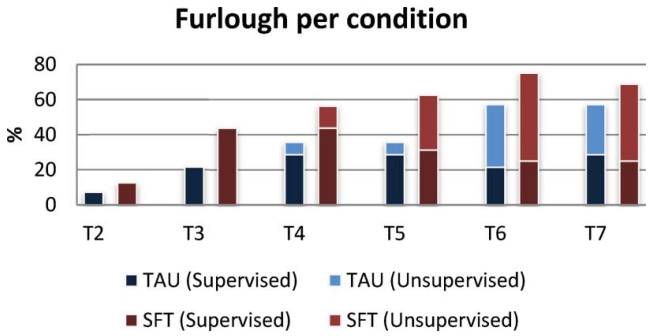


FIGURE 2 Percent of patients receiving supervised and unsupervised leave by treatment condition (Color figure available online).

both analyses, inspection of the survival functions suggested that the ST patients received leave more rapidly than the TAU patients, though these differences were not statistically significant (Figures 3 and 4; supervised leave: $\beta = -.32$, $t(27) = .62$, $p = .43$; unsupervised leave: $\beta = -.71$, $t(27) = 1.9$, $p = .17$). In the case of unsupervised leave, PCL-R scores were a significant covariate ($\beta = -.07$, $t(27) = 4.2$, $p = .04$), while in the case of supervised leave, it was not ($\beta = -.72$, $t(27) = 2.0$, $p = .19$).

Of the patients who received supervised leave, ST patients needed an average of 137 fewer days ($M = 424.38$, $SD = 309.65$) to get supervised leave than TAU patients ($M = 561.91$, $SD = 317.55$), though this difference was not statistically significant ($t(22) = 1.07$, $p = .30$). Of the patients who received unsupervised leave, ST patients required an average of 138 fewer days to receive unsupervised leave ($M = 679.80$, $SD = 183.17$) than TAU patients ($M = 817.13$, $SD = 189.89$). Again, this difference was not yet statistically significant ($t(16) = 1.56$, $p = .14$).

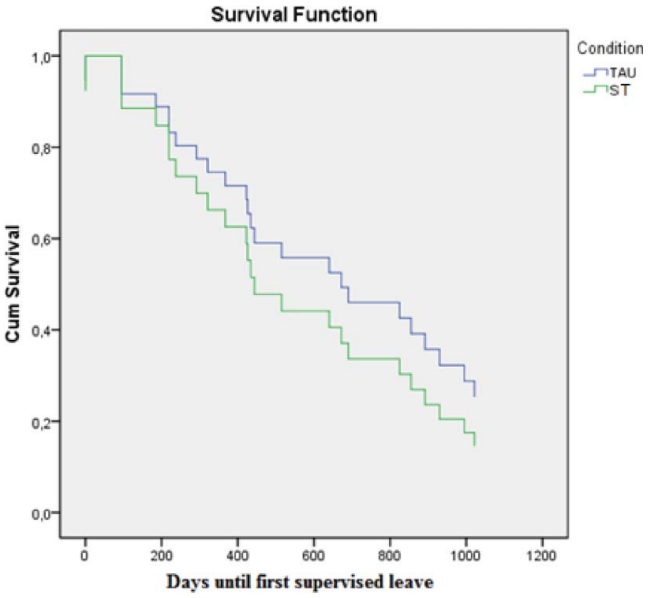


FIGURE 3 Days until first supervised leave (Color figure available online).

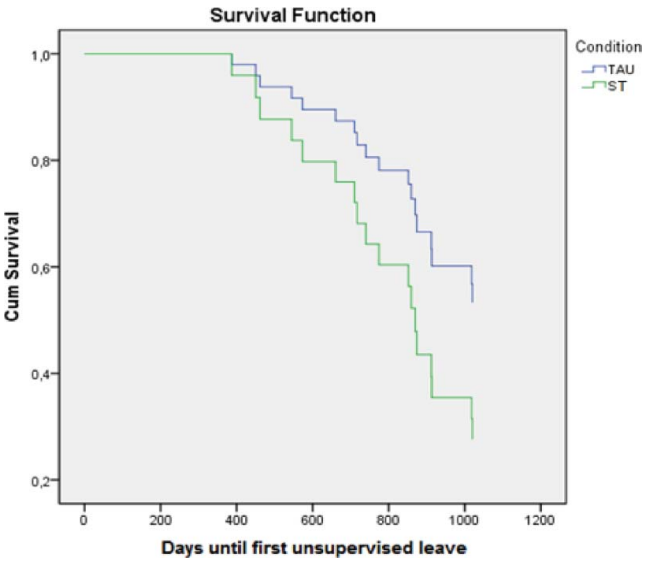


FIGURE 4 Days until first unsupervised leave (Color figure available online).

