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Psychological interventions for antisocial personality disorder (Review)

Gibbon S, Khalifa NR, Cheung NHY, Völlm BA, McCarthy L

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[Intervention Review]

Psychological interventions for antisocial personality disorder

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ABSTRACT

Background

Antisocial personality disorder (AsPD) is associated with poor mental health, criminality, substance use and relationship difficulties. This review updates Gibbon 2010 (previous version of the review).

Objectives

To evaluate the potential benefits and adverse effects of psychological interventions for adults with AsPD.

Search methods

We searched CENTRAL, MEDLINE, Embase, 13 other databases and two trials registers up to 5 September 2019. We also searched reference lists and contacted study authors to identify studies.

Selection criteria

Randomised controlled trials of adults, where participants with an AsPD or dissocial personality disorder diagnosis comprised at least 75% of the sample randomly allocated to receive a psychological intervention, treatment-as-usual (TAU), waiting list or no treatment. The primary outcomes were aggression, reconviction, global state/functioning, social functioning and adverse events.

Data collection and analysis

We used standard methodological procedures expected by Cochrane.

Main results

This review includes 19 studies (eight new to this update), comparing a psychological intervention against TAU (also called 'standard Maintenance'(SM) in some studies). Eight of the 18 psychological interventions reported data on our primary outcomes.

Four studies focussed exclusively on participants with AsPD, and 15 on subgroups of participants with AsPD. Data were available from only 10 studies involving 605 participants.

Eight studies were conducted in the UK and North America, and one each in Iran, Denmark and the Netherlands. Study duration ranged from 4 to 156 weeks (median = 26 weeks). Most participants (75%) were male; the mean age was 35.5 years. Eleven studies (58%) were funded by research councils. Risk of bias was high for 13% of criteria, unclear for 54% and low for 33%.

Cognitive behaviour therapy (CBT) + TAU versus TAU

One study (52 participants) found no evidence of a difference between CBT + TAU and TAU for physical aggression (odds ratio (OR) 0.92, 95% CI 0.28 to 3.07; low-certainty evidence) for outpatients at 12 months post-intervention.

One study (39 participants) found no evidence of a difference between CBT + TAU and TAU for social functioning (mean difference (MD) −1.60 points, 95% CI −5.21 to 2.01; very low-certainty evidence), measured by the Social Functioning Questionnaire (SFQ; range = 0-24), for outpatients at 12 months post-intervention.

Impulsive lifestyle counselling (ILC) + TAU versus TAU

One study (118 participants) found no evidence of a difference between ILC + TAU and TAU for trait aggression (assessed with Buss-Perry Aggression Questionnaire-Short Form) for outpatients at nine months (MD 0.07, CI −0.35 to 0.49; very low-certainty evidence).

One study (142 participants) found no evidence of a difference between ILC + TAU and TAU alone for the adverse event of death (OR 0.40, 95% CI 0.04 to 4.54; very low-certainty evidence) or incarceration (OR 0.70, 95% CI 0.27 to 1.86; very low-certainty evidence) for outpatients between three and nine months follow-up.

Contingency management (CM) + SM versus SM

One study (83 participants) found evidence that, compared to SM alone, CM + SM may improve social functioning measured by family/social scores on the Addiction Severity Index (ASI; range = 0 (no problems) to 1 (severe problems); MD −0.08, 95% CI −0.14 to −0.02; low-certainty evidence) for outpatients at six months.

'Driving whilst intoxicated' programme (DWI) + incarceration versus incarceration

One study (52 participants) found no evidence of a difference between DWI + incarceration and incarceration alone on reconviction rates (hazard ratio 0.56, CI −0.19 to 1.31; very low-certainty evidence) for prisoner participants at 24 months.

Schema therapy (ST) versus TAU

One study (30 participants in a secure psychiatric hospital, 87% had AsPD diagnosis) found no evidence of a difference between ST and TAU for the number of participants who were reconvicted (OR 2.81, 95% CI 0.11 to 74.56, P = 0.54) at three years. The same study found that ST may be more likely to improve social functioning (assessed by the mean number of days until patients gain unsupervised leave (MD −137.33, 95% CI −271.31 to −3.35) compared to TAU, and no evidence of a difference between the groups for overall adverse events, classified as the number of people experiencing a global negative outcome over a three-year period (OR 0.42, 95% CI 0.08 to 2.19). The certainty of the evidence for all outcomes was very low.

Social problem-solving (SPS) + psychoeducation (PE) versus TAU

One study (17 participants) found no evidence of a difference between SPS + PE and TAU for participants' level of social functioning (MD −1.60 points, 95% CI −5.43 to 2.23; very low-certainty evidence) assessed with the SFQ at six months post-intervention.

Dialectical behaviour therapy versus TAU

One study (skewed data, 14 participants) provided very low-certainty, narrative evidence that DBT may reduce the number of self-harm days for outpatients at two months post-intervention compared to TAU.

Psychosocial risk management (PSRM; 'Resettle') versus TAU

One study (skewed data, 35 participants) found no evidence of a difference between PSRM and TAU for a number of officially recorded offences at one year after release from prison. It also found no evidence of difference between the PSRM and TAU for the adverse event of death during the study period (OR 0.89, 95% CI 0.05 to 14.83, P = 0.94, 72 participants (90% had AsPD), 1 study, very low-certainty evidence).

Authors' conclusions

There is very limited evidence available on psychological interventions for adults with AsPD. Few interventions addressed the primary outcomes of this review and, of the eight that did, only three (CM + SM, ST and DBT) showed evidence that the intervention may be more effective than the control condition. No intervention reported compelling evidence of change in antisocial behaviour. Overall, the certainty of the evidence was low or very low, meaning that we have little confidence in the effect estimates reported.

The conclusions of this update have not changed from those of the original review, despite the addition of eight new studies. This highlights the ongoing need for further methodologically rigorous studies to yield further data to guide the development and application of psychological interventions for AsPD and may suggest that a new approach is required.

PLAIN LANGUAGE SUMMARY

Psychological treatments for people with antisocial personality disorder

Background

People with antisocial personality disorder (AsPD) may behave in a way that is harmful to themselves or others and is against the law. They can be dishonest and act aggressively without thinking. Many also misuse drugs and alcohol. Certain types of psychological treatment, such as talking or thinking therapies, may help people with AsPD. Such treatments aim to change the person's behaviour, to change the person's thinking, or to help the person manage feelings of anger, self-harm, drug and alcohol abuse or negative behaviour.

This review updates one published in 2010.

Review question

What are the effects of talking or thinking therapies for adults (aged 18 years and older) with AsPD, compared to treatment-as-usual (TAU), waiting list or no treatment?

Study characteristics

We searched for relevant studies up to 5 September 2019. We found 19 relevant studies for 18 different psychological interventions. Data were reported for 10 studies involving 605 adults (aged 18 years and older) with a diagnosis of AsPD, living in the community, hospital or prison. Eight interventions reported on the main outcomes of the review (aggression, reconviction, general/social functioning and adverse events), but few had data for participants with AsPD. The studies compared a psychological intervention against TAU, which is sometimes referred to as 'standard maintenance' (SM).

Most studies were conducted in the UK or North America and were financed by grants from major research councils. They included more male (75%) participants than females (25%), the average age of which was 35.5 years. The length of the studies ranged from 4 weeks to 156 weeks. Most of the studies (10 of the 19) used methods that were flawed, which means we cannot be certain of their findings and, as a result, are unable to draw any firm conclusions.

Main results

Below, we report the findings for each comparison, where data were available for a primary outcome.

Cognitive behaviour therapy (CBT) + TAU versus TAU. There was no difference between CBT + TAU and TAU for physical aggression or social functioning but the evidence is uncertain.

Impulsive lifestyle counselling (ILC) + TAU versus TAU. There was no difference between ILC + TAU and TAU for aggression or the adverse events of death or incarceration but the evidence is very uncertain.

Contingency management (CM) + SM versus SM. CM + SM, compared to SM, may improve social functioning slightly.

'Driving whilst intoxicated' programme (DWI) + incarceration versus incarceration. There was no difference between DWI + incarceration and incarceration on reconviction (re-arrest) rates but the evidence is very uncertain.

Schema therapy (ST) versus TAU. The evidence is very uncertain about the effect of ST compared to TAU on reconviction. There is some evidence that, compared to TAU, ST may improve one aspect of social functioning: time to unescorted leave. There was no difference between ST and TAU for overall adverse events classified globally as negative outcomes but the evidence is very uncertain.

Social problem-solving therapy (SPS) + psychoeducation (PE) versus TAU. There was no difference between SPS + PE and TAU for participants' level of social functioning but the evidence is very uncertain.

Dialectical behaviour therapy (DBT) versus TAU. There was a suggestion that, compared to TAU, DBT may reduce for the number of self-harm days but the evidence is very uncertain.

Psychosocial risk management (PSRM 'Resettle' programme) versus TAU. There was no difference between PSRM and TAU for the number of offences reported one year after release from prison, or for the risk of dying during the study, although the evidence is very uncertain.

Conclusions

The review shows that there is not enough good quality evidence to recommend or reject any psychological treatment for people with a diagnosis of AsPD.

Summary of findings 1. Cognitive behaviour therapy + treatment-as-usual versus treatment-as-usual alone for antisocial personality disorder

Cognitive behaviour therapy + treatment-as-usual versus treatment-as-usual alone for antisocial personality disorder

Patient or population: adults with antisocial personality disorder
Setting: outpatient
Intervention: cognitive behaviour therapy + treatment-as-usual
Comparison: treatment-as-usual alone

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with treatment-as-usual alone	Risk with cognitive behaviour therapy + treatment-as-usual				
Aggression (any act of physical aggression) Assessed by: number reporting any act of physical aggression measured with the MacArthur Community Violence Screening Instrument (MCVSI) (9 behavioural items, rated yes/no; higher score = greater number of violent behaviour reported) Timing of assessment: 12 months	**Study population** **296 per 1000**	**279 per 1000** (17 fewer per 1000; from 191 fewer to 268 more)	**OR 0.92** (0.28 to 3.07)	52 (1 RCT)	⊕⊕⊖⊖ **Low**[a]	-
Reconviction	-	-	-	-	-	No data available
Global state/functioning	-	-	-	-	-	No data available
Social functioning Assessed by: Social Functioning Questionnaire (range of possible scores = 0-24; higher score = poorer outcome) Timing of assessment: 12 months	The mean social functioning score in the control group was **11.6 points**	The mean social functioning score in the intervention group was **1.6 points lower** (5.21 lower to 2.01 higher)	-	39 (1 RCT)	⊕⊖⊖⊖ **Very low**[b]	-
Adverse events	-	-	-	-	-	No data available

*__The risk in the intervention group__ (and its 95% CI) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: confidence interval; **OR:** odds ratio; **RCT:** Randomised controlled trial.

