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Exploratory Randomised Control Trial of Schema Modal Therapy in the Personality Disorder Service at Ashworth Hospital

Nick Tarrier, Mairead Dolan, Michael Doyle, Graham Dunn, Jenny Shaw and Ron Blackburn

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Contents

List of figures and tables

Policy briefing

- The assessment and management of risk in personality disordered offender populations has become a policy priority in the UK. Recent studies demonstrate the effectiveness of Schema Modal Therapy for patients with borderline personality disorder. This study examined the effectiveness of SMT in forensic patients with personality disorder and explored the feasibility of conducting Randomised Control Trials in a forensic inpatient setting.
- Experience from this study suggests that conducting an RCT in a high secure hospital is feasible, although there are many challenges relating to characteristics of the research population, participant recruitment/retention, attrition, treatment as usual, therapist preparation, institutional effects, length of stay and progress through the clinical pathway. The challenges identified must be taken into account when considering the conclusions based on the findings of this study.
- Using an Intent-To-Treat (ITT) approach, no significant treatment effect was found on dynamic measures of risk, personality, mental state, schema or interpersonal style as a result of SMT. Therefore, based on the methodology and findings from this study, there is insufficient evidence to recommend SMT as an effective therapeutic intervention for patients with personality disorder in Ashworth high secure hospital.
- Future larger trials of SMT may be warranted if controlled studies are designed to fully replicate the methodologies emerging from very recent studies in predominantly outpatient samples that demonstrate effectiveness of SMT for borderline personality disorder.
- Other recent research suggests that any future studies investigating the application of individual SMT will need to commit therapists to providing at least three years of therapy for two sessions per week, and prepare participants to receive this dosage. However, such long-term frequent therapy provision would be resource intensive and the likelihood of bias due to the unpredictable characteristics of participants with personality disorder (PD), discharge from hospital and risk of attrition of both the therapist and participant would be increased.
- Future randomised controlled trials of SMT and related psychotherapies in high secure and forensic settings need to consider the lessons learned in this study relating to the design, dosage of therapy, therapist preparation, the confounding nature of existing treatments provided, attrition, issues of compliance, implications of legal status, length of stay and progress through the care pathway.

Summary

Context

In recent years, the assessment and management of risk in personality disordered offender populations has become a policy priority in the UK (see Appleby, 2000; Dolan & Doyle, 2000). In forensic settings, it is increasingly recognised that psychological treatment interventions need to be designed to address mental health issues, offending, risk and interpersonal functioning.

In Schema Modal Therapy, the emphasis is on Schema Modes. These are sets of schemata with an associated state of emotional arousal and patterns of interpersonal behaviour. Schema Modal Therapy comprises a set of techniques that enables the therapist to work with the rapidly fluctuating emotional states and coping responses that are so characteristic of severe personality disorders. Schema Modes are defined as the emotional state or 'part of the person' that dominates a person's thoughts, feelings, and behaviour at a given moment in time (Young *et al.*, 2003).

Despite the research evidence that Cognitive Behavioural Therapy (CBT) based approaches have positive effects in anti-social groups (see Losel, 1998 for review), there are few detailed therapeutic intervention studies using schema-focused models in UK high secure samples with a primary diagnosis of personality disorder, particularly Anti-Social Personality Disorder (ASPD).

The aims of the study were to:

- assess the feasibility of using an RCT to evaluate treatments for individuals with severe personality disorder in high secure care;
- conduct an independent evaluation of a two-year SMT intervention for personality disordered patients at Ashworth hospital, using an RCT design;
- evaluate the treatment process and integrity and identify areas for improvement to inform the delivery of future programmes;
- evaluate treatment effects and assess whether any detected treatment effects are maintained at the 36-months follow-up.

Approach

The study was an independent phase two MRC exploratory trial to test SMT in a sample of high secure patients diagnosed with a personality disorder, to see whether SMT + TAU is effective when compared with TAU alone. The **Evaluation Team** were independent of the **Treatment Team** who provided the SMT intervention.

Baseline assessments were conducted by researchers prior to randomisation. Following the completion of the baseline assessment, patients were randomly assigned to the treatment conditions of SMT + TAU and TAU. Randomisation was conducted independently via a remote telephone randomisation service. All participants were subjected to a baseline assessment that included a detailed battery of assessments. Data were then collected at baseline, at six months, 12 months, 24 months and 36 months to allow evaluation of key dynamic outcome measures of personality, mental state, risk, schemata and interpersonal style.

Statistical analyses of treatment effects were carried out using the Intention-To-Treat (ITT) principle. That is, outcomes were compared for participants as they were randomised and not according to the treatment or interventions that they actually received. Outcomes at the four different follow-up times (6, 12, 24 and 36 months) were analysed simultaneously in a repeated measures analysis, using all available data.

Findings

The treatment group receiving SMT + TAU intervention did not demonstrate statistically significant improvement in scores on dynamic measures of risk, schemata, personality and interpersonal style, when compared to the TAU group.

Conducting an RCT in a high secure hospital is feasible, although there are many challenges relating to characteristics of the research population, participant recruitment/retention, attrition, treatment as usual, therapist preparation and competence, institutional effects, length of stay, progress through the clinical pathway and timescale are key findings from this study. A substantial number of the participants were discharged and maintaining the integrity of the SMT intervention proved challenging at a time when new methods of assessment and evaluation were being developed and findings from ongoing research were emerging.

Recommendations

Based on the methodology and findings from this study, there is insufficient evidence to recommend SMT as an effective therapeutic intervention for patients with personality disorder in Ashworth high secure hospital. Future larger trials of SMT in a forensic context cannot be recommended unless the methodological aspects/limitations found in this study are adequately addressed.

Future studies investigating the effectiveness of SMT or similar therapies should only be considered if new data emerge and the difficulties experienced in this study are addressed and remedial measures are included in the proposal prior to commencement.

Recent research into the effectiveness of schema-focused therapy suggests that future studies investigating the application of individual SMT will need to commit therapists to providing at least three years of therapy for two sessions per week, and prepare participants to receive this dosage. However, such long-term frequent therapy provision would be resource intensive and because of the likelihood of bias due to the unpredictable characteristics of participants with personality disorder, discharge from hospital and risk of attrition of both the therapist and participant would be increased.

Future randomised controlled trials of SMT and related psychotherapies in high secure and forensic settings need to consider the lessons learned in this study relating to the design, dosage of therapy, therapist preparation, the confounding nature of existing treatments provided, attrition, issues of compliance, implications of legal status, length of stay and progress through the care pathway.

1. Context

In recent years, the assessment and management of risk in personality disordered offender populations has become a policy priority in the UK (see Appleby, 2000; Dolan & Doyle, 2000). The Department of Health and Home Office consultation document *Dangerous and Severe Personality Disorder* (DSPD) and the White Paper *Reforming the Mental Health Act* (Department of Health, 2000), as well as the document *Personality Disorder: No longer a diagnosis of exclusion* (NIMHE: National Institute for Mental Health in England, 2003) highlighted the need to develop appropriate multidisciplinary services for personality disordered offenders delivered in accordance with the Care Programme Approach (a system defining the process of how mental health services assess users' needs, plan ways to meet them and check that they are being met). In forensic settings, it is increasingly recognised that treatment interventions need to be designed to address mental health issues, offending, risk and interpersonal functioning, and the link between personality pathology and risk should be a key treatment target.

A number of meta-analyses and reviews (e.g. Andrews *et al.*, 1990; Antonowicz & Ross, 1994; Lipsey, 1992; Losel, 1998; Warren *et al.*, 2003; Duggan *et al.*, 2007) have demonstrated the effectiveness of a variety of interventions to reduce recidivism in offender populations. Effective programmes tend to address criminogenic needs, are multi-modal with a cognitive component, have treatment integrity, and run for longer than 12 months (Hollin, 1999; Losel, 1998). Although there has been significant therapeutic nihilism about effective interventions for personality disordered offenders, emerging evidence suggests that personality dysfunction can be amenable to change (Sanislow & McGlashan, 1998), and moderate treatment effects have been reported for some personality disorders, particularly borderline and avoidant personality disorders (Bateman & Fonagy, 2000; Losel, 1998; Perry *et al.*, 1999). The evidence for robust treatment effects in anti-social personality disorders and psychopathy is more limited, but Salekin's (2002) meta-analytic review suggests some evidence of short-term effects using cognitive-behavioural techniques and interventions that specifically address perceptions of the self and the world, cognitive processes and core belief systems. Meta-analytic reviews of the literature on Therapeutic Community (TC) interventions with high-risk offenders with personality pathology and co-morbid substance misuse (e.g. Lipton *et al.*, 2002) also suggest that this treatment modality shows moderate positive effects sizes even when treatment is delivered on a mandatory basis (Farabee *et al.*, 1998). In high secure hospital settings, a variety of Milieu Therapy (MT) and TC models have been implemented for patients with primary diagnoses of ASPD, but there has been little systematic evaluation of their effectiveness. Studies in the USA suggest that in some situations, TC approaches may be less effective for patients meeting Hare's criteria for psychopathy, which has been shown to be a significant moderator of treatment effects regardless of the intervention or therapeutic model (Losel, 1998).

