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International Journal of Law and Psychiatry

journal homepage: www.elsevier.com/locate/ijlawpsy

A pilot randomised controlled trial of a programme of psychosocial interventions (Resettle) for high risk personality disordered offenders



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ARTICLE INFO

Keywords:

Personality disorder

RCT

Offenders

Offending

Intervention

ABSTRACT

Background: Offenders with personality disorder experience significant co-morbid mental health problems and present with an increased risk of offending. The evidence for the effectiveness of interventions for personality disordered offenders in the community is limited. This study was a pilot study to determine the feasibility of a randomised controlled trial (RCT) of an intervention known as Resettle for personality disordered offenders and to explore the possible effects of this intervention.

Methods: Potential participants were recruited from referrals of male prisoners to Resettle. Those consenting underwent baseline assessments before being randomised to Resettle or treatment as usual. Officially recorded and self-report offending was assessed over two years following release from custody. Of the 110 eligible participants, 72 (65%) participated in the study of whom 38 were randomised to Resettle and 34 to treatment as usual. The two groups had a similar psychiatric and offending profile.

Results: Analysis of officially recorded offences at two years found mixed results, but whether adopting an intent-to-treat approach or including only those who received the intervention there was no clear evidence of an effect of the intervention. A comparison of self-report offending found no effect of Resettle in an intent-to-treat analysis, but there was an effect when the analysis involved only those participating in the intervention.

Conclusions: This study demonstrated that with some adjustments it was possible to carry out an RCT of a complex intervention for personality disordered offenders in a criminal justice setting. Some, but not conclusive, evidence was found in favour of the intervention.

1. Introduction

Personality disorders are common among service users in health and forensic services (Fazel & Danesh, 2002; Newton-Howes et al., 2010; Zimmerman, Rothschild, & Chelminski, 2005). Offenders with a personality disorder are at a higher risk of reoffending compared to offenders without personality disorder (Coid et al., 2007; Howard, Huband, Duggan, & Mannion, 2008). As a consequence this group presents an increased risk to the public in comparison to non-personality disordered offenders. This group also present a significant risk to themselves, since increased levels of reckless and suicidal behaviours contribute to higher rates of premature mortality when compared to

non-disordered groups (Black, Baumgard, Bell, & Kao, 1996; Lesage, Boyer, Grunberg, & Vanier, 1994; Martin, Cloninger, Guze, & Clayton, 1985). Antisocial personality disorder (ASPD), one of the ten personality disorders identified by the diagnostic and statistical manual of mental disorders (5th edition) (DSM 5; American Psychiatric Association, 2013), is characterised by reckless behaviour, a disregard of societal rules, high impulsivity, reoccurring deceitfulness and lack of remorse. Given these core features, it is unsurprising that ASPD is prevalent among prison populations with around half of all prisoners thought to meet the criteria for ASPD (Fazel & Danesh, 2002; Singleton, Gatward, & Meltzer, 1998.) Elevated rates of other personality disorder categories (e.g. paranoid personality disorder and borderline

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<https://doi.org/10.1016/j.ijlp.2019.101463>

Received 5 February 2019; Received in revised form 4 June 2019; Accepted 25 June 2019

Available online 08 July 2019

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personality disorder) have been found in prison populations (Singleton et al., 1998). In addition, people with personality disorders often experience comorbid mental health problems such as depression (e.g. Corruble, Ginestet, & Guelfi, 1996), anxiety (e.g. Sanderson, Wetzler, Beck, & Betz, 1994) and substance abuse and/or dependency (e.g. Johnson et al., 2005; Robins, Tipp, & Pryzbeck, 1991). Support to manage these additional mental health problems is often the primary reason people with personality disorders come into contact with health services (Coid et al., 2009).

1.1. How to treat offenders with personality disorder

Despite the limited evidence base, a range of psychological interventions have been advocated for antisocial personality disorder, including psychotherapy (Perry, Banon, & Ianni, 1999), group-based approaches (Winship & Hardy, 2007) and therapeutic communities (Duggan, 2009; Lipton, Pearson, Cleland, & Yee, 2002). The National Institute of Clinical Excellence (NICE) recommends the use of cognitive and behavioural group-based treatment for ASPD (NICE, 2009a). Multi-agency input and a focus on comorbid problems are also considered key in treatment design. There is a larger evidence base supporting psychological interventions for borderline personality disorder (NICE, 2009b), but limited empirical support for the effectiveness of interventions for other personality disorder categories present at elevated rates in offender populations such as paranoid personality disorder and narcissistic personality disorder (Singleton et al., 1998).

From a treatment perspective it is not clear whether offending can be reduced independently from improved personality functioning, or whether offending behaviour requires separate interventions. The challenge of treating offenders with personality disorders is that in the majority of cases both a personality disorder and an offending-behaviour focus are required (Howells, Krishnan, & Daffern, 2007). Although personality disorder is prevalent among prisoners, psychological treatment for this group has been limited. Offenders exhibiting features of ASPD such as deceitfulness and a disregard for societal rules are frequently considered a challenging group for clinicians to manage (Duggan, 2009). People with ASPD have often been found to routinely reject treatment attempts (Tyrer, Mitchard, Methuen, & Ranger, 2003) which has led to low levels of engagement or 'readiness' (Howells & Day, 2007). This could be due to an overall lack of motivation or distrust of staff (Sheldon, Howells, & Patel, 2010). Challenges in successfully delivering interventions to offenders are not unique to ASPD. Low engagement and failure to complete interventions are general features across offender groups (Howells & Day, 2007).