GRADE Working Group grades of evidence (Schünemann 2013)
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

[a]Evidence downgraded two levels overall. We downgraded one level due to limitations in the design/implementation suggested possible risk of bias ('blinding of participants' bias and possible risk of 'blinding of personnel' bias), and one level for imprecision due to optimal information size criterion not being met.
[b]Evidence downgraded three levels overall. We downgraded one level due to limitations in the design/implementation suggested possible risk of bias ('blinding of participants' bias and possible risk of 'blinding of personnel' bias), one level for imprecision due to optimal information size criterion not being met, and one level for indirectness as the outcome was measured by a questionnaire.

Summary of findings 2. Impulsive lifestyle counselling + treatment-as-usual versus treatment-as-usual alone for antisocial personality disorder

Impulsive lifestyle counselling + treatment-as-usual versus treatment-as-usual alone for antisocial personality disorder

Patient or population: adults with antisocial personality disorder
Setting: outpatient
Intervention: Impulsive lifestyle counselling + treatment-as-usual
Comparison: treatment-as-usual alone

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with treatment-as-usual alone	Risk with impulsive lifestyle counselling + treatment-as-usual				
Aggression: trait Assessed by: Buss-Perry Aggression Questionnaire - Short Form (12 items rated on 5-point Likert scale ranging from extremely uncharacteristic (1) to extremely characteristic (5); range = 12-60; high score = poor outcome) Timing of assessment: 9 months	The mean trait aggression score in the control group was **3.52 points**	The mean trait aggression score in the intervention group was **0.07 points higher** (0.35 lower to 0.49 higher)	-	118 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	-

Reconviction	-	-	-	-	-	No data available
Global state/functioning	-	-	-	-	-	No data available
Social functioning	-	-	-	-	-	No data available
Adverse events: death Assessed by: number of participant deaths between a 3- and 9-month follow-up period Timing of assessment: between 3 and 9 months	**Study population** **31 per 1000**	**13 per 1000** (19 fewer per 1000; from 30 fewer to 96 more)	**OR 0.40** (0.04 to 4.54)	142 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	-
Adverse events: incarceration Assessed by: incarceration between a 3- and 9-month follow-up period Timing of assessment: 9 months	**Study population** **156 per 1000**	**115 per 1000** (41 fewer per 1000; from 109 fewer to 100 more)	**OR 0.70** (0.27 to 1.86)	142 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	-

*__The risk in the intervention group__ (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** odds ratio; **RCT:** Randomised controlled trial.

GRADE Working Group grades of evidence (Schünemann 2013)
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

[a]Evidence downgraded three levels overall. We downgraded two levels for limitations in the design/implementation suggested high risk of bias ('incomplete outcome data/attrition' bias; possible risk of 'allocation concealment' bias, 'blinding of participants' bias, 'blinding of personnel' bias, 'blinding of outcome assessors' bias, 'selective reporting' bias and 'other' bias), and one level for imprecision due to optimal information size criterion not being met .

Summary of findings 3. Contingency management + standard maintenance versus standard maintenance alone for antisocial personality disorder

Contingency management + standard maintenance versus standard maintenance alone for antisocial personality disorder
Patient or population: adults with antisocial personality disorder

Setting: outpatient
Intervention: contingency management + standard maintenance
Comparison: standard maintenance alone

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with standard maintenance alone	Risk with contingency management + standard maintenance				
Aggression	-	-	-	-	-	No data available
Reconviction	-	-	-	-	-	No data available
Global state/functioning	-	-	-	-	-	No data available
Social functioning Assessed by: adjusted composite scores on the Family/Social domain of the Addiction Severity Index (composite scores range from no problems (0) to severe problems (1); higher score = worse outcome) Timing of assessment: 6 months	The mean social functioning score in the control group was **0.16 points**	The mean social functioning score in the intervention group was **0.08 points lower** (0.14 lower to 0.02 lower)	-	83 (1 RCT)	⊕⊕⊖⊖ **Low**[a]	Analysis based on summary data of completers supplied by the trial investigators and derived from a mixed regression model that included time-specific random effects and an interaction term (see Table 13).
Adverse events	-	-	-	-	-	No data available

*__The risk in the intervention group__ (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RCT:** Randomised controlled trial.

GRADE Working Group grades of evidence (Schünemann 2013)
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

[a]Evidence downgraded two levels overall. We downgraded one level due to possible risk of bias ('blinding of participants' bias, possible risk of 'blinding of personnel' and possible risk of 'incomplete outcome data/attrition' bias), and one level due to likely imprecision due to optimal information size criterion not met.

Summary of findings 4. 'Driving whilst intoxicated' programme + incarceration versus incarceration alone for antisocial personality disorder

'Driving whilst intoxicated programme' + incarceration versus incarceration alone for antisocial personality disorder						
Patient or population: adults with antisocial personality disorder **Setting:** prison **Intervention:** 'driving whilst intoxicated' programme + incarceration **Comparison:** incarceration alone						
Outcomes	**Anticipated absolute effects* (95% CI)**		**Relative effect (95% CI)**	**Number of participants (studies)**	**Certainty of the evidence (GRADE)**	**Comments**
	Risk with incarceration alone	**Risk with 'driving whilst intoxicated' programme + incarceration**				
Aggression	-	-	-	-	-	No data available
Reconviction (for drink-driving) Assessed by: Cox regression of re-arrest rates over 24 months Timing of assessment: 24 months	-	-	**HR 0.56** (−0.19 to 1.31)	52 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	-
Global state/functioning	-	-	-	-	-	No data available
Social functioning	-	-	-	-	-	No data available
Adverse events	-	-	-	-	-	No data available

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **HR:** hazard ratio; **RCT:** Randomised controlled trial.

GRADE Working Group grades of evidence (Schünemann 2013)

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

[a]Evidence downgraded three levels overall. We downgraded two levels for limitations in the design/implementation suggested possible risk of bias ('random sequence generation' bias, 'allocation concealment' bias, 'blinding of participants' bias, 'blinding of personnel' bias, 'blinding of outcome assessors' bias, 'incomplete outcome data/attrition' bias and 'other' bias), and one level for likely imprecision due to optimal information size criterion not being met.

Summary of findings 5. Schema therapy versus treatment-as-usual for antisocial personality disorder

Schema therapy versus treatment-as-usual for antisocial personality disorder

Patient or population: adults with antisocial personality disorder
Setting: forensic psychiatric clinic
Intervention: schema therapy
Comparison: treatment-as-usual

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with treatment-as-usual	Risk with schema therapy				
Aggression	-		-	-	-	No data available
Reconviction Assessed by: number of participants documented to have recidivated (documented as a global negative outcome) Timing of assessment: over the 3 years	**Study population** **0 per 1000**	**63 per 1000** (0 fewer to 0 more)	**OR 2.81** (0.11 to 74.56)	30 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	-
Global state/functioning	-		-	-	-	No data available
Social functioning Assessed by: mean number of days until unsupervised leave granted[b] Timing of assessment: over the 3 years	The mean number of days to unsupervised leave in the control	The mean number of days to unsupervised leave in the intervention group was**137.33 few-**	-	30 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	-

	group was**817.13 days**	**er days** (271.31 fewer to 3.35 fewer)				
Adverse events Assessed by: number of participants with a global negative outcome (e.g. dropping out of therapy, recidivism or being transferred to another facility due to poor treatment response) overall Timing of assessment: over the 3 years	**Study population** **357 per 1000**	**189 per 1000** (168 fewer per 1000; 315 fewer to 192 more)	**OR 0.42** (0.08 to 2.19)	30 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	-

*__The risk in the intervention group__ (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

AsPD: antisocial personality disorder; **CI:** confidence interval; **df:** degrees of freedom **OR:** odds ratio; **RCT:** Randomised controlled trial.

GRADE Working Group grades of evidence (Schünemann 2013)
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

[a]Evidence was downgraded three levels overall. We downgraded one level due to limitations in the design/implementation suggested high risk of bias ('selective reporting' bias; possible risk of 'blinding of participants' bias, 'blinding of personnel' bias, 'blinding of outcome assessors' bias and 'other' bias), one level for indirectness (only 87% of the population had a diagnosis of AsPD and subgroup data for AsPD only were not available), and one level for imprecision due to optimal information size criterion not being met.
[b]We chose to report 'days to unescorted leave' (rather than 'days to escorted leave'), as the measure of social functioning, as this reflects the person gaining a higher level of independence and progress. The results for 'days to escorted leave' (at both two and three years) are reported in the Effects of interventions section.

Summary of findings 6. Social problem-solving therapy + psychoeducation versus treatment-as-usual for antisocial personality disorder

Social problem-solving therapy + psychoeducation versus treatment-as-usual for antisocial personality disorder

Patient or population: adults with antisocial personality disorder
Setting: outpatient
Intervention: social problem-solving therapy + psychoeducation
Comparison: treatment-as-usual

Outcomes	Anticipated absolute effects* (95% CI)	Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments

	Risk with treatment-as-usual	Risk with social problem-solving therapy + psychoeducation				
Aggression	-	-	-	-	-	No data available
Reconviction	-	-	-	-	-	No data available
Global state/functioning	-	-	-	-	-	No data available
Social functioning Assessed by: Social Functioning Questionnaire (8 items rated on 4-point scale; anchors vary across items; high score = poor outcome) Timing of assessment: 6 months	The mean social functioning score in the control group was **11.78 points**	The mean social functioning score in the intervention group was **1.60 points lower** (5.43 lower to 2.23 higher)	-	17 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	-
Adverse events	-	-	-	-	-	No data available

*__The risk in the intervention group__ (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RCT:** Randomised controlled trial.

