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Schema Therapy augmented Exposure and Response Prevention in Patients with Obsessive-Compulsive Disorder: Feasibility and Efficacy of a Pilot Study

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Abstract

**Background:** In spite of the availability of effective treatments for obsessive-compulsive disorder (OCD), many patients do not respond sufficiently or relapse. Treatments using other potentially effective methods such as experiential techniques need to be investigated. We developed a 12-week inpatient treatment augmenting exposure and response prevention (ERP) with schema therapy (ST) called STERP. The feasibility and effectiveness of STERP was tested.

**Methods:** In a pilot study, 10 inpatients with OCD who failed to respond to Cognitive Behavioral Therapy (CBT) with ERP received STERP. The Yale-Brown Obsessive Compulsive Scale (Y-BOCS) served as primary outcome. Secondary outcome measures were the Obsessive Compulsive Inventory-revised (OCI-R) and the Beck Depression Inventory (BDI-II). Treatment effects were assessed with t-tests for paired samples.

**Results:** Significant reductions of the Y-BOCS, OCI-R and the BDI-II were found, with very large effect sizes (Cohen's $d = 1.48 - 2.25$). Results remained stable at 6 months follow-up. Five prior non-responders responded according to the 35% Y-BOCS symptom reduction criterion.

**Limitations:** Lack of control group, small sample size and lack of repeated outcome measures during baseline.

**Conclusions:** STERP may be a feasible and potentially effective treatment for prior non-responders among OCD patients and thus worth further investigation in randomized controlled trials.

**Keywords:** Obsessive-compulsive disorder, Cognitive Behavior Therapy, exposure and response prevention, schema therapy
1. Introduction

Obsessive-compulsive disorder (OCD) is a chronic and debilitating mental disorder that affects 2-3% of the general population (Abramowitz, 2006; Ruscio, Stein, Chiu & Kessler, 2010). OCD typically severely impairs patient’s job performance and their capacity to function in social contexts or at home. The course of OCD is often chronic and full symptom remission is rare (Catapano et al., 2006; Eisen, Pinto, Mancebo, Dyck, Orlando & Rasmussen, 2010). Cognitive-Behavioral Therapy (CBT) with Exposure and Response Prevention (ERP) is the first-line treatment for OCD according to standard guidelines (Eisen et al., 2010; Foa, Liebowitz, Kozak, Davies, Campeas, & Franklin, 2005; National Institute for Health and Clinical Excellence [NICE], 2005). Even though several meta-analyses postulate the relative efficacy of ERP, pharmacotherapy, or their combination, a systematic review proves that 10 to 37% of patients suffering from OCD do not respond satisfyingly to CBT (Podea, Suciu, Suciu, & Ardelean, 2009; Schruers, Koning, Luermans, Haack, & Griez, 2005). Typical difficulties that complicate treatment are the refusal to perform exposure in approximately 25-30% of the patients and therapy drop-out in 28% (Emmelkamp & Foa, 1983; Kozak, Liebowitz, & Foa, 2000). In the long term, more than one third of the completers remain symptomatic and a meta-analysis postulates that even after adequate treatment, OCD symptoms often persist at moderate levels and patients suffer from disabling symptoms (Alonso et al., 2001; Eddy, Dutra, Bradley, & Westen, 2004). Moreover, in a prospective, naturalistic study assessing OCD symptoms annually over five years, 59% of treatment-seeking OCD patients relapse after an adequate treatment, especially after experiencing only partial remission (Eisen et al., 2013). Without adequate treatment, OCD typically takes a chronic course (Abramowitz, 2006).

Non-response in OCD is, among other factors, associated with greater OCD symptom severity at baseline, earlier age at onset, higher illness burden, social and occupational impairment and the need for more inpatient care (Eisen et al., 2010; Keeley, Storch, Merlo, & Geffken, 2008; Pinto, Mancebo, Eisen, Pagano, & Rasmussen, 2006; Van Minnen, Arntz, & Keijsers, 2002). Additional factors that may contribute to a negative treatment outcome are comorbid personality and axis I disorders, childhood traumatization and a distinct functionality of symptoms (Thiel, Hertenstein, Nissen, Herbst, Kuelz & Voderholzer, 2013; Abramowitz, Franklin, Street, Kozak, & Foa, 2000; Fricke et al., 2006; Keeley et al., 2008; Külz, Lump, Herbst, Stelzer, Förstner, & Vorderholzer, 2010; Maier, Kuelz, & Voderholzer, 2009). The term “functionality of symptoms” represents circumstances that give symptoms a sense or meaning in the life and experiences of a person (Külz et al., 2010). An example may be the use of compulsive behavior to regulate personal negative emotions or to set a limit to others.
Consequently, the development of new strategies and effective alternative psychotherapeutic approaches for non-responding OCD patients is needed. Given the complexity of these patients, specifically tailored treatment approaches for individual case constellations with complex symptomatology and comorbid axis II disorders are required (Franz et al., 2013; Fricke et al., 2006).