Core elements of treatment programmes

Although MT or TC models of care can provide a general context for individuals to develop and change their relationships with others and become more accountable for their actions, this model of care alone is unlikely to significantly alter core beliefs or even address persistent interpersonal relationship difficulties. In recent years, a number of structured or manual-based treatment programmes have been designed for use in inpatient and community settings to enable individuals to alter their core beliefs, personal constructs or interpersonal functioning regardless of the treatment setting or model of care. One such approach is Cognitive Behavioural Therapy (Beck *et al.*, 1990) with a particular emphasis on schema modification (Young, 1990), for the treatment of personality disorders. CBT aims to define personality problems in concrete terms, set specific, realistic goals for treatment, and modify maladaptive core beliefs or schemata and associated problematic behaviours. Cognitive-behavioural approaches have generally been found to be more effective than any other psychotherapeutic interventions in treating people with personality disorder (McMurran, 2002; Salekin, 2002; Warren *et al.*, 2003) and formulation based Cognitive Behavioural Interventions are seen by many as the psychological treatment of choice when working with violent and forensic populations (McGuire, 1995; Wong and Gordon, 2006; Novaco, 1997).

Despite the promise of CBT for people with personality disorder, Young (2003) argues that short-term cognitive therapy is unlikely to be successful for patients with personality disorders as three main characteristics of personality disorders (rigidity, avoidance and long-term interpersonal difficulties), lead to considerable difficulty in applying CBT. These characteristics are not compatible with features of CBT described above. For example, for short-term cognitive therapy to succeed, patients have to have relatively easy access to their thoughts and feelings. However, in many personality disorders, thoughts and feelings are often avoided because of the pain they cause to the patient.

Young (2003) proposed that cognitive therapists should primarily focus on the deepest level of cognition, the **Early Maladaptive Schema**, if cognitive therapy for people with personality disorder was going to be effective. Therefore, Jeffrey Young and colleagues (2003) developed a model for schema therapy (ST) where the Early Maladaptive Schemas (EMSs) were used as the basic units of analysis.

Schema Modal Therapy

Over time, Young found that standard ST techniques emphasizing EMSs were of limited effectiveness in treating severe personality disorders (Young *et al.*, 2003). One reason for this is that patients with severe personality disorders often have so many EMSs that discussing them all becomes unwieldy. Secondly, people with severe personality disorders have relatively unintegrated personalities. As a result, they often switch rapidly between emotional states, making it difficult for therapists to know how to target their interventions. Young developed Schema Modal Work as a more manageable and effective alternative for treating these shifting emotional states (Young *et al.*, 2003).

In **Schema Modal Therapy**, the emphasis is on **Schema Modes**. These are sets of schemata with an associated state of emotional arousal and patterns of interpersonal behaviour. The basis of the model lies in the modes' derivation in the child's attempts to cope with the distress from neglect and abuse, focusing then on where these maladaptive patterns continue into adulthood. Schema Modal Therapy comprises a set of techniques that enable the therapist to work with the rapidly fluctuating emotional states and coping responses that are so characteristic of severe personality disorders. Schema Modes are defined as the emotional state or 'part of the person' that dominates a person's thoughts, feelings, and behaviour at a given moment in time (Young *et al.*, 2003).

Evidence-base for Schema Modal Therapy

Prior to the start of this study, there was limited literature supporting the evidence base for SMT due to the recency of its development. However, since this study began there have been some promising findings supporting its use.

Evidence supporting the schema modal model has been increasing (Arntz *et al.*, 2005; Lobbestael *et al.*, 2008). A small single case series of schema therapy for borderline personality disorder (BPD) patients (N = 6; Nordahl & Nysaeter, 2005) found positive results, as the majority had large improvements in symptoms that were maintained at follow-up. Kellogg & Young (2006) also cite a preliminary report about the effectiveness of schema therapy (Lobbestael *et al.*, 2005) but argue for more "rigorously controlled studies of schema therapy before its effectiveness as a treatment approach can be seen as established" (p.457). It has also been noted that the comparability of treatments (across studies) is limited by the use of different outcome measures employed (Moher *et al.*, 2001). Giesen-Bloo *et al.* (2006) compared the effectiveness of Schema-Focused Therapy (SFT) and Transference-Focused Therapy (TFT) in patients with borderline personality disorder. The randomised trial found that three years of either therapy, twice a week, proved effective in reducing borderline personality disorder symptoms and improving quality of life (statistically and clinically significant). Schema-Focused Therapy was found to be more effective for all measures; there was a significantly lower attrition rate and significantly more SFT patients recovered or showed clinical improvements. Schema-Focused Therapy has also been demonstrated to be cost-effective when based on clinical outcome measures and was found to be less costly than TFT (Van Asselt *et al.*, 2008). Farrell *et al.* (2009) conducted a randomised control trial of a schema therapy group plus psychotherapy versus treatment as usual (TAU, psychotherapy alone) for a sample of 32 outpatients with borderline personality disorder. This involved a 30-session, eight-month group programme. The treatment group had statistically and clinically significant improvements on all outcome measures of BPD symptoms; these were maintained and even improved for some at the six-month follow-up. In summary, research has thus far supported the effectiveness of Schema Modal Therapy in outpatients with borderline PD. The findings suggest that individual therapy is required for at least 18 months, (preferably 24 months) up to a recommended treatment period of 36

months (Nordahl and Nysaeter, 2005; Kellog and Young, 2006). No studies identified where schema therapy was not found to be effective, although no studies have yet been conducted on the high secure PD population.

Rationale

Despite the research evidence that CBT-based approaches have positive effects in anti-social groups (see Losel, 1998, for review), there are few detailed therapeutic intervention studies using enhanced or schema-focused models in UK high secure samples with a primary diagnosis of personality disorder, particularly ASPD.

The vast majority of follow-up treatment studies in forensic settings for personality disordered groups have provided limited data on the personality profiles of the patient samples or the nature of the treatment package, and the outcomes have been restricted to re-offending, from six months to 14 years post-discharge (Bailey and McCulloch, 1992). This limits the utility of these studies in subsequent meta-analyses of the effect sizes of specific interventions in high-risk anti-social populations.

Although Dialectical Behaviour Therapy (DBT) (Linehan, 1993; Linehan *et al.*, 1991) approaches have been advocated for incarcerated personality disordered samples, the research evidence suggests these may be primarily suited to borderline rather than anti-social personality disorder pathology (Verheul *et al.*, 2003).

To date, there have been no randomised controlled treatment trials of the impact of treatments delivered to incarcerated samples with primary diagnoses of ASPD largely because of the limited evidence base on 'what works' with ASPD samples.

In people with severe personality disorders and a propensity to violence, schema modes often play themselves out in a predictable pattern with tragic consequences (Bernstein *et al.*. 2007). Schema modes are closely connected to the patient's risk of violence and recidivism. By targeting and ameliorating the patient's schema modes, SMT may achieve a reduction in violent and offending behaviour.

The current study provides feasibility data on SMT approaches in high secure settings by using a phase two Medical Research Council exploratory study model.

Aims

The aims of the study were to:

- assess the feasibility of using an RCT to evaluate treatments for individuals with severe personality disorder in high secure care;
- conduct an independent evaluation of a two-year SMT intervention for personality disordered patients at Ashworth hospital, using an RCT design;
- evaluate the treatment process and integrity and identify areas for improvement to inform the delivery of future programmes;
- evaluate treatment effects and assess whether any detected treatment effects are maintained at the 36-months follow-up.

Hypothesis

The treatment group receiving the Schema Modal Therapy intervention plus Treatment as Usual will show statistically significant improvement in scores on dynamic measures of risk, schemata, personality and interpersonal style, when compared to the Treatment as Usual group.

