

Results of a Multicenter Randomized Controlled Trial of the Clinical Effectiveness of Schema Therapy for Personality Disorders

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Objective: The authors compared the effectiveness of 50 sessions of schema therapy with clarification-oriented psychotherapy and with treatment as usual among patients with cluster C, paranoid, histrionic, or narcissistic personality disorder.

Method: A multicenter randomized controlled trial, with a single-blind parallel design, was conducted between 2006 and 2011 in 12 Dutch mental health institutes. A total of 323 patients with personality disorders were randomly assigned (schema therapy, N=147; treatment as usual, N=135; clarification-oriented psychotherapy, N=41). There were two cohorts of schema therapy therapists, with the first trained primarily with lectures and the second primarily with exercises. The primary outcome was recovery from personality disorder 3 years after treatment started (assessed by blinded interviewers). Secondary outcomes were dropout rates and measures of personality disorder traits, depressive and anxiety disorders, general psychological complaints, general and social functioning, self-ideal discrepancy, and quality of life.

Results: A significantly greater proportion of patients recovered in schema therapy compared with treatment as usual and clarification-oriented psychotherapy. Second-cohort schema therapists had better results than first-cohort therapists. Clarification-oriented psychotherapy and treatment as usual did not differ. Findings did not vary with specific personality disorder diagnosis. Dropout was lower in the schema therapy and clarification-oriented psychotherapy conditions. All treatments showed improvements on secondary outcomes. Schema therapy patients had less depressive disorder and higher general and social functioning at follow-up. While interview-based measures demonstrated significant differences between treatments, differences were not found with self-report measures.

Conclusions: Schema therapy was superior to treatment as usual on recovery, other interview-based outcomes, and dropout. Exercise-based schema therapy training was superior to lecture-based training.

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Personality disorders are complex mental health problems associated with chronic dysfunction in several life domains (social, work, self-care) (1, 2), reduced quality of life (3), high societal costs (4), and a high prevalence rate (3%–15% in the general population) (5). Although psychological treatment is considered to be the treatment of choice for personality disorders (6, 7), research into its effectiveness is still in its infancy, troubled with methodological issues and strongly focused on borderline personality disorder. Studying the effectiveness of treatment for understudied personality disorders is a highly prioritized recommendation in several reviews (8–10).

Schema therapy is a form of psychotherapy that has proven to be efficacious for borderline personality disorder. A randomized controlled trial comparing schema therapy with transference-focused psychotherapy found dominance of schema therapy over transference-focused psychotherapy on all outcome measures and a significantly lower dropout rate in schema therapy (11). Schema therapy also proved to be a more cost-effective treatment

(12). A subsequent study found that schema therapy can be successfully implemented in regular mental health care (13). Another study reported superiority of schema therapy over treatment as usual for borderline personality disorder (14). However, the effectiveness of schema therapy for personality disorders other than borderline personality disorder remains to be evaluated.

The main objective of the present randomized controlled trial was to examine the clinical effectiveness of schema therapy for a group of six personality disorders: cluster C (avoidant, dependent, and obsessive-compulsive), histrionic, narcissistic, and paranoid personality disorders. Other personality disorders were excluded because they were deemed to require highly specialized and lengthier treatment protocols. A treatment protocol of 50 schema therapy sessions was compared with treatment as usual, which is primarily psychological treatment in the Netherlands, varying from supportive low-frequency contacts to advanced psychotherapy. Because any novel specialized psychotherapy might be more effective than treatment as

usual, we also wanted to compare treatment as usual with a specialized psychotherapy other than schema therapy. Therefore, we added clarification-oriented psychotherapy, a form of client-centered therapy developed for personality disorders (15). We hypothesized that schema therapy would be superior to treatment as usual in preventing treatment dropout and on primary and secondary outcome measures. We explored whether similar effects would be found for clarification-oriented psychotherapy. If both experimental conditions could be superior to treatment as usual, follow-up tests could compare schema therapy and clarification-oriented psychotherapy. Schema therapy therapists were trained in two cohorts with different educational formats, one mainly based on lectures and the other on structured experiential training of techniques. Training therapists in two cohorts at different time points was necessitated by the need for additional therapists during trial execution (since one center withdrew participation before the start of the study). Investigating the effects of therapist training on treatment outcome is an important, though neglected, topic (16, 17). Therefore, although initially not a research question, we tested schema therapy cohort differences and controlled condition effects for cohort.

Method

In this multicenter, pragmatic randomized controlled trial (parallel-group design), patients from 12 Dutch mental health institutes were enrolled (18), and three of the 12 centers had enough client-centered-therapists available to add clarification-oriented psychotherapy as a third arm (hence, comparisons involving clarification-oriented psychotherapy had a smaller sample size). Participants had at least one of the personality disorder diagnoses discussed above, based on the Structured Clinical Interview for DSM-IV Axis I Personality Disorders (SCID II [19]), as the principal diagnosis (diagnosis for which the patient seeks help). Additional inclusion criteria were availability to participate in the study and age 18 to 65. Exclusion criteria were the presence (also subthreshold) of antisocial, schizotypal, schizoid, or borderline personality disorder; lifetime prevalence of psychosis or bipolar disorder; IQ <80; and immediate suicide risk or substance abuse needing clinical detoxification. With 125 participants per arm, the study was powered at 90% to detect a schema therapy versus treatment as usual recovery difference of an odds ratio of 2.70 at an alpha of 0.05 (80% power to detect for clarification-oriented psychotherapy [N=50] versus treatment as usual) (18). An independent statistician generated computer-based lists using adaptive biased urn randomization for small strata (20). After checking the inclusion and exclusion criteria, an independent research assistant randomly assigned patients to two groups (schema therapy compared with treatment as usual with equal prior rates) per center in nine participating centers and to three groups (schema therapy compared with treatment as usual compared with clarification-oriented psychotherapy with equal prior rates) per center in three participating centers. Matching of patient to therapist was done through local schema therapy and clarification-oriented psychotherapy peer-supervision groups or by local staff in treatment as usual. A test battery including assessor-based and self-report instruments was administered at 6, 12, 18, 24, and 36 months. At 36 months (the 3-year follow-up), diagnostic interviews were repeated. Assessments

were conducted by independent research assistants at local sites, except for 3-year follow-up diagnostic interviews that were conducted by central blinded interviewers. All patients provided written informed consent before participating in the study, and the study was approved by the medical ethical committee of Maastricht University.

The primary outcome measure was recovery from all personality disorders (defined as not meeting criteria for any personality disorder), as measured with SCID II by blinded independent interviewers at the 3-year follow-up. Data from 42 double-rated audiotaped interviews demonstrated good inter-rater reliability, with the mean intraclass correlation coefficient between interviewers being 0.84 (from 0.50 to 0.97 over subscales). Missing SCID II assessments were replaced by personality disorder diagnoses obtained from the most recent scores on the Assessment of DSM-IV Personality Disorders Questionnaire (21), using the categorical scoring algorithms (22). Assessor-based secondary measures were axis I mood and anxiety disorders (assessed with SCID I [23] by SCID II interviewers) and Global Assessment of Functioning Scale (24) and Social and Occupational Functioning Assessment Scale (24) scores, assessed by research assistants at regular assessments, who also monitored medication use. Self-report secondary measures included the Assessment of DSM-IV Personality Disorders Questionnaire dimensional subscales, the Symptom Checklist-90 (25) for general symptoms, the Work and Social Adjustment Scale (26) for social functioning, the Miskimins Self-Goal-Other Discrepancy Scale (27) for actual-ideal self-discrepancy, and the modified World Health Organization Quality of Life Assessment (28).

Treatment, Therapists, and Treatment Integrity Check

Descriptions and comparisons of schema therapy and clarification-oriented psychotherapy are presented in Figure 1 and Table 1; our design for specific characteristics of treatment conditions has been described elsewhere (18). Schema therapy and clarification-oriented psychotherapy were both individual outpatient psychotherapies (initially) delivered weekly and included a standardized treatment protocol (15, 29). Schema therapy consisted of 40 sessions in the first year and 10 booster sessions in the second year, while clarification-oriented psychotherapy was open-ended. Therapists in both conditions received a 4-day training session at the start of the study, yearly national supervision, and weekly local peer supervision. Clarification-oriented psychotherapists were required to be accredited client-centered therapists or trainees, while any theoretical orientation was allowed for schema therapists. Therapists eventually included in the schema therapy arm were recruited through self-expressed interest to learn schema therapy. All other therapists could be treatment as usual therapists. In treatment as usual, local intake staff chose a specific treatment method and modality for a particular patient, depending on the patient's capacity, needs, and circumstances. In this way, treatment as usual was optimized and mimicked usual practice. Treatment as usual did not include a standardized study protocol or training/supervision of therapists. Treatment as usual therapists had standard, local peer supervision. Therapists in this condition were expected to follow the clinical guidelines for personality disorders in the Netherlands. All primary treatment as usual was psychological treatment (insight-oriented psychotherapy, 42%; supportive therapy, 32%; cognitive-behavioral therapy, 19%; eye movement desensitization and reprocessing, 1.5%). For all three conditions, if the patients discontinued treatment or were referred again for treatment after treatment termination, another treatment was offered with a different therapist, if deemed necessary or helpful. Because of the naturalistic treatment flow of this trial, it was possible that patients

could still receive treatment at the 3-year follow-up. Baseline demographic and clinical characteristics of patients and the treatments they received are presented in Table 2.