Schema therapy (ST) was primarily developed for patients with severe personality disorders (PD) and for patients with chronic mental disorders who insufficiently responded to traditional CBT (Young, Klosko, & Weishaar, 2003). It is considered an approach to be provided to treatment-resistant patients (Bernstein, Arntz, & de Vos, 2007). As an integrative treatment it combines attachment theory, cognitive, behavioral, psychodynamic, emotion-focused and gestalt therapy (Kellogg & Young, 2006). Since ST focuses on the treatment of negative childhood experiences, underlying core beliefs, comorbid personality disorders and distinct functionality of symptoms, we assume that ST is suitable for non-responding OCD patients since these factors are related to treatment failure in CBT for OCD (Young et al., 2003).

Additionally, the work on early maladaptive schemas (EMS) and schema modes is of great interest. EMS are dysfunctional cognitive patterns that arise from unmet basic needs and traumatic experiences during childhood (Young et al., 2003). When an individual gets into a life situation, to which it is sensitive to, EMS are triggered and schema modes get activated. Schema modes are predominant emotional states and coping responses that are currently active for the individual. They regulate the current mood and behavior of the person. Three studies examined EMS and schema modes in OCD and showed that patients presented significantly higher scores than healthy controls or other axis I disorders (Atalay, Atalay, Karahan, & Caliskan, 2008; Lochner et al., 2005; Voderholzer et al., 2013). In addition, two studies investigated the predictive value of EMS in OCD identifying the EMS abandonment, failure and emotional inhibition as negative predictors for CBT outcome (Haaland et al., 2011; Thiel et al., 2014). Concerning the EMS emotional inhibition, suppressing emotions can have a negative impact on ERP sessions, since confrontation and habituation are impaired. ST employs a variety of experiential and emotion-inducing treatment techniques, which may be especially indicated in patients who suppress emotional experiences (Young et al., 2003). Moreover, one aim of ST is to establish a so called healthy adult mode. This mode performs appropriate adult functions such as accepting responsibility, taking care of ones health, working and parenting. We assume that the specific strengthening of a healthy and adult coping response by ST will encourage patients to perform ERP sessions and to stay motivated in treatment. We do not assume that OCD patients with a co-morbid PD will positively respond, since PD outpatient studies feature average treatment durations of 2-3 years.
Initial studies showed good efficacy in the treatment of patients with Borderline PD in the one-on-one (Giesen-Bloo et al., 2006; Nadort et al., 2009) and group therapy setting (Farrell, Shaw, & Webber, 2009), as well as in the treatment of other PDs including cluster C, paranoid, histrionic and narcissistic PD (Arntz, 2012) and forensic patients (Bernstein, Nijman, Karos, Keulen-de Vos, de Vogel, & Lucker, 2012). One study showed positive effects of ST on co-morbid depression in patients suffering a cluster C PD (Bamelis, Evers, Spinhoven, & Arntz, 2014). Only a few studies investigated the application of ST in axis I disorders. One randomized clinical trial compared ST and CBT in 100 outpatients with a major depressive episode and showed comparable efficacy of both treatments (Carter, McIntosh, Jordan, Porter, Frampton, & Joyce 2013). Two single case series tested ST in chronically depressed patients and showed high remission rates along with large effect sizes (Malogiannis et al., 2014; Renner, Arntz, Leeuw, & Huibers, 2013). Moreover, the use of ST as a promising new approach is discussed for other axis I disorders with mostly chronic courses such as eating, anxiety and obsessive compulsive disorders. So far, case series provide information of case formulation procedures and processes within ST for example in chronic eating or anxiety disorders (Gross, Stelzer, & Jacob, 2012; Hoffart, o. J.; Simpson, 2012). Hoffart (2012) assumes that some patients with panic disorder fail to progress during CBT due to schema-related issues and that changes in anxiety symptoms may partially prevented by underlying EMS. Concerning OCD, two case examples provide promising results of the use of a combination of ST with CBT (Gross et al., 2012). Mode models oriented to OCD and the use of schematherapeutic techniques are presented to respond to problems in the therapy, for example if patients refuse to do ERP sessions or do not respond (Gross et al., 2012). These findings and the evidence for insufficient treatment response of OCD patients to traditional CBT with ERP suggest that schema therapy may be suitable and an effective approach for OCD patients with prior non-response to CBT with ERP. As to date ERP is the most effective technique for the treatment of OCD, we developed a 12-week treatment augmenting ERP with ST. In this treatment protocol ST elements are combined with the use of ERP called STERP and we tested STERP in a pilot study with previously non-responding OCD patients. Since non-responders who usually present a severe OCD were included, STERP was examined in an inpatient setting. This had the advantage that ERP sessions could be often accompanied and prompt debriefed. Moreover, ecological validity was increased, since the study was realised in the setting usually indicated for long existing, very impairing symptoms. But, due to the time-limited setting, ST had to be adapted and shortened. To the best of our knowledge, this is the first study on the application of ST with ERP for non-responding OCD patients.
The present study tested three hypotheses. Firstly, we assume that STERP is feasible and will be accepted by patients with OCD. Secondly, we hypothesized that STERP is efficient and leads to a significant reduction of OC symptoms, and thirdly, we expected that the symptom reduction will be sustained for a period of six months.