2. Approach

The study was an independent phase two MRC exploratory trial to test SMT in a sample of high secure patients diagnosed with a personality disorder, to see whether SMT + TAU is effective when compared with TAU alone using an RCT methodology. Ethical approval was obtained from the Local Ethics Committee and research site, and all recruitment of participants went through clinical teams. The trial was registered with the **Current Controlled Trials Ltd** (ISRCTN89423966). The **Evaluation Team** were independent of the **Treatment Team** who provided the SMT intervention.

Research site

Ashworth Hospital was chosen as the pilot site for the proposed study as it had a potential population of 95 patients in the Personality Disorder Service (PDS) and other patients who met the inclusion criteria in neighbouring wards. Funding had been secured to develop an SMT service within the PDS. This allowed for sufficient therapy staff to provide input for patients in the Experimental vs. Treatment as Usual interventions. The characteristics of the Ashworth sample appeared be the most suitable to test the effectiveness of an SMT package on personality and risk issues, especially as both national and local research studies indicate that Ashworth has the highest proportion of PD patients with a primary diagnosis of ASPD and therefore a greater propensity to violence (Horne and Kilcoyne, 2002). Therefore, a study designed to evaluate change with treatment in Ashworth Hospital was likely to have implications for future intervention studies with PD populations in other high secure settings.

Recruitment and allocation

The proposed study, rationale and inclusion criteria were presented to the clinical teams within the research site. After gaining permission from the responsible medical officer and clinical team, each patient was approached and invited to participate in the study. Recruitment took place over a 12-month period: November 2004 to November 2005. Patients who consented to participate were assessed to ensure that they met the study inclusion criteria of having a primary diagnosis of DSM-IV Axis II disorder (*Structured Clinical Interview for DSM-IV Axis II personality disorder; (SCID-II)*, First *et al.*, 1994). Exclusion criteria included current psychotic illness or an organic brain syndrome and IQ of less than 80. Participants were screened for current Axis I disorders (using the Structured Clinical Interview for DSM-IV Axis I disorders; SCID-I, First *et al.*, 2002) and information on acquired brain injury/loss of consciousness was collected and the severity assessed using items from the Silver-Caton Head Injury Questionnaire (Silver & Caton, 1989).

Baseline assessments were conducted by researchers prior to randomisation. Following the completion of the intake assessment, patients were randomly assigned to the treatment conditions of SMT + TAU and TAU. Randomisation was conducted independently via a remote telephone randomisation service based at Christie's Hospital, Manchester, with the purpose of avoiding any potential bias in treatment group allocation.

A number of safeguards were put in place to try and ensure that independent researchers were blinded to treatment allocation. These included: anonymised data sets; using separate offices and administrative procedures; instructing patients not to reveal details of their care; data entry being carried out independent of the assessors; sanitising clinical notes to remove any reference to psychological treatment received before being used in assessments; and using coding systems for treatment groups.

Sample

The sample consisted of 63 male patients, primarily from the Personality Disorder Service at Ashworth Hospital, who had met the study criteria (Figure 3.1). The sample size was felt to be adequate for a pilot exploratory trial, based on sample sizes used in previous trials using cognitive behavioural interventions for anger and schizophrenia (Tarrier, 2005; Novaco, 1997) that achieved significant effects sizes. Prior to commencing the study, no previous trials of Schema Modal Therapy were available so no expected effect size existed to enable a formal power calculation.

Schema Modal Therapy intervention

The preparation of the therapists was in accordance with best practice standards when the study began and followed advice from experts in schema therapy. However, since the study began, clearer international standards have been developed. Two therapists delivered the individual SMT. Both were experienced therapists with cognitive therapy and psychotherapy qualifications. They also received additional specialised training in SMT combined with ongoing supervised practice and clinical supervision from experts in SMT. Treatment sessions for the SMT + TAU group were in accordance with a treatment protocol (Horne, 2004) that was adapted from Young *et al.* (2003). Each session was planned for 60 minutes on a weekly basis. All sessions were audio taped and/or videotaped for up to two years of the therapy provision to allow evaluation of treatment adherence and quality. A random selection of tapes was chosen to assess treatment fidelity. Independent experts in SMT rated the tapes. In the absence of a fully validated rating scale the Schema Therapy Rating Scale (STRS) (Young, 2005) was used to rate skills competence and adherence to SMT. This is a 14-item scale with an overall ratings and comments section. The clinical supervisor also rated the competence of the therapists using this scale in ongoing supervision sessions throughout the two-year treatment period.

After allocation to a therapist for SMT, therapists reviewed the clinical records of patients and liaised with their care team to identify relevant information prior to engagement with the client. Initial contact consisted of forming a therapeutic alliance, developing therapy goals and administering assessment tools specifically designed for use during the assessment, education and therapy phases of the process (Young's Schema Questionnaire: YSQ; Young's Parenting Inventory; Young's Compensation Inventory; YCI; Young-Rygh Avoidance Inventory, Y-RAI; Young's Assessment of Modes Inventory Y-AMI – see www.schematherapy.com). The inventories aided the process of identifying clients' modes in order to then modify them using a range of techniques (Young *et al.*, 2003).

Evaluation measures

All participants recruited were subjected to a baseline assessment that included a detailed battery of assessments (Table 2.1). In addition, nursing staff working closely with each participant were interviewed to gather collateral information and to help score assessment instruments. Data were collected at baseline then at six months, 12 months, 24 months and 36 months to allow evaluation of key dynamic outcome measures of personality, mental state, risk, schemata and interpersonal style.

DSM-IV Axis II personality disorders were assessed using the Structured Clinical Interview for DSM-IV Axis II Disorders (SCID-II; First *et al.*, 1994). Psychopathy was assessed using the Psychopathy Checklist-Revised (PCL-R) (Hare, 1991).

Personality based measures included the self-report Novaco Anger Scale (NAS) (Novaco, 2003) and the Barratt Impulsiveness Scale (BIS-II) (Barratt, 1994), which have proved to be robust predictors of future violence and recidivism (Novaco, 2003; Monahan *et al.*, 2001), and the Anti-social Personality Questionnaire (APQ) that assesses cognitive, affective and behavioural dispositions of relevance to anti-social behaviour. The APQ was selected as it has been validated in high secure settings (Blackburn & Fawcett, 1999).

Table 2.1 Evaluation measures

Type	Measure
Personality	Psychopathy Checklist Revised (PCL-R)*
	Structured Clinical Interview for DSM-IV Axis II Disorders (SCID-II)*
	Anti-social Personality Questionnaire (APQ)
	The Novaco Anger Scale (NAS)
	Barratt Impulsiveness Scale (BIS-11)
Mental State	Brief Psychiatric Rating Scale (BPRS)
	Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I)*
Risk	Historical Clinical Risk - 20 items (HCR-20)
	Modified Overt Aggression Scale (MOAS)
	Violence Risk Scale (VRS)
	Institutional Behaviour Rating Scale (IBRS)
Schemata	Young Schema Questionnaire (YSQ)
Interpersonal Style	Chart of Interpersonal Reactions in Close Living Environments (CIRCLE)

* Only rated at baseline, as these variables are relatively fixed-static variables not sensitive to change.

Diagnosis of current Axis I disorders was undertaken using the Structured Clinical Interview for DSM-IV Axis I disorders (SCID-I; First *et al.*, 2002) and the Brief Psychiatric Rating Scale (BPRS) (Overall and Gorham, 1962), an 18-item clinically rated scale based on interview and observation that was used to measure mental state and specific symptoms at baseline and at follow-up.

The 20-item HCR-20, version 2 (Webster *et al.*, 1997) made up of three subscales of historical-static factors (rated at baseline only) and clinical and risk management items, was used to measure risk of violence. The Violence Risk Scale (VRS) (Wong and Gordon, 2006) was also used to assess the risk of violent recidivism for institutionalised forensic clients and was scored from the client's notes and from interview material.

Primary nurses completed a number of measures including the Institutional Behaviour Rating Scale (IBRS; Dolan and Fullam, 2001) to measure anti-social behaviour over the previous month, and the Modified Overt Aggression Scale (MOAS) (adapted from Kho *et al.*, 1998), that has been used in previous studies in forensic settings (Doyle and Dolan, 2006), which captured levels of verbal, property, self and physical aggression over the previous six months. The Chart of Interpersonal Reactions in Closed Living Environments (CIRCLE) (Blackburn & Renwick, 1996), which originated from high secure hospital settings, was also rated by staff. This 51-item observational scale yields eight scales that assess styles – dominant, coercive, hostile, withdrawn, submissive, compliant, nurturant, gregarious – around the circle, based on ward observations made by two observers.