1.2. The state of evaluations of personality disorder treatment

There is a paucity of research evaluating psychological interventions for offenders with personality disorder. The majority of studies have focused on borderline personality disorder (BPD). Very few trials have used a sample consisting exclusively of people with ASPD (Duggan, Huband, Smailagic, Ferriter, & Adams, 2007; Gibbon et al., 2010). Furthermore only one randomised controlled trial has evaluated a psychological intervention in the community specifically for people with an ASPD diagnosis (Davidson et al., 2009; Gibbon et al., 2010). This found that cognitive behaviour therapy did not reduce levels of aggression over a one year follow up period.

In England and Wales, changes to the Mental Health Act (2007) resulted in clinicians and practitioners taking more responsibility for overseeing the management and treatment of people with personality disorder (Beck, 2010). In particular, before the amendments to the Mental Health Act, personality disorder fell within a specific category which required the assessing doctor to be satisfied that the proposed treatment would be likely to alleviate or prevent a deterioration of the patient's condition before making a recommendation for involuntary detention (a rider that did not apply to mental illness). The legislative

change introduced a broad category of 'mental disorder' which in effect removed any difference in law between personality disorder and mental illness. Preceding this, the lack of support and provision for people with personality disorder became apparent, underlining the need to develop specific services devoted to the assessment and treatment of personality disorder (National Institute for Mental Health in England NIMHE, 2003). Services dedicated to the management and treatment of 'severe' personality disorders were implemented through a national programme in England and Wales for offenders who were considered to be at a high risk of reoffending identified by the non-clinical policy term 'Dangerous and Severe Personality Disorder' (DSPD) (Home Office and the Department of Health, 1999). The DSPD programme involved the development of specialist residential units, initially in high secure prisons and hospitals. In addition, community based services were piloted, of which Resettle was one. Innovatively, Resettle was specifically designed to allow evaluation using a randomised controlled trial methodology, which we implement here.

1.3. Resettle intervention programme

The Resettle programme (formerly known as the Community Risk Assessment and Case Management Service 'CRACMS') was jointly funded by the Ministry of Justice and the Department of Health (England and Wales) as part of the Dangerous and Severe Personality Disorder (DSPD) services. The programme commenced in April 2008 and was based in the Merseyside area. The intervention was an intensive, community-based, psychosocial programme for personality disordered offenders with a focus on reducing reoffending, managing risk in the community, improving wellbeing and promoting social inclusion (Miller, Baker, & Olyonye, 2010). Resettle was developed to provide risk assessment and management of men considered to have personality disorders who were identified as high or very high risk of harm to others. All cases were subject to Multi Agency Public Protection Arrangements (MAPPA) through which probation, police and the prison service share responsibility with other agencies for offenders who pose a risk in relation to violent or sexual offending. MAPPA eligibility is defined by National Guidance issued by the Ministry of Justice (MOJ) and National Offender Management Service (NOMS).

1.4. Study objectives

The objectives of this study were to i) test the feasibility of a randomised controlled trial of a complex intervention designed to address personality dysfunction and offending behaviours among high risk personality disordered offenders on release from prison, and ii) gather initial evidence regarding possible treatment effects.

2. Method

2.1. Trial design

This study was a phase II exploratory randomised controlled trial (Medical Research Council, 2000) of a treatment programme (Resettle) designed to reduce reoffending by treating personality dysfunction and addressing offending among high-risk personality disordered offenders released from prison (trial registration: ISRCTN00991963). The design, eligibility criteria and primary outcome measure were not modified from the registered study protocol. Recruitment took place in prison and follow-up assessments were conducted at 1 and 2 years after release.

2.2. Recruitment and randomisation

Potential participants were identified through probation offices which have complete records of all offending males in prison. Recruitment occurred between May 2008 and May 2013 across a region

in the North West of England. Offender managers were asked to identify potential participants who were (1) over 18; (2) likely to have personality disorder; and (3) identified in need of multi-agency risk management arrangements (MAPPA) and hence high risk. Offender managers have overall responsibility for offenders over a substantial period for release and follow up, so were deemed best able to make recommendations. A checklist, which was developed by Resettle, was used to identify likely personality disorder. The checklist used information already contained in a standardised probation risk assessment tool. Senior Resettle practitioners delivered training sessions to offender manager teams regarding identification of personality disorder among offenders. Thus the final sample was defined in terms of a broad assessment of risk and of antisocial personality disorder. Exclusion criteria were severe intellectual impairment or psychotic mental illness identified from a review of the records or from the initial baseline assessment.

Following identification, the offender manager met with the potential participant to ask whether he agreed to meet the researcher. Where consent was obtained, the researcher met with the subject in the prison where they were residing. Although subjects were identified by virtue of the fact they were returning to the Merseyside area, when in custody they were distributed among a wide range of prisons across England. In the course of the study, twenty-one prisons were visited. Due to the large number of prisons and the fact that the locations of the prisoners were not known in advance of offender manager identification and consent, it was not feasible to get agreement to audio-record interviews. In the event of the participant's consent, the baseline assessments (which took between 2 and 4 h) were undertaken, sometimes over a number of visits.

Baseline assessments were completed and scored prior to randomisation. Randomisation was carried out by an administrator unconnected to the study using random numbers generated by the study statistician. The Minim stratified randomisation programme was utilised to minimise the imbalance between the two groups for the type of index offence (violent versus sexual offence), SCID I diagnosis of drug and alcohol abuse (presence versus absence), and the designated probation office. The administrator informed the researcher, who had undertaken the baseline assessment, of the group allocation. In turn, the researcher informed the offender manager of allocation. For control group allocation, the offender manager made usual arrangements. In the event of allocation to the intervention group, there was liaison between the offender manager and the Resettle service.