With regard to global therapy outcome, ST patients also showed fewer overall negative outcomes (18.8%, $N = 3$) than the TAU patients (35.7%, $N = 5$), over the entire 3 years of therapy. However, this difference was not statistically significant ($\chi^2(1, N = 30) = 1.1$, $p = .3$). Of the eight patients with negative outcomes, three patients (ST, $N = 1$, TAU, $N = 2$) were transferred to other clinics due to a lack of treatment response; one patient (TAU, $N = 1$) had to terminate therapy due to a worsening of his psychiatric condition; one patient (TAU, $N = 1$) had to terminate therapy due to a lack of treatment response; one patient recidivated (ST, $N = 1$); and two patients were terminated due to lack of cooperation with the research (ST, $N = 1$, TAU, $N = 1$).

When we examined the effect of treatment condition on change in patients' HCR-20 total scores, using repeated measures ANOVA, the scores of the ST patients appeared to improve more rapidly than those of the TAU patients (Figure 5), though again, no statistically significant effects of treatment were found. PCL-R scores were centered and entered as a covariate to increase statistical power. The effect of PCL-R scores on patients' HCR-20 scores was highly statistically significant ($F(1, 20) = 17.47$, $p < .001$). There was a statistically significant effect of time ($F(6, 15) = 4.13$, $p = .01$), but no main effect of treatment condition on HCR-20 scores ($F(1, 20) = 0.18$, $p = .67$). There was also no overall interaction of treatment condition with time ($F(6 , 16) = 1.16$, $p = .38$). However, when we examined the components of the interaction of treatment condition by time (i.e., within subject contrasts), there was no linear effect ($F(1, 20) = .12$, $p = .73$), but there was a trend towards statistical significance for the quadratic component of the interaction ($F(1, 20) = 3.24$, $p = .09$), suggesting a curvilinear relationship of treatment condition by time.

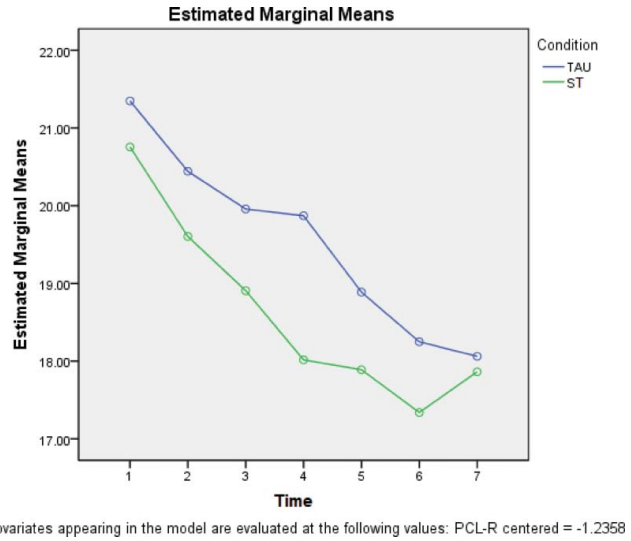


FIGURE 5 Effect of treatment condition on HCR-20 total scores over time (Color figure available online).