Sixty-four therapists treated one patient (schema therapy, N=13; treatment as usual, N=50; clarification-oriented psychotherapy, N=1), 55 treated two (schema therapy, N=32; treatment as usual, N=15; clarification-oriented psychotherapy, N=8), 32 treated three (schema therapy, N=17; treatment as usual, N=11; clarification-oriented psychotherapy, N=4), nine treated four (schema therapy, N=4; treatment as usual, N=2; clarification-oriented psychotherapy, N=3), and one treated five (treatment as usual). Training of schema therapy therapists occurred in two waves (referred to as cohorts) (18). Cohort 1 received mainly lectures and video demonstrations, while cohort 2 was trained by another trainer, actively participated in compulsory role-play, and received individual feedback (see the data supplement that accompanies the online version of this article). Cohort effects were incorporated in the analyses. All therapists had previous experience in psychological treatment (mean years: schema therapy, 16.05 years [SD=7.72]; treatment as usual, 16.10 years [SD=9.82]; clarification-oriented psychotherapy, 20.38 years [SD=8.58]), with no between-group differences. Therapists were asked to rate their experience with delivered treatment on a scale from 0 (none) to 5 (professional). As expected, treatment as usual therapists (4.12 [SD=1.43]) were more experienced than schema therapy (2.20 [SD=1.81]) and clarification-oriented psychotherapy (1.82 [SD=2.24]), $p < 0.001$ therapists with regard to treatments delivered to study patients.

Treatment integrity (adherence to protocol) was monitored by means of supervision (see reference 18). Independent blinded raters scored randomly selected audiotapes on a series of 7-point Likert scales, indicating the amount of time specific therapeutic interventions were heard. In addition to specific schema therapy and clarification-oriented psychotherapy techniques, we assessed two general therapeutic styles, taken from the Collaborative Study Psychotherapy Rating Scale, version 6 (30): facilitative conditions (e.g., supportive encouragement, involvement) and explicit directiveness (e.g., level of verbal activity, explicit guidance). While 16.87% of audiotapes were missing or lost because of poor sound quality, the remaining audiotapes were rated by nine independent raters who were blind to allocation. The mean intraclass correlation coefficient across subscales of 78 double-rated audiotapes was 0.52, ranging from 0.33 (explicit directiveness) to 0.85 (schema therapy items). Results of 631 audiotapes are presented in Table 2. Condition-specific techniques were highest in schema therapy and clarification-oriented psychotherapy ($p < 0.001$), respectively, although schema therapy also differed significantly from treatment as usual on clarification-oriented psychotherapy techniques. Therapists in the second-cohort schema therapy group scored significantly higher on schema therapy-specific techniques ($p < 0.05$). The two general therapeutic styles were most prominent in schema therapy.

Statistical Analyses

A detailed description of statistical procedures is presented in the online data supplement. Results were analyzed according to the intent-to-treat principle using SPSS, version 19.0 (SPSS, Inc., Chicago), for logistic and linear mixed regression, with center as random effect. For repeated measures, unstructured covariance was used. Cohort and baseline severity were used as covariates (the latter in analyses of diagnostic outcomes unless indicated). Baseline severity index was a composite measure based on standardized baseline values of the number of axis I and II disorders, Assessment of DSM-IV Personality Disorders Questionnaire trait and distress scores, Symptom Checklist-90 score, Global Assessment of Functioning Scale score, Social and Occupational Functioning Assessment Scale score, and disability

FIGURE 1. Descriptions of Schema Therapy and Clarification-Oriented Psychotherapy

Schema therapy and clarification-oriented psychotherapy are both based on schema-conceptualizations and the idea that rigid pathological characteristics of personality disorders are the result of a negative childhood environment in which core fundamental needs were not met. Although they share similar underlying theoretical constructs, there are important differences.

Core Aspects of Schema Therapy:

- Integrative psychotherapy; combines cognitive, experiential, behavioral, and interpersonal techniques
- Mode model (cf. “ego-states”: modes refer to particular sets of schemas and coping styles that are active at a given time and can be either adaptive or maladaptive) and specific therapy techniques for each mode
- Emphasis on the therapeutic relationship as a limited way of fulfilling needs and more directive and personal than most other approaches
- Extensive processing of negative childhood experiences (including trauma) with specific techniques (e.g., imagery rescripting)
- Experiential work to evoke emotions and facilitate emotional change, in addition to cognitive-behavioral therapy and relational techniques

Core Aspects of Clarification-Oriented Psychotherapy:

- Originates in client-centered psychotherapy
- A conceptual model stressing dysfunctional interaction behavior as a strategy to get unfulfilled needs met
- Primary channel of change is through insight
- Therapists help patients to discover dysfunctional patterns and functional ways to get needs adequately met, in a nondirective way
- An important technique is to respond to dysfunctional behavior in noncomplementary ways and then to invite the patient to express his or her needs in a functional way

(internal consistency, 0.77). For the primary outcome, a series of sensitivity analyses was conducted. Dropout was analyzed with survival analysis controlling for severity and cohort, as well as with mixed logistic regression, using the same model used in the primary outcome analysis. Because estimation failed in mixed analyses of depressive and anxiety disorder presence at the 3-year follow-up (as a result of missing data), multiple imputation followed by logistic regression was used. For diagnostic outcomes, we report effects of all condition comparisons, schema therapy-by-cohort, and severity and sensitivity covariates when applicable. For repeated measures, we report effects of time, all condition comparisons of time effects, and (schema therapy compared with treatment as usual)-by-cohort-by-time as relevant to the research questions.

Results

Patient Accrual

The study was conducted between May 2006 and January 2011. The CONSORT diagram for the study is presented in Figure 2. A total of 624 patients were initially referred to the study, 285 of whom were excluded during the screening procedure. A total of 140 individuals did not meet diagnostic criteria; 108 met exclusion criteria (89 had a diagnosis or subthreshold diagnosis of borderline, antisocial, schizotypal, or schizoid personality disorder; 11

TABLE 1. Comparison of Schema Therapy and Clarification-Oriented Psychotherapy

Schema Therapy	Clarification-Oriented Psychotherapy
Therapeutic relationship	
Directive (with regard to both content and process).	Nondirective as to content, directive with regard to process (the therapist proposes processes that foster clarification, confrontation with interfering processes).
Limited re-parenting: The therapist partly meets unmet childhood needs within healthy therapy boundaries (e.g., offers safe attachment, praises the patient, stimulates playfulness, and sets limits).	No focus on meeting the patient's unmet childhood needs in the therapeutic relationship but on helping the patient to become aware of dysfunctional ways in which basic needs and motives are expressed. When the patient displays dysfunctional, unauthentic behavior, the therapist responds in ways not expected by patient ("noncomplementary response").
The therapist is open about personal responses evoked by the patient, with frequent self-disclosure if deemed helpful.	Rogerian therapy conditions (unconditional acceptance, empathy, and genuineness) are necessary but not sufficient for change.
Psychoeducation: The therapist teaches the patient about core needs, as well as functional and dysfunctional behaviors, and links present problems to childhood experiences.	No psychoeducation.
Conceptual model of the personality disorder	
The patient's problems are framed through schema modes: different "sides" of themselves that become activated by triggers related to childhood experiences. These modes govern the patient's emotions, cognitions, and behaviors.	The patient's problems are framed as dysfunctional interpersonal strategies to get basic motives/needs met. These nonauthentic and manipulative interpersonal strategies are shaped by cognitive-affective schemas about self, personal problems, and relationships with others evolved during development.
Importance of determining childhood origins of schemas/schema modes	
Central to model and treatment. Dysfunctional parenting and traumas in childhood are viewed as origins of dysfunctional schemas/modes. The therapist frequently links the present and the past. Extensive processing of childhood experiences (including traumas) and correcting internalized messages are achieved.	Childhood origins are important to understand development of cognitive-affective schemas but are not targets of specific change techniques.
Main mechanisms of change	
Corrective emotional experiences, cognitive change, and change in behaviors. The therapist is internalized as the "healthy adult."	Insight: Patients should become aware of their authentic motives/needs and the dysfunctional cognitive-affective schemas interfering with functional interpersonal behaviors.
Targets of interventions	
Therapeutic relationship (limited re-parenting).	Process: Promote clarification (e.g., by proposing to attend to a basic need/motive) and challenge attempts to avoid clarification.
Memories of childhood are linked to present problems. Present problems outside therapy.	Schema change: Acquiring insight that dysfunctional schemas are incorrect.
Main techniques	
Experiential, cognitive, and behavioral techniques are geared to specific modes.	The therapist responds to problem behavior during the session in unexpected (noncomplementary) ways to create awareness.
The therapist initially takes the lead (e.g., challenges punitive parent mode on empty chair, intervenes in imagery re-scripting, empathically confronts the patient with dysfunctional behaviors, and proposes and stimulates functional behaviors).	The therapist responds to functional behavior in accepting ("complementary") ways to strengthen the behavior.
Gradually, patients apply techniques themselves.	The therapist proposes constructive clarification processes and challenges avoidance. The therapist facilitates patients to acquire insight into the incorrectness of cognitive-affective schemas (e.g., by one-person role-play).
Treatment phase	
Year 1	
Session 1–6: introduction into schema therapy, bonding and case conceptualization in terms of mode model.	Phase 1: Bonding, understanding the patient, and being complementary to authentic expression of basic needs and not complementary to unauthentic expression.
Session 7–24: focus on reducing coping modes and on historical and experiential work (e.g., imagery re-scripting, empty chair technique).	Phase 2: Bonding, confronting dysfunctional interpersonal strategies, and defining treatment goals.
Session 25–40: focus mostly on present (e.g. behavioral pattern breaking).	Phase 3: Bonding, clarification of schemas, and confronting avoidance tendencies.
Year 2	
Session 41–50: monthly booster sessions to maintain and deepen changes.	Phase 4: Facilitating patients in acquiring insight into incorrectness of cognitive-affective schemas (e.g., with one-person role-play). Phase 5: Transfer to behavior: facilitating patients to change their behaviors.

