

SFT for Forensic PD Patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24138

Source

Nationaal Trial Register

Brief title

FOR-SFT study

Health condition

1. Antisocial Personality Disorder;
2. Borderline Personality Disorder;
3. Narcissistic Personality Disorder;
4. Paranoid Personality Disorder.

Sponsors and support

Primary sponsor: University of Maastricht

Source(s) of monetary or material Support: TBS clinics, Ministry of Justice

Intervention

Outcome measures

Primary outcome

The primary outcome measures in this study are the severity of personality disorder

symptoms and risk of recidivism and violence. To circumvent the problem of patients' tendency to "fake good," we will base our assessments on observations of patients' behavior provided by knowledgeable staff members, rather than on patients' own self-reports. We hypothesize the patients receiving SFT will show reduced levels of personality disorder symptoms and reduced risk of violence and recidivism, compared with patients receiving TAU. We also hypothesize that patients receiving SFT will show better treatment engagement and retention, and have a more positive therapeutic alliance, compared to patients receiving TAU. Finally, we predict that SFT patients will show greater improvements in the maladaptive schemas and related psychological processes that are hypothesized to underlie personality disorders in the SFT model. In a future study, we will follow-up these patients to determine their risk of actual recidivism after some of them are released to the community.

Secondary outcome

As secondary outcome measures, we will assess differences between the two treatment conditions in therapy process variables (e.g., therapeutic engagement, quality of the therapeutic alliance), and changes in the psychological processes (i.e., Early Maladaptive Schemas, Schema Modes) that are hypothesized to mediate changes in personality disorders in the Schema Focused Therapy model.

Study description

Background summary

Personality disorders are highly prevalent in forensic institutions, both in the Netherlands and worldwide (de Ruiter, & Greeven, 2000; Hildebrand & de Ruiter, 2004; Leue, Borchard, & Hoyer, 2004; Rasmussen, Storsaeter, & Levander, 1999; Timmerman & Emmelkamp, 2001), and are associated with increased risk of violence and criminal recidivism (Hemphill, Hare, & Wong, 1998; Hiscoke, Langstrom, Ottosson, & Grann, 2003; Jamieson & Taylor, 2004; Putkonen, Komulainen, Virkkunen, Eronen, & Lonnqvist, 2003; Rosenfeld, 2003; Salekin, Rogers, & Sewell, 1996). Patients with Antisocial, Narcissistic, Borderline, or Paranoid Personality Disorders are especially likely to commit violent acts within forensic settings, and to engage in crime and violence after release from incarceration. However, despite the risks posed by forensic patients with personality disorders, only a few previous studies have examined the effectiveness of treatments for these patients (Eveshed, Tennant, Boomer, Rees, Barkham, & Watson, 2003; Greenen, & de Ruiter, 2004; Timmerman, & Emmelkamp, 2005), and no major randomized clinical trials of psychotherapy with this population have been reported. These considerations suggest that developing and testing promising treatments for forensic patients with personality disorders should be a major priority.

Recently, progress has been made in developing new forms of psychotherapy that have considerable promise for treating personality disorders that have usually been considered "untreatable." In a recent randomized clinical trial, Schema Focused Therapy (SFT) – a novel form of cognitive therapy for personality disorders – was found to be highly effective in

ameliorating the symptoms of Borderline Personality Disorder (Giesen-Bloo, et al., 2006). These findings raise the possibility that SFT may prove effective in treating personality disorders in forensic settings.

In this study, we will test the efficacy of SFT in forensic patients with 4 severe personality disorders: Antisocial, Narcissistic, Borderline, and Paranoid Personality Disorders. One hundred male patients with Antisocial, Narcissistic, Borderline, or Paranoid Personality Disorders will be recruited from 4 Dutch forensic psychiatric hospitals ("TBS clinics") – the Rooyse Wissel in Venray, the Van der Hoeven clinic in Utrecht, the Oostvaarders clinic in Amsterdam and Utrecht, and another site that we are pursuing. Only male patients will be assessed because they are over-represented in criminal populations, and represent a greater risk for future crime and violence. Twenty-five patients from each clinic will be randomly assigned to receive either SFT or Treatment as Usual (TAU). TAU is defined as the customary treatment at that facility, which is typically a form of cognitive-behavioral, psychodynamic, or humanistic psychotherapy. Patients receiving SFT will receive twice weekly psychotherapy session, which is the recommended "dose" of SFT for patients with severe personality disorders (Young et al., 2003). Patients receiving TAU will receive once per week psychotherapy, because this is the customary practice at TBS institutions. Thus, the two treatments will not be equated for frequency, because the goal of the study is to determine whether SFT produces benefits beyond that of usual TBS practice.