GRADE Working Group grades of evidence (Schünemann 2013)
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

[a]Evidence downgraded three levels overall. We downgraded one level for limitations in the design/implementation suggested possible risk of bias, one level for indirectness (the outcome was measured by questionnaire), and one level for imprecision due to optimal information size criterion not being met.

Summary of findings 7. Dialectical behaviour therapy versus treatment-as-usual for antisocial personality disorder

Dialectical behaviour therapy versus treatment-as-usual for antisocial personality disorder
Patient or population: adults with antisocial personality disorder

Setting: outpatient
Intervention: dialectical behaviour therapy
Comparison: treatment-as-usual

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with treatment-as-usual	Risk with dialectical behaviour therapy				
Aggression	-	-	-	-	-	No data available
Reconviction	-	-	-	-	-	No data available
Global state/functioning	-	-	-	-	-	No data available
Social functioning	-	-	-	-	-	No data available
Adverse events (self-harm) Assessed by: mean number of self-harm days in past 2 months Timing of assessment: 2 months	The mean number of self-harm days for participants in the DBT group was 3.6 (SD = 6.95, range = 0 to 160), compared to 12.22 (SD = 19.58, range = 0 to 57) for participants in the TAU group		-	14 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	Narrative data only (skewed data; see Table 20)

*__The risk in the intervention group__ (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **DBT:** dialectical behaviour therapy; **RCT:** Randomised controlled trial; **SD:** standard deviation; **TAU:** treatment-as-usual.

GRADE Working Group grades of evidence (Schünemann 2013)
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

[a]Evidence downgraded three levels overall, due to possible risk of bias ('blinding of participants' bias, 'blinding of personnel' bias, 'blinding of outcome assessors' bias, 'incomplete outcome data/attrition' bias and 'selective reporting' bias; downgraded one level), and likely imprecision (downgraded two levels) due to optimal information size criterion not being met as well as skewed data.

Summary of findings 8. Psychosocial risk management ('Resettle' programme) versus treatment-as-usual for antisocial personality disorder

Psychosocial risk management ('Resettle' programme) compared with treatment-as-usual (standard probation supervision) for antisocial personality disorder

Patient or population: adults with antisocial personality disorder

Settings: prison and community

Intervention: psychosocial risk management (PSRM 'Resettle' programme)

Comparison: treatment-as-usual (standard probation supervision)

Outcomes	Anticipated absolute effects (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with treatment-as-usual alone	Risk with psychosocial risk management 'Resettle'				
Aggression	-	-	-	-	-	No data available
Reconviction: total number of official offences recorded (higher number = worse outcome) Timing of the assessment: 1 year after release from prison	The mean number of official offences recorded for 16 participants in the PSRM group one year after release from prison was 4.13 (SD = 5.78, range = 0 to 22), compared to 5.21 (SD = 3.28, range = 0 to 11) for 19 participants in the TAU group		-	35 (1 study)	⊕⊖⊖⊖ **Very low**[a]	Narrative data only (skewed data), see Table 23
Global state/functioning	-	-	-	-	-	No data available
Social functioning	-	-	-	-	-	No data available
Adverse events: death during the study period Timing of assessment: 2 years after release from prison	**29 per 1000**	**26 per 1000** 3 fewer per 1000 (28 fewer to 281 more)	OR 0.89 (0.05 to 14.83)	35 (1 study)	⊕⊖⊖⊖ **Very low**[a]	-

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **OR:** Odds ratio; **PSRM:** Psychosocial risk management; **RCT:** Randomised controlled trial; **SD:** Standard deviation; **TAU:** Treatment-as-usual.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

[a]Evidence downgraded three levels overall due to high risk of bias ('blinding of personnel' bias, 'blinding of outcome assessors' bias, 'incomplete outcome data/attrition' bias, 'selective reporting' bias and 'other' bias; downgraded two levels), and likely imprecision (downgraded one level) due to optimal information size criterion not being met as well as skewed data.

BACKGROUND

Description of the condition

Antisocial personality disorder (AsPD) is one of the 10 specific personality disorder categories in the current edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5). The DSM-5 defines personality disorder as "an enduring pattern of inner experience and behaviour that deviates markedly from the expectations of the individual's culture, is pervasive and inflexible, has an onset in adolescence or early adulthood, is stable over time, and leads to distress or impairment" (p 645). The general criteria for personality disorder according to DSM-5 are given in Table 1.

AsPD is described in the DSM-5 as “a pattern of disregard for, and violation of, the rights of others” (p 645). In order to be diagnosed with AsPD (301.7) according to the DSM-5, a person must fulfil both the general criteria for personality disorder outlined above and also the specific criteria for AsPD (criteria A, B, C and D, as shown in Table 2). DSM-5 also states, in reference to the traits of AsPD, that “this pattern has also been referred to as psychopathy, sociopathy or dyssocial personality disorder” (p 659). There continues, however, to be debate about the status of psychopathy compared to AsPD (for example, see Ogloff 2006), how it is measured and the degree to which it is subject to change, which is beyond the scope of this review.

The focus of this review is AsPD, although this condition is often classified as dissocial personality disorder (F60.2) also, using the *International Classification of Diseases - 10 Edition* (ICD-10). AsPD and dissocial personality disorder are often used interchangeably by clinicians and they describe a very similar presentation. While there is considerable overlap between these two diagnostic systems, they differ in two respects. First, the DSM-5 requires that those meeting the diagnostic criteria also show evidence of conduct disorder with onset before the age of 15 years, whereas there is no such requirement when making the diagnosis of dissocial personality disorder using ICD-10 criteria. However, a study comparing participants meeting the full criteria for AsPD (which the DSM-5 has retained) with those who otherwise fulfilled criteria for AsPD but who did not demonstrate evidence of childhood conduct disorder, did not find any clinically important differences (Perdikouri 2007). Second, dissocial personality disorder focuses more on interpersonal deficits (for example, incapacity to experience guilt, a very low tolerance of frustration, proneness to blame others) and less on antisocial behaviour. Table 3 shows the ICD-10 diagnostic criteria to diagnose dissocial personality disorder (F60.2).

It is acknowledged that the classification and diagnosis of personality disorder is an area of controversy and complexity with ongoing debate about the usefulness of multiple categories of personality disorder versus a dimensional approach (Tyrer 2015; Skodol 2018), and others who feel the very label of personality disorder to be pejorative and unhelpful (Johnstone 2018, p 221). Indeed, a major paradigm shift in the conceptualisation of personality disorder is being suggested in the latest iteration of the *International Classification of Diseases* (ICD-11). The proposed ICD-11 model takes a dimensional approach and is made up of three components; a general severity rating; five maladaptive personality trait domains; and a borderline pattern qualifier (Oltmanns 2019). The proposed classification changes to personality disorder, however, are outside the scope of this review, which is focussed on interventions for AsPD, as defined in the current, predominant classification systems of DSM-5 and ICD-10.

Most studies report the prevalence of AsPD to be between 2% and 3% in the general population (Moran 1999; Coid 2006; NICE 2015). A systematic review and meta-analysis of the prevalence of personality disorders in the general adult population in Western countries found a prevalence rate for AsPD of 3% (Volkert 2018). Prevalence rates are considerably higher in men compared with women (Dolan 2009; NICE 2015) and a 3:1 ratio of men to women has been described (Compton 2005). It has also been suggested that there are sex differences in how this condition may present, with women with AsPD being less likely than men with AsPD to present with violent antisocial behaviour (Alegria 2013). AsPD (and other personality disorder diagnoses) may be less likely to be diagnosed in non-white populations (McGilloway 2010).

As would be expected, AsPD is especially common in prison settings. In the UK prison population, the prevalence of people with AsPD has been identified as 63% in male remand prisoners, 49% in male sentenced prisoners and 31% in female prisoners (Singleton 1998). A systematic review of mental disorders in prisoners examined 62 studies from 12 countries and reported the prevalence of AsPD in male prisoners to be 47%, with prisoners approximately 10 times more likely to have AsPD than the general population (Fazel 2002).

The condition is associated with a wide range of disturbance, including greatly increased rates of criminality, substance use, unemployment, homelessness and relationship difficulties (Martens 2000), as well as negative long-term outcomes. Many adults with AsPD are imprisoned at some point in their life. Although follow-up studies have demonstrated some improvement over the longer term, particularly in rates of re-offending (Weissman 1993; Grilo 1998; Martens 2000), men with AsPD who reduce their offending behaviour over time may nonetheless continue to have major problems in their interpersonal relationships (Paris 2003). Black 1996 found that men with AsPD who were younger than 40 years of age had a strikingly high rate of premature death, and obtained a value of 33 for the standardised mortality rate (the age-adjusted ratio of observed deaths to expected deaths), meaning that they were 33 times more likely to die than males of the same age without this condition. This increased mortality was linked not only to an increased rate of suicide but also to reckless behaviours such as drug misuse and aggression. A 27-year follow-up study also found AsPD to be a strong predictor of all-cause mortality (Krasnova 2019). Black 2015 noted that earlier age of onset has been linked to poorer long-term outcomes, although marriage, employment, early incarceration and degree of socialisation may act as moderating factors. Follow-up studies in forensic psychiatric settings suggest a similarly concerning picture. For example, Davies 2007 reported that 20 years after discharge from a medium-secure unit almost half of the patients were reconvicted, with reconviction rates higher in those with personality disorder compared to those with mental illness (such as schizophrenia and bipolar affective disorder). Similarly, Coid 2015 examined reconviction after discharge from seven medium-secure units in England and Wales and found that patients with personality disorder were more than two and a half times more likely than those with schizophrenia/schizoaffective disorder to violently offend after discharge.