TABLE 2. Baseline Demographic and Clinical Characteristics of Patients With Personality Disorders by Treatment Received

Characteristic	Treatment						Analysis
	Schema Therapy (N=145)		Clarification-Oriented Psychotherapy (N=41)		Treatment As Usual (N=134)		
	Mean	SD	Mean	SD	Mean	SD	
Age (years)	37.57	9.69	39.20	9.37	38.06	9.63	0.63
	N	%	N	%	N	%	p ^b
Male	66	45.5	18	43.9	55	41	0.75
Education							
Primary school	6	4.1	3	7.3	3	2.2	0.85 ^c
Lower vocational	6	4.1	4	9.8	15	11.2	
Lower secondary	22	15.2	3	7.3	8	6	
Higher secondary	11	7.6	2	4.9	15	11.2	
Intermediate vocational	46	31.7	15	36.6	45	33.6	
Preuniversity	11	7.6	2	4.9	10	7.5	
Higher vocational	29	20	12	29.3	25	18.7	
Academic	14	9.7	0	0	13	9.7	
Employment status							
Housewife	7	4.8	1	2.4	5	3.7	0.96
Student	7	4.8	3	7.3	6	4.5	
Employed	66	45.5	16	39	63	47	
Disability	47	32.4	17	41.5	46	34.3	
Welfare	17	11.7	4	9.8	14	10.4	
Retired	1	0.7	0	0	0	0	
Primary personality disorder diagnosis							
Avoidant	74	51	19	46.3	70	52.2	0.86
Dependent	16	11	6	14.6	14	10.4	
Obsessive-compulsive	41	28.3	11	26.8	37	27.6	
Paranoid	8	5.5	1	2.4	5	3.7	
Histrionic	0	0	1	2.4	1	0.7	
Narcissistic	6	4.1	3	7.3	7	5.2	
Secondary personality disorder diagnosis							
None	80	55.2	19	46.3	69	51.5	0.58
Avoidant	13	9	8	19.5	22	16.4	0.09
Dependent	9	6.2	3	7.3	2	1.5	1.00
Obsessive-compulsive	11	7.6	7	17.1	15	11.2	0.19
Paranoid	3	2.1	3	7.3	4	3	0.23
Histrionic	0	0	0	0	0	0	
Narcissistic	0	0	0	0	1	0.7	0.50
Passive-aggressive	6	4.1	1	2.4	3	2.2	0.64
Depressive	41	28.3	13	31.7	39	29.1	0.91
Axis I comorbidity (current)							
Anxiety disorders	82	56.6	25	61	80	59.7	0.82
Depressive disorder	61	42.1	23	56.1	59	44.0	0.28
Somatoform disorders	17	11.7	4	9.8	11	8.2	0.62
Substance abuse	7	4.8	5	12.2	1	0.7	<0.01
Eating disorders	3	2.1	1	2.4	6	4.5	0.50
Other axis I disorders	11	7.6	7	17.1	19	14.2	0.11
Psychotropic medication at baseline	71	49	18	43.9	74	55.2	0.36
	Mean	SD	Mean	SD	Mean	SD	p
Number of treatments before baseline	2.44	2.35	2.12	3.3	2.28	2.22	0.72 ^a
Number of treatment modalities before baseline	1.51	1.23	1.27	1.30	1.36	1.18	0.41 ^a
Total duration of previous treatments (months)	29.73	42.70	31.98	78.51	35.75	63.73	0.68 ^a
Number of principal treatments over 3 years	1.33	0.69	1.51	0.93	1.39	0.73	0.40 ^c
Number of secondary treatments over 3 years ^d	0.68	1.04	0.85	1.04	0.92	1.32	0.14 ^c

continued

TABLE 2. Baseline Demographic and Clinical Characteristics of Patients With Personality Disorders by Treatment Received (continued)

Characteristic	Treatment						Analysis
	Schema Therapy (N=145)		Clarification-Oriented Psychotherapy (N=41)		Treatment As Usual (N=134)		
	Median	25th–75th Percentile	Median	25th–75th Percentile	Median	25th–75th Percentile	p ^c
Total number of sessions of indicated principal treatments over 3 years	50	31–50	51	28–74	22	11–47	<0.01
Total number of sessions of additional treatments over 3 years	0	0–11	5	0–18	3	0–18	0.04
Total number of days in principal treatments over 3 years	694	481–766	895	393–1038	522	243–863	<0.01
	N	%	N	%	N	%	p
Distribution of indicated principal treatments							
Did not receive indicated treatment	2	1.4	0	0	7	5.2	
Schema therapy	143	98.6	0	0	0	0	
Clarification-oriented psychotherapy	0	0	41	100.0	0	0	
Cognitive-behavioral therapy	0	0	0	0	26	19.4	
Eye movement desensitization and reprocessing	0	0	0	0	2	1.5	
Insight-oriented psychotherapy	0	0	0	0	56	41.8	
Supportive therapy	0	0	0	0	43	32.1	
	%	95% CI	%	95% CI	%	95% CI	p ^f
Medication use during 3 years	40.4 ^e	34–47.1	50.0	40.1–59.8	58.2	51.2–64.9	<0.001
	N	%	N	%	N	%	p ^b
Number of patients still in treatment at follow-up	19	13.1	15	36.6	35	26.1	<0.01
Results of treatment integrity tests	Mean	SD	Mean	SD	Mean	SD	p ^a
Schema therapy techniques	1.65 ^g	0.40	1.19	0.15	1.21	0.16	<0.001
Clarification-oriented psychotherapy techniques	1.60	0.41	1.79 ^h	0.46	1.51 ⁱ	0.38	<0.001
Facilitative conditions	3.80 ^g	0.63	3.52	0.67	3.45	0.69	<0.001
Explicit directiveness	3.47 ^g	0.50	3.15	0.48	3.24	0.60	<0.001

^a Value is based on analysis of variance F test.

^b Value is based on the Pearson’s chi-square test unless otherwise indicated.

^c Value is based on the Kruskal-Wallis test.

^d Secondary treatments are therapies given to patients alongside principal treatments.

^e Schema therapy differs significantly from treatment as usual and clarification-oriented psychotherapy (p<0.05).

^f Value is based on an F test from mixed logistic regression.

^g Schema therapy differs significantly from treatment as usual and clarification-oriented psychotherapy (p<0.01).

^h Clarification-oriented psychotherapy differs significantly from schema therapy and treatment as usual (p<0.01).