2. Materials and Methods

2.1 Subjects

Ten inpatients diagnosed with OCD were included in this pilot study and recruited from the Department of Psychiatry and Psychotherapy, University Medical Center Freiburg. The inclusion criteria were a primary diagnosis of OCD assessed by the Structured Clinical Interview for DSM-IV (SCID-I) and an age between 18 and 65 years (Wittchen, Zaudig, & Fydrich, 1997). Moreover, the participants had to be non-responders to at least one CBT treatment which featured exposure exercises conducted following expert guidelines either in an inpatient setting in a hospital specialized in the treatment of OCD or a disorder-specific outpatient treatment of at least six months duration. In addition, patients had gone through at least one unsuccessful attempt of pharmacotherapy with a first-line drug in adequate dosage and treatment duration (SSRI: Citalopram, Escitalopram, Fluoxetine, Fluvoxamine, Paroxetine, Sertralin (“AWMF: Detail“, n.d.). Non-response was examined by studying the final reports of the prior treatments and the patients' personal assessment. Whenever pre- and post-treatment results of the Yale-Brown Obsessive Compulsive Scales (see 2.2) were available, a reduction of less than 25% was considered a non-response (Pallanti & Quercioli, 2006). SCID-I and –II interviews were administered by trained and experienced clinicians. All clinicians attended a SCID-I and –II training, that consisted of a two-day theoretical training by a certified trainer for SCID. The exclusion criteria were a primary diagnosis other than OCD, psychotic disorders, substantial neurological impairment, severe cognitive dysfunction, severe Tourette syndrome and any acute addictive disorder. Due to the limited time of the study protocol, existing pharmacotherapy at the time of admission was not discontinued. No new psychotropic medication was applied, but blood levels of existing medication were examined and adjusted if necessary. Accordingly, patients continued their pharmacotherapy in addition to STERP in compliance with current and international guidelines for OCD treatment (“AWMF: Detail“, n.d.). The mean age of the sample was 35.26 years ($SD=11.11$). 50% were female. Nine patients had at least one other co-morbid axis I diagnosis and five patients suffered a co-morbid axis II diagnosis. Details on sociodemographic and clinical characteristics are given in Table 1.

| Title: Sociodemographic and Clinical Characteristics of Study Participants (N=10) |
| Insert Table 1 approximately here |
Table 1

Sociodemographic and clinical characteristics of the participants

<table>
<thead>
<tr>
<th>Participant</th>
<th>Age</th>
<th>Marital status</th>
<th>Education (years)</th>
<th>Age at onset of OCD</th>
<th>Previous treatments (inpatient/outpatient)</th>
<th>Medication</th>
<th>Comorbid axis I diagnosis (SCID-I)</th>
<th>Comorbid axis II diagnosis (SCID-II)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 F</td>
<td>30</td>
<td>Single</td>
<td>14</td>
<td>9</td>
<td>1/3</td>
<td>SSRI</td>
<td>Moderate MDD, rec.</td>
<td>Avoidant PD</td>
</tr>
<tr>
<td>2 M</td>
<td>48</td>
<td>Married, 1 child</td>
<td>11</td>
<td>14</td>
<td>7/3</td>
<td>AP</td>
<td>Tourette syndrome</td>
<td>Obsessive Compulsive and Paranoid PD</td>
</tr>
<tr>
<td>3 F</td>
<td>54</td>
<td>Single</td>
<td>13</td>
<td>19</td>
<td>8/2</td>
<td>SSRI + NaSSA + AP</td>
<td>Moderate MDD, rec.</td>
<td>Dependent PD</td>
</tr>
<tr>
<td>4 M</td>
<td>33</td>
<td>Single</td>
<td>26</td>
<td>22</td>
<td>-/2</td>
<td>SSRI</td>
<td>Insomnia</td>
<td>Narcissistic PD</td>
</tr>
<tr>
<td>5 F</td>
<td>23</td>
<td>Single</td>
<td>13</td>
<td>16</td>
<td>2/1</td>
<td>SSRI</td>
<td>Severe MDD, rec.</td>
<td>-</td>
</tr>
<tr>
<td>6 M</td>
<td>33</td>
<td>Single</td>
<td>23</td>
<td>10</td>
<td>3/3</td>
<td>SSRI + AAP + AP</td>
<td>Moderate MDD, rec.</td>
<td>-</td>
</tr>
<tr>
<td>7 F</td>
<td>50</td>
<td>Married, 1 child</td>
<td>13</td>
<td>12</td>
<td>1/2</td>
<td>SSRI</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>8 M</td>
<td>30</td>
<td>Single</td>
<td>19</td>
<td>13</td>
<td>4/2</td>
<td>SSNRI</td>
<td>Severe MDD, rec.</td>
<td>-</td>
</tr>
<tr>
<td>9 F</td>
<td>39</td>
<td>Married</td>
<td>11</td>
<td>27</td>
<td>5/1</td>
<td>SSRI + TZA</td>
<td>Moderate MDD, rec.</td>
<td>Avoidant PD</td>
</tr>
<tr>
<td>10 M</td>
<td>24</td>
<td>Single</td>
<td>17</td>
<td>21</td>
<td>2/1</td>
<td>TZA</td>
<td>Moderate MDD, rec.</td>
<td>-</td>
</tr>
</tbody>
</table>