Significant comorbidity exists between AsPD and many mental health conditions; mood and anxiety disorders are common (Goodwin 2003; Black 2010; Galbraith 2014). The presence of personality disorder co-occurring with another mental health condition may have a negative impact on the outcome of the latter (Skodol 2005; Newton-Howes 2006). There is a particularly strong association between AsPD and substance use disorders (Robins 1998). Compared to those without AsPD, those with AsPD are 15 times more likely to meet the criteria for drug dependence and seven times more likely to meet the criteria for alcohol dependence (Trull 2010). Guy 2018 reported that 77% of people with AsPD met the lifetime criteria for alcohol use disorder.

Description of the intervention

Psychological interventions have traditionally been the mainstay of treatment for AsPD, but the evidence upon which this is based is weak (Duggan 2007; Gibbon 2010; NICE 2010). Psychological therapies encompass a wide range of interventions (Bateman 2004a), and those that may be used in AsPD are drawn from all the main areas of psychological treatment. These interventions may be delivered on an individual basis, in a group, or in a mixture of group and individual sessions. By their nature, such interventions tend to be delivered over many weeks and typically last between three months and 12 months. Due to the heterogeneity of possible psychological interventions, it is beyond the scope of this review to summarise them in detail.

Table 4 gives a summary of examples of psychological interventions that may be used for this condition. Those wishing to learn more about the theoretical basis and delivery of specific therapies are directed to the references provided in Table 4.

It is important to note that this review considers all relevant studies without restriction on the type of psychological therapy, and also considers psychological interventions where drugs are given as an adjunctive intervention.

How the intervention might work

The exact mechanism of action of psychological interventions is unclear and different psychological treatments place different emphasis upon particular putative mechanisms of action. For example, cognitive behaviour therapy (CBT)-based techniques place emphasis on changing thinking patterns and behaviours, whilst more psychoanalytic-based approaches place greater emphasis on aiding the person to develop a better understanding of their current self and how this relates to their past experiences, and how unconscious processes and conflict influence interpersonal relationships. Common aspects of psychological therapies are the use of direct (usually verbal) communication between the therapist and the person, to develop a shared understanding of difficulties, and linking this to changes in thinking and behaviour (Muran 2018). These therapies may also involve changing behaviours and the environment as a way to change thinking and encourage more positive actions.

When treating AsPD, it is hoped that psychological interventions will allow the person to develop a better understanding of themselves, others and their difficulties, and that from this they will develop new skills in order to better manage themselves and life difficulties, leading to a decrease in impulsivity, anger, self-harm, rule-breaking, substance abuse and negative behaviour.

Those wishing to learn more about the theoretical basis of specific therapies are directed to the additional references provided in Table 4.

Why it is important to do this review

AsPD is an important condition that has a considerable impact on individuals, families and society. Even by the most conservative estimate, AsPD appears to have the same prevalence in men as schizophrenia, the condition that receives the greatest attention from mental health professionals. Furthermore, AsPD is associated with significant costs (Sampson 2013), arising from emotional and physical damage to people, damage to property, use of police time and involvement of the criminal justice system and prison services. Related costs include increased use of healthcare facilities, lost employment opportunities, family disruption, gambling and problems related to alcohol and substance misuse (Myers 1998; Kershaw 1999). In one study, Scott 2001, the lifetime public services costs for a group of adults with a history of conduct disorder (of which 50% will go on to develop adult AsPD) were found to be 10 times those for a similar group without the disorder.

AsPD is closely associated with criminal offending and any intervention that seeks to improve the outcome of AsPD is also likely to impact upon this offending. Aos 1999 reported that for some crimes (especially those involving violence), the cost benefits in favour of intervention are often considerable, as the costs of these types of crimes are often very high.

Despite this, there is currently a dearth of evidence on how best to treat people diagnosed with AsPD, and to date, the few reviews that have been carried out have been inconclusive and hampered by poor methodology. These issues were highlighted in Dolan and Coid's extensive review of the treatment of psychopathy and AsPD (Dolan 1993). In our previous review of psychological interventions for this condition, Gibbon 2010, we found a lack of high-quality evidence. The current NICE clinical practice guidelines on the treatment of AsPD rely heavily upon expert opinion and comment that "(a)lthough the evidence base is expanding, there are a number of major gaps..." (NICE 2010, p 9)

It had been hoped that since the last publication of this review, good-quality studies had been conducted that addressed the methodological issues highlighted in Gibbon 2010, to address this important topic.

OBJECTIVES

To evaluate the potential benefits and adverse effects of psychological interventions for people with AsPD.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) in which participants were randomly allocated to an experimental group and a control group, where the control condition was either treatment-as-usual (TAU), waiting list or no treatment. We included all relevant RCTs, with or without blinding of the assessors, that were published in any language.

Types of participants

We included studies involving adult (18 years or over) men or women with a diagnosis of AsPD or dissocial personality disorder defined by the DSM (DSM-IV; DSM-IV-TR; DSM-5) and ICD-10 diagnostic classification systems. We excluded studies of people with major functional mental illnesses (i.e. schizophrenia, schizoaffective disorder or bipolar disorder), organic brain disease, and intellectual disability. The decision to exclude persons with these conditions is based on the rationale that the presence of such disorders (and the possible confounding effects of any associated management or treatment) might obscure whatever other psychopathology (including personality disorder) might be present. However, we included studies of people diagnosed with AsPD who also had other comorbid personality disorders or other mental health problems. We placed no restrictions on setting and included studies with participants living in the community as well as those incarcerated in prison or detained in hospital settings. We included studies with subsamples of patients with AsPD provided that the data for this group were available separately. We also included studies where participants with a AsPD diagnosis comprised at least 75% of the sample. Lastly, we required studies where participants with antisocial or dissocial personality disorder formed a small subgroup to have randomised at least five people with AsPD.

Types of interventions

We included studies of psychological interventions, both group and individual-based. This included, but was not limited to, interventions such as:

- behaviour therapy;
- cognitive analytic therapy (CAT);
- cognitive behavioural therapy (CBT);
- dialectical behaviour therapy (DBT);
- psychodynamic psychotherapy;
- transference-focussed psychotherapy;
- group psychotherapy;
- mentalisation-based therapy (MBT);
- nidotherapy;
- schema therapy;
- social problem-solving therapy;
- therapeutic community (TC) treatment; and
- contingency management.

We included studies of psychological interventions where medication was given as an adjunctive intervention to all groups but reported separately any studies where the comparison was directly between a psychological and a pharmacological intervention.

We only included studies where an intervention was compared to TAU, waiting list or no treatment. We did not include head-to-head trials that compared two or more psychological interventions directly with one another without an adequate control condition.

Types of outcome measures

The primary and secondary outcomes are listed below in terms of single constructs. Given the relatively stable nature of traits of AsPD (by definition), we chose outcomes that could be subject to change and that were potentially measurable by a variety of means (including self-report and observation). Some traits, such as risk-taking, are difficult to measure directly. Given the large negative impact of aggression and reconviction, we thought these particularly important; such outcomes could represent a final common pathway encompassing a variety of traits, including failure to confirm to social norms, deceitfulness, impulsivity, recklessness, irresponsibility and lack of remorse. These outcomes are also measurable by self-report, psychometrics, observed behaviour, informant information and official records. We were also mindful of the issues described in DSM-5 (p 659): “Because deceit and manipulation are central features of antisocial personality disorder, it may be especially helpful to integrate information acquired from systematic clinical assessments with information collected from collateral sources”. We anticipated that the studies included in this review would have used a range of outcome measures (for example, aggression could have been measured by a self-report instrument or by an external observer). We provide examples of potential measures of each outcome; however, we also accepted other, similar ways of recording each outcome.

Primary outcomes

- Aggression (trait aggression or state/dynamic/current aggression; reduction in aggressive behaviour or aggressive feelings; continuous or dichotomous outcome dependent upon how this was reported), measured through changes in scores on the Aggression Questionnaire (AQ; Buss 1992) for trait aggression, the Modified Overt Aggression Scale (MOAS; Malone 1994) for state aggression, or a similar, validated instrument; or as number of observed incidents.
- Reconviction (continuous, dichotomous, or time-to-event outcome dependent upon how these data were reported), measured as reconviction in terms of the overall reconviction rate or numbers reconvicted for the sample (continuous), recidivism yes/no (dichotomous), or time to reconviction/reoffending (time-to-event data).
- Global state/functioning (continuous outcome), measured through improvement on the Global Assessment of Functioning (GAF) numeric scale (DSM-IV-TR).
- Social functioning (continuous or dichotomous outcome dependent upon how this was reported), measured through improvement in scores on the Social Adjustment Scale-Self-Report (SAS-SR; Weissman 1976), the Social Functioning Questionnaire (SFQ; Tyrer 2005b), a similar, validated instrument, or a proxy measure of social functioning (e.g. decreased level of support required/time taken to achieve leave from hospital).
- Adverse events (the incidence of overall adverse events and of the three most common adverse events; dichotomous outcome), measured as numbers reported.

Secondary outcomes

- Quality of life (self-reported improvement in overall quality of life; continuous outcome), measured through improvement in scores on the European Quality of Life (EuroQol) instrument (EuroQoL Group 1990), or a similar, validated instrument.
- Engagement with services (health-seeking engagement with services; continuous outcome), measured though improvement in scores on the Service Engagement Scale (SES; Tait 2002), or a similar, validated instrument.