Young Schema Questionnaire (YSQ-S2) (Young & Brown, 2001) identified maladaptive schemata and previous findings support the discriminant validity of the YSQ (Stopa *et al.*, 2001).

A number of steps were taken to ensure satisfactory agreement between different raters. Formal training and supervised practice in the measures were provided to raters at baseline and when they joined the study. Dual rating of items was encouraged where any doubt existed, and consensus rating with supervisor was used if necessary. Inter-rater reliability between the research assistants was analysed. A random sample of 10% (N = 7) of the participants was selected. The coefficients of reliability (intra-class correlation) scores based on seven randomly selected cases were as follows: PCL-R Total = .95; PCL-R Interpersonal = .86; PCL-R Social deviance = .94; VRS = .96; HCR-20 = .83; BPRS = .94. This represented satisfactory inter-rater reliability. Inter-rater reliability tests were not conducted for the SCID-II, although this was addressed during formal SCID-II training prior to use.

Data analyses

All statistical analyses of treatment effects were carried out using the Intention-To-Treat principle. That is, outcomes were compared for participants as they were randomised and not according to the treatment or interventions that they actually received. Outcomes at the four different follow-up times (6, 12, 24 and 36 months) were analysed simultaneously in a repeated measures analysis, using all available data. All analyses were carried out using random effects regression (xtreg) in the statistical software package Stata version 9 (StataCorp, 2005). The phrase 'random effects' here allows for random variation between subjects, recognising that the outcomes being measured at the four follow-up times are repeated measures on the same individuals (i.e. not independent observations). Each of

the outcome measures was subject to a separate statistical analysis. All of these regression analyses controlled for the baseline (pre-randomisation) value of the relevant outcome variable (as a covariate) and for the time of the follow-up (a discrete factor with four levels) – in essence they were evaluating the treatment effects on the change in the outcome variable from its baseline value (allowing for differences in that baseline value). Estimated differences in the means of the outcomes for the SMT + TAU and TAU groups are presented, together with their standard errors, 95% confidence intervals and P-values (the indicator of statistical significance). An initial examination of the outcome data indicated that there was little sign of systematic variation in the difference between the SMT and TAU groups over the four follow-up times, so the formal analyses presented here were of a treatment effect (difference between groups) that was assumed to be constant over time. The analyses were first carried out using data from the treatment phase (6, 12 and 24 months), and then repeated after the addition of the 36-month follow-up data collected 12 months after treatment was completed.

Repeated binary (yes/no) outcomes were similarly analysed using Stata's random effects xtlogit command. The random effects analyses were based on the assumption that missing data were **Missing at Random** (MAR) or **Ignorable** using the terminology of Little and Rubin (2002). In this context, the word ignorable does not imply that missing data were ignored but that there is no need to formally specify the missing data mechanism in the likelihood equation for the repeated measures. Quantitative outcomes were assumed to be approximately normally distributed, but with a repeated measures data set of this size the majority of the analyses will be robust to small departures from this assumption (the Central Limit Theorem). However, because the variables Institutional Behaviour Rating Scale (IBRS) **self-destructive behaviour** and IBRS **destructive behaviour** were measured on an ordinal five-point scale (highly skewed and obviously not normally distributed) the standard errors and confidence intervals for the treatment effects for these two variables were estimated using the bootstrap.

Statistical significance for each individual outcome measure was assessed using a significance level of 0.05. No formal adjustments were made for repeated significance testing (approximately 50 outcomes were looked at) but the use of a Bonferoni adjustment (dividing the nominal significance level by the number of outcomes) would suggest using a significance level of about 0.001 for each individual treatment effect (this would ensure a significance level for the trial as a whole – taking all outcomes together – would be at the nominal value, that is 0.05).

The strategy for the analyses was to first look for statistically significant overall treatment effects, and then to look at the outcomes for the significant results in further detail to establish exactly what appeared to be affected and when.

3. Results

Of the 126 patients at the research site, 23 (18.25%) met the exclusion criteria (Figure 3.1). Of the 103 patients who met the inclusion criteria, 40 (38.88%) did not consent or withdrew prior to randomisation. Difficulties were encountered when recruiting participants that appeared to reflect the characteristics of the PD population in terms of poor engagement and non-compliance, but also because some of the patients were due to be discharged and did not want to commence long-term therapy. It was not possible to confirm why some patients refused to participate. Therefore, 63 (61.17%) consented to participate and were recruited and randomised in to either Schema Modal Therapy group + Treatment as Usual group or TAU group. Thirty-four (54%) were randomised into TAU group whereas the remaining 29 (46%) were assigned into SMT + TAU group. Figure 3.1 illustrates the randomisation and follow-up.

Comparison of SMT + TAU and TAU groups

The vast majority of the sample were White caucasian and the average length of stay in Ashworth was over 13 years (Table 3.1). Nearly two-thirds of the sample (N=39, 61.9%) would have met the diagnostic cut-off for psychopathy based on PCL-R score, and over two-thirds (N=43, 68.3%) met the criteria for anti-social personality disorder. The majority of patients (n=36, 57.1%) had more than one personality disorder based on SCID-II diagnoses.

Table 3.1 Comparison of Schema Modal Therapy group and Treatment as Usual group at baseline

Variable	Total Sample N=63		Schema Therapy N=29		Treatment As Usual N=34	
Participants	63		29		34	
PCL-R score 25+	39		16		26	
White Caucasian	55		26		29	
Section 37/41 *	30		14		16	
Violent in past month	14		8		6	
Self-harm in past month	11		6		5	
Borderline PD	20		8		12	
Anti-social PD	43		18		25	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
Age (years)	42.33	(11.27)	41.8	(9.92)	42.74	(12.44)
Past convictions	7.4	(6.42)	7.2	(5.86)	7.5	(6.95)
Length of stay (days)	4,945	(3,465)	5,259	(3,012)	4,678	(3,835)
PCL-R total score	24.61	(6.87)	23.8	(7.58)	25.3	(6.24)
BPRS total score	33.14	(7.38)	31.83	(7.13)	34.26	(7.51)
HCR-20 total score	26	(5.97)	25.86	(7)	26.12	(5.07)
VRS total score	52.66	(10.72)	51.35	(11.14)	53.77	(10.39)

* Also referred to as a Restriction Order where all leave outside of the hospital is directed by the Ministry of Justice.

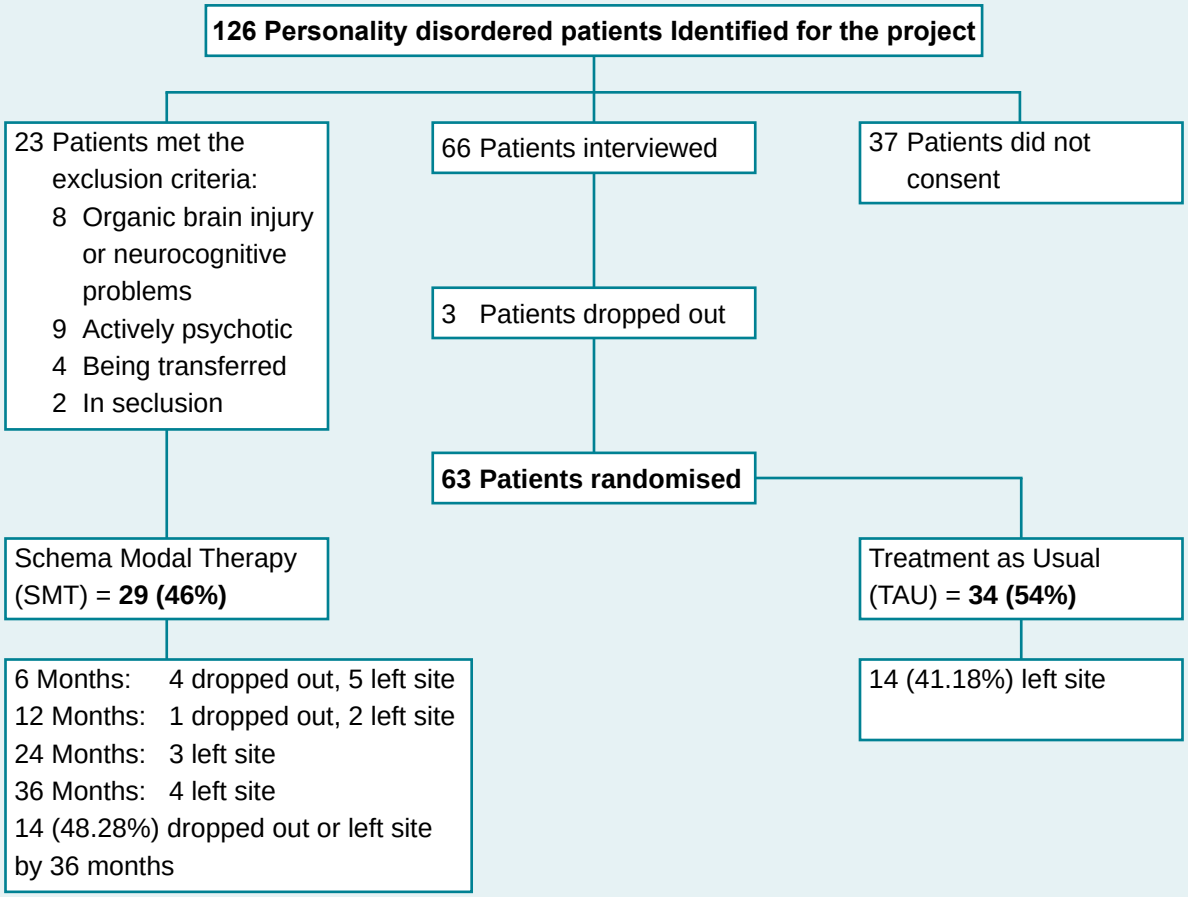
As expected, as a result of the randomisation process, there were no statistically significant differences between the SMT + TAU and TAU groups based on the variables presented in Table 3.1. In general, the SMT + TAU group had been in hospital longer, more had committed violence to others and self-harmed in the previous month, whereas the TAU group had more participants who met criteria for psychopathy (using European cut-off of 25), more participants with ASPD and had a higher mean score on the BPRS. Nearly the entire sample (n = 60, 95.23%) had a violent index offence and nearly half (n = 27, 42.86%) had a sexually violent index offence. There were no significant differences in the frequency and type of index offences or scores on any of the evaluation measures at baseline between the SMT + TAU and TAU groups.