Note: F=Female, M=Male, SSRI= Selective serotonin reuptake inhibitor; AP=Antipsychotics; AAP=atypical antipsychotic; NaSSA= Noradrenergic and specific serotonergic antidepressant; TCA=tricyclic antidepressant; MDD=Major Depressive Disorder, rec.=recurrent, PD=Personality disorder
At pre-treatment, the sample was characterised by severe levels of obsessive-compulsive symptom severity \((M=25.8, \text{ } SD=2.95)\) on the Y-BOCS. On average, the OCD began at the age of 19.7 years \((SD=9.9)\) and the mean duration of OCD was 16.3 years \((SD=5.8)\).

Patients went through an average 3.4 \((SD=2.5)\) inpatient stays and 2 \((SD=0.8)\) outpatient treatments for their OCD. The main reasons patients reported for the non-response during previous treatments were problems complying with the exposure, lack of emotional activation during exposure exercises, and failure to transfer the results into their everyday life.

The study was approved by the local Ethics Committee for research with human subjects. Written informed consent was obtained from all participants prior to baseline assessment.

### 2.2 Measures

A clinical assessment of the patients’ axis I diagnoses was conducted before and after treatment and at a 6-months follow-up (SCID-I). Additionally, axis II diagnoses were assessed pre-treatment (SCID-II). The OCD diagnosis was ascertained by the outpatient clinic (see 2.4), the therapist in the study and the SCID-I. The main outcome measure was the Yale-Brown Obsessive Compulsive Scale (Y-BOCS) (Goodman et al., 1989). The Y-BOCS is a semi-structured, clinician-administered interview that is considered the gold standard for assessing OCD symptom severity (Jacobsen, Kloss, Fricke, Hand, & Moritz, 2003; Taylor, 1998). It was conducted pre-as well as post-treatment and at follow-up. Following Pallanti and Quercioli (2006), we defined full response as a Y-BOCS reduction of at least 35%. All interviews were conducted by a trained and experienced psychologist who was not involved in the treatment and who was blind for the results. Furthermore, a comprehensive battery of standard self-report instruments including the Obsessive Compulsive Inventory-revised (OCI-R; Gönner, Leonhart, & Ecker, 2008), the Beck Depression Inventory-II (BDI-II; Beck, Steer, Ball, & Ranieri, 1996), the Working Alliance Inventory – Short Revised (WAI-SR; Wilmers et al., 2008) was administered. The severity rating of the DSM-IV general adaptive functioning scale (GAF; axis V) was assessed by the therapist at pre-, post-treatment and follow-up. Additionally, to measure patients’ global improvement after the treatment, therapist (Clinical Global Impression – Improvement Scale (CGI-I)) and patient (Patient Global Impression – Improvement Scale (PGI-I)) applied the Improvement Scale (Collegium Internationale Psychiatrie Scalarum, 1996). In addition, a self-rating questionnaire was designed regarding the evaluation of the program, including current satisfaction with life and the treatment \((10 = \text{very satisfied}; \quad 1 = \text{very dissatisfied})\), the recommendation of STERP and a section in which experiences with STERP could be described in a continuous text. Moreover, patients were asked about the difference between STERP and previously known treatments and also about whether they had done exposure
at follow-up, patients were asked about life events, utilization of therapeutic interventions and the subjective development of symptoms during the follow-up period.

2.3 Procedure
Ten inpatients participated in this study testing the feasibility of the STERP treatment. Patients with OCD who want to attend an inpatient treatment at the University Hospital in Freiburg, sign in at the OCD outpatient clinic of our hospital. At the outpatient clinic, patients are seen to an one-hour personal interview by a psychiatrist or psychotherapist who confirms the OCD diagnosis and illustrates the inpatient treatment. Subsequently, patients are enrolled on a waiting list for inpatient treatment. This waiting list was screened for appropriate patients and all appropriate subjects (N=13) were informed about the study. All 13 subjects agreed to participate in the study. Written informed consent was obtained, but three patients had to be excluded because they did not fulfill the in- or exclusion criteria (see 2.2). After the waiting period for inpatient admission, the pre-treatment measures were conducted and the 12 weeks combined treatment STERP was administered.

2.4 Treatment
The treatment consisted of two individual therapy sessions per week (50 min each) with a therapist (NT) appropriately trained and experienced in ST and CBT with ERP. The therapist received weekly supervision by a trainer in ST and CBT (GJ).

STERP consisted of 3 treatment segments: An introduction phase (3 weeks), a change phase (6 weeks) and a final phase (3 weeks) (Stelzer et al., 2011; Stelzer, Herbst, Kuelz, Nissen & Voderholzer, 2011). The introduction started with a detailed case history. A general education about ST and the discussion of the ST questionnaire results followed. The ERP rationale was revised only briefly, since all participants had previously received a CBT with ERP treatment. The CBT with ERP treatment was based on the established and evidence-based treatment by Lakatos and Reinecker (2007). An individual fear hierarchy was established and the first exposure session was initialized. The therapeutic relationship was characterized by limited reparenting (soothing, support, guidance). It is established on the assumption that EMS and schema modes arise when core needs are not met. The foundation is the establishment of a secure therapeutic relationship and the therapist supports the patient to meet these unmet needs within the bounds of the professional relationship.