- Satisfaction with treatment (continuous outcome), measured through improvement in scores on the Client Satisfaction Questionnaire-8 (CSQ-8; Attkisson 1982), or a similar, validated instrument.
- Leaving the study early (dichotomous outcome), measured as proportion of participants discontinuing treatment.
- Substance misuse (dichotomous outcome), measured as an improvement on the Substance Use Rating Scale Patient version (SURSp; Duke 1994), or a similar, validated instrument; or biological measurements of substance use (such as urine illicit drug testing). Where possible, we differentiated between drug misuse outcomes and alcohol misuse outcomes.
- Employment status (continuous outcome), measured as number of days in employment over the assessment period or similar.
- Housing/accommodation status (continuous outcome), measured as number of days living in independent housing/accommodation over the assessment period.
- Economic outcomes (any economic outcome such as cost-effectiveness; continuous outcome), measured using cost-benefit ratios or incremental cost-effectiveness ratios (ICERs).
- Impulsivity (state or trait impulsivity, self-reported improvement in impulsivity; continuous outcome), measured through reduction in scores on the Barratt Impulsivity Scale (BIS; Patton 1995), or a similar, validated instrument.
- Anger (self-reported improvement in anger expression and control; continuous outcome), measured through reduction in scores on the State-Trait Anger Expression Inventory-2 (STAXI-II; Spielberger 1999), or a similar, validated instrument.
- Mental state (continuous outcome): general mental state, such as ratings of general mental health symptoms, measured by the Brief Psychiatric Rating Scale (BPRS; Overall 1962) or the Symptom Check List-90 (SCL-90; Derogatis 1973); or specific symptoms, such as dissociative experiences measured by the Dissociative Experiences Scale (DES; Carlson 1993), mood/anxiety measured by the Hospital Anxiety and Depression Scale (HADS; Zigmond 1983), or the Beck Anxiety and Depression Scale (BADS; Beck 1988); or global mental health, measured by the Clinical Outcomes in Routine Evaluation–Outcome Measure (CORE-OM; Barkham 2001).
- Prison and service outcomes (for example, retention in community or prison programmes or use of resources such as hospital admission; continuous outcome), measured by trial authors.
- Other outcomes measured in the included studies that did not fall into one of the above categories (continuous or dichotomous outcomes dependent upon how the outcomes were reported).

Whilst acknowledging that the nature of the disorder can lead to difficulty in long-term follow-up of individuals with AsPD, we reported relevant outcomes with no restriction on period of follow-up. We divided outcomes into immediate (within six months), short-term (> six months to 24 months), medium term (> 24 months to five years) and long-term (> five years) follow-up, where there were sufficient studies to warrant this.

Search methods for identification of studies

The searches for the previous version of this review were designed to find studies for a suite of reviews on a range of personality disorders. For this update, we revised the population section of the strategy by including only the search terms relevant to antisocial personality disorder. We also made changes to the databases we searched (see Differences between protocol and review).

Electronic searches

We ran searches in the following electronic databases and trial registers in September 2016, followed by top-up searches in October 2017, October 2018 and September 2019.

- Cochrane Central Register of Controlled Trials (CENTRAL; 2019, Issue 9) in the Cochrane Library, which includes the Cochrane Developmental, Psychosocial and Learning Problems Specialised Register (searched 5 September 2019).
- MEDLINE Ovid (1946 to August Week 5 2019).
- MEDLINE In-Process & Other Non-Indexed Citations Ovid (searched 5 September 2019).
- MEDLINE Epub Ahead of Print Ovid (searched 5 September 2019).
- Embase OVID (1974 to 4 September 2019).
- CINAHL Plus EBSCOhost (Cumulative Index to Nursing and Allied Health Literature; 1937 to 5 September 2019).
- PsycINFO OVID (1967 to September Week 1 2019).
- Science Citation Index Web of Science (1970 to 5 September 2019).
- Social Sciences Citation Index Web of Science (1970 to 5 September 2019).
- Conference Proceedings Citation Index - Science Web of Science (1990 to 5 September 2019).
- Conference Proceedings Citation Index - Social Science & Humanities Web of Science (1990 to 5 September 2019).
- Sociological Abstracts Proquest (1952 to 5 September 2019).
- Criminal Justice Abstracts EBSCOhost (1910 to 5 September 2019).
- *Cochrane Database of Systematic Reviews* (CDSR; 2019, Issue 9), part of the Cochrane Library (searched 5 September 2019).
- Database of Abstracts of Reviews of Effects (DARE; 2015, Issue 2. Final Issue), part of the Cochrane Library (searched 5 September 2019).
- ClinicalTrials.gov (www.clinicaltrials.gov; searched 5 September 2019).
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP; apps.who.int/trialsearch/AdvSearch.aspx; searched 5 September 2019).
- WorldCat (limited to theses; www.worldcat.org; searched 5 September 2019).

Detailed search strategies for each of these sources are provided in Appendix 1. The searches were designed to find records for two separate reviews of interventions for AsPD or dissocial personality disorder; a) psychological interventions and b) pharmacological interventions (Khalifa 2010). For this review, we selected only those studies that were relevant to psychological interventions.

Searching other resources

We searched the reference lists of included and excluded studies for additional trials. We also examined bibliographies of systematic reviews identified in the search to identify relevant studies. We contacted the authors of relevant studies to enquire

about other sources of information, and the first author or corresponding author of each included study for information regarding unpublished data.

Data collection and analysis

In the following sections, we report only the methods that we were able to use in this review. We direct the reader to our protocol, Gibbon 2009, and Table 5, for information on additional methods that we intend to use in future updates of this review, should data permit.

Selection of studies

Working independently, two review authors read the titles and abstracts generated by the searches and discarded those that were clearly irrelevant. They next obtained the full-text reports of those deemed potentially relevant or for which more information was need to determine relevance, and assessed them against the inclusion criteria (Criteria for considering studies for this review). The reviewers resolved uncertainties concerning the appropriateness of studies for inclusion in the review through consultation with a third review author who had not been involved in the initial screening. We recorded the selection process in a PRISMA diagram (Moher 2009).

For studies reported in a language other than English, we initially examined the English version of the title and abstract, before obtaining a translation of the full paper in order to reach a decision on its eligibility.

Data extraction and management

Four review authors extracted data independently for all studies using a data extraction form (which had previously been piloted) (see Appendix 2). Where data were not available in the published trial reports, we contacted the study authors and asked them to supply the missing information. Two review authors entered the data into Review Manager 5 (Review Manager 2014), which one review author checked for accuracy. Disagreements were resolved by consultation with a third review author; less than 5% of papers required such discussion.

Assessment of risk of bias in included studies

For each included study, two review authors independently completed Cochrane's tool for assessing risk of bias (Higgins 2011b), resolving any disagreements through consultation with a third review author (from the same subgroup). We assessed the papers against the following domains:

- random sequence generation (selection bias);
- allocation concealment (selection bias);
- blinding of participants and personnel to intervention received (performance bias);
- blinding of outcome assessment (detection bias);
- incomplete outcome data (attrition bias);
- selective outcome reporting (reporting bias); and
- other sources of bias, including allegiance bias and treatment adherence.

For each domain, we allocated ratings of 'high', 'low' or 'unclear' risk of bias, where we considered the risk of bias to be high, low or uncertain or unknown, respectively.

Overall risk of bias

We assessed the overall risk of bias within studies using the method recommended by Higgins 2011b. We assessed a study at low risk of bias overall if we rated it at low risk of bias on all key domains; at unclear risk of bias overall where we assessed the study at unclear risk of bias on one or more key domains; and at high risk of bias overall where we rated the study at high risk of bias on one or more key domains. If a single domain was rated a high risk but other domains were unclear, we rated the study at high risk of bias overall. We used the results of this assessment to inform our GRADE ratings (see section on 'Summary of findings' below).

Measures of treatment effect

Dichotomous data

For dichotomous (binary) data, we used the odds ratio (OR) presented with 95% confidence intervals (CI), to summarise results within each study. We chose the OR because it has statistical advantages relating to its sampling distribution and its suitability for modelling, and because it is a relative measure and so can be used to combine studies.

Continuous data

For continuous data, such as the measurement of impulsiveness on a scale, we compared the mean score for each outcome, as determined by a standardised tool between the two groups, to give a mean difference (MD) and presented this with 95% CI. We used the mean difference (MD) where the same outcome measure was reported in more than one study, and the standardised mean difference (SMD) if studies used different outcome measures of the same construct.

We reported continuous data that were skewed in a separate table, and did not calculate treatment effect sizes, to minimise the risk of applying parametric statistics to data that departed significantly from a normal distribution. However, if the trial investigators provided results of their own statistical analysis on such data (e.g. hazard ratios), we reported their results descriptively within the section on Effects of interventions. We defined skewness as occurring when, for a scale or measure with positive values and a minimum value of zero, the mean was less than twice the standard deviation (SD) (Altman 1996).

Time-to-event data

For time-to-event data, we used the hazard ratio (HR) with 95% CI. Reconviction (dichotomous or time-to-event outcome dependent upon how this was reported), was measured as the overall reconviction rate for the sample or as an analysis of time to reconviction (please see Differences between protocol and review).

Other

Where possible, we made these comparisons at specific follow-up periods: immediate (within six months), short-term (> six months to 24 months), medium term (> 24 months to five years) and long-term (> five years) follow-up. Where possible, we presented endpoint data.

Unit of analysis issues

We did not identify any cluster-randomised trials or multi-arm trials or issues with multiplicity. For information on how we will handle

these issues should they arise in future updates of this review, please see our protocol, Gibbon 2009, and Table 5.

Dealing with missing data

We attempted to contact the original investigators to request any missing data and information on whether or not the data could be assumed to be 'missing at random'. If these data were made available to us, we included the data in the review. If data were not forthcoming, we attempted to contact at least one of the co-investigators. We permitted a reasonable length of time (at least 12 weeks) for the investigator(s) to supply the missing data before we proceeded with the analysis.

For dichotomous data, we reported missing data and dropouts for each included study, and the number of participants who were included in the final analysis as a proportion of all participants in each study. We provided reasons for the missing data in the narrative summary, where these were available.

For missing continuous data, we provided a qualitative summary. We reported missing data information in the 'incomplete outcome data' section of the 'Risk of Bias' tables.

Assessment of heterogeneity

We assessed the clinical homogeneity of studies with regard to the type of therapeutic intervention reported, the setting, and the population from which AsPD participants were drawn. We assessed the methodological heterogeneity of studies with regard to the study design. We assessed the extent of between-trial differences and the consistency of results of any meta-analysis in three ways: first, by visual inspection of the forest plots; second, by performing the Chi^2 test of heterogeneity (where a significance level less than 0.10 was interpreted as evidence of heterogeneity); and finally by examining the I^2 statistic (Higgins 2011a, section 9.5.2). The I^2 statistic describes approximately the proportion of variation in point estimates due to heterogeneity rather than sampling error. We considered I^2 values less than 30% as indicating low heterogeneity, values in the range 30% to 70% as indicating moderate heterogeneity, and values greater than 70% as indicating high heterogeneity. We attempted to identify any significant determinants of heterogeneity categorised as moderate or high.

