

# Efficacy of Schema-Focused Therapy versus Usual Treatment in Forensic Patients with Personality Disorders: A Three-Year Randomized Clinical Trial

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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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Personality disorders and disturbances in behaviour
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON30603

### Source

ToetsingOnline

### Brief title

Schematherapy in Forensic Patients

### Condition

- Personality disorders and disturbances in behaviour

### Synonym

personality disorders, personality problems

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universiteit Maastricht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## **Intervention**

**Keyword:** clinical trials, forensic, personality disorders, psychotherapy

## **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.

### 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**

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. Patients in both groups will receive 3 years of psychotherapy.

Patients will be assessed at the beginning of treatment and every 6 months for the duration of the study. To circumvent the problem of patients\* tendency to \*fake good,\* we will base our assessments primarily on observations of patients\* behavior provided by knowledgeable staff members, rather than on

patients\* own self-reports.

## **Intervention**

SFT is an integrative form of psychotherapy that combines cognitive, behavioral, psychodynamic object relations, and humanistic/existential approaches (Young et al., 2003). Unlike most other forms of cognitive-behavioral therapy, SFT was developed explicitly as a treatment for patients with personality disorders, who often respond poorly to traditional therapeutic methods (Reich, 2003). The focus in SFT is on modifying self-defeating patterns of thinking and feeling (i.e., Early Maladaptive Schemas), and maladaptive emotional states (i.e., Schema Modes) that originate in aversive childhood experiences in combination with the child\*s innate temperament. SFT is a moderate- to long-term form of psychotherapy. Treatment usually occurs once to twice per week for a period of one to two years on average, or longer, depending on the patient. For patients with severe personality disorders, such as those that are most prevalent in Dutch TBS institutions (e.g., Antisocial, Borderline, Narcissistic), a duration of at least three years of therapy is often indicated. This duration of treatment is necessary because longstanding personality features are only ameliorable with intensive treatment (Giesen-Bloo et al., 2006; Young et al., 2003).

The control therapy will consist of \*Treatment as Usual (TAU).\* TAU is defined as whatever form of verbal therapy is usually given at the participating institutions. This may include cognitive, psychodynamic, humanistic, or other commonly used forms of verbal psychotherapy.

## **Study burden and risks**

There are only minimal risks associated with either of the psychotherapies that will be delivered in this study. These risks are not different than the risks posed by other forms of psychotherapy (e.g., possible feelings of discomfort when disclosing personal information to a therapist). There is a possible risk to patients' confidentiality posed by the collection and storage of data. Precautions will be taken to protect the confidentiality of these data, such as omitting identifying information from data bases, and identifying participants only by identification number (a longer description of these procedures is found in the research proposal under "Ethical Issues").

The risks associated with this study are expected to be minimal. On the other hand, there are potential benefits for patients, who may experience improvement in their personality disorder symptoms and risk of future criminal behavior as a result of receiving the therapeutic interventions in this study. Moreover, the potential benefit to society if this experimental treatment, Schema Focused Therapy, proves successful, is great. Thus, the potential benefits of this study are expected to far outweigh the risks.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

DSM-IV Antisocial, Borderline, Narcissistic or Paranoid Personality Disorder, and TBS status

### Exclusion criteria

Exclusion criteria are (a) the presence of a current psychotic symptoms, (b) schizophrenia or bipolar disorder, (c) current drug or alcohol dependence (but not abuse), (d) low intelligence (i.e., Full Scale IQ < 80), (e) serious neurological impairment (e.g., dementia), (f) an autistic spectrum disorder (e.g., Autism, Aspergers Disorder), and (g) pedophilia (i.e., a fixated sexual preference for children).

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2007
Enrollment:	100
Type:	Actual

## Ethics review

Approved WMO	
Date:	07-11-2006
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	23-01-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	24-11-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24138

Source: Nationaal Trial Register

Title:

### In other registers

Register	ID
CCMO	NL14219.068.06
OMON	NL-OMON24138