In the change phase, an individual schema mode model was created to reach a shared understanding of the patient’s schema modes, distress and interpersonal difficulties. For examples of typical individual mode models see (Gross et al., 2012; Thiel & Voderholzer, 2013a, 2013b). The exposure sessions started with moderately anxiety-provoking situations
in vivo and gradually increased to more distressing fears. Exposure consisted of therapist-accompanied sessions but also of self-administered homework assignments. Additionally, specific schematherapeutic techniques were used: with the use of chair work, the patient moves between different chairs and has a dialogue between different schema modes for example the obsessive compulsive mode and the healthy adult mode. By the technique of imagery rescripting, painful memories are revised and the therapist assists the patient to satisfy unmet needs that were injured in the past. Flashcards are written statements that were used by the patient in-between sessions for examples to increase the motivation before starting self-administered exposure exercises. As homework assignments patients conducted ERP exercises or filled out schema memos. Schema memos are forms that provide a guide for the patient to become aware of the personal EMS driven reactions. The patient notes thoughts, feelings, problematic behavior, EMS and healthy perspectives and behavior. At the beginning of the change phase the focus of the sessions was alternating between ST elements and ERP. Gradually, when the patient increasingly self-administered exposure, the focus shifted toward ST elements to work on interpersonal coping skills and schema modes and to overcome difficulties and crises. Symptom functionality (regulation of emotions, limit setting) was addressed from the very beginning with the aim of strengthening treatment motivation. The following examples should illustrate how ST and ERP complemented each other. Chair work preceded exposure exercises to ensure that exposure sessions were conducted in the healthy adult mode and not in a coping or avoidance mode from which patients do not benefit. Audiotape messages and schema memos were drafted for situations in which the patient felt overwhelmed for examples self-administered exposure sessions. Emotions that occurred after exposure exercises (anger, sadness, shame, guilt) were treated with schema-therapeutic imaginative re-scripting.

In the final phase, the focus was on transferring newly learned skills to the home environment, on relapse prevention, arrangement of outpatient psychotherapy, gradual termination and phasing out of therapy.

In addition to individual sessions, inpatients attended a weekly educational group (90 min) conducted by experienced therapists, and ergotherapy as well as therapeutic exercises. Team meetings took place to discuss ongoing cases and difficulties.

### 2.6 Data analysis

The IBM Statistical Package for Social Sciences (SPSS), version 21, was used for statistical analysis. One participant who did not complete the study was considered a drop-out. The missing data of this drop-out at post-treatment was imputed by the Last-Observation-Carried-Forward method, since untreated OCD manifest a rather stable symptomatology. Data of the Y-BOCS, OCI-r and BDI-II were analysed for goodness of fit to a normal distribution with a
Kolmogorov-Smirnov test, which showed non-significance. Accordingly, means and standard deviations were compared using t-tests for paired samples. Full treatment response was defined a priori as a reduction in symptom severity of at least 35% and partial response as a reduction of at least 25% on the Y-BOCS (Pallanti & Quercioli, 2006). To classify the therapeutic success, effect sizes (Cohen’s d) were calculated. Clinical significance concerning depressive symptoms was examined with the reliable change index (RCI). The RCI was calculated based on the test-retest reliability of the BDI-II (r= 0.92) according to Hautzinger, Keller and Kühner (2006).

### 3 Results

#### Hypothesis 1: STERP is feasible and will be accepted by patients with OCD.

Concerning feasibility, nine of the ten patients included in the study completed the treatment and follow-up assessment. One participant dropped out three weeks into the introduction phase and did not enter the treatment phase. This participant admitted to have started treatment under pressure from her parents; however, she did not develop treatment motivation herself. No participant was excluded due to dissatisfaction with the combined treatment or suicidal ideation. The evaluation of the experience with and acceptance of STERP revealed that average satisfaction scored a 9 (10 = ‘very satisfied’; 1 = ‘very unsatisfied’). Eight of the nine completers would recommend STERP to other persons with OCD. STERP proved to be feasible and there were no reportable difficulties integrating the combined treatment into the daily clinical routine. The treatment could be conducted within 12 weeks as planned.

#### Hypothesis 2: STERP is efficient and leads to a significant reduction of OC symptoms

T-tests for paired samples revealed significant improvements from severe to moderate OC symptoms. For the calculation of the effect sizes, data of the standard deviation of a representative study were used to detect more valuable results (SD pre: 4.6; SD post: 8.2) (Foa et al., 2005). The study of Foa et al., (2005) was considered representative compared to our study since patients also received a 12 week ERP treatment in combination with medication but with a larger study sample. A large effect size in the primary outcome measure Y-BOCS could be detected (Cohen’s d Y-BOCS_{pre-post}: d=1.29) (see table 2). At post-treatment assessment 4 patients (40%) fully responded (participant 1,3,6,7) and another 2 patients (20%) responded partially (participants 2,9).