Assessment of reporting biases

Due to insufficient data, we were unable to conduct our preplanned funnel plots (see Gibbon 2009; Table 5), to assess reporting biases.

Data synthesis

We combined comparable outcome measures across studies of clinically homogeneous interventions (where the interventions and populations did not differ substantially) in a meta-analysis using a fixed-effect model. For single studies, or where studies were too clinically diverse to be combined, we provided a narrative description of the results. Although we considered multiplicity (the concern that performing multiple comparisons increases the risk of falsely rejecting the null hypothesis), this was not an issue in this review, as the available data did not allow the making of multiple comparisons. We have outlined how we will address multiplicity in future reviews in Table 5.

Subgroup analysis and investigation of heterogeneity

Due to insufficient data we were unable to conduct any of our preplanned subgroup analyses (see Gibbon 2009; Table 5).

Sensitivity analysis

Due to insufficient data we were unable to conduct any of our preplanned sensitivity analyses (see Gibbon 2009; Table 5).

Summary of findings and assessment of the certainty of the evidence

Following the guidelines set out in Schünemann 2013, we used GRADEpro GDT software (GRADEpro) to prepare 'Summary of findings' tables for the following comparisons.

- Cognitive behaviour therapy + treatment-as-usual versus treatment-as-usual alone
- Impulsive lifestyle counselling + treatment-as-usual versus treatment-as-usual alone
- Contingency management + standard maintenance versus standard maintenance alone
- 'Driving whilst intoxicated' programme + incarceration versus treatment-as-usual alone
- Schema therapy versus treatment-as-usual
- Social problem-solving therapy + psychoeducation versus treatment-as-usual
- Dialectical behaviour therapy versus treatment-as-usual

We presented all primary outcomes (aggression, reconviction, global/state functioning, social functioning and adverse events), assessed at any time point, in the 'Summary of findings' tables, presenting pooled data where possible.

Two review authors independently assessed the overall certainty of the evidence for all primary outcomes using the GRADE approach (Schünemann 2013), which considers the risk of bias in the study, level of inconsistency, indirectness, imprecision and publication bias. We rated the certainty of the evidence for each outcome as being high, moderate, low or very low certainty, and where relevant, provided reasons for downgrading the certainty of the evidence in the footnotes. We resolved any disagreements by discussion, or in consultation with a third review author.

RESULTS

Description of studies

Results of the search

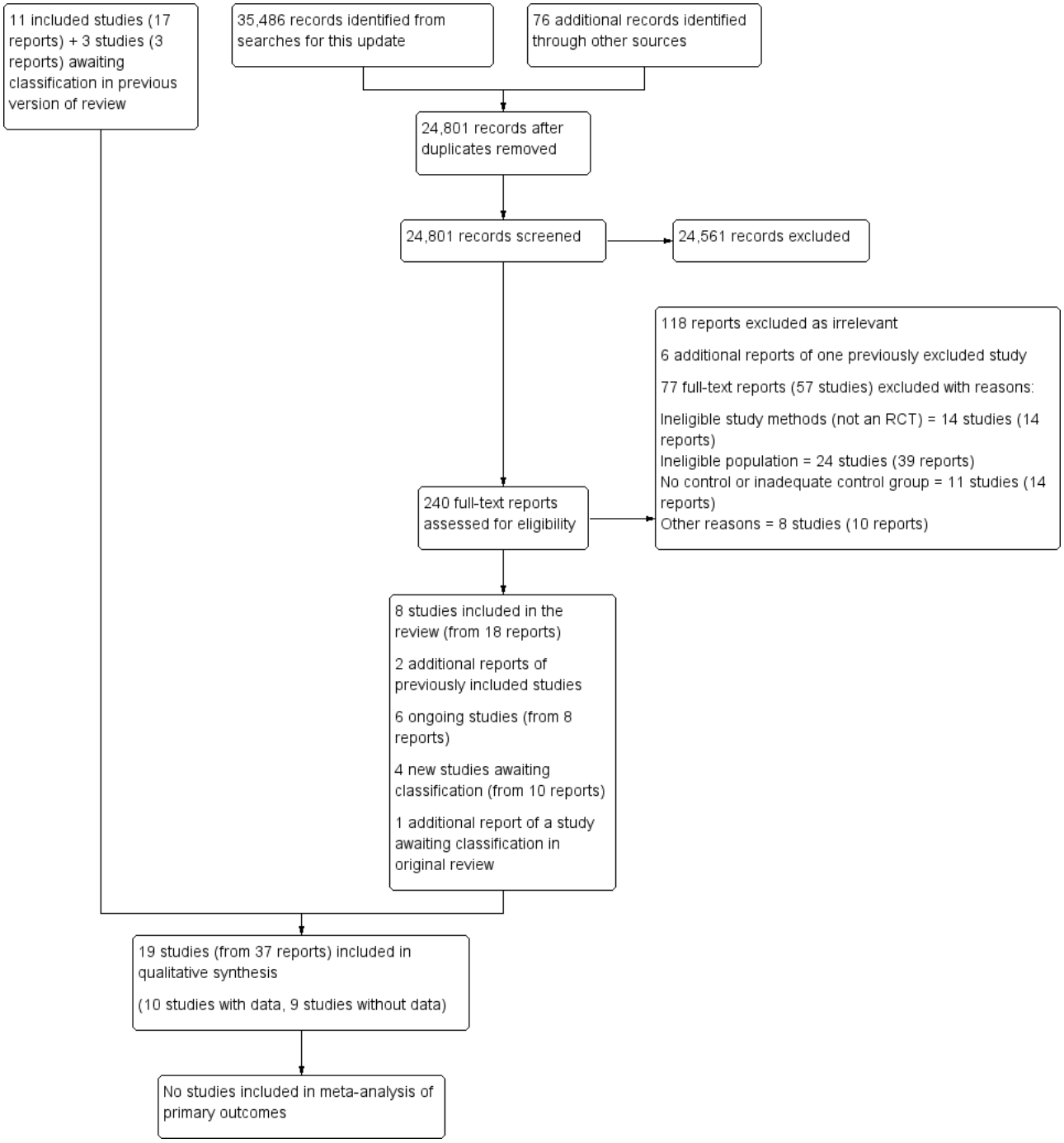
For the original version of this review (Gibbon 2010), we searched for studies from the inception of each database to September 2009. These searches identified in excess of 16,398 records, of which 48 appeared to merit closer inspection. From these, we identified 11 studies (from 17 reports) that met the inclusion criteria.

We ran the searches for this update from September 2009 to September 2019. and found a total of 35,562 records. Once duplicate records were removed, we were left with 24,801 unique records which we screened by title and abstract. We excluded 24,561 irrelevant records, and retrieved the full text of the remaining 240 records for closer inspection. From these, we identified two additional reports of previously included studies and

eight new studies (from 18 reports) that fully met the inclusion criteria. We calculated the inter-rater agreement for the selection of studies by the reviewer, which was kappa = 0.72; the strength of this agreement is classified as good by Altman 1996 (< 0.20 = poor, 0.21 to 0.40 = fair, 0.41 to 0.60 = moderate, 0.61 to 0.80 = good, 0.81 to 1.00 = very good).

In total, this review now has 19 included studies (from 37 reports) and 89 excluded studies (from 117 reports). We also identified seven studies which are awaiting classification, and six ongoing studies. The flow of studies for this updated review is shown in Figure 1, as recommended by Stovold 2014.

Figure 1. Study flow diagram showing the results of an updated literature search (5 September 2019).



Included studies

In the original version of this review (Gibbon 2010), we performed electronic searches over two consecutive time periods to minimise the difficulty in managing large numbers of citations. Searches to December 2006 produced in excess of 10,000 records. Searches from December 2006 to September 2009 produced 6398 records. These original searches identified 48 records where all or part of

the sample appeared to meet diagnostic criteria for antisocial or dissocial personality disorders, and resulted in 11 studies being included in the review. The searches in 2019 identified eight additional included studies. Further details are provided in the 'Characteristics of included studies' tables.

Design

Seventeen of the 19 included studies were parallel trials with allocation by individual participant. The two remaining studies were cluster-RCTs: Havens 2007 was a cluster-RCT where the unit of allocation was treatment site; Feigenbaum 2012 was a cluster-RCT where allocation was balanced for geographic, gender and diagnostic criteria (i.e. presence of borderline personality disorder). The 17 parallel trials included two three-armed trials (Woody 1985; Asmand 2015) and one four-armed trial (Messina 2003).

Sample sizes

There was some variation in sample size between studies. Overall, 848 participants with antisocial or dissocial personality disorder were randomised in the 17 trials where this allocation was reported unambiguously, with the size of sample ranging from 11 (Feigenbaum 2012) to 176 (Thylstrup 2015) participants (mean = 49.8, SD = 38.1). Data were available for eight trials where 100% of the sample/subsample of participants had AsPD (Woody 1985; Messina 2003; Huband 2007; Woodall 2007; Neufeld 2008; Davidson 2009; Asmand 2015; Thylstrup 2015); in these eight studies, 514 participants with antisocial or dissocial personality disorder were randomised, and the sample size ranged from 14 (Priebe 2012) to 176 (Thylstrup 2015) participants (mean = 64.3, SD = 48.4). We included, and reported separately, data from one study with an 87% subsample of participants with AsPD (AsPD n = 26) (Bernstein 2012), and data from one study with a 90% subsample of participants with AsPD (AsPD n = 65) (Nathan 2019). The number of participants completing was reported unambiguously in 11 studies (Messina 2003; Havens 2007; Woodall 2007; Neufeld 2008; Davidson 2009; Tarrier 2010; Bernstein 2012; Feigenbaum 2012; Priebe 2012; Asmand 2015; Nathan 2019), in which the proportion ranged from 55.5% (Tarrier 2010) to 100% (Woodall 2007; Asmand 2015) (mean = 83.1%).