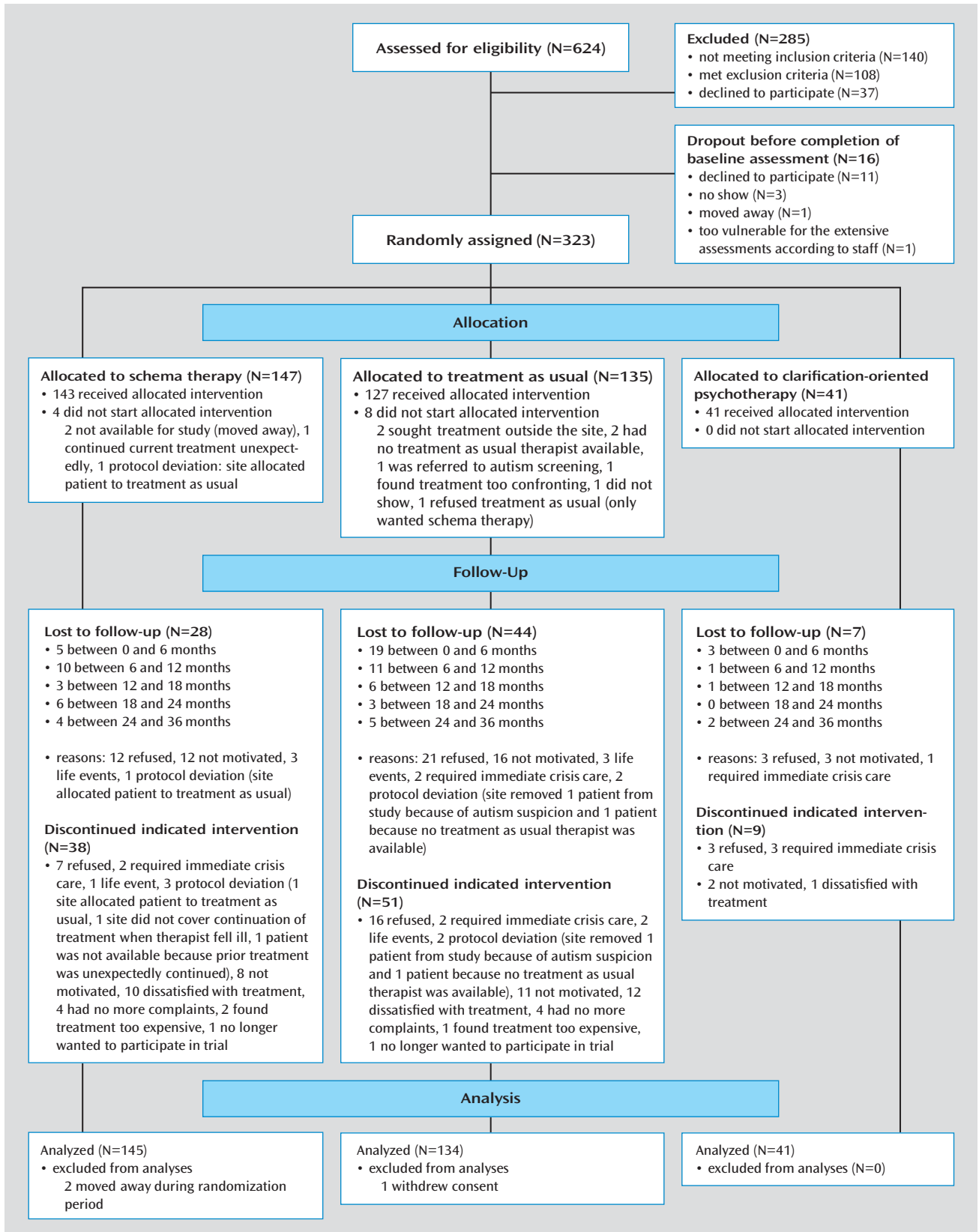
ⁱ Treatment as usual differs significantly from schema therapy (p<0.05) and from clarification-oriented psychotherapy (p<0.01).

had lifetime psychotic disorder; four had lifetime bipolar disorder; two had an IQ <80; and two suffered from substance abuse needing detoxification); and 37 declined further participation (21 did not agree with the study procedure; seven did not show; six did not want to focus on personality; one had a life-threatening disease; one had insufficient availability; and one felt too miserable to participate). Another 16 patients dropped out before baseline assessment, and thus 323 patients were randomly assigned (schema therapy, N=147; treatment as usual, N=135; clarification-oriented psychotherapy, N=41). Despite extending the inclusion period originally allowed by

the grant, inclusion at sites offering clarification-oriented psychotherapy progressed too slowly to achieve the intended 50, while in schema therapy and treatment as usual more than the planned minimal 125 were randomly assigned. Four patients in schema therapy and eight in treatment as usual did not start treatment (no single session).

The percentage of missing data ranged from 8.4% (at 6 months) to 24.6% (at 3 years; schema therapy, N=28; treatment as usual, N=44; clarification-oriented psychotherapy, N=7 [Figure 2]). The SCID assessments at follow-up took place apart from other assessments, with 35.9%

FIGURE 2. Study CONSORT Diagram



missing data (schema therapy, $N=43$; treatment as usual, $N=61$; clarification-oriented psychotherapy, $N=11$). Three randomly assigned patients were excluded from analyses: one withdrew consent (treatment as usual), and two withdrew participation during the randomization procedure because of their decision to move (schema therapy). The trial ended when the scheduled closure date was reached (3 years after patients who were included last started treatment).

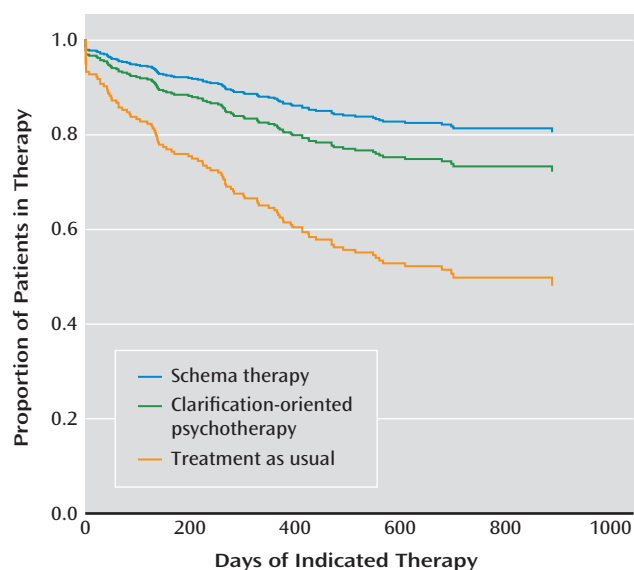
Thirty-eight patients in schema therapy (25.8%), 51 in treatment as usual (37.8%), and nine in clarification-oriented psychotherapy (22%) dropped out of indicated treatment (Figure 2, Figure 3). Survival analysis showed that patients in schema therapy had a significantly lower dropout risk than those in treatment as usual (Cox regression: $\beta=-1.22$, $p=0.002$; relative risk=0.30, 95% confidence interval [CI]=0.14–0.65), while a significant interaction between therapist cohort and condition revealed higher treatment retention in schema therapy compared with treatment as usual with the second-therapist cohort relative to the first ($\beta=-1.72$, $p=0.03$; relative risk=0.18, 95% CI=0.04–0.85). Comparing clarification-oriented psychotherapy and treatment as usual revealed a significant difference in favor of clarification-oriented psychotherapy with regard to dropout risk ($\beta=-0.81$, $p=0.03$; relative risk=0.45, 95% CI=0.21–0.93). Schema therapy and clarification-oriented psychotherapy did not significantly differ. Covariate severity was not significant. Mixed logistic regression revealed similar effects when controlling for baseline severity (Table 3). When not controlling for baseline severity, clarification-oriented psychotherapy lost its dominance in treatment retention over treatment as usual.

There was one serious adverse event reported: one patient in treatment as usual died, and postmortem analysis revealed that the patient may have committed suicide.

Treatment Outcomes

Primary outcome. Results of primary outcome analyses are summarized in Table 3. Schema therapy was dominant over treatment as usual, with a significantly greater proportion of recovered patients in this group than in the treatment as usual group (Figure 4), while the significant condition-by-cohort interaction showed that recovery was relatively higher among those receiving schema therapy from second-cohort therapists. The comparison of treatment as usual with clarification-oriented psychotherapy revealed greater recovery in treatment as usual but did not reach statistical significance. The severity effect reflects less recovery among patients with worse baseline severity. Effects were replicated in all sensitivity analyses and also when recovery was controlled for assessment type (diagnoses based on SCID II compared with Assessment of DSM-IV Personality Disorders). Schema therapy outperformed clarification-oriented psychotherapy in the primary analysis and in all but two sensitivity analyses

FIGURE 3. Proportion of Patients in Indicated Principal Treatment (Schema Therapy, Treatment as Usual, or Clarification-Oriented Psychotherapy)^a



^a Successful termination of indicated therapy was not coded as dropout.

(recovery controlled for assessment type and recovery defined by absence of subthreshold personality disorder). Estimated recovery proportions and 95% confidence intervals by condition are presented in Table 3.