## DISCUSSION

These findings are preliminary and not statistically significant in this small sample of 30 patients, and therefore need to be interpreted with caution. Nevertheless, they suggest that ST may be a promising form of treatment for forensic patients with personality disorders. Of particular note is the observation that the ST patients appeared to be outperforming the TAU patients, despite having a much larger number, six versus two, of highly psychopathic patients with PCL-R score of 30 or greater in the ST condition than in the TAU condition. ST may promote more rapid progress into and through the resocialization phase of treatment, a crucial step in patients' re-entry into the community, though it is still too early to draw more than tentative conclusions. The 16 patients receiving ST were more likely to receive both supervised and unsupervised leave, and to do so more quickly, than the 14 patients receiving TAU. The apparent success of ST patients in obtaining leave bears an obvious relationship to their risk levels, as leave decisions are based on an assessment of patients' risk. Leave decisions are quite stringent in the TBS system, where they must be approved first by the clinic in which the patient resides, and then again by the Ministry of Justice, which has final authority over the decision, on the basis of the advice of the Leave Advisory Board (AVT; see introduction). Thus, the apparent success of ST patients in getting permission for leave is an important clinical indication that they are being judged to have a lowered level of risk. Our analysis of patients' scores on the HCR-20 points in this same direction, with ST patients showing a curvilinear trend towards more rapid reduction in risk, though again, these findings need to be confirmed in our complete sample.

The observation that ST patients moved through the resocialization process more rapidly than the TAU patients, receiving leave on average about 4.5 months faster for both unsupervised and supervised leave, raises the possibility that it may be a cost-effective form of treatment. We estimate the entire additional cost of delivering three years of ST to one patient (over and above the other costs of TBS), as €20.392, including the costs of training and supervising the therapist (€5.403), as well as the portion of the therapist's salary devoted to the therapy, for a senior therapist (€14.989). The annual cost of TBS treatment for one patient is approximately €160.000, per year. Thus, the full additional cost of delivering ST for three years can be completely recouped by reducing the patient's length of stay in the clinic by just two months. Thus, it seems possible that ST will result in reduced treatment costs, as patients are more rapidly able to leave detention. This cost savings, of course, does not even include the enormous financial and public safety benefits, if ST proves to reduce recidivism.

It should also be noted that TAU appeared to be an effective form of treatment for many personality disorder patients, reducing their risk and promoting their re-entry into the community. As noted earlier, there is evidence that TBS treatment reduces recidivism rates substantially compared to imprisonment, though randomized clinical trials comparing forensic treatment to incarceration are lacking (Bregman & Wartna, 2010; Wartna et al., 2006). The performance of TAU patients in this study appears to be comparable to that of previous studies of patients undergoing TBS treatment (de Jonge et al., 2009). Thus, our study supports the notion that usual TBS treatment is effective for many patients. It also raises questions about which patients should be offered ST, in light of its greater cost, and the generally good effectiveness of TAU. The extra costs of ST include the costs of specialized training and biweekly supervision, and the provision of therapy sessions twice per week versus once per week, over the three-year treatment. Where resources are limited, it may be that ST should be reserved for patients who don't respond as well to TAU. However, we will need to await the findings from our complete sample before making more definitive recommendations regarding triage to ST or TAU for forensic patients with Antisocial, Borderline, Narcissistic, or Paranoid PDs.

If ST does prove to be effective, it could be attributable to a number of factors. Our model hypothesizes that the therapist's ability to form a genuine emotional bond with the patient, overcome the patient's emotional detachment, and reach more vulnerable emotions, is critical to lowering risk in these patients (Bernstein et al., 2007). Previous research in non-forensic patients with Borderline PD suggests that ST is particularly effective at fostering a therapeutic alliance, and that the alliance is, in turn, a mediator of treatment outcomes in these patients (Spinhoven et al., 2007). Thus, the therapy relationship appears to be an important ingredient in the effectiveness of ST. In a pilot study of 10 randomly selected patients from our clinical trial (van den Broek et al., 2011), we found that forensic patients receiving ST ($N = 6$) showed

approximately twice as much emotional vulnerability ($p = .09$) as patients receiving TAU ($N = 4$) after completing 12 to 18 months of treatment. These findings suggest that ST is more effective than TAU in overcoming patients' emotional detachment and reaching their vulnerable emotions, a central contention of the theoretical model that guides our treatment. At the same time, the use of specific techniques, such as emotion-focused techniques, as well as non-specific factors, such as the therapist's sense of optimism and efficacy, may also help to explain some of the effectiveness of ST. Our ongoing research will provide more insight into the mechanisms that explain the apparent effectiveness of ST in forensic PD patients, including some psychopathic patients.