2.3. Intervention

Resettle is based on a version of sociotherapy that has been delivered in forensic services (De Boer-van Schaik & Derks, 2010). The model emphasises the importance of interaction and the social environment as a context for learning (Baker, Johnson, & Oluonye, 2013). The model consists of three levels, all of which are underpinned by risk management requirements linked to probation supervision arrangements. The first level is the therapeutic milieu generated by appropriate and prosocial relationships. There is a focus on interactions as opportunities to enhance social learning within a safe and bounded environment. The second level comprises regular group work, through which participants develop enhanced capacities for self-reflection and understanding of others. Individually-tailored psychosocial interventions, with a focus on risk management, wellbeing and social integration form the final level of the model. All participants are subject to detailed case formulations which are the basis of individual risk management and intervention plans.

Resettle is primarily a community-based service, but there is a critical preparatory phase of engagement delivered by Resettle practitioners over at least six months prior to release. The Resettle programme was delivered by trained sociotherapists who were recruited from clinical and probation backgrounds and received regular

supervision. Resettle was delivered according to an explicit model of care, but it was not manualised. Resettle key workers first visited the participant in prison and undertook in-reach work which included, introduction to the programme, motivational work, assessment of risk, planning for release and identification of goals. In the immediate post-release period the focus of the intervention was on practical support relating to living skills and reintegration into the community. While attending the programme, the participants were expected to take part in a number of daily and weekly group meetings, individual psychosocial sessions, offence focused work, and other sessions such as psycho-education, health living and arts and creativity. In a weekly review meeting the participant was assisted to reflect on, and engage in discussions about, their week. Participants initially attended Resettle for 6 days each week. In this phase, there were two key-worker sessions a week. Following a period of familiarisation, less frequent weekly attendance could be negotiated on the basis of individualised assessments of need and risk. If the participant was returned to prison, Resettle practitioners visited the prison to maintain the therapeutic relationship.

2.4. Usual care

Usual care involved standard probation supervision following release from prison custody. This entailed regular meetings (weekly initially) with the offender manager and engagement with other services where specified in the licence conditions. Although the offender manager may have visited the participant in prison prior to release and if he was returned, this was very limited contact in comparison to the contact between the Resettle practitioners and the participants randomised to the intervention group.

2.5. Measures

2.5.1. Baseline measures

Personality disorders were assessed using the DSM-IV version of the International Personality Disorder Examination (IPDE) (Loranger, 1999). The IPDE is administered using a 90-item semi-structured interview.

The Structured Clinical Interview for Axis I Disorders (SCID I) (First, Gibbon, Spitzer, Williams, & Benjamin, 1997) is an interview-based measure of Axis I disorders (mood disorders, psychotic disorders, substance disorders and anxiety) as defined in the Diagnostic and Statistical Manual of Mental Disorders (DSM IV). DSM V had not been published at the time the study commenced. Good inter-rater reliability has been reported. (Skre, Onstad, Torgersen, & Kringlen, 2007).

The Psychopathy Checklist Screening Version (PCL: SV) (Hart, Cox, & Hare, 1995) was used to investigate psychopathic traits. It is a 12-item measure that requires the assessor to rate the presence of affective/interpersonal (factor 1) and deviant/impulsive factors (factor 2) that have been shown by research to make up the psychopathy construct (Guy & Douglas, 2006).

The Symptom Checklist Revised (SCL-90-R) (Derogatis, Rickels, & Rock, 1976) was administered to measure mental health symptoms over the previous 7 days. The SCL-90-R measures symptoms of somatisation, obsessive-compulsive disorder, interpersonal sensitivity, depression and anxiety, along with phobic anxiety, paranoid ideation, psychoticism, and hostility (Wilson et al., 1985). It has been found to correlate well with other measures of mental state, and has discriminant validity on some subscales (Wilson, Taylor, & Robertson, 1985).

Training on interviewing and coding the IPDE, PCL-R-SV and SCID-I was provided to the research assistants on UK nationally accredited training programmes. In order to ensure criteria for inclusion were met, cases close to threshold for ASPD were discussed with RN.