Secondary outcomes. Results of mixed-regression analyses with estimated group differences and their effect sizes on secondary outcome measures are summarized in Table 4. On all outcome measures, the main time effect was significant, pointing at improvement during therapy ($p<0.001$). Global Assessment of Functioning Scale scores improved significantly more among patients in schema therapy than among those in treatment as usual ($p<0.05$), while no difference between schema therapy and clarification-oriented-psychotherapy was found. The time-by-condition-by-cohort interaction was significant, indicating a superior effect in the cohort with therapists who followed exercised-based training for schema therapy. Changes in Social and Occupational Functioning Assessment Scale scores revealed dominance of schema therapy over treatment as usual and clarification-oriented psychotherapy ($p<0.03$), while clarification-oriented psychotherapy and treatment as usual did not differ, and the three-way interaction was not significant. No significant effect involving condition or cohort was found on the Symptom Checklist-90, the Assessment of DSM-IV Personality Disorders Questionnaire, the Work and Social Adjustment Scale, the Miskimins Self-Goal-Other Discrepancy Scale, or the World Health Organization Quality of Life Assessment. The only exception was a significant time-by-condition-by-cohort effect on the Miskimins Self-Goal-Other Discrepancy Scale, indicating that patients receiving schema therapy from

TABLE 3. Mixed Logistic Regression Analyses of Recovery and Dropout Among Patients With Personality Disorders Randomly Assigned to Schema Therapy (ST), Clarification-Oriented Psychotherapy (COP), or Treatment as Usual (TAU)^a

Analysis and Contrast	Analysis						Outcome	
	B	t	df	p	Exp(B) ^b	95% CI	Estimated Proportion	95% CI
Primary analysis								
Recovery controlled for baseline severity^{c, d}								
ST versus TAU	1.404	3.326	314	0.001	4.073	1.774–9.350		
COP versus TAU	0.334	0.725	314	0.47	1.397	0.564–3.459		
ST versus COP	1.070	2.047	314	0.041	2.916	1.043–8.157		
Cohort-by-schema therapy	2.120	2.520	314	0.012	8.334	1.592–43.631		
Severity	-1.178	-5.252	314	<0.001	0.308	0.198–0.479		
Follow-up at 3 years								
Schema therapy							0.814	0.674–0.902
Clarification-oriented psychotherapy							0.600	0.406–0.767
Treatment as usual							0.518	0.383–0.650
Sensitivity analysis								
Recovery not controlled for baseline severity								
ST versus TAU	1.224	3.134	315	0.002	3.402	1.577–7.338		
COP versus TAU	0.026	0.062	315	0.95	1.027	0.45–2.372		
ST versus COP	1.198	2.471	315	0.014	3.313	1.276–8.601		
Cohort-by-schema therapy	1.869	2.391	315	0.017	6.479	1.393–30.138		
Follow-up at 3 years								
Schema therapy							0.796	0.663–0.885
Clarification-oriented psychotherapy							0.541	0.364–0.708
Treatment as usual							0.534	0.409–0.654
Recovery controlled for assessment time^e								
ST versus TAU	1.073	2.399	313	0.017	2.925	1.213–7.052		
COP versus TAU	-0.003	-0.006	313	>0.99	0.997	0.386–2.574		
ST versus COP	1.076	1.999	313	0.046	2.933	1.017–8.458		
Cohort-by-schema therapy	2.112	2.367	313	0.019	8.261	1.428–47.810		
Severity	-1.335	-5.330	313	<0.001	0.263	0.161–0.431		
Assessment time	0.489	6.743	313	<0.001	1.631	1.414–1.881		
Follow-up at 3 years								
Schema therapy							0.869	0.755–0.935
Clarification-oriented psychotherapy							0.694	0.503–0.835
Treatment as usual							0.694	0.558–0.804
Recovery controlled for assessment type^f								
ST versus TAU	1.049	2.405	313	0.017	2.856	1.210–6.738		
COP versus TAU	0.016	0.034	313	0.97	1.016	0.400–2.584		
ST versus COP	1.033	1.952	313	0.05	2.810	0.992–7.958		
Cohort-by-schema therapy	1.835	2.119	313	0.035	6.264	1.140–34.427		
Severity	-1.185	-5.048	313	<0.001	0.306	0.193–0.485		
Assessment type	1.740	6.121	313	<0.001	5.696	3.256–9.963		
Follow-up at 3 years								
Schema therapy							0.746	0.582–0.861
Clarification-oriented psychotherapy							0.511	0.320–0.699
Treatment as usual							0.507	0.373–0.639
Recovery in subsample that started indicated treatment								
ST versus TAU	1.298	3.071	304	0.002	3.664	1.594–8.418		
COP versus TAU	0.226	0.496	304	0.62	1.254	0.511–3.075		
ST versus COP	1.072	2.071	304	0.039	2.922	1.055–8.094		
Cohort-by-schema therapy	2.289	2.712	304	0.007	9.864	1.873–51.932		
Severity	-1.185	-5.201	304	<0.001	0.306	0.195–0.479		

continued

TABLE 3. Mixed Logistic Regression Analyses of Recovery and Dropout Among Patients With Personality Disorders Randomly Assigned to Schema Therapy (ST), Clarification-Oriented Psychotherapy (COP), or Treatment as Usual (TAU)^a (continued)

Analysis and Contrast	Analysis						Outcome	
	B	t	df	p	Exp(B) ^b	95% CI	Estimated Proportion	95% CI
Follow-up at 3 years								
Schema therapy							0.819	0.684–0.904
Clarification-oriented psychotherapy							0.607	0.417–0.770
Treatment as usual							0.552	0.419–0.679
Recovery defined by absence of subthreshold personality disorder (stringent criterion)^g								
ST versus TAU	1.410	3.436	314	0.001	4.096	1.827–9.185		
COP versus TAU	0.454	1.012	314	0.31	1.574	0.652–3.800		
ST versus COP	0.957	1.886	314	0.06	2.603	0.959–7.061		
Cohort-by-schema therapy	2.219	2.713	314	0.007	9.202	1.840–46.018		
Severity	–0.979	–4.612	314	<0.001	0.376	0.248–0.571		
Follow-up at 3 years								
Schema therapy							0.789	0.645–0.885
Clarification-oriented psychotherapy							0.589	0.402–0.754
Treatment as usual							0.477	0.350–0.607
Recovery controlled for personality disorder category^h								
ST versus TAU	1.428	3.374	311	0.001	4.172	1.814–9.597		
COP versus TAU	0.342	0.741	311	0.46	1.408	0.568–3.490		
ST versus COP	1.087	2.075	311	0.039	2.964	1.058–8.304		
Cohort-by-schema therapy	2.164	2.567	311	0.011	8.709	1.658–45.753		
Severity	–1.215	–5.335	311	<0.001	0.297	0.190–0.465		
Dependent personality disorder	–0.075	–0.174	311	0.86	0.928	0.399–2.160		
Obsessive-compulsive personality disorder	–0.410	–1.354	311	0.18	0.664	0.366–1.204		
Paranoid, narcissistic, or histrionic personality disorder	–0.102	–0.236	311	0.81	0.903	0.386–2.112		
Follow-up at 3 years								
Schema therapy							0.813	0.666–0.904
Clarification-oriented psychotherapy							0.594	0.395–0.766
Treatment as usual							0.510	0.367–0.651
Recovery controlled for medication use at treatment start								
ST versus TAU	1.420	3.352	313	0.001	4.136	0.180–0.458		
COP versus TAU	0.355	0.771	313	0.44	1.427	0.576–3.533		
ST versus COP	1.064	2.036	313	0.043	2.899	1.036–8.110		
Cohort-by-schema therapy	2.072	2.456	313	0.015	7.937	1.511–41.667		
Severity	–1.248	–5.256	313	<0.001	0.287	0.180–0.458		
Medication use at treatment start	0.264	0.969	313	0.33	1.302	0.762–2.223		
Follow-up at 3 years								
Schema therapy							0.817	0.678–0.904
Clarification-oriented psychotherapy							0.606	0.412–0.772
Treatment as usual							0.519	0.384–0.651
Recovery controlled for medication use during 3 yearsⁱ								
ST versus TAU	1.416	3.343	313	0.001	4.120	1.791–9.478		
COP versus TAU	0.342	0.741	313	0.459	1.408	0.568–3.492		
ST versus COP	1.074	2.052	313	0.041	2.926	1.045–8.192		
Cohort-by-schema therapy	2.114	2.511	313	0.013	8.280	1.580–43.383		
Severity	–1.200	–5.146	313	<0.001	0.301	0.190–0.477		
Medication use during trial	0.107	0.344	313	0.731	1.113	0.602–2.057		
Follow-up at 3 years								
Schema therapy							0.815	0.675–0.903
Clarification-oriented psychotherapy							0.600	0.406–0.767
Treatment as usual							0.516	0.381–0.649

continued

TABLE 3. Mixed Logistic Regression Analyses of Recovery and Dropout Among Patients With Personality Disorders Randomly Assigned to Schema Therapy (ST), Clarification-Oriented Psychotherapy (COP), or Treatment as Usual (TAU)^a (continued)

Analysis and Contrast	Analysis						Outcome	
	B	t	df	p	Exp(B) ^b	95% CI	Estimated Proportion	95% CI
Dropout analysis								
Dropout controlled for baseline severity								
ST versus TAU	-1.321	-3.003	314	0.003	0.267	0.112–0.634		
COP versus TAU	-0.951	-2.003	314	0.046	0.386	0.152–0.983		
ST versus COP	-0.370	-0.654	314	0.51	0.691	0.227–2.103		
Cohort-by-schema therapy	-2.149	-2.443	314	0.015	0.117	0.021–0.658		
Severity	0.287	1.383	314	0.167	1.333	0.886–2.005		
Follow-up at 3 years								
Schema therapy							0.154	0.076–0.285
Clarification-oriented psychotherapy							0.208	0.103–0.376
Treatment as usual							0.405	0.294–0.527
Dropout not controlled for baseline severity								
ST versus TAU	-1.309	-2.984	315	0.003	0.270	0.114–0.640		
COP versus TAU	-0.878	-1.901	315	0.06	0.416	0.168–1.031		
ST versus COP	-0.431	-0.775	315	0.44	0.650	0.218–1.941		
Cohort-by-schema therapy	-2.137	-2.435	315	0.015	0.118	0.021–0.663		
Follow-up at 3 years								
Schema therapy							0.154	0.077–0.283
Clarification-oriented psychotherapy							0.219	0.112–0.384
Treatment as usual							0.402	0.296–0.519

^a All analyses included baseline severity as a covariate, except when indicated; higher-order interactions involving baseline severity were not significant; bold indicates significant values; cohort was coded as -0.5 for cohort 1 (schema therapy, treatment as usual), 0.5 for cohort 2 (schema therapy, treatment as usual), and 0 for clarification-oriented psychotherapy.