Title: Psychometric scores at baseline, after STERP (post) and at follow-up.

Insert Table 2 approximately here
Table 2

Psychometric scores at baseline, after STERP (post) and at follow-up.

<table>
<thead>
<tr>
<th></th>
<th>M ± SD</th>
<th>Pre vs. post</th>
<th>Pre vs. fu</th>
<th>Post vs. Pre</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre</td>
<td>post</td>
<td>6 month follow-up</td>
<td>t</td>
</tr>
<tr>
<td>Y-BOCS global</td>
<td>25.8±2.8</td>
<td>17.8±4.6</td>
<td>16.6±4.3</td>
<td>5.59</td>
</tr>
<tr>
<td>OCI-R global</td>
<td>31.9±10.3</td>
<td>19.1±6.9</td>
<td>17.5±7.1</td>
<td>4.95</td>
</tr>
<tr>
<td>BDI-II</td>
<td>29.7±12.5</td>
<td>15.1±7.5</td>
<td>22.3±11.9</td>
<td>3.94</td>
</tr>
<tr>
<td>GAF</td>
<td>50.7±7.1</td>
<td>61.7±5.5</td>
<td>57.5±10.1</td>
<td>-5.44</td>
</tr>
</tbody>
</table>

Note: Y-BOCS = Yale-Brown Obsessive-Compulsive Scale, OCI-R = Obsessive Compulsive Inventory-revised, BDI-II = Beck Depression Inventory II, GAF = General Adaptive Functioning Scale. * p<.05, ** p <.01, *** p<.001.
Hypothesis 3: The symptom reduction can be maintained for a period of six months.

Follow-up assessments were completed by all nine patients who completed treatment. Seven patients continued outpatient psychotherapy (CBT: 3, ST: 4). Concerning OCD symptoms, two full responders (6,7), one partial responder (9) and one non-responder (8) continued outpatient psychotherapy with a combination of CBT with ERP and ST. Within the 6-month follow-up period, these responders remained in response, the partial responder achieved response and the non-responder achieved partial response wherein scores on depression remained stable. Besides, two full responders (1,3) and one partial responder (2) continued outpatient CBT psychotherapy. All of these three participants maintained their results concerning the OC symptoms but deteriorated regarding the depressive symptoms. Overall, the follow-up scores on the Y-BOCS were non-significant compared to the post-treatment scores and were significantly reduced compared to baseline (Table 2). For three of the five responders medication remained unchanged during and after inpatient treatment. In two participants the dosage was adjusted according to the blood levels of the medication during inpatient treatment. Six of the nine completers were still on the same dosage of psychotropic medication at follow-up. One non-responder discontinued pharmacotherapy. Consequently, we found five responders and two partial responders at follow-up. Two patients were non-responders, but there was no exacerbation of OCD symptoms. Figure 1 presents the scores for Y-BOCS, OCI-r and BDI-II for each participant and the mean.

Title: Scores on standardized measures for Y-BOCS, OCI-r and BDI-II for each participant and mean (N=10)

Figure 1
Scores on standardized measures for Y-BOCS, OCIr, BDI-II for each participant and overall mean.
Note: Y-BOCS = Yale-Brown Obsessive-Compulsive Scale, OCI-R = Obsessive Compulsive Inventory-revised, BDI-II = Beck Depression Inventory II.

**Exploratory outcomes:** The significant improvements in and large effect sizes on OCD symptoms could be asserted by the OCI-R at post-treatment and follow-up (OCI-R<sub>pre-post</sub>: $d=1.53$). In addition, t-tests results indicated significant improvements in general adaptive functioning (GAF) from baseline to post-treatment. While the GAF score increased by 15%, there was no significant improvement from baseline to follow-up.

The BDI-II changes between pre- and post-treatment were large and statistically significant ($p<.003$; Cohen's $d$ BDI-II<sub>pre-post</sub>: $d=1.48$). Subjects were, on average, severely depressed before treatment and only marginally depressed at post-treatment. The average follow-up score showed no significant differences to the post-treatment and the baseline score (Table...
2). Clinical significant changes could be detected in five participants (1, 6, 7, 8, 9) (RCI > 1.96).

In three patients, depression scores remained unchanged compared to the baseline BDI-II score (2, 3, 10) and participant 4 deteriorated significantly. Participant 3, a full responder concerning OC symptoms suffered a relapse of the recurrent moderate MDD. Participant 2 who partially responded concerning the OC symptoms worsened compared to his baseline BDI-II score. He named the separation from his wife in the follow-up period as a reason. Participant 4 (Y-BOCS non-responder) reported that his depressive symptoms worsened because he was under psychological pressure as he had to terminate his studies because of the OCD. He discontinued outpatient psycho- and pharmacotherapy.

The general quality of the therapy relationship received a 3.9 (SD = 0.8) rating on the WAI-SR at post-treatment (5 = ‘always’; 1 = ‘seldom’ a good relation). The development of an affective bond was rated with 4.2 (SD = 0.6).