2.5.2. Outcome measures, assessed also at baseline

2.5.2.1. Primary outcome. The primary outcome was number and type

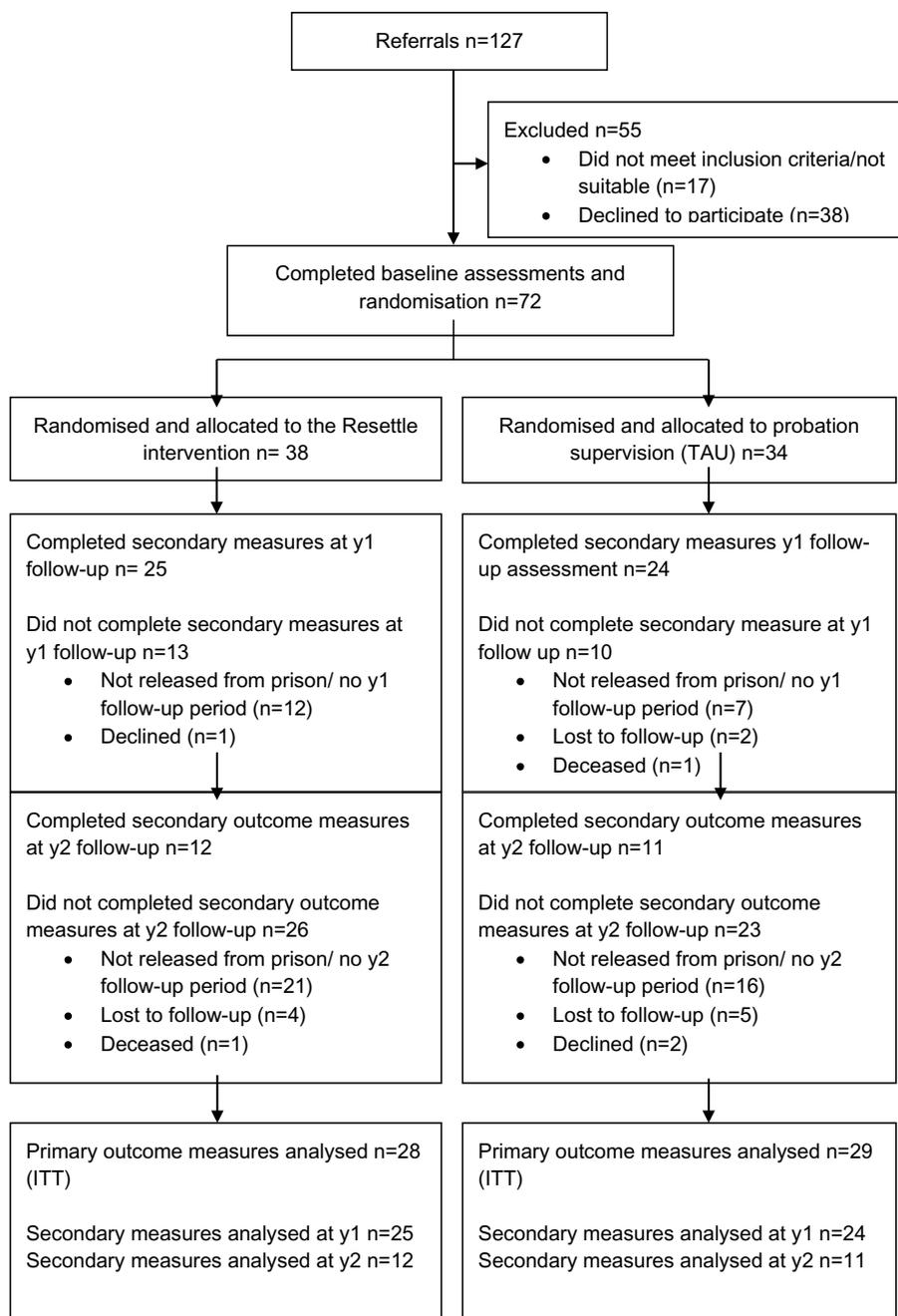


Fig. 1. Flow diagram of progress through pilot RCT.

of officially recorded offending according to the Police National Computer (PNC). This database contains information relating to recorded convictions, cautions and reprimands in England and Wales. Data was obtained for every offence recorded on the PNC between the point of initial release until the completion of the study.

2.5.2.2. Secondary outcomes. The secondary outcome measure was self-reported antisocial behaviour. This was recorded at 1 and 2 year follow-up assessments using the Self-reported Delinquency Scale (SRD) (Huizinga & Elliott, 1986) amended for use in an adult group (Palmer & Hollin, 2000). The SRD scale is a 32-item self-report measure that asks respondents to indicate the frequency with which they have engaged in a wide range of antisocial behaviours (from theft to sexual or violent offending) over the previous year (Huizinga & Elliot, 1986; Thornberry & Krohn, 2000).

Follow-up was not conducted blindly because assignment to the

treatment and control groups was evident from the contact process. However, the primary outcome was number of officially recorded offences. Fig. 1 shows the referral and randomisation process during the trial.

2.6. Analysis

Official records of offending were reviewed for the entire two year follow-up period. Participants were also asked to self-report the number of offences at the year-1 and year-2 follow-ups and the maximum value across the two years was taken as the dependent measure due to missing data at the second follow-up. Thus, the dependent measures were total official offences and self-report of antisocial behaviour across the two year follow-up period.

To address the question regarding the effectiveness of the Resettle programme, there was first an examination of whether those randomly

assigned to the control condition were significantly different from those assigned to the Resettle programme. The intent-to-treat and the actively participating Resettle groups were not separated in the first planned contrasted effect, because recommendations are to conservatively test treatment effects by including intent-to-treat individuals in analyses (Gupta, 2011). In the second contrasted effect, there was an examination of whether those in the treatment group who followed protocol (i.e., those who actively participated in Resettle) showed fewer offences over time. This second effect can address the active treatment effects of the programme.

Two regressions each statistically predicting (1) offences and (2) self-report of delinquent acts were run in Mplus 7.3 (Muthén & Muthén, 2012) using contrast coding of the control group, the intent-to-treat group, and the participating Resettle group. Two contrasts were created: one was created to examine control versus intent-to-treat and participating Resettle group (−1, 0.5, 0.5). The other was created to examine the difference between the participating Resettle group versus the control group (1, −1) while intent-to-treat was coded 0. Maximum-likelihood with robust standard error estimations and manifest (not latent) variables were used. A Poisson distribution was fitted to offending and self-reported antisocial behaviour. A zero-inflation factor was added to the model predicting official offences to deal with the high proportion of zeros in offending (0.68) and the overdispersed distribution (standard deviation that is higher than the mean). For the regression with official offending, the analysis was conducted while controlling for the length of time spent released within the community, since those offenders with greater lengths of time in the community will have had greater opportunity to offend.