^b Data represent the effect size odds ratio expressing the effect as estimated in the mixed-regression analysis; treatment as usual is the reference condition; an odds ratio >1 denotes superior effects in schema therapy respectively, clarification-oriented psychotherapy compared with treatment as usual; for the cohort-by-schema therapy interaction, an odds ratio >1 denotes superior effects of schema therapy compared with treatment as usual in the group with second-cohort therapists, compared with first-cohort therapists; for dropout, smaller odds ratios denote superior effects.

^c The raw estimates for schema therapy, clarification-oriented psychotherapy, and treatment as usual are 0.710, 0.561, and 0.582, respectively.

^d Higher-order interactions involving severity were not significant.

^e Time of last assessment was added as a covariate; higher-order interactions involving time were not significant.

^f Type of assessment (Structured Clinical Interview for DSM-IV Axis II Personality Disorders [SCID II] or Assessment of DSM-IV Personality Disorders Questionnaire in case the patient declined to take the SCID II) was added as a covariate; higher-order interactions involving this covariate were not significant.

^g The stringent recovery criterion was defined as not meeting any personality disorder or subthreshold personality disorder diagnosis, with subthreshold defined as the number of criteria required for a personality disorder diagnosis minus 1.

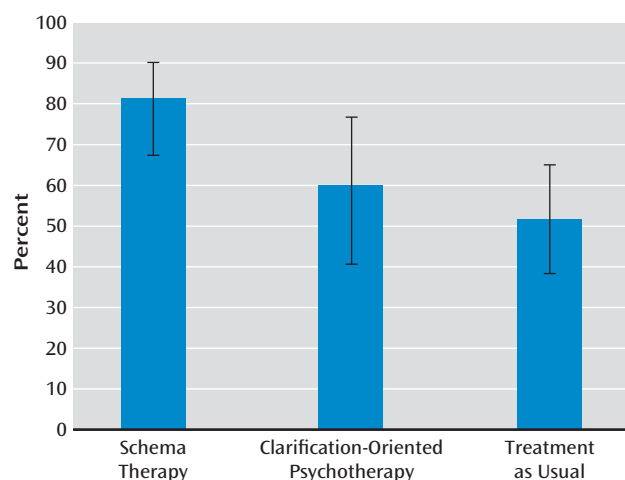
^h The primary personality disorder diagnosis is grouped into four categories: avoidant (reference condition); dependent; obsessive-compulsive; and paranoid, histrionic, and narcissistic personality disorders combined; the main effect of primary personality disorder diagnosis and higher-order interactions involving primary personality disorder were not significant.

ⁱ Medication use during the trial is the mean number of years with medication use during the 3-year study period.

the second-cohort therapists achieved better results in reducing self-ideal discrepancy compared with patients in treatment as usual, whereas patients receiving schema therapy from first-cohort therapists did not ($p=0.035$). All within-condition effect sizes were large, ranging from 0.86 to 1.76 (Table 4). For depressive and anxiety disorders (measured assessor-based only at baseline and follow-up), multiple imputation-based logistic regression revealed a significant main effect of schema therapy on depressive disorder diagnoses, with an odds ratio of 0.23, reflecting lower risk of depressive disorder at follow-up in schema therapy. No condition differences regarding anxiety disorders were found.

Discussion

We compared the effectiveness of schema therapy and clarification-oriented psychotherapy with treatment as usual for cluster C, paranoid, histrionic, and narcissistic personality disorders. The primary analysis and all sensitivity analyses revealed consistently that schema therapy was superior to treatment as usual on primary outcome (greater recovery from personality disorder), as well as when recovery was defined more stringently, and when we controlled for assessment instrument. Patients receiving schema therapy showed greater improvement in scores on the Global Assessment of Functioning Scale and the Social

FIGURE 4. Recovery Rate Per Treatment Condition^a

^a Estimated proportions are based on primary analysis; error bars represent 95% confidence intervals.

and Occupational Functioning Assessment Scale and had lower depressive disorder rates at follow-up compared with patients in treatment as usual. The lower dropout rate in schema therapy suggests higher acceptability by patients. Patients receiving schema therapy showed greater improvement in recovery from personality disorders and in scores on the Social and Occupational Assessment Scale than patients receiving clarification-oriented psychotherapy, but schema therapy patients did not show a significant difference in dropout rate or in scores on the Global Assessment of Functioning Scale. Clarification-oriented psychotherapy did not outperform treatment as usual on any measure, countering the argument that any experimental treatment achieves better results than treatment as usual. On other secondary measures assessing anxiety disorders, general pathology, personality disorder traits, social functioning, quality of life, and self-ideal discrepancy, improvement over time occurred in all conditions, with large effect sizes. However, no between-condition differences emerged. The number of patients still in treatment after 3 years was lowest in the schema therapy group (13% compared with 26% in treatment as usual and 36.6% in clarification-oriented psychotherapy), pointing to the ability of schema therapy to achieve at least comparable results in less time. The type of schema therapy training among therapists influenced dropout, recovery, global functioning, and self-ideal discrepancy, with exercise-based training attaining superior effects. In trying to detect specific elements that may account for schema therapy superiority, several aspects can be mentioned. First, an adjacent qualitative study assessing patient and therapist perspectives on schema therapy (N. De Klerk et al., unpublished 2013 data) revealed that working with the mode model was highly appreciated by patients and therapists, since it guided therapists in choosing adequate techniques and helped patients to better understand their own behaviors and

feelings. Schema therapy may also be highly effective because multiple channels are addressed to achieve structural personality change by using experiential, behavioral, cognitive, and interpersonal techniques. Experiential techniques have been experienced as very helpful by patients and therapists (M.C. Ten Napel-Schutz et al., unpublished 2013 data). Unlike most other treatments for personality disorders, schema therapy involves extensive processing of traumatic and other aversive childhood experiences, core factors in the development of personality disorders, which may be another reason for its effectiveness.

Since the present study was aimed to be an effectiveness trial, rather than an efficacy trial, many aspects resembled clinical reality (e.g., no preselection of therapists, no optimal training, no detailed treatment manual, no supervised pilot treatment before starting the study, and no intensive central supervision during the trial). Staying close to daily practice, our approach enhances the generalizability of our findings and yields a valid indication for effects of schema therapy implementation. Other strengths include a large sample size, multicenter design, long-term duration of the study, broad range of outcomes, intention-to-treat analyses, and an extensive integrity check with good results. Schema therapy and clarification-oriented psychotherapy share some conceptual overlap, but the techniques differ substantially, which was confirmed by our integrity check. Major differences include 1) the higher directiveness of schema therapy, which includes content (e.g., psychoeducation); 2) the therapeutic relationship, in which schema therapists attempt to meet the unmet childhood needs of patients; 3) extensive processing of childhood trauma; and 4) behavioral pattern breaking. Some limitations of this study also should be mentioned. Comparing experimental treatments with treatment as usual inherently means impossibility to control for factors such as session frequency and treatment dosage. Because treatment as usual therapists received no central training and supervision, there may have been between-group differences in treatment/study commitment. On the other hand, therapists in the schema therapy and clarification-oriented psychotherapy groups were less experienced in their methods and reported uncertainty. Strong conclusions about the three noncluster C personality disorders cannot be made because of the limited numbers of patients with these disorders. Conditions differed in the proportions of patients with substance abuse disorders, but given the low numbers of these patients, we could not control for this statistically. Another limitation is with regard to the fact that some intraclass correlation coefficients of scales assessing treatment integrity were only modest. Additionally, the fact that patients in the treatment as usual condition received a much lower number of sessions on average but completed treatment less often complicated simple interpretation of the results. Lastly, the clarification-oriented psychotherapy sample size limited power to detect clarification-oriented psychotherapy-treatment as usual differences, although no

TABLE 4. Secondary Outcome Measure Analyses Among Patients With Personality Disorders Randomly Assigned to Schema Therapy (ST), Clarification-Oriented Psychotherapy (COP), or Treatment as Usual (TAU)^a