Attrition from study and therapy

The SMT was provided in accordance with the treatment manual and treatment stages (see Appendix 1). Of the original sample of 63, five (7.9%) withdrew (including one who was discharged into the community), two by 12 months and a further three by 36 months. Information was incomplete due to nine (14.28%) of the participants refusing to be interviewed or not completing questionnaires correctly on at least one occasion. Full data were available for analyses on a minimum of 49 (77.78%) participants throughout the 36-month study period, 25 (86.21%) in the SMT + TAU group and 24 (70.59%) in the TAU group. This was despite the long period of time over which the follow-ups were conducted and the movement of participants between institutions throughout England.

Of the 29 participants randomised into the SMT + TAU group, one received no sessions and the maximum number of sessions provided was 96 over the two-year treatment period. The mean number of sessions provided was 62 and median number 72. Using a minimum 18-month, 72-session dosage as a cut-off, over half, 16 of the 29, received 72 sessions or more over a minimum 18-month period. Five participants dropped out of SMT; four by six months and one by 12 months. The therapy attrition rate due to transfer from research site was 14 participants, five by six months, two by 12 months, three by 24 months and four by 36 months. Retention in SMT by the end of the 24-months treatment period was 65.5% (n = 19). Similarly, 14 (41,18%) of the TAU group were discharged from Ashworth. Of the 28 who left Ashworth during the study period, five transferred to Broadmoor high secure hospital, two were transferred to prison, 20 were stepped down to a medium secure facility and one was discharged into the community. Contact with participants was maintained throughout the three-year study period and data were available on a minimum of 49 (77.78%) participants throughout the 36-month study period. The reason for the move on to other facilities was unclear, and it was not possible to determine if this was due to a successful treatment response.

Figure 3.1 Participant recruitment



Therapist evaluation

Three therapists were recruited initially although only two conducted therapy for the full term of the study, picking up participants from the third therapist before he left. Evaluations of the therapists were conducted using the Schema Therapy Rating Scale based on randomly selected videotaped therapy sessions from each of the therapists at two time points: three each at mid-term and two each from late-term in therapy. This was to allow independent evaluation and comparison of the therapists throughout the study. Two independent expert evaluators and the therapy supervisor rated the videotapes. In each of the items on the scale, a minimum score of three (on a seven-point scale) on any item is viewed as adequate quality and adherence in the session. The total scores can be adjusted to control for how difficult it was to work with the individual patient on a scale from zero = very easy and receptive, to six = extremely difficult. The mean scores were adjusted to account for a difficulty score of six to reflect the nature of the sample.

Mid-term therapy sessions showed that Therapist 1 had a mean score of 3.02 whereas Therapist 2 had a mean score of 2.43. Based on evaluations of two later-term tapes each, Therapist 1 had a mean score of 2.69 and Therapist 2 had a mean score of 3.79. Based on all five tapes for each therapist from mid- and late-term therapy, and based on ratings by two independent expert

evaluators and the therapy supervisor, Therapist 1 had a mean score of 2.86 and Therapist 2 had a mean score of 3.11. However, there was little agreement between the three raters (which may have been partly due to the validity and reliability of the rating scale) and evaluation of the two therapists by the clinical supervisor over a two-year period suggested a higher level of competence (M. Sloane, personal communication). More recent developments in standards for delivering schema therapy recommend a minimum score of four on each of the items of the STRS, but none of the therapists achieved this standard during the study.

Treatment as usual

Treatment as Usual logs for participants at Ashworth were completed by the treatment team at three-monthly intervals from 15 November 2004 up to 29 February 2008. As the research site did not routinely collect this data, a specific TAU log was designed that allowed collection of TAU for analyses. The evaluation team conducted analyses of the Treatment as Usual logs which have been summarised in to **Early** (15/11/2004-31/5/2007) and **Late** (1/6/2007-29/2/2008) time periods, to allow comparison over time on what type and frequency of treatment was provided (Table 3.2). As far as the evaluation team are aware, data provided by the treatment team on TAU were complete and there were no missing data.

Group-based enhanced thinking skills and sex offender treatment were the most frequently provided therapies recorded on the TAU logs. Social therapy (not specified) was identified as a distinct therapy in later stages but classed as an 'other' therapy in early stages. A significant amount of 'other' therapy was provided, especially in the earlier stages. This included: resettlement work; a feedback session to review a clinical or psychology report; a discussion of continuation of therapy; neuro-rehabilitation; a review of previous assessments; the end of therapy meeting support work; and a 'talking session'. Participants in the study and patients in the research site were also regularly involved in social, occupational and recreational activities that were not classed as formal therapy.

The number of different therapies participants received are summarised in Table 3.3. Except for the first and seventh quarter, over half of the sample had at least one psychological treatment. When the numbers of therapies received by the SMT + TAU and TAU groups were compared, the TAU group received a significantly higher number of therapies than the SMT + TAU group (10 v 6.76: $t = 2.21$, $p = 0.03$) and a significantly higher mean number of therapies than the SMT + TAU group (Mean .91 v .61: $t = 2.21$, $p = 0.03$) across the 11 quarters of the study period. This could be due to the fact that the SMT + TAU group were already receiving SMT, which would not be highlighted in the TAU log.

Results of the exploratory statistical analyses

Analyses of each of the specified outcomes during the treatment phase (6, 12 and 24 months) only, using the repeated measures (random effects) model, produced significant group differences for only two of the outcomes: VRS dynamic total score and YSQ

defectiveness/shame schema (Table 3.4). Repeating the analysis after the inclusion of the 36-month follow-up data did not change the interpretation of the results. The estimated treatment effects (group differences) that were common to all follow-up times are shown in Table 3.4. In view of the many tests being carried out, the two statistically significant results may be simply due to chance. It is difficult to explain why there were apparent treatment effects on just these two outcomes and no others. The IBRS scales with ordinal data and the APQ binary variables also demonstrated no significant effects as a result of SMT.