After the treatment 11% percent (N=1) of the nine completers rated the condition on the PGI-I as very much improved, four (144%) as much improved and three (33%) as slightly improved. One (11%) reported no change and no patient reported a worsening of symptoms. The evaluation of the clinician on the CGI-I was similar: 33% of the completers had improved a lot and 44% slightly. The mean PGI-I score did not differ statistically from the CGI-I score.

Overall, the therapists rated patients’ condition on CGI-I as ‘slightly improved’ (M=2.8; SD=0.6). The patients gave their improvement an average score between ‘improved a lot’ and ‘slightly improved’ (M=2.6; SD=0.9).

Patients’ life satisfaction significantly improved from baseline to post-treatment (pre M=2.2, SD=1.1; post M=5.1, SD=1.5; t=6.33, p=.000) but not from baseline to follow-up (M=4.22; SD=3.3).

When asked to describe the difference between STERP and other treatments, participants stated that it was helpful how STERP made them understand their problematic behavior within the mode model. They were able to take a different approach to their OC behavior by working with the schema mode model, and they better understood why particular events triggered their symptoms. Moreover, patients reported that the classification of compulsive symptoms in the mode model caused distance to their symptoms. Some patients stated that, as a result, they were able to better comply with exposure sessions. All of them were able to perform therapist-accompanied as well as self-administered exposure exercises. Establishing the individual mode model, the chair technique and exposure sessions were considered very helpful. At follow-up, five participants stated that they were still ‘in contact’ with their different schema modes in everyday situations.
4 Discussion

The results of this study provide first evidence for the feasibility and efficacy of STERP, a combination of schema therapy with ERP for patients with OCD who did not respond to traditional CBT. Consistent with our hypothesis, we demonstrated feasibility and acceptance of the treatment by OCD patients. Additionally, significant improvements from severe to moderate OC symptoms and large effect sizes in the primary outcome Y-BOCS were shown and could be maintained for a 6-months period.

Five out of ten OCD patients who had previously not responded to traditional CBT responded to STERP short- and long-term with regard to their obsessive compulsive behavior. The large post-treatment effect sizes concerning OC symptoms were proven both through an interview (Y-BOCS) and a self-rating instrument (OCI-R). Additionally, significant and considerable pre-post improvements in depression severity and general adaptive functioning were demonstrated. Since there were no or only slight changes in medication especially for the responders, we hypothesize that symptom improvement is not attributable to pharmacotherapy. The majority of the patients rated their condition and life satisfaction after STERP as improved. Moreover, a high satisfaction with the treatment could be demonstrated: 89% would recommend STERP to other OCD patients. The 12-week STERP protocol could be integrated into clinical routine without reportable difficulties.

Our experience was that implementing the combination of ST and ERP went well. The work with the ST mode model was particularly suitable for OCD patients since the work with the mode model caused distance to their problematic behavior. We assume that this distance facilitated the implementation of exposure exercises. OCD patients who previously failed to respond to CBT received a new psychotherapeutic approach by working with the mode model and each patient conducted exposure exercises, even if they had excluded it at the beginning of treatment due to negative prior experiences. It was probably helpful that specific attention was paid to the fact that exposure sessions were conducted in the healthy adult mode. Moreover, other schematherapeutic strategies (chair work, imaginative rescripting, schema memos) were assessed as helpful by patients and therapists. Schema therapy worked well in combination with ERP and extended the ERP treatment in a helpful and positive way.

Our participants reached similar results as average OCD patients in inpatient treatments ($d=1.7 - 2.5$) (Gönner, Limbacher, & Ecker, 2012; Höhagen, Winkelmann, & Rasche-Räuchle, 1998; Kordon, Kahl, & Brooks, 2005; Müller-Svitak, Reinecker, Rief, & Fichter, 2002). It should be noted though that our patients had not responded to traditional treatments before and had a longer OCD history.

In our sample, patients who continued outpatient psychotherapy with a combination of CBT with ERP and ST benefitted most from the new approach. Follow-up results are remarkable.
in as far as remitted patients remained in remission over a period of 6 months, and that a partial responder achieved response. Although we examined former non-responders, our results are comparable with some OCD studies observing the maintenance of clinical benefit over extended follow-up periods. They even exceed results from other studies investigating less affected participants (van Oppen, van Balkom, de Haan, & van Dyck, 2005; Rufer, et al., 2005). Notably, no participant’s OC symptoms deteriorated. These findings are promising, since often a considerable proportion of OCD patients worsen between discharge and follow-up even with subsequent outpatient treatment (Fricke et al., 2006).