Analysis and Measure	Analysis					Effect Size		
	B	95% CI (B)	t	df	p	r ^b	d ^c	Within Condition ^d
Mixed-regression repeated-measures analyses								
Global Assessment of Functioning Scale score								
Time ^e	2.10	1.28 to 2.91	5.22	29.64	<0.001	0.69	1.27	
Time-by-condition								
ST versus TAU	0.83	0.03 to 1.62	2.05	224.87	0.042	0.14	0.50	
COP versus TAU	-0.27	-1.43 to 0.90	-0.46	135.56	0.65	0.04	-0.16	
ST versus COP	1.09	-0.04 to 2.22	1.92	126.62	0.057	0.17	0.66	
Time-by-cohort-by-schema therapy	1.77	0.18 to 3.35	2.20	224.49	0.029	0.15	0.53	
Change over 3 years								
Schema therapy								1.76
Clarification-oriented psychotherapy								1.11
Treatment as usual								1.27
Social and Occupational Functioning Assessment score								
Time ^e	1.97	1.13 to 2.81	4.82	25.89	<0.001	0.69	1.05	
Time-by-condition								
ST versus TAU	1.12	0.35 to 1.89	2.87	217.61	<0.005	0.19	0.60	
COP versus TAU	-0.17	-1.34 to 0.99	-0.29	138.32	0.77	0.02	-0.09	
ST versus COP	1.29	0.15 to 2.42	2.26	128.91	0.025	0.20	0.69	
Time-by-cohort-by schema therapy	1.44	-0.10 to 2.99	1.85	217.21	0.066	0.12	0.39	
Change over 3 years								
Schema therapy								1.65
Clarification-oriented psychotherapy								0.96
Treatment as usual								1.05
Symptom Checklist-90 score ^f								
Time ^e	-0.143	-0.186 to -0.101	-6.77	50.05	<0.001	0.69	0.95	
Time-by-condition								
ST versus TAU	0.004	-0.047 to 0.055	0.14	265.16	0.89	0.01	-0.02	
COP versus TAU	-0.027	-0.097 to 0.043	-0.77	105.34	0.45	0.07	0.18	
ST versus COP	0.031	-0.037 to 0.098	0.90	100.87	0.37	0.09	-0.20	
Time-by-cohort-by-schema therapy	-0.059	-0.160 to 0.043	-1.14	264.72	0.26	0.07	0.19	
Change over 3 years								
Schema therapy								0.93
Clarification-oriented psychotherapy								1.13
Treatment as usual								0.95
Assessment of DSM-IV Personality Disorders Questionnaire trait score ^g								
Time ^e	-0.157	-0.200 to -0.114	-7.39	35.90	<0.001	0.78	1.14	
Time-by-condition								
ST versus TAU	0.039	-0.012 to 0.091	1.50	261.34	0.14	0.09	-0.28	
COP versus TAU	-0.001	-0.152 to 0.054	-0.04	80.57	0.97	0.00	0.01	
ST versus COP	0.04	-0.028 to 0.109	1.18	77.01	0.24	0.13	-0.29	
Time-by-cohort-by-schema therapy	-0.049	-0.152 to 0.054	-0.93	260.58	0.35	0.06	0.18	
Change over 3 years								
Schema therapy								0.86
Clarification-oriented psychotherapy								1.13
Treatment as usual								1.14
Work and Social Adjustment Scale score								
Time ^e	-1.19	-1.75 to -0.63	-4.34	29.49	<0.001	0.62	0.77	
Time-by-condition								
ST versus TAU	-0.16	-0.72 to 0.40	-0.56	249.18	0.57	0.04	0.10	
COP versus TAU	-0.31	-1.14 to 0.51	-0.75	133.65	0.45	0.06	0.20	
ST versus COP	0.15	-0.64 to 0.95	0.38	124.29	0.71	0.03	-0.10	
Time-by-cohort-by-schema therapy	-0.52	-1.64 to 0.60	-0.91	248.74	0.36	0.06	0.17	
Change over 3 years								
Schema therapy								0.87
Clarification-oriented psychotherapy								0.97
Treatment as usual								0.77

continued

TABLE 4. Secondary Outcome Measure Analyses Among Patients With Personality Disorders Randomly Assigned to Schema Therapy (ST), Clarification-Oriented Psychotherapy (COP), or Treatment as Usual (TAU)^a (continued)

Analysis and Measure	Analysis						Effect Size	
	B	95% CI (B)	t	df	p	r ^b	d ^c	Within Condition ^d
Mixed-regression repeated-measures analyses								
Miskimins Self-Goal-Other Discrepancy Scale score ^f								
Time ^e	-0.171	-0.211 to -0.131	-8.64	39.99	<0.001	0.81	1.32	
Time-by-condition								
ST versus TAU	0.006	-0.041 to 0.053	0.25	256.34	0.80	0.02	-0.05	
COP versus TAU	-0.024	-0.089 to 0.041	-0.73	107.40	0.47	0.07	0.18	
ST versus COP	0.030	-0.033 to 0.093	0.95	100.52	0.35	0.09	-0.23	
Time-by-cohort-by-schema therapy	-0.101	-0.195 to -0.007	-2.12	255.65	0.035	0.13	0.78	
Change over 3 years								
Schema therapy								1.27
Clarification-oriented psychotherapy								1.55
Treatment as usual								1.32
World Health Organization Quality of Life Assessment score ^g								
Time ^e	10.14	7.14 to 13.14	6.83	40.44	< 0.001	0.73	1.04	
Time-by-condition								
ST versus TAU	-0.60	-4.03 to 2.82	-0.35	255.43	0.73	0.02	-0.06	
COP versus TAU	1.44	-3.36 to 6.24	0.60	115.86	0.55	0.06	0.15	
ST versus COP	-2.04	-6.70 to 2.61	-0.87	110.08	0.39	0.08	-0.21	
Time-by-cohort-by-schema therapy	3.12	-3.73 to 9.96	0.90	254.98	0.37	0.06	0.16	
Change over 3 years								
Schema therapy								0.98
Clarification-oriented psychotherapy								1.19
Treatment as usual								1.04
Multiple imputation logistic regression analyses^h								
	B	SE(B)	p	Odds Ratio	95% CI			Estimated Proportion
Depressive disorders (at 3 years)								
Baseline depressive disorder	1.94	2.41	0.46	6.95	0.01–3868.76			
Severity	1.08	0.82	0.24	2.94	0.40–21.69			
ST versus TAU	-1.45	0.68	0.033	0.23	0.06–0.89			
COP versus TAU	-1.83	1.43	0.23	0.16	0.01–3.70			
ST versus COP	0.37	1.30	0.78	1.45	0.10–21.93			
Cohort-by-schema therapy	-2.00	1.32	0.13	0.14	0.01–1.81			
Presence at follow-up by condition ⁱ								
Schema therapy								0.135
Clarification-oriented psychotherapy								0.122
Treatment as usual								0.252
Anxiety disorders (any at 3 years)								
Number of baseline anxiety disorders	0.32	0.69	0.67	1.37	0.224–8.40			
Severity	0.83	0.42	0.066	2.30	0.94–5.65			
ST versus TAU	0.09	0.64	0.89	1.10	0.27–4.44			
COP versus TAU	0.03	0.72	0.97	1.03	0.25–4.22			
ST versus COP	0.07	0.78	0.93	1.07	0.23–5.09			
Cohort-by-schema therapy	-0.87	1.31	0.52	0.42	0.02–7.41			
Presence at follow-up by condition ⁱ								
Schema therapy								0.275
Clarification-oriented psychotherapy								0.351
Treatment as usual								0.274

^a Data represent all models with random intercept and time effects (at center level); bold indicates significance; cohort was coded as -0.5 for cohort 1 (schema therapy, treatment as usual), 0.5 for cohort 2 (schema therapy, treatment as usual), and 0 for clarification-oriented psychotherapy.

^b Data represent the effect size (r) expressing the change effect as estimated in the mixed-regression analysis; absolute values are given.

^c Data represent the effect size (Cohen's d) expressing the change effect at the 3-year follow-up as related to baseline standard deviation ("d_{RAW}," see Feingold [reference 32]), with baseline standard deviation from the mixed-regression residual baseline variance; positive values indicate more improvement and negative values less improvement.

^d Data represent the effect sizes of change over 3 years with Cohen's d per condition.

^e The time effect is that of the primary reference category, the treatment as usual condition.

^f Both dependent variable scores and time were log-transformed to reduce skewness and to model a linear time-response relationship.

^g Time was log-transformed to model a linear time-response relationship.

^h Multiple imputation based logistic regression (with center as factor) as mixed-regression estimations failed.

ⁱ Data represent the 3-year depressive and anxiety disorder proportion estimates per condition from logistic regression, controlled for center effects.