Table 3.2 Summary of therapy provided to total sample as Treatment As Usual (TAU) during early and late stages of project

Type of therapy/assessment completed	Late: 1 June 2007 – 29 February 2008		Early: 15 November 2004 – 31 May 2007	
	N of participants	Mean N of sessions	N of participants	Mean N of sessions
Enhanced Thinking Skills (ETS, R&R)	14	11.2	17	6.37
Sexual Offending (e.g. SOTP)	23	11.67	21	8.12
Cognitive Analytic Therapy (CAT)	3	4.67	8	4.86
Psychotherapy	9	10	12	6.49
Cognitive Behavioural Therapy (CBT)	7	7.57	10	7.47
'Mind Over Mood' (CBT for depression/anxiety)	3	9.5	4	4.19
Violence Work (e.g. Life Minus Violence)	3	12	2	6
Psychological Input	9	6.9	7	3.67
Psychological Assessment	22	3.67	28	3.31
Risk Assessment (e.g. RSVP)	3	1.67	8	2.43
Mental Health Awareness	4	4	-	-
Substance Misuse Work	4	3.5	-	-
Social Therapy	18	6	-	-
OTHER	13	3.4	32	7.13

Table 3.3 Frequency of different formal therapies; the total sample received during study period

Number of Different Therapies	Quarter										
	1st	2nd	3rd	4th	5th	6th	7th	8th	9th	10th	11th
0	40/63	30/63	28/63	29/63	29/63	30/63	34/63	21/63	19/63	18/63	13/63
1	20/63	26/63	23/63	23/63	25/63	27/63	19/63	23/63	21/63	15/63	14/63
2	2/63	7/63	10/63	11/63	7/63	6/63	9/63	6/63	9/63	10/63	16/63
3	1/63	-	2/63	-	2/63	-	1/63	-	-	1/63	1/63
4	-	-	-	-	-	-	-	-	-	1/63	-
Left Ashworth	-	-	-	-	-	-	-	13/63	14/63	18/63	19/63

Table 3.4 Estimated treatment effects (mean outcome for TAU minus mean outcome for SMT + TAU), their standard errors (SE), P-values and 95% confidence intervals (95%CI)

Outcome variable	Effect	SE	P-value	95% CI	
HCR Clinical & Risk	0.03	0.78	0.971	-1.50	1.56
HCR Clinical	-0.19	0.48	0.694	-1.12	0.75
HCR Risk	0.12	0.35	0.727	-0.57	0.82
BPRS Total	0.29	0.90	0.743	-1.46	2.05
BIS Total	-0.01	1.79	0.996	-3.52	3.50
BIS Cognitive	0.27	0.67	0.689	-1.04	1.58
BIS Motor	-0.60	1.09	0.613	-2.94	1.73
BIS Non-planning	0.49	0.87	0.568	-1.20	2.19
VRS Dynamic Total	**-3.43**	**1.65**	**0.038**	**-6.66**	**-0.19**
NAS Total	0.27	2.43	0.912	-4.50	5.03
NAS Cognitive domain	-0.57	0.79	0.467	-2.12	0.97
NAS Arousal domain	-0.92	0.98	0.346	-2.83	0.99
NAS Behavioural domain	0.44	0.96	0.650	-1.45	2.32
NAS Regulation domain	1.03	0.85	0.228	-0.65	2.70
APQ Self-control	-0.44	0.67	0.514	-1.76	0.88
APQ Self-esteem	0.28	0.66	0.674	-1.02	1.58
APQ Avoidance	0.60	0.60	0.312	-0.57	1.77
APQ Paranoid	0.01	0.70	0.992	-1.36	1.38
APQ Resentful	0.79	0.77	0.305	-0.72	2.29
APQ Aggression	0.29	0.68	0.671	-1.04	1.62
APQ Deviance	0.58	0.48	0.224	-0.36	1.52
APQ Extravert	0.84	0.58	0.145	-0.29	1.97
APQ Impulsive	1.39	1.14	0.222	-0.84	3.63
APQ Withdrawn	-0.40	0.76	0.602	-1.89	1.10
Circle Withdrawn	-0.46	0.58	0.423	-1.60	0.67
Circle Dominant	0.95	0.59	0.107	-0.21	2.10
Circle Coercive	0.22	0.76	0.774	-1.28	1.72
Circle Hostile	-0.73	0.68	0.282	-2.07	0.60
Circle Compliant	-0.02	0.59	0.972	-1.17	1.13
Circle Nurturant	0.57	0.45	0.210	-0.32	1.46
Circle Gregarious	0.30	0.43	0.490	-0.54	1.13
Circle Submissive	-0.10	0.47	0.830	-1.02	0.82
YSQ Emotional deprivation	-1.79	1.03	0.084	-3.81	0.24
YSQ Abandonment total	-1.10	1.04	0.289	-3.13	0.93
YSQ Mistrust/ abuse total	-1.14	1.19	0.338	-3.47	1.19
YSQ Social isolation total	-1.63	0.99	0.102	-3.58	0.32
YSQ Defectiveness/shame total	**-2.47**	**0.93**	**0.008**	**-4.29**	**-0.64**
YSQ Failure total	-0.39	1.02	0.702	-2.40	1.62
YSQ Dependence/ incompetence	-0.13	0.79	0.871	-1.68	1.43
YSQ Vulnerability to harm and illness	1.09	1.00	0.275	-0.87	3.05
YSQ Enmeshment	0.88	0.96	0.358	-0.99	2.75
YSQ Subjugation	-0.57	0.76	0.456	-2.06	0.92
YSQ Self-sacrificing	0.05	1.20	0.968	-2.31	2.40
YSQ Emotional inhibition	-1.27	0.96	0.183	-3.15	0.60
YSQ Unrelenting standards	-0.70	1.07	0.513	-2.79	1.39
YSQ Entitlement	0.29	0.89	0.746	-1.46	2.04
YSQ insufficient self-control/self-discipline	-0.36	1.08	0.737	-2.47	1.75

A positive estimate indicates that the mean for that variable is higher in the TAU group. A negative estimate (-) means that it is lower.

Analysis of SMT + TAU group

Progress within the SMT + TAU group between baseline and 36 months were also considered. There were improvements on a number of variables between baseline and final 36-month follow-up that were not replicated in the TAU group. Improvements that were likely to be significant clinically were noted on the BIS scales, NAS scales, CIRCLE scales, VRS dynamic score, and HCR-20 Clinical and Risk Management items (Table 3.5). The participants receiving SMT + TAU made definite improvements in some areas, although based on the findings from the analyses within one group, it cannot be concluded that this was due to the effect of SMT.

Table 3.5 Comparison of baseline and 36-month scores in the SMT + TAU group

Variable	Time	Mean	Std. Deviation	N	P value
BIS total	Baseline	62.86	11.60	22	.012*
BIS total	36 Months	58.18	12.03	22	
NAS total	Baseline	104.59	13.85	22	.793
NAS total	36 Months	103.77	18.08	22	
Circle dominance	Baseline	7.100	4.21	25	.053
Circle dominance	36 Months	5.340	2.70	25	
Circle coercive	Baseline	8.280	6.18	25	.034*
Circle coercive	36 Months	5.500	3.67	25	
Circle hostility	Baseline	7.980	3.19	25	.884
Circle hostility	36 Months	7.840	4.27	25	
VRS dynamic total[a]	Baseline	39.7848	8.51	29	< .001***
VRS dynamic total	36 Months	16.5093	8.28	29	
HCR clinical and risk total	Baseline	11.24	4.15	29	.001**
HCR clinical and risk total	36 Months	7.76	4.28	29	

a Baseline VRS dynamic factors rated based on lifetime functioning.
* P <.05.
** P <.01.
*** P <.001.

As schemata were the primary target of the therapeutic intervention, changes in 15 schemata of the YSQ between baseline and 36 months were compared. There were clinically significant improvements in the right direction on all the YSQ schemata (n = 14: Table 3.6) over the course of the study except for the ‘abandonment’ schema. None of these changes were statistically significant and in seven cases the data were incomplete or missing at 36 months due to attrition from the study and failure/refusal to complete the YSQ correctly. This could have influenced the findings together with the fact that not all 15 schemata would necessarily have been targeted during therapy. This makes it difficult to confirm whether the lack of change was due to schemata not being addressed or ineffective SMT intervention.