The primary outcome measures in this study are the severity of personality disorder symptoms and risk of recidivism and violence. To circumvent the problem of patients' tendency to "fake good," we will base our assessments on observations of patients' behavior provided by knowledgeable staff members, rather than on patients' own self-reports. We hypothesize the patients receiving SFT will show reduced levels of personality disorder symptoms and reduced risk of violence and recidivism, compared with patients receiving TAU. We also hypothesize that patients receiving SFT will show better treatment engagement and retention, and have a more positive therapeutic alliance, compared to patients receiving TAU. We predict that SFT patients will show greater improvements in the maladaptive schemas and related psychological processes that are hypothesized to underlie personality disorders in the SFT model. Finally, we predict that patients given SFT will show reduced levels of general psychopathology, compared to patients given TAU. In a future study, we will follow-up these patients to determine their risk of actual recidivism after some of them are released to the community.

Study objective

In this study, we will test the efficacy of SFT in forensic patients with 4 severe personality disorders -- Antisocial, Narcissistic, Borderline, and Paranoid Personality Disorders -- in ameliorating personality disorder symptoms and reducing risk of criminal and violence recidivism.

The specific aims of the proposed study are the following:

Aim 1 -- Test the three-year efficacy of SFT in male forensic patients with Antisocial, Narcissistic, Borderline, or Paranoid Personality Disorder for reducing personality disorder symptoms and lowering the risk of future violence and recidivism, compared to treatment as usual (TAU).

Hypothesis 1a:

Patients given SFT will show greater improvement in symptoms of Antisocial, Narcissistic, Borderline, and Paranoid Personality Disorder, compared to patients given TAU.

Hypothesis 1b:

Patients given SFT will show greater improvement in dynamic (i.e., changeable) risk factors for violence and recidivism (e.g., predictors of future violence and recidivism), compared to patients given TAU.

Aim 2 -- Investigate the effect of SFT on psychotherapy process variables, such as treatment engagement and therapeutic alliance, and on treatment retention.

Hypothesis 2a: Patients given SFT will show greater engagement in the therapeutic process, and a better alliance with their therapists, compared to patients given TAU.

Hypothesis 2b: Patients given SFT will show greater treatment retention (i.e., lower rates of drop-out), compared to patients given TAU.

Aim 3 -- Investigate the effects of SFT on the personality constructs hypothesized to mediate the effects of SFT on personality disorders.

Hypothesis 3: Patients given SFT will show greater improvements in Early Maladaptive Schemas, Maladaptive Coping Mechanisms, and Schema Modes, compared to patients given TAU.

Study design

Primary outcome measurement at baseline, every six months.

Intervention

Individual SFT versus individual treatment as usual for patients with antisocial, borderline, narcissistic and paranoid personality disorder in a forensic inpatient setting.

Contacts

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Eligibility criteria

Inclusion criteria

The study population consists of forensic patients with Antisocial, Borderline, Narcissistic, or Paranoid Personality Disorder.

Exclusion criteria

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, Aspergers Disorder), and (g) pedophilia (i.e., a fixated sexual preference for children). Patients with fixated pedophilia will be excluded from the study, because the nature of their problems suggests the need for treatment methods that are beyond the scope of the present study. In contrast, patients whose crimes include both sexual offenses against adults and children, and whose sexual offenses against children do not appear to reflect a fixed sexual preference for children, will not be excluded. With this one exception (i.e., fixated pedophiles), participants will not be included in or excluded from the study on the basis of their crimes.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2007
Enrollment:	114
Type:	Anticipated

Ethics review

Positive opinion	
Date:	16-01-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 30603
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1144
NTR-old	NTR1186
CCMO	NL14219.068.06
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON30603

Study results

Summary results

Bernstein, D.P., Arntz, A & de Vos, M.E. (2007). Schemagerichte Therapie in de Forensische Setting: Theoretisch model en voorstellen voor best clinical practice. Tijdschrift voor Psychotherapie, 33 (2), 120-139.

Bernstein, D.P., Arntz, A. & de Vos, M.E. (2007). Schema Focused Therapy in Forensic Settings:

Theoretical Model and Recommendations for Best Clinical Practice. International Journal of Forensic Mental Health, 6(2),169-183.