Patient Perspectives

Schema Therapy

“Ms. A” is a 30-year-old married woman who was referred by her general practitioner for treatment of anxiety and depression. After partially successful treatment of axis I disorders, the patient reveals that she continues to struggle with uncertainties and perfectionism and fears experiencing a new burnout if she were to resume employment. She does not dare have children, although she clearly wants to have them. Scores on the Structured Clinical Interview for DSM-IV Axis II Personality Disorders (SCID-II) revealed dependent and obsessive-compulsive personality disorders and avoidant traits. The patient grew up on a small farm where the children had to work hard and had little autonomy. Her mother was overconcerned, cold, controlling, rigid (about work, morals, and religion), and suffered from depressive episodes. When angry at her daughter, the mother sometimes refused to speak and remained in bed for days, which induced a feeling of “being bad” in the patient. The father was submissive to the mother and avoided conflicts. The patient’s anxiety and depression increased when she was put under pressure on her job, where she could not set limits and felt overwhelmed by responsibilities. She quit her job. Her request for help is to get rid of her anxieties and worries.

Therapy for this patient is divided into four phases, following each other but without strict boundaries.

1) Starting phase (sessions 1–6)

The request for help, current problems, and life history are explored. The patient imagines being a child alone with her mother and alone with her father, and affect, unmet needs, cognitions, and behavioral patterns are explored. Based on this information, a schema mode model, depicting central emotional cognitive-behavioral states, is formulated. For this patient, the following modes are formulated: punitive-demanding parent (guilt feelings and high standards internalized from the mother’s behavior); vulnerable-dependent child (feeling vulnerable and overwhelmed as a little child given too much responsibility); perfectionistic overcompensator (perfectionism and overdedication to work to cope with uncertainties); compliant surrender (being compliant with others’ requests, even when she disagrees). Healthy adult and happy child modes are underdeveloped.

2) Addressing historical roots of dysfunctional modes (sessions 7–25)

Using exploration, psychoeducation, and experiential work, childhood memories of experiences associated with the dysfunctional modes are addressed. Central with this patient are confronting the punitive-demanding parent mode, both on an empty chair (with the therapist firmly disagreeing with the voice of the mode and standing up for the patient) and in imagery re-scripting (with the therapist entering in fantasy the image of childhood memories and standing up for the rights and needs of the child, e.g., by

stopping the mother’s abuse and confronting the father’s avoidance). The therapist chooses to first address the mode that is activated during the session or that played a role in recent problems. With perfectionistic-overcompensator and surrender modes, the function is discussed, and the triggering events are explored, after which the therapist helps the patient to access the punitive-demanding parent and/or the vulnerable-dependent child mode, which are then addressed. Gradually, the patient experiences anger toward the parents and sadness about what she missed in childhood. She reports becoming more assertive and starts to do more pleasurable things. She starts to take the lead in the experiential exercises.

3) Addressing current problems and behavioral change (sessions 26–40)

The focus is now more on current problems, and the therapist pushes toward actual behavioral change. For example, the patient practices with becoming more assertive instead of submissive and expresses her needs more. She has a difficult discussion with her parents about what she has missed in her childhood and how she often felt guilty by her mother’s responses. This helps her to emancipate from her parents’ values and to lead her own life.

4) Booster sessions (sessions 41–50)

In the second year, once every month, a booster session is planned. The patient reports how she looked for a job and found one, and the therapist supports her in preventing to return to perfectionism and overworking. Assertiveness is practiced when needed (related to work and family issues). Halfway through the second year, the patient reveals that she is pregnant and is happy about the pregnancy. The future responsibilities of becoming a mother are also a topic.

Clarification-Oriented Psychotherapy

“Mr. B” is a 35-year old married father of two, who is referred by a crisis service and diagnosed with major depression and dependent personality traits (which turned out to be a dependent personality disorder based on SCID II criteria). He has suicidal ideations but no concrete plans. He experienced mood complaints since his youth. He was born as the youngest of three, with two older sisters, a dominant father, and a mother who hardly set any boundaries. The family never quarreled, since they strived for perfect harmony. The patient never learned to deal with problems because every problem was taken out of his hands. Achievement was an important issue for the outside world.

Since his oldest child was born, 6 years ago, the patient has felt that his problems have increased. He feels pressured by his current responsibilities. During his referral, he said that he wanted to learn to get in contact with his feelings and to set boundaries.

Therapy for this patient is divided into five phases, following each other but without strict boundaries.

1) Building of relationship

In order to establish a safe and workable therapeutic relationship, the therapist is complementary with the patient's basic unfulfilled needs (in this case, solidarity and reliability) and noncomplementary with manipulative behavior (dysfunctional interpersonal behavior; in the present case, attempts to hand over responsibility by behaving as a child or acting helpless).

2) Developing treatment goals and confronting manipulative behavior

Patients with very rigid interaction patterns do not have genuine therapy goals but merely aim at stabilizing their system (both their inner and outer worlds). To formulate true goals, it is necessary that the patient is confronted with his or her manipulative behaviors and what these cost. When the therapeutic relationship is growing, the patient is bound to test whether the therapeutic relation is authentic or not. In the above case, the patient tests whether the solidarity and reliability of the therapist is real. Gradually, he learns to formulate true treatment goals: he wants to feel less vulnerable and small.

3) Clarifying schemas

For the patient, it was not clear on what experiences his self- and relation schemas were based. By making this explicit, it becomes clear that it concerned a subtle but

intrusive interaction pattern between him and his parents. Throughout his childhood and youth, he learned that he could not rely on his parents for support, and he felt alone all the time. Based on his biography, his relation schema is "you will be left alone in relationships, there is no support," and his self-schema is "I am small."

4) Schema work

When manipulative behavior is decreased and the patient is truly experiencing his or her feelings, the actual content of the schema is further explored (e.g., by using focusing techniques) and affectively and cognitively restructured. Restructuring is mostly done by a one-person role-play. In this role-play, the patient, coached by the therapist, plays a therapist who challenges the dysfunctional schemas symbolically seated on an empty chair. The aim is that patients not only understand but also experience that their schemas are not true. The patient in the present case would then feel that he is not small and that he is not abandoned in relationships per se.

5) Translation to behavior

This patient tries out new behavior and starts to take up his responsibilities. He feels less anxious inside and dares to accept challenges, such as starting his own company.

indications of superiority of clarification-oriented psychotherapy over treatment as usual were found, except perhaps with regard to dropout and depressive disorder.

Comparing results with previous studies, our findings resemble those of previous randomized controlled trials that demonstrated more recovery and less dropout with schema therapy among individuals with borderline personality disorder (11, 13, 14), while our effect sizes are in the same range as those found in previous research on schema therapy techniques for personality disorders (31). What is different is the fact that our study does not demonstrate overall supremacy of schema therapy (i.e., schema therapy did not excel on self-reported measures). The discrepancy in results obtained with self-reports compared with assessor-based instruments is remarkable but not without precedent. Other studies have found such differences (e.g., personality disorders [33] and mood disorders [34]). There are indications that interviews more validly assess objectifiable symptom manifestations and self-reports better capture symptom experience (35), while the discrepancy between these kinds of measures is related to personality characteristics, such as neuroticism (34). Especially in personality disorders, in which symptoms are ego-syntonic, other measures may better and more rapidly detect objective changes than the patients themselves, since it might take more time to change one's self-representation than to change primary cognitions, feelings, behaviors, and impulse regulation. For example, the self-definition and thus self-report as a mature person

may lag behind the new mature behavior that is observable by others. It may therefore be concluded that schema therapy is especially effective in the objectifiable domain of psychopathology manifestations, at least in the time scale of our study.

The finding that positive schema therapy effects on assessor-based instruments emerged with different interviewers for the SCID assessments, the Global Assessment of Functioning Scale, and the Social and Occupational Functioning Assessment Scale enlarges the validity of the study results. In addition, the schema therapy compared with treatment as usual contrast may have been limited by individual optimization of treatment as usual. Instead of low-intensive maintenance care these patients usually receive (36), psychotherapy was dominant in treatment as usual and was akin to what is also labeled as community treatment by experts (37).

Despite large effect sizes, we believe that there is room for improvement of schema therapy. First, further elaboration of the schema therapy protocol with techniques fine-tuned for specific personality disorders and the possibility to increase treatment duration when necessary might increase effects. Second, therapists reported the reluctance to undergo personality changing treatment among some patients as related to rigidity and motivational problems. Future studies should assess this formally. We advise assessing "readiness" for change and presence of autism-related disorders (since these often co-occur with personality disorder [38] and may indicate inability to

change). A motivational module may prepare patients better. Third, as indicated in previous research, effectiveness might increase when therapists become more experienced (31). Fourth, training method influences outcome. Our adjacent qualitative study revealed that therapists who followed the exercise-based training felt better equipped to integrate all methods and techniques and to apply them in practice than those who followed the lecture-based training. Thus, exercise-based training using experiential learning (e.g., role-playing to exercise specific techniques with immediate feedback) may increase effects.

In conclusion, this trial found large improvements in time in all treatment conditions, with superior recovery from personality disorder and depressive disorder, better general and social functioning, and less dropout in schema therapy. Thus, with our study, we enlarge evidence-based support for schema therapy as a valuable treatment for personality disorders. We also found that how therapists are trained in a new method influences clinical effectiveness. The results point toward the possibility of schema therapy being not only clinically effective but also cost effective. Because the latter is an important additional aspect in evaluating new treatments, this is the topic of a separate article on the economic evaluation of the present trial.

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