Only four of the 19 studies focussed exclusively on participants with a diagnosis of AsPD (Neufeld 2008; Davidson 2009; Asmand 2015; Thylstrup 2015). For the remaining 15 studies, participants with antisocial or dissocial personality formed a subgroup. The size of this antisocial subgroup ranged from 11 to 65 participants, representing 3.1% to 90.3% respectively of the total sample (mean = 37.8%). Data on the entire antisocial subgroup were available to us for only four of these 15 studies (Messina 2003; Huband 2007; Woodall 2007; Priebe 2012). In line with our plan to include data where the subgroup of a sample with AsPD comprised over 75% of the total sample but where the data were not presented by subgroup, we also examined the data from Bernstein 2012 and Nathan 2019, where the AsPD subgroups consisted of 87% and 90.3% of the total sample respectively.

Setting

Eight studies were carried out in the UK (Tyrer 2004; Huband 2007; Davidson 2009; Tarrier 2010; Feigenbaum 2012; Priebe 2012; McMurran 2016; Nathan 2019), eight took place in North America (Woody 1985; McKay 2000; Messina 2003; Ball 2005; Havens 2007; Marlowe 2007; Woodall 2007; Neufeld 2008), with a single study each from Denmark (Thylstrup 2015), Iran (Asmand 2015) and the Netherlands (Bernstein 2012). Nine were multicentre trials: Messina 2003 and Davidson 2009 with two sites; Tyrer 2004 and Huband 2007 with five sites; Bernstein 2012 with seven sites; Havens 2007 with 10 sites; Thylstrup 2015 with 13 sites; Nathan 2019 with 21 sites; and McMurran 2016 with an unspecified number of sites. Two studies took place in a hospital inpatient setting (Tarrier 2010; Bernstein 2012). Thirteen studies took place in an outpatient or community setting, and three studies took place in a prison or custodial environment (Marlowe 2007; Woodall 2007; Asmand 2015). Two studies took place in a community or custodial environment, or both (Thylstrup 2015; Nathan 2019).

Participants

Seven studies restricted participants to males (Woody 1985; McKay 2000; Davidson 2009; Tarrier 2010; Bernstein 2012; Asmand 2015; Nathan 2019). The remaining 12 studies had a mix of male and female participants, with all but four of these studies randomising more men than women (Tyrer 2004; Feigenbaum 2012; Priebe 2012; McMurran 2016). The overall mix was 75% men compared to 25% women. All 19 studies involved adult participants, with the mean age per study ranging between 25.1 and 43.5 years (mean = 35.5 years, SD = 5.2).

Nine studies focussed on participants with substance misuse difficulties. For these, inclusion criteria included: opioid substance dependence disorder (Woody 1985; Neufeld 2008); cocaine dependence disorder (McKay 2000; Messina 2003); recent alcohol or drug use whilst homeless (Ball 2005); being an intravenous drug user (Havens 2007); being sentenced for a drug-related offence (Marlowe 2007); being sentenced for driving whilst intoxicated (Woodall 2007); and receiving outpatient treatment for substance (drug or alcohol) use disorder (Thylstrup 2015). The remaining 10 studies did not recruit participants on the basis of substance misuse. For these studies, the focus was on recurrent self-harm (Tyrer 2004), violence (Davidson 2009), meeting DSM-IV criteria for any personality disorder (Huband 2007; Tarrier 2010; Feigenbaum 2012; Priebe 2012; McMurran 2016), meeting DSM-IV criteria for AsPD (Asmand 2015), meeting criteria for any cluster B personality disorder (Bernstein 2012), or high-risk personality disordered offenders (Nathan 2019).

The precise definition of AsPD and the method by which it was assessed varied between the studies. Eighteen studies included participants with AsPD (under DSM criteria).

- Fourteen studies used DSM-IV criteria. Six of these studies made assessments using the Structured Clinical Interview for DSM-IV Axis II Personality Disorders (SCID-II) (Messina 2003; Havens 2007; Davidson 2009; Tarrier 2010; Feigenbaum 2012; Priebe 2012). For the remaining eight studies, one used an antisocial PD interview developed by the investigators from the SCID-II (Marlowe 2007); one study used the Personality Disorder Questionnaire (Ball 2005); three studies used the International Personality Disorder Examination (Huband 2007; McMurran 2016; Nathan 2019); one study used the Structured Interview for DSM-IV Personality Disorders (Bernstein 2012); one study used the Millon Clinical Multiaxial Inventory (Asmand 2015); and one study used the Mini International Neuropsychiatric Interview (Thylstrup 2015).

- Three studies used DSM-III-R criteria and made assessments using the SCID-II (McKay 2000; Neufeld 2008), or the Diagnostic Interview Schedule (Woodall 2007).
- One earlier study used DSM-III criteria and made assessments using the Schedule for Affective Disorders & Schizophrenia and the Maudsley Personality Inventory (Woody 1985).
- One study used ICD-10 criteria and made assessments using the PAS-Q Quick Personality Assessment Schedule (Tyrer 2004).

Five studies did not report the ethnicity of participants (Tyrer 2004; Huband 2007; Bernstein 2012; Feigenbaum 2012; Thylstrup 2015). Where ethnicity was reported, the proportion of the sample described by the investigators as either 'white' or 'Caucasian' ranged from 7% (McKay 2000) to 94.5% (Nathan 2019). The total proportion of white participants randomised (expressed as a percentage of the total number randomised) was 53.5% for those studies where this information was available (Woody 1985; McKay 2000; Messina 2003; Ball 2005; Marlowe 2007; Woodall 2007; Neufeld 2008; Davidson 2009; Tarrier 2010; Priebe 2012; McMurran 2016; Nathan 2019).

Interventions

The following types of interventions were represented: case-management (Havens 2007); cognitive behaviour therapy (Tyrer 2004; Davidson 2009); cognitive behaviour therapy + standard maintenance (Messina 2003); cognitive behaviour therapy + contingency management + standard maintenance (Messina 2003); contingency management (Messina 2003; Neufeld 2008); dialectical behaviour therapy (Feigenbaum 2012; Priebe 2012; Asmand 2015); 'driving whilst intoxicated' programme (Woodall 2007); dual focus schema therapy (Ball 2005); impulsive lifestyle counselling (Thylstrup 2015); optimal judicial supervision (Marlowe 2007); psychoeducation and social problem-solving therapy (Huband 2007); psychoeducation + social problem-solving therapy + treatment-as-usual (TAU) (McMurran 2016); psychosocial risk management (Nathan 2019); rational emotive behaviour therapy (Asmand 2015); relapse prevention (McKay 2000); schema modal therapy (Tarrier 2010); schema therapy (Bernstein 2012); and supportive expressive psychotherapy (Woody 1985). Interventions that were group-based may have included elements of group psychotherapy, depending on how group psychotherapy was defined. None of the 19 included studies evaluated therapeutic community treatment, cognitive analytic therapy, mentalisation-based therapy or nidotherapy.

The duration of the interventions ranged between four (Ball 2005) and 156 weeks (Tarrier 2010; Bernstein 2012) (mean = 55.8 weeks, median = 26 weeks). Thirteen studies followed up participants beyond the end of the intervention period by, on average, 52 weeks (range = 4 to 104 weeks) (McKay 2000; Messina 2003; Tyrer 2004; Ball 2005; Havens 2007; Marlowe 2007; Woodall 2007; Tarrier 2010; Feigenbaum 2012; Priebe 2012; Thylstrup 2015; McMurran 2016; Nathan 2019). One study, Bernstein 2012, had not yet completed the follow-up stage of the study at the time of this review.

Full details of the psychological interventions are provided in the 'Characteristics of included studies' tables and summarised in Table 6.

Control conditions

The 19 included studies compared the 18 psychological interventions to a relevant control condition (i.e. TAU, waiting list or no treatment), as required by the inclusion criteria for this review (see Types of studies). Full details are provided in the 'Characteristics of included studies' tables and summarised in Table 7. It is important to note that participants allocated to the experimental condition in these studies commonly received some degree of TAU in addition to the intervention under evaluation. We considered that all 19 studies had a control condition that could be described as TAU. This decision was straightforward for 13 of the 19 studies, as follows. For seven studies, it was clear that TAU simply comprised whatever treatment the participants would have received had the trial not taken place (Tyrer 2004; Davidson 2009; Tarrier 2010; Bernstein 2012; Feigenbaum 2012; Priebe 2012; McMurran 2016). For one study, Huband 2007, TAU was the treatment they had whilst on the waiting list for the intervention. In the five remaining studies, TAU was passive referral in Havens 2007, standard ('unmatched') scheduled court hearings in Marlowe 2007, incarceration in Woodall 2007 and Asmand 2015, and standard probation supervision following release from prison custody in Nathan 2019.

For the remaining six studies, all of which focussed on participants with substance misuse difficulties, we considered carefully whether the control condition was TAU or an intervention in its own right. In each case, we concluded that the control condition could properly be described as TAU because it represented what a treatment-seeking participant with similar substance misuse problems would normally experience had the trial not taken place. The control conditions for these six studies are summarised below.

- Woody 1985: standard drug counselling, which the investigators described as "a standard individual counselling intervention focussed on providing external services rather than dealing with intra-psychic processes", plus standard methadone maintenance.
- McKay 2000: two group therapy sessions per week based on addictions counselling and 12-step recovery practices, which the trial investigators described as "standard continuing care treatment".
- Messina 2003: one counselling session per fortnight, standard methadone maintenance, case management visits and medical care, which the trial investigators described as "methadone maintenance".
- Ball 2005: up to three sessions per week of group counselling and psychoeducation sessions plus standard methadone maintenance, where appropriate, which the trial investigators described as "standard group substance abuse counselling".
- Neufeld 2008: two individual counselling sessions per week with standard methadone maintenance treatment, which the trial investigators described as "standard methadone treatment".
- Thylstrup 2015: access to opioid substitution treatment (if required); psychosocial support such as casework, counselling, or referral to residential rehabilitation; or referral to 'off-site' psychiatrist for treatment of other psychiatric conditions (if required).

None of the active interventions were used as the control condition in any of the studies.

Outcomes

Primary outcomes

There were five studies that did not report on any of the primary outcomes defined in the protocol for this review (Gibbon 2009): Woody 1985; McKay 2000; Messina 2003; Havens 2007 and Asmand 2015. For the 14 studies that did report on one or more of our primary outcomes, we provide a summary below of which studies assessed which primary outcomes.