The improvement of depressive symptoms exceeded the results in the study by Gönner et al., (2008), likely because baseline depression was higher and treatment duration was longer in the present study compared to the Gönner study, investigating outcome of inpatient CBT in 108 OCD patients. However, at follow-up four patients, including two OC responders, worsened with regard to depressive symptoms. Four out of five OC full responders presented a MDD at baseline with two having a depression relapse at follow-up. The results of studies investigating the predictive value of depressive symptoms in OCD on treatment outcome are inconsistent (Abramowitz et al., 2000; Franklin, Abramowitz, Kozak, Levitt, & Foa, 2000; Keijser, Hoogduin, & Schaap, 1994; Steketee, Chambless, & Tran, 2001; Steketee, Siev, Fama, Keshaviah, Chosak, & Wilhelm, 2011; Rufer, Fricke, Moritz, Kloss, & Hand, 2006; Anholt et al., 2011). However, severe depression or a MDD is consistently linked with a negative treatment outcome (Abramowitz, 2004; Abramowitz & Foa, 2000). Thus, it is particularly promising that even those participants with remitting depression could maintain their treatment effect with regard to OCD symptoms.

So far, schema therapy has mainly been tested as a treatment for personality disorders. Half of our sample was diagnosed with at least one co-morbid personality disorder. However, both subjects with and without PD responded well to our treatment. Especially the long-term responders tended not to present a PD. Thus, our effects cannot be explained by mere improvements of the PD pathology of our patients, since STERP seems to be suitable for OCD patients both with and without co-morbid PD. STERP is relatively short with a mere 24 inpatient sessions in comparison with outpatient ST studies for PD patients with at least 60 sessions (Giesen-Bloo et al., 2006; Malogiannis et al., 2014). Studies are needed to test STERP as an outpatient treatment with longer duration in such samples.
Limitations:

Obviously, our pilot study only yields preliminary results. This study has several limitations including lack of a control condition, small sample size and heterogeneity of the participants. Since no control condition was examined, repeated outcome measures during the baseline phase would have been of advantage to exclude spontaneous symptom changes. Previous treatments were naturalistic and partly no reliable information about treatment response was given. As a result, the information about prior treatment response was often restricted to final reports and patients’ personal assessment. In addition, due to the complex individual medication histories and the time-limited study, pharmacotherapy during the study could not be standardized. The slight changes of medication dependent on the blood levels of the psychotropic drugs have to be regarded as an independent variable that may have affected the treatment outcome. However, 50% of the patients did not change medication in the study and no additional psychotropic medication was applied. Since we applied a very complex treatment we do not know whether the observed effects were attributable to ST techniques, ERP techniques or other aspects of the inpatient treatment. However, since all participants had previously received a specialized CBT with ERP treatment, it is conceivable that success results from the combined treatment. Randomized studies are needed that compare STERP with ERP in comparable settings.

Interpretation of the follow-up data is somewhat limited, since changing medication and restarting any kind of outpatient psychotherapy was not excluded as a potential confounder. We have not prohibited a subsequent outpatient treatment, since it was important to continue the work on the developed strategies in the outpatient setting. However, continuing with outpatient therapy to maintain the treatment outcome was of great interest to the treating study psychiatrists and psychotherapists. With regard to the assessment of treatment satisfaction, self-ratings always carry a risk of participants answering in a socially desired manner. Studies with more standardized treatments after inpatient therapy are needed.

This study has been conducted in an inpatient setting. Most psychotherapy studies on OCD took place in outpatient settings and are thus not fully comparable. However, follow-up results give us at least some indication of the maintenance of effects in the outpatient setting.

Strengths:

The proof-of-concept character of this study allowed for less restrictive exclusion criteria. The inclusion of a severely disturbed patient population is a strength of the present study. Severely ill patients in need of inpatient treatment and with many prior pre-treatments, high co-morbidity rates and a long duration of OCD could be included. Another strength is a very limited number of exclusion criteria to investigate a preferably natural, representative population and to improve external validity of the study. One advantage of the STERP...
treatment is that it attends overt symptoms (obsessive compulsive behavior, different moods, interpersonal problems) and underlying themes (EMS and schema modes) in an understandable way to the patient and theoretically consistent to the therapist.

Recent research showed that standard CBT is of limited efficacy in some OCD patients. To our knowledge, this was the first study combining ST techniques with CBT with ERP in the treatment of an axis I diagnosis. In summary, the present findings demonstrate that the combined treatment approach STERP can be adapted for OCD patients who previously did not respond to ERP. STERP seems to be a powerful therapeutic approach that can bring about clinically significant symptom improvement with large effect sizes, a good working alliance and a positive feedback from the participants. Thus, despite being limited by the small sample size, the results suggest that STERP might become a well-accepted and effective new approach for OCD patients who do not optimally respond to traditional CBT with ERP. We believe that these results deserve further and more thorough investigation in randomized controlled trials.

**Competing interests**
The authors declare that they have no competing interests except of CN who has received speaker honoraria from Servier.

**Authors’ contributions**
NT and GJ carried out the study. CN, BTC and NH helped to draft the manuscript. UV and participated in the design and coordination of the study and drafted the manuscript. NT and AKK performed the statistical analysis. EH acquired the data of the study. All authors read and approved the final manuscript.

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Highlights

- Prior non-responding obsessive-compulsive disorder patients (OCD) were examined.
- Exposure and response prevention was augmented with schema therapy called STERP.
- STERP is feasible and accepted in an inpatient pilot study.
- STERP significantly reduced symptoms and showed large effect sizes.