When conducting zero-inflated regression models, Mplus creates a continuous outcome measure as well as a latent binary outcome measure, since zero-inflated measures benefit from examining whether participants who score zero versus any other value other than zero might differ in relation to the independent variables. Positive values on the binary outcome are interpreted to mean that lower values are related to greater chance of the dependent variable assuming zero values. Negative values on the binary outcome are interpreted to mean that higher values (using categorical contrast coding) on the independent variable are related to more non-zero values on the dependent variable.

3. Results

3.1. Is an RCT of a complex intervention to address personality dysfunction and offending behaviours among high risk personality disordered offenders feasible with regard to recruitment, retention and acceptability?

The initial intention was to recruit 60 participants over two years. Despite recruiting close to the anticipated yearly number of recruits in the first 12 months ($n = 29$), it became apparent that participants already randomised had release dates later than planned for and that there was a strong possibility that too few would be released over the 3 year period of the study to provide follow up after Resettle treatment. An application for additional funding for a further two years was made and accepted.

Of the 110 men identified in the extended study period as eligible for the study, 72 (65%) consented to take part and participated in the baseline assessment (Fig. 1). Although the men were returned to a defined geographical area, whilst in prison they were distributed widely across the prison estate. Thus a practical implication for undertaking the trial was the researchers travelling extensively. Following baseline assessments, thirty-eight were randomised to Resettle and 34 to the control group.

As can be seen in Tables 1 and 2, randomisation yielded groups that were very similar by demographic features, offending history, psychopathy, mental health symptoms and personality disorder diagnoses. The majority had offended from an early age and had committed a large number of diverse offences, thus indicating the severity of this sample.

Table 1

Age, ethnicity, offending, PCL-R scores, and time from release to follow-up of treatment and control groups.

	Resettle (treatment group (N = 38))	Control group (N = 34)	Total
Age, M (s.d.)	35.82 (11.31)	32.62 (11.57)	34.31 (11.47)
Ethnicity			
White British	34 (89.5%)	33 (97.1%)	67 (93.1%)
White Irish	1 (2.6%)	0	1 (1.4%)
White & black Caribbean	0	1 (2.9%)	1 (1.4%)
African	1 (2.6%)	0	1 (1.4%)
Other mixed background	2 (5.3)	0	2 (2.8%)
Age at first conviction			
Before age 15	13 (34.2%)	13 (38.2%)	26 (36.1%)
Age 15–17	11 (28.9%)	12 (35.5%)	23 (31.9%)
18 +	14 (36.8%)	9 (26.5%)	23 (31.9%)
No. of previous convictions	13.26 (9.6)	14.24 (10.9%)	13.72 (10.2%)
No. of previously convicted offences	32.46 (25.4)	30.15 (27.2%)	31.35 (26.1%)
Index offence			
Violent	25 (65.8%)	25 (73.5%)	50 (69.4%)
Sexual	10 (26.3%)	5 (14.7%)	15 (20.8%)
Burglary	1 (2.6%)	3 (8.8%)	4 (5.6%)
Robbery	7 (18.4%)	7 (20.6%)	15 (20.8%)
Other	7 (18.4%)	5 (14.7%)	12 (16.7%)
PCL:SV mean scores (s.d.)			
Total	16.16 (4.64)	15.74 (4.53)	15.96 (4.56)
Facet 1	7.08 (3.04)	6.53 (3.51)	6.82 (3.26)
Facet 2	8.97 (3.31)	9.15 (2.36)	9.06 (2.88)
Mean days from release to follow-up (s.d.)	882.5 (187.1)	832.6 (144.1)	864.1 (170.1)
SCL-90 global severity index mean scores (s.d.)	0.85 (0.66)	0.82 (0.78)	0.84 (0.71)

Forty three (60%) had scores above the published threshold for high psychopathic traits of 15–16 (Guy & Douglas, 2006; Hart et al., 1995).

The most common categorical personality disorder diagnosis after antisocial personality disorder was borderline personality disorder which was present in similar proportions between the two groups (Table 2). Consistent with evidence on comorbidity of personality disorders many participants had more than one diagnosis (Black, Gunter, Loveless, Allen, & Sieleni, 2010).

There were a number of challenges to implementing the RCT methodology in a newly commissioned service. After commencement of the service and its evaluation, there remained questions from referrers and commissioners about the need for an evaluation. It was evident that some potential referrers (e.g. offender managers and MAPPA panels) had a limited recognition of the need to formally evaluate new intervention services. Furthermore, randomisation was seen to restrict access to an effective specialist service. Comments by referrers suggested that the one in two likelihood of receiving the new service was a disincentive to undertaking the process of referral. Within the service itself, this was perceived to be a particular problem given difficulties ensuring sufficient referrals to justify the allocated resources.

3.2. Is There Evidence for the Effectiveness of the Resettle Programme in Reducing Offending as Compared to the Control Group's Level of Offending When Using the Intent-to-Treat analysis?

The model with official offending retained 72 observations. Fig. 2 shows the unstandardized estimates and confidence intervals in statistically predicting the Poisson distribution of total offences on release and the zero-inflated binary latent factor. When examining official offending, those offenders assigned to Resettle had higher total offences in the two year follow-up as compared to the control group, with the

Table 2
IPDE DSM-IV personality disorders in Resettle and control groups.