Our findings have a number of limitations, most obviously the fact that they are based on a sample of 30 patients and are not statistically significant. Whether the possible advantages for ST that we report here will be confirmed in our complete sample is impossible to predict. Our findings, though in the hypothesized direction, could still be attributable to chance in this small, preliminary sample. Moreover, we did not test interaction effects with psychopathy scores due to low statistical power. Thus, at this time, we can't make statements about the effectiveness of ST for patients with different degrees of psychopathy; however, we will be able to test these interactions with satisfactory power in our complete sample. We must also await the results of our follow up study, to be concluded in 2018, before we can determine whether ST is successful in reducing recidivism.

There are also a number of limitations of our research design, such as the greater frequency of therapy sessions in the ST versus TAU conditions (i.e., twice versus once per week), and the fact that research assistants were not blind to the patients' treatment conditions. Our decision not to equate the treatment conditions in terms of frequency of therapy sessions was due to the fact that "treatment as usual" in TBS clinics involves once per week individual psychotherapy. Moreover, at the time that we undertook this study, no other specific moderate- to long-term treatments for offenders with Cluster B PD offenders, which might have served as comparison treatments, were available. If we can demonstrate that ST is superior to TAU, it would justify further studies comparing ST to other specific treatments delivered with equivalent frequency. Nevertheless, if we do find an effect of ST in the present study, it is impossible to conclude with certainty that it is not solely due to treatment intensity. On the other hand, it should be noted that the patients in our study receive a number of other interventions, such as group therapy, creative arts therapies, and specific therapy modules (e.g., relapse prevention, violence prevention), in addition to ST or TAU. Thus, the effect of ST versus TAU is being measured over and above that of the other interventions that the patients receive. If ST shows an advantage over TAU, given the evident effectiveness of TAU for many patients and the number of interventions that these patients receive, it would be quite impressive.

Furthermore, it was not possible to keep research assistants blind to treatment condition over a three-year study, in which they frequently needed to discuss the patients' clinical status with treatment staff, and gather information from patients' clinical files. However, when we blindly double scored our risk assessment measures, we found good agreement between research assistants who knew the patients' treatment condition, and independent raters, who did not. This suggests that our risk assessments were unbiased by knowledge of patients' treatment condition.

Finally, as this report is preliminary in nature, we did not provide full information about all aspects of the research design (e.g., number of sessions of ST versus TAU) or the results; we will provide further details when we publish our complete findings. Although we considered waiting to publish any findings until our study is complete, we decided that the importance of the topic warranted this preliminary report, despite the tentative nature of the conclusions that can be drawn at this time.

Our group is engaging in a broad research program to answer questions about the effectiveness of ST in forensic populations, such as which patients benefit the most from ST; whether some patients are contraindicated for ST; and by which mechanisms does ST work. We are also conducting research to investigate alternative forms of ST which may be more suitable for some forensic patients, or may enhance their effectiveness, including forensic group ST (Beckley & Gordon, 2009), creative arts therapy ST (Keulen-de Vos, van den Broek et al., 2012, submitted; van den Broek et al., 2011), and ST for adolescents with "emerging personality disorders." Research is also needed to determine whether ST can be further adapted to make it suitable for subgroups of forensic PD patients who were excluded from our randomized clinical trial, such as patients with lower intelligence, autistic spectrum disorders, psychotic disorders, and the exclusive subtype of pedophilia. Such research could expand the range of forensic PD patients whom ST might help.

Finally, we hope that our study inspires others to investigate other promising forms of therapy for forensic patients with PDs. Other specific treatments for PDs may work via other mechanisms, and be more suitable for certain patients or problems (Keulen-de Vos, Bernstein, & Duggan, 2012b, submitted). Although a number of promising treatments for forensic PD patients exist (Keulen-de Vos et al., 2012a, submitted), randomized clinical trials have so far been lacking. Such studies are expensive and time consuming, and present formidable logistical and institutional challenges. However, randomized clinical trials remain the gold standard for investigating the effectiveness of treatments. Without them, there is likely to be little progress in determining what is effective for this highly challenging group of patients.

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