Table 3.6 Change in schema in Schema Modal Therapy group between baseline and 36 months

Schema	Baseline		36 Months	
	Mean	Std Dev	Mean	Std Dev
YSQ Emotional deprivation	16.31	5.874	15.59	6.053
YSQ Abandonment total	14.86	8.039	15.41	8.285
YSQ Mistrust/ abuse total	15.66	7.575	14.36	7.416
YSQ Social isolation total	15.76	7.244	13.95	7.448
YSQ Defectiveness/ shame total	12.97	6.121	12.95	7.094
YSQ Failure total	13.14	6.818	11.68	5.541
YSQ Dependence/ incompetence	12.52	5.047	11.45	4.906
YSQ Vulnerability to harm and illness	12.21	6.930	9.68	5.694
YSQ Enmeshment	12.10	6.715	8.86	3.212
YSQ Subjugation	14.48	6.104	12.95	4.971
YSQ Self-sacrificing	16.76	7.467	15.36	6.772
YSQ Emotional inhibition	13.97	5.710	13.00	6.510
YSQ Unrelenting standards	17.41	5.822	16.59	5.795
YSQ Entitlement	14.31	5.708	12.32	4.581
YSQ insufficient self-control/ self-discipline	14.48	6.104	11.18	4.992

Aggression over the study period

The prevalence of aggression as measured by the MOAS, decreased significantly over time in the sample as a whole. The level of overall aggression to self and others increased between baseline and six-month follow-up, from a mean of 6.86 incidents to 10.85 incidents in the SMT + TAU group with only a slight increase in TAU group. This would suggest that SMT may have resulted in an initial increase in aggression. The number of incidents then decreased sharply to 2.44 incidents by the 36-month follow-up (Figure 3.2). The level of aggression also declined in the TAU group, but much more gradually from 6.35 incidents at baseline to 2.46 incidents at the 36-month follow-up. The similarity of the outcomes suggests that SMT does not offer any added value.

When aggression to self was excluded from the MOAS analysis, the mean sum of incidents of verbal aggression, property damage and physical aggression to others also showed a sharp fall over the study period from a high of 9.26 incidents at the six-months follow-up to 2.32 incidents at the 36-month follow-up in the SMT + TAU group (Figure 3.3). Again the change in the level of aggression in the TAU group was more gradual over the four follow-up periods from a mean of 5.26 incidents at baseline to 1.32 at 36 months. In both analyses there were missing or incomplete data due to attrition and failure to complete at the new institution. There were data missing on six participants at six months, six participants at 12 months, 15 participants at 24 months and ten participants at 36 months. Missing data were controlled for in exploratory statistical analyses (Table 3.4) as this could have influenced the findings.

Figure 3.2 Comparison of Treatment as Usual and Schema Modal Therapy groups by aggression to self and others

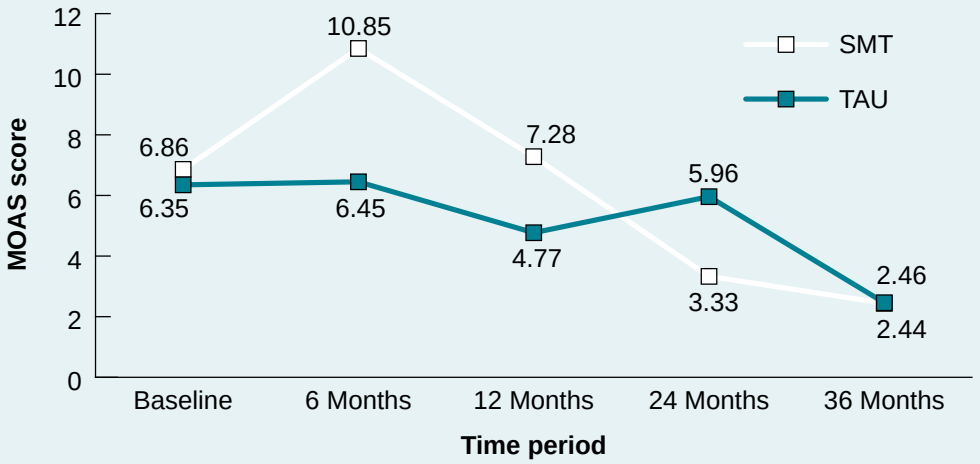
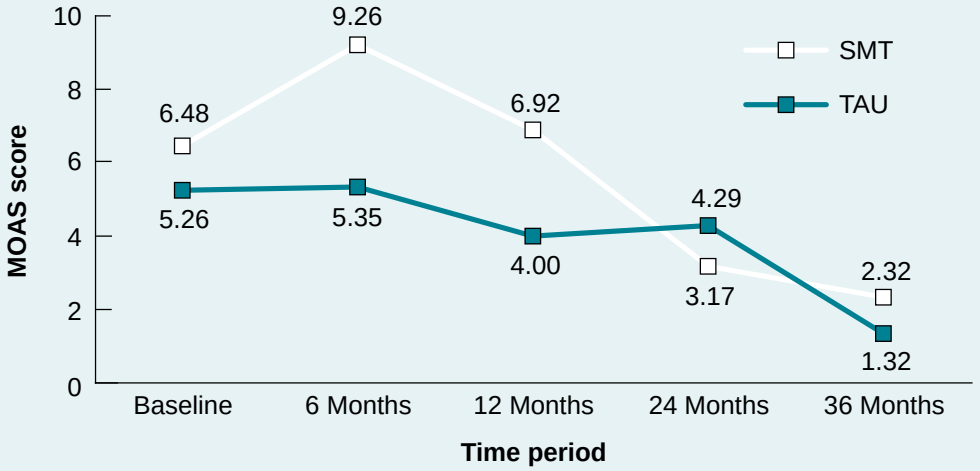


Figure 3.3 Comparison of Treatment as Usual and Schema Modal Therapy groups by verbal aggression, property damage and physical aggression to others



4. Discussion

This study was the first RCT to investigate the treatment effect of SMT on a personality-disordered population in a high secure hospital. The evidence base for the effectiveness of SMT that existed at the outset of the study was very limited and non-existent within a hospital setting. Therefore, this study should be judged as an exploratory trial, which should be useful as a platform to inform the design of future similar trials of psychological intervention in high secure settings.

No formal power calculation was performed prior to the study due to the lack of suitable data that would have informed such a calculation, and therefore it is possible the lack of a treatment effect was due to the trial being underpowered.

There were no treatment effects as a result of the SMT intervention and therefore it was not possible to calculate effect sizes that would inform the required sample size for future larger studies. Multiple measures used in this study increase the risk of Type 1 errors where differences in the outcome measures could have arisen by chance and a number of possible confounders existed that may have impacted on the findings from this study. The control group received substantial amounts of TAU throughout the duration of the study and more than the SMT + TAU group. This is likely to have had an independent treatment effect on the primary outcomes related to risk, personality, mental state, schemata and interpersonal functioning. Controlling and limiting the TAU provided to the sample may have helped control for this effect. However, withholding potentially effective interventions for the purposes of research would not be ethically acceptable, especially in a sample of patients detained against their will to allow treatment to aid recovery and rehabilitation. As the TAU group received a significantly higher number of therapies than the SMT + TAU group, it could, in principle, be argued that SMT was more economical as there were no differences in the outcomes.

Attrition is always a concern in studies of this type and this is especially true when considering the high levels of anti-social behaviour and non-compliance prevalent in this sample. The average length of stay of the sample was approximately 13 years. Future studies may wish to focus on new admissions to reduce the likelihood of participants moving on and out of the study, as attrition from the SMT + TAU group was compounded by the fact that nearly half the sample were discharged. This made it very difficult, if not impossible, to provide therapy as planned, although telephone contact was attempted in some cases. In addition, there were missing data throughout the follow-up periods which would also have influenced findings. This was mainly due to participants dropping out and/or refusing to complete self-report questionnaires and due to staff failing to complete staff-rated scales within agreed time frames.

Of the 126 patients who met the criteria for the study, 63 (50%) consented to participate and were randomised. This is very similar to a recent study by Giesen-Bloo *et al.* (2006) where 51% of those eligible were randomised, although less than that reported by Farrel *et al.*, (2009) where 80% of the 40 patients eligible were randomised. The retention rate for the two-year treatment period was 65.5% in this study, compared with 73.3% in the Giesen-Bloo study and 100% in the study by Farrel, both of which recruited non-forensic patients. The retention in this study is favourable when considering the discharge rate and the fact that non-compliance, anti-social behaviour and poor engagement are typical characteristics of the high secure PD population in the research site, evidenced by the relatively high rates of psychopathic traits. In addition, some of the sample had co-morbid Axis 1 mental disorders, such as schizophrenia and bipolar disorder, which could have influenced the findings (i.e. affected responsivity to treatment).

Recent evidence from trials of SMT with samples of people with borderline personality disorder (Giesen-Bloo *et al.*, 2006; Nordahl and Nysaeter, 2005; Kellog and Young, 2006) suggests that, ideally, SMT should be provided for two sessions per week over a three-year period for this client group. Clearly this is a significantly larger dosage than provided in this study, where the aim was to provide SMT for one session per week for two years with 18 months seen as absolute minimum dosage. Only just over half the SMT + TAU group completed the minimum of 72 sessions over 18 months, and only one actually completed a full dosage of 96 sessions over the two years. Providing such a frequent intervention over such a long time period may prove resource intensive and future studies will need to consider an economic evaluation of the impact of SMT to include a cost-benefit analysis. Future studies should consider an economic evaluation as part of the project specification. Evaluating the effect of SMT on those study participants with borderline personality disorder was considered, although as there were only 20 who met the diagnostic criteria, it was felt this would be an insufficient number to robustly evaluate treatment effect.