DSM-IV personality disorders	Resettle (treatment)		Control		Total	
	n (%)		n (%)		n (%)	
	Probable	Definite	Probable	Definite	Probable	Definite
Paranoid	3 (7.9)	5 (12.2)	1 (2.9)	1 (2.9)	4 (5.6)	6 (8.3)
Schizoid	3 (7.9)	0	2 (5.9)	0	5 (6.9)	0
Schizotypal	0	0	0	1 (2.9)	0	1 (1.4)
Antisocial	2 (5.3)	34 (89.5)	2 (5.9)	31 (91.2)	4 (5.6)	65 (90.3)
Borderline	7 (18.4)	9 (23.7)	5 (14.7)	4 (11.8)	12 (16.7)	13 (18.1)
Narcissistic	0	1 (2.6)	0	2 (5.9)	0	3 (4.2)
Avoidant	3 (7.9)	1 (2.6)	1 (2.9)	1 (2.9)	4 (5.6)	2 (2.8)
Obsessive Compulsive	1 (2.6)	0	1 (2.9)	2 (5.9)	2 (2.8)	2 (2.8)
Not Otherwise Specified	0	3 (7.9)	3 (8.8)	3 (8.8)	3 (4.2)	6 (8.3)

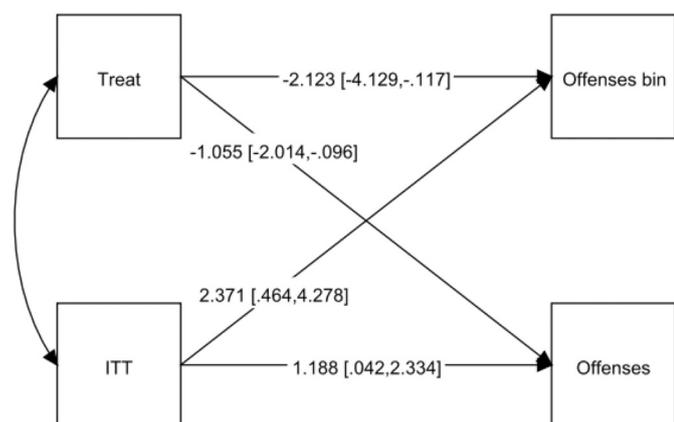


Fig. 2. Statistical prediction of number of Poisson-distributed official offences and the zero-inflation binary (“bin”) factor by participating Resettle group (Treat) and by Intent-to-Treat groups (ITT) versus the control group. Note: confidence intervals which did not include zero were significant at $p < .05$.

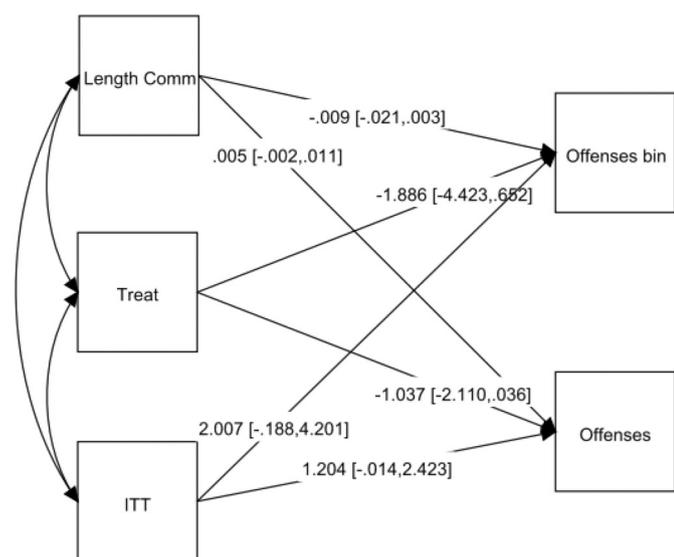


Fig. 3. Statistical prediction of number of Poisson-distributed official offences and the zero-inflation binary (“bin”) factor by participating Resettle group (Treat) and by Intent-to-Treat groups (ITT) versus the control group, while controlling for length of time released in the community (Length Comm). Note: confidence intervals which did not include zero were significant at $p < .05$.

Intent-to-Treat groups higher by a factor of just over 1 in the Poisson-distributed rate of arrests over the two year period (estimate = 1.188, SE = 0.585, $p = .042$, 95%CI = -0.042, 2.334). This may be somewhat driven by the fact that one offender in the intent-to-treat group had nine offences and that was the maximum score in the entire cohort. Examining the zero-inflation factor, those assigned to Resettle were significantly more likely to assume a zero value (in comparison to any value equal or above one arrest) than those in the control group (estimate = 2.371, SE = 0.973, $p = .015$, 95%CI = 0.464, 4.278). That is, there was about a 2 times higher odds that offenders (including the intent-to-treat offenders) in the Resettle programme had no offending (rather than any level of offending) in the two year follow-up period than offenders in the control group. When running the regression again with length of time in the community added to the regression, none of the predictors were significant any longer (see Fig. 3; estimate = 1.204, SE = 0.621, $p = .053$, 95%CI = -0.014, 2.423; estimate = 2.077, SE = 0.1.12, $p = .073$, 95%CI = -0.877, 4.201, respectively). Yet the incremental variance of length in time in the community was non-significant after including treatment groups (Δ -2LL (df = 2) = 3.573, $p > .05$). Also, the unstandardized betas were non-significant. Thus, adding length of time with opportunity to offend may have limited the ability to find significant effects.

No significant effects of being assigned to Resettle were found for self-report of antisocial behaviour in Fig. 4 (estimate = 2.534, SE = 0.889, $p = .085$, 95%CI = -0.210, 3.277). This analysis retained 20 observations, so the low sample size should be noted.

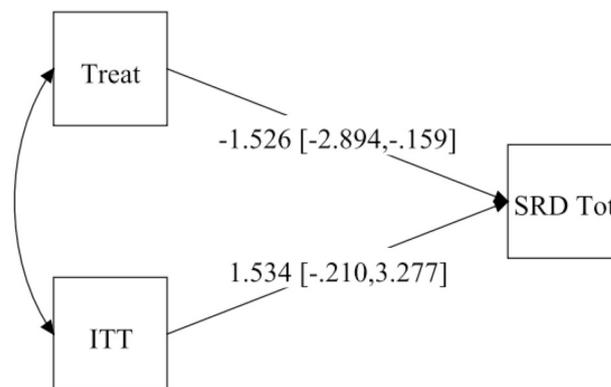


Fig. 4. Statistical prediction of number of Poisson-distributed self-report of antisocial behaviour (SRD Tot) by participating Resettle group (Treat) and by Intent-to-Treat groups (ITT) versus the control group. Note: confidence intervals which did not include zero were significant at $p < .05$.

3.3. Is There Evidence for the Effectiveness of the Resettle Programme in Reducing Offending as Compared to the Control Group's Level of Offending When Only Comparing the Participating Resettle Group?

The participating Resettle group (Treatment group) had fewer official offences as compared to the control group, with a lower rate of Poisson-distributed arrests of about 1 over the two year period (see Fig. 2; estimate = -1.055, SE = 0.489, $p = .031$, 95%CI = -2.014, -0.096). Further, 20% of the variance in offending was explained by the programme groupings. However, the Resettle group was less likely to assume zero-values on offending than the control (estimate = -2.123, SE = 1.023, $p = .038$, 95%CI = -4.129, -0.117). In other words, the Resettle group was more likely to have any level of offending than the control group, although the total count was reduced for the Resettle participating group as compared to control or usual care.

When including length of time in the community, as above and shown in Fig. 3, the effects dropped to nonsignificant (estimate = -1.037, SE = 0.547, $p = .058$, 95%CI = -2.110, 0.036; estimate = -1.886, SE = 1.294, $p = .145$, 95%CI = -4.423, 0.652, respectively), yet again it is noted that it had no significant incremental variance (Δ -2LL (df = 2) = 3.573, $p > .05$) and did not significantly predict offences.

For self-report of antisocial behaviour, the Resettle group reported significantly less antisocial behaviour over the two years than the control group (estimate = -1.526, SE = 0.698, $p = .029$, 95%CI = -2.894, -0.159). Of note, this effect remained significant even when controlling for length of time in the community (estimate = -1.524, SE = 0.707, $p = .031$, 95%CI = -2.909, -0.138), and this effect was of moderate size and indicates a 1.5 increase in the ordinal count of delinquent activity in the control group as compared to the Resettle programme group. The effect of length in community was non-significant and is not included in Fig. 5 for that reason (estimate = 0.00, SE = 0.003, $p = .969$, 95%CI = -0.007, 0.006). Thus, both regressions show that the Resettle group had fewer number of offences, whether measured via official records or self-report, although some variance in the official offending data was taken up by opportunity to offend.

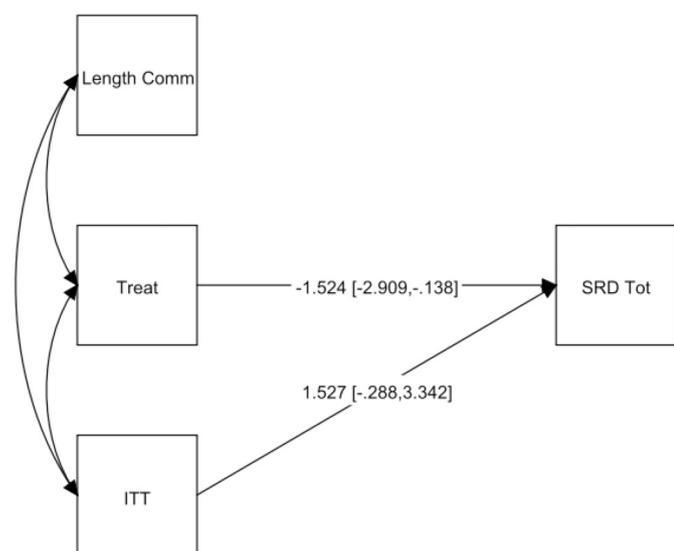


Fig. 5. Statistical prediction of number of Poisson-distributed self-report of antisocial behaviour (SRD Tot) by participating Resettle group (Treat) and by Intent-to-Treat groups (ITT) versus the control group, while controlling for length of time in the community (Length Comm). Note: confidence intervals which did not include zero were significant at $p < .05$.

4. Discussion

4.1. Feasibility

This was the first ever randomised controlled trial (RCT) of prison and community treatment of consecutively identified high risk personality disordered offenders recruited in prison. The evidence from the baseline measures was that, not only did nearly all participants meet criteria for antisocial personality disorder, but many met criteria for more than one personality disorder including psychopathy. These added factors make treatment challenging (e.g., Salekin, Worley, & Grimes, 2010).

Recruitment of 72/110 (65%) of eligible men in prison was high, and comparable to RCTs of non-offending samples (Walters et al., 2017). The number of participants available for follow-up was affected by the uncertainty regarding the actual release dates. This complication was not taken into account in the initial study design and thus the study duration had to be extended at extra cost. Although the numbers recruited to the study were higher than originally planned, the numbers of prisoners released and available for treatment and follow up were lower, because of the substantial periods of time that many remained in prison after recruitment to the study. This was the case even after extension of the study time period to take account of the problem. Future studies will have to anticipate this phenomenon, by planning to recruit larger numbers, and to build in longer study time to allow for the necessary time within the community.