Therapy dosage ranged from 0 – 96 sessions. As this study used an **Intention-To-Treat** principle, outcomes were compared for participants, as they were randomised, and not according to the dosage of treatment or interventions that they actually received. Therefore, the participant who received no sessions would be classed as receiving the same dosage of treatment. Controlling for ‘dosage’ of SMT received was considered, but if there is no ITT effect then this is likely to imply that there is no dose effect (Maracy and Dunn, 2008).

Due to the infancy and groundbreaking nature of SMT at the commencement of this study in 2003/04, maintaining treatment fidelity throughout the study was problematic due to ongoing developments in the area and updates emerging from research. The two therapists would not have met the recent standard for delivering schema therapy based on the STRS. In addition, methods of reliably evaluating adherence and quality to the SMT approach were still very much in their infancy during the study period, evidenced by the fact that the best available

treatment fidelity rating scale, the Schema Therapy Rating Scale used in the study, had not in fact been empirically tested. Very recently the STRS has been updated (Young, 2008: www.schematherapy.com). The promising research evidence emerging from schema focused therapy for people with borderline PD would suggest that the therapy would need to be provided for three years with at least two sessions per week. Although it cannot be assumed that the standards for BPD will automatically be the same for other PD groups, therapists will need to be thoroughly prepared to deliver the specialist SMT intervention; achieve the standard score of four on the STRS before providing therapy; be flexible enough to respond to changing standards; and ideally be in post throughout the three-year treatment period.

Bernstein and colleagues (2007) recently proposed that SMT would be well suited for forensic patients. Unfortunately the results from this study do not support this view. Nevertheless, future RCTs in a forensic population could only be justified if they were designed to take account of the lessons learned in this study and based on the promising findings found in other trials of SMT in studies investigating the effects of SMT on participants with borderline personality disorder. Researchers would need to balance the costs of such an intensive dosage of therapy with likely benefits. No evidence exists that benefits can be realised although this could change as new data emerges and different methods are tested.

There were some significant improvements that were found within the SMT + TAU and not in the TAU group in relation to impulsiveness, anger regulation, violence risk and interpersonal style. In all but one of the 15 schemata measured, there were improvements from baseline to final follow-up. However, based on the findings reported here it is impossible to conclude that any clinically significant improvements in the SMT + TAU group resulted from the effect of the SMT. Maturation, another treatment-management intervention and/or institutional effects could have accounted for this improvement. Therefore, these clinical improvements alone would not justify investment in a future larger trial of SMT in a forensic setting.

Previous research has noted the mitigating effects that the length of stay in an institution can have on level of aggression and scores on risk measures such as the HCR-20, irrespective of therapeutic interventions (Belfrage and Douglas, 2002). This was supported here by the reduction in aggressive acts committed by the sample during the study period. Future research in this area will need to consider the impact of the institution independent of specific interventions, or at least control for this as a potential confounding factor.

5. Conclusion

As this was an exploratory small-scale RCT there are limits to what conclusions can be drawn. In terms of the study hypothesis, the treatment group receiving SMT + TAU intervention did not demonstrate statistically significant improvement in scores on dynamic measures of risk, schemata, personality and interpersonal style, when compared to the TAU group. However, a number of crucial findings have been made with regard to the feasibility of conducting a randomised control trial of a psychological intervention in a secure hospital over a long time period.

Issues relating to characteristics of the research population, participant recruitment/retention, attrition, treatment as usual, therapist preparation and competence, institutional effects, length of stay, progress through the clinical pathway and timescale are key findings from this study. A substantial number of the participants were discharged and it is not possible to confirm whether this was due to SMT. Maintaining the integrity of the SMT intervention proved challenging at a time when new methods of assessment and evaluation were being developed and findings from ongoing research were emerging.

This study provides a feasible framework for future RCTs in high secure settings, although based on these findings, future larger trials of SMT in a forensic context cannot be recommended unless the methodological aspects/limitations found in this study are adequately addressed. Future studies investigating the effectiveness of SMT or similar therapies should only be considered if new data emerge and the difficulties experienced in this study are addressed and remedial measures are included in the proposal prior to commencement.

Future randomised controlled trials of SMT and related psychotherapies in high secure and forensic settings need to consider the lessons learned in this study. In particular, future studies need to ensure comprehensive therapist preparation, control of treatment as usual, bigger samples supported by a power calculation, methods to address attrition and discharge and more intensive therapy.

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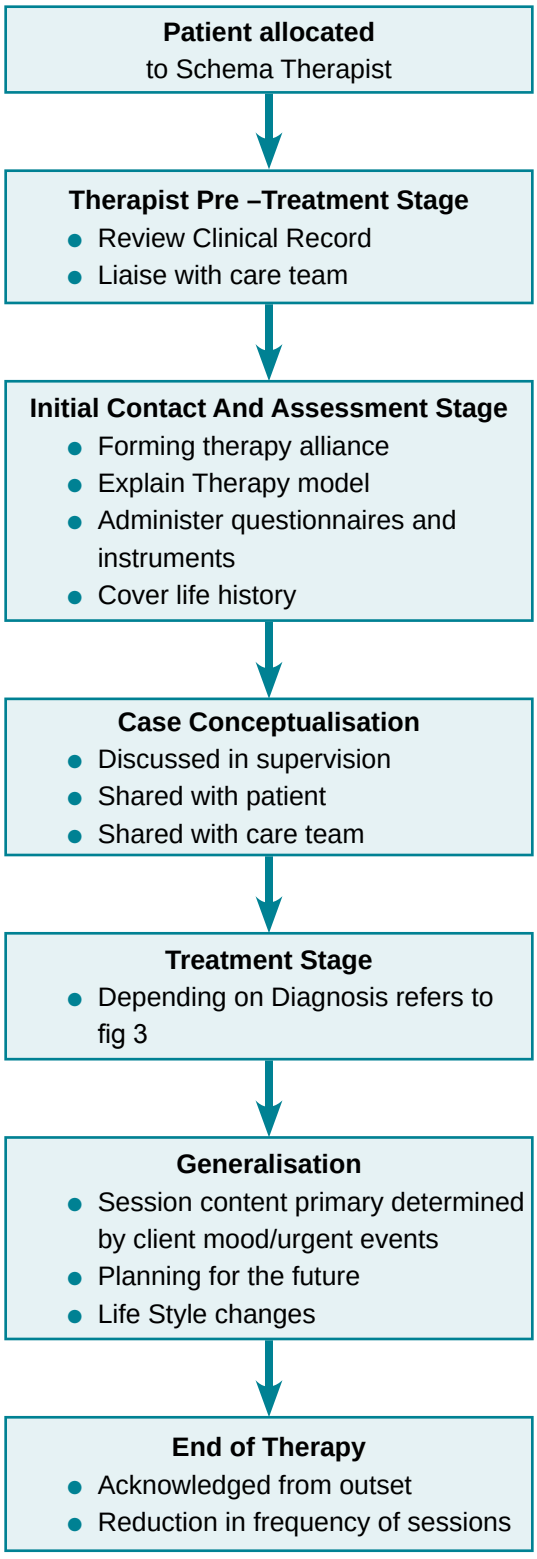
Additional resources

Dr. Jeffrey Young, *Schema Therapy:* http://www.schematherapy.com

Treatment Manual: Outline Therapy Protocol for use in Schema Mode Therapy Evaluation Study in the Personality Disorder Service at Ashworth Hospital. Louise.horne@merseycare.nhs.uk

Appendix 1 Stages of Schema Therapy in the study



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Exploratory Randomised Control Trial of Schema Modal Therapy in the Personality Disorder Service at Ashworth Hospital

The purpose of the study was to evaluate the treatment effects of Schema Modal Therapy (SMT) in a sample of personality disordered patients in Ashworth high secure hospital. Outcome measures of schemata, risk, mental state, personality and interpersonal style were included. The study was an independent phase two Medical Research Council (MRC) exploratory trial. Findings of the study suggest that conducting a Randomised Control Trial (RCT) in a high secure hospital is feasible, although there are many challenges relating to a number of issues including attrition, treatment as usual and therapist preparation. No significant treatment effect was found as a result of SMT. Future trials of SMT in high secure and forensic settings need to consider the lessons learned in this study.

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