Randomisation was effective in generating groups that were very similar on rates of previous convictions, and numbers of personality disorders. Follow up rates were excellent at one year, and good at two years in both treatment and control groups. The process required a high level of co-ordination between the Resettle treatment team and the research team. Substantial sophistication was required of the treatment team, on the one hand to maintain therapeutic commitment, and on the other hand create the conditions for an objective evaluation.

A number of processes contributed to the challenges implementing the RCT approach to a new service, including general questions about the need for evaluation and more specific questions about the RCT methodology. In building an RCT design into the implementation of a new service, there is a difficult balance to be struck. The service providers are likely to share their therapeutic optimism with potential referrers. This can lead to the referrers coming to believe that the RCT element interferes with their access to a service that is assumed without evidence to be effective. On the basis of the experience of maintaining the RCT design in relation to Resettle, it is recommended that the researchers and service providers agree in advance how to instill moderated enthusiasm whilst still being able to “sell” the usefulness of a rigorous testing approach which necessarily demands random assignment to conditions. A priori assumptions among referrers and providers about the effectiveness of new intervention services for offenders may in part be linked to beliefs that greater levels of supervision and control of offenders is associated with a reduced likelihood of offending, despite the lack of empirical support for this conclusion (MacKenzie & Farrington, 2015). With regard to treatment of personality disorder, the evidence base suggests that the critical ingredient is the quality of the contact rather than the frequency per se (Grattet & Lin, 2016; Lipsey, 2009).

A number of recommendations for implementing future researched services arise from the review of the challenges in this case. The implications of the evaluation approach needs to be thought through in detail at the outset so that potential challenges can be understood and anticipated. This may be achieved by joint modeling of the service delivery and research approaches. There should be a clear governance structure both to oversee service delivery and to facilitate the evaluation. Ideally, recruitment and training of staff to deliver a researched service should include support to understand (i) the rationale for evaluating services and (ii) the hierarchy of trial designs.

4.2. Treatment effects

The findings of effectiveness from this pilot study were mixed. The most robust measure of outcome, police records of offences over the period since initial release, effectively provided 100% follow up, and over the maximum possible follow up period. Of the 72 men recruited to the study, 57 were released from prison, 28 in the Resettle treatment group, and 29 in the control group. Undertaking intent-to-treat analyses did not find clear evidence of an effect of the intervention on officially recorded offending. Comparison of absolute numbers of offences between the groups found higher levels of offending in the Resettle group. However, of the participants allocated at randomisation to the Resettle group there was about a 2 times higher odds that they had *no* offending compared to participants allocated to the control group. Analyses comparing only those *participating* in the intervention with the control group found that offending numbers were reduced for the intervention group; although they were more likely to offend at all when compared to the control group, they were nonetheless offending at lower rates. Whether adopting an intent-to-treat approach or just including offenders participating in Resettle, the significant effects noted above became nonsignificant once accounting for time in the community. This inclusion may have reduced power, but this is something for future research to determine with a greater sample size.

Comparing self-reported offending found no effect of Resettle in the intent-to-treat analysis. However, research participants who also became service participants (i.e. with Resettle) reported reduced offending in the follow-up period compared to the control group. Importantly, this remained significant even after controlling for time in the community.

The findings indicate promise for the treatment without providing conclusive evidence in its favour. The police records were an objective measure not open to self-report biases. However as was evident in the differences between numbers of offences detected and those reported by participants, many go undetected; thus, they are not without bias and may not represent the entirety of offending behaviour. On the other hand, Resettle participants may have under-reported their offending more than control participants, because of optimism for their futures engendered by participation in the project. Conversely they may have been more willing to disclose further offending given their experience of a supportive relationship focussed on addressing their criminogenic needs. Comparisons of police records were also affected by the different times in the community in each of the three groups: Resettle participants, those who declined Resettle, and controls. This may have arisen from the effect on decisions about release of whether or not offenders were randomised to, or took up the offer of, Resettle treatment.

Around one half of those randomised to Resettle declined to take part. This is valuable information for the planning of treatments, and also poses a challenge to their evaluation. While intention to treat analyses provide the best indicator of effectiveness (Yelland et al., 2015), they were to some degree undermined by the inclusion of participants who did not receive any Resettle input, either while in prison or afterwards. Caution also needs to be exercised when interpreting the results as this study was designed as a feasibility study and as such was not based on an informed power calculation of the sample size needed to detect a known effect of the treatment.

4.3. Limitations

Whilst the primary outcome measure (officially recorded offences) is robust insofar as it is not subject to self-report biases that may differ between the two groups, it is likely in general to underrepresent the extent of offending. There was a lower number of participants available for follow-up than expected within the initial planned study duration due to the unexpected length of time it took for many of the participants to achieve approval for release from prison into the community. Consequently, it was necessary to extend the study by two years. Even

so, the numbers for follow-up were lower than planned. The most important limitation to any interpretation of any outcome differences between the intervention and control groups is that these findings arise from a study whose sample size is not based on a power calculation.

5. Conclusions

In spite of formidable challenges, the present study demonstrated that a high quality RCT can be conducted with very high risk personality disordered offenders. It has also documented the severity and complexity of the psychiatric needs of this population. Combining that with the rigours demanded of conducting an RCT requires joint planning and management of the treatment and the research. The findings support continued investment in this approach with refinements both of the treatment and the design of studies.

Funding

This work was supported by the 'Dangerous and Severe Personality Disorder' (DSPD) programme established by the UK Home Office and the Department of Health, 1999.

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