- Five studies included aggression as an outcome: Davidson 2009, Tarrier 2010, Bernstein 2012, Feigenbaum 2012 and Thylstrup 2015.
- Four studies included reconviction as an outcome: Marlowe 2007, Woodall 2007, Bernstein 2012 and Nathan 2019.
- Three studies reported global state/functioning as an outcome: Tyrer 2004 and McMurran 2016, both of whom used the Global Assessment of Functioning (GAF) scale; and Bernstein 2012 who reported a dichotomous global outcome for participants.
- Eight studies included self-reported social functioning as an outcome: Tyrer 2004, Huband 2007, Davidson 2009 and McMurran 2016, all of whom used the Social Functioning Questionnaire; and Ball 2005, Neufeld 2008, Tarrier 2010 and Bernstein 2012 who used other methods.
- Seven studies reported data on adverse events: Tyrer 2004, Marlowe 2007, Feigenbaum 2012, Priebe 2012, Thylstrup 2015, McMurran 2016, and Nathan 2019.

Please see Appendix 3 for full details of all the primary outcomes and measures used.

Secondary outcomes

Fourteen of the included studies addressed one or more of the secondary outcomes defined in this review. Below, we provide a summary of which studies assessed which secondary outcomes. Please see Appendix 3 for full details of all the secondary outcomes.

- Three studies reported on quality of life: Tyrer 2004, Priebe 2012 and McMurran 2016.
- Four studies reported on engagement with services: Havens 2007, Neufeld 2008, Bernstein 2012 and McMurran 2016.
- Only a single study examined satisfaction with treatment: Davidson 2009.
- Thirteen studies reported data on leaving the study early: Woody 1985, McKay 2000, Messina 2003, Ball 2005, Marlowe 2007, Neufeld 2008, Davidson 2009, Tarrier 2010, Bernstein 2012, Priebe 2012, Thylstrup 2015, McMurran 2016 and Nathan 2019. Of these 13 studies, four had data available for participants with AsPD: Messina 2003, Neufeld 2008, Davidson 2009 and Thylstrup 2015.
- Eight studies reported on substance misuse. To aid interpretation, we considered substance misuse as two separate outcomes: substance misuse - drugs; and substance misuse - alcohol. Six studies examined substance misuse - drugs: Woody 1985, McKay 2000, Messina 2003, Marlowe 2007, Neufeld 2008 and Thylstrup 2015. Six studies examined substance misuse - alcohol: McKay 2000, Marlowe 2007, Woodall 2007, Neufeld 2008, Davidson 2009 and Thylstrup 2015.
- Two studies considered employment status: Neufeld 2008 and McMurran 2016.
- Four studies considered economic outcomes: Tyrer 2004, Davidson 2009, Priebe 2012 and McMurran 2016 examined direct economic outcomes; and Feigenbaum 2012 and McMurran 2016 examined indirect economic outcomes.
- Two studies measured self-reported impulsivity: Huband 2007 and Tarrier 2010.
- Four studies included a self-reported measure of anger: Huband 2007, Davidson 2009, Tarrier 2010 and Feigenbaum 2012.
- Eight studies assessed mental state: Woody 1985, Davidson 2009, Tarrier 2010, Bernstein 2012, Feigenbaum 2012, Priebe 2012, Asmand 2015 and McMurran 2016.
- Six studies assessed other outcomes. Four of these six studies assessed early maladaptive schemas and schema modes (Ball 2005; Davidson 2009; Tarrier 2010; Bernstein 2012), and two studies assessed dissociation using the Dissociative Experiences Scale (DES) (Huband 2007; Feigenbaum 2012).

No study assessed housing/accommodation status or prison/service outcomes.

Appendix 3 provides details of other relevant outcomes reported by the included studies; this includes details of psychometric assessments of mental state, measurements of change on risk assessment tools, and measures of therapy adherence.

Study funding sources

The 19 included studies were funded by a variety of sources, including research councils, government departments, charities and commercial organisations. Of the 19 studies, 13 were funded by grants from a single organisation; five studies received financial support from two or more organisations (Huband 2007; Bernstein 2012; Feigenbaum 2012; Thylstrup 2015; Nathan 2019); and one study was not directly funded (Asmand 2015). Eleven studies were funded through grants from major research councils such as: Medical Research Council (UK) (Tyrer 2004; Davidson 2009); National Institute for Health Research (UK) (Priebe 2012; McMurran 2016); National Institute on Alcohol Abuse and Alcoholism (USA) (Woodall 2007); National Institute on Drug Abuse (USA) (Woody 1985; McKay 2000; Messina 2003; Havens 2007; Marlowe 2007; Neufeld 2008). Four studies were fully or partially funded by government departments (Huband 2007; Tarrier 2010; Bernstein 2012; Nathan 2019) and two studies were funded by not-for-profit or charitable organisations (Ball 2005; Thylstrup 2015); Thylstrup 2015 was also partially funded by a commercial organisation. Full details of study funding is provided in the 'Notes' section in each of the Characteristics of included studies tables.

Excluded studies

We excluded a total of 201 full-text reports from the updated searches; 118 reports were irrelevant and are not reported in any more detail. The remaining 57 studies (from 77 reports) initially appeared to meet the inclusion criteria, but on closer inspection did not. The reasons for excluding these studies are reported in the Characteristics of excluded studies table following guidance in Chapter Four of the *Cochrane Handbook of Systematic Reviews of Interventions* (Lefebvre 2019), together with details of 32 studies excluded from the original review (Gibbon 2010). Two additional studies excluded from the previous review are actually additional reports of Vinnars 2005 and treated as such in this update. Readers are advised that studies may be excluded for multiple reasons and not all reasons may be noted.

In summary, we excluded 89 studies (from 117 reports) for the following reasons: 19 studies were not RCTs; 38 studies had an ineligible population (e.g. AsPD was a diagnosis of exclusion, no AsPD participants, comorbid diagnosis of a major mental illness); 21 studies used a control condition that was not considered to be TAU, waiting list, or a 'no treatment' control; 11 studies for other reasons (e.g. insufficient number of AsPD participants to allow the mean or SD to be calculated for group data, non-psychological intervention).

Studies awaiting classification

In the original review (Gibbon 2010), we categorised three studies as awaiting classification (Evans 1999; Linehan 2006; Berget 2008). We identified a new citation for Berget 2008 in the updated searches and sought clarification from the trial investigators; however, no further information was available at the time this review was prepared.

The updated searches identified a further four studies categorised as awaiting classification. Of these, there were three studies of psychological treatments for samples of participants with a mixture of personality disorders, where it remains unclear whether or not a subgroup of participants with a diagnosis of antisocial or dissocial personality disorder have been included (Clarke 2013; Jochems 2015; Black 2016). We sought clarification from the trial investigators; however, no further information was available at the time this review was prepared. We also identified one study where the study authors provided a manuscript that was 'under review' with a journal, but not yet published (Buric 2019).

We summarise these seven studies below. Further details on these studies are provided in the Characteristics of studies awaiting classification tables.

- Evans 1999 compared manual assisted cognitive behavioural therapy (MACT) with TAU for individuals with a recent self-harm episode and personality disturbance. The study may have a subgroup of participants with a diagnosis of AsPD.
- Linehan 2006 compared dialectical behaviour therapy with community treatment by experts for women with recent suicidal and self-injurious behaviours meeting the criteria for borderline personality disorder (BPD). The study may have recruited a subgroup with AsPD since 11 of 101 participants (10.9%) had a cluster B personality disorder other than BPD.
- Berget 2008 compared animal-assisted therapy with a control condition in individuals with psychiatric disorders, and may have recruited a subgroup with dissocial personality disorder, since 22 of the 90 participants had a disorder diagnosed under sections F60 to 69 (disorders of adult personality and behaviour) in the ICD-10.
- Clarke 2013 compared cognitive analytic therapy + TAU with TAU alone in individuals with personality disorder referred to a specialist outpatient service. Of the 99 randomised participants, at least 18 had a cluster B personality disorder. We contacted the trial author with a request to identify the potential number of participants with AsPD.
- Jochems 2015 compared motivational feedback with TAU for patients receiving individual outpatient treatment for a mental disorder. Ordinarily, this study would meet the exclusion criteria for this review as it included patients with psychotic disorders. However, it reported an interaction effect of personality disorder on outcomes. Correspondence with the study author confirmed 25/294 (8%) participants with AsPD at baseline and 12/254 (5%) participants with AsPD at follow-up; however, further clarification is required regarding the presence or absence of comorbid psychotic disorder.
- Black 2016 reported a secondary analysis of previously unpublished data from two studies of Systems Training for Emotional Predictability and Problem Solving (STEPPS) + TAU compared with TAU. Published data are provided for AsPD participants in the intervention group (n = 16) and the reviewers contacted the study author to request information on any AsPD participants in the control group.
- Buric 2019 reported unpublished data comparing mindfulness meditation, yoga, and waiting-list control for inmates in a clinical prison unit for individuals with severe personality disorder.

Ongoing studies

Six ongoing studies were identified in the updated searches (NCT03883646; NCT02524171; ISRCTN32309003; ISRCTN14994755; Van Dijk 2019; NCT04033835). A brief summary of these studies is provided below; comprehensive details of the studies can be found in the Characteristics of ongoing studies tables.

- NCT03883646 is comparing mindfulness, relapse prevention, waiting-list control and TAU (intervention duration is not stated) for female prisoners with alcohol use disorders. The study investigators have confirmed that they are assessing antisocial personality disorder and psychopathy (NCT03883646). The primary outcomes of the study include alcohol craving, alcohol consumption, temptation to drink alcohol and criminal behaviour.
- NCT02524171 is comparing a 12-week, group-based, cognitive-behavioural intervention (moral reconation therapy plus usual care) with usual care for veterans with AsPD or substance use disorder (or both). The primary outcome of the trial is risk for criminal recidivism. Secondary outcomes include substance use, mental health and housing/employment problems.
- ISRCTN32309003 is comparing a group or individual intervention (one-hour session of individual MBT plus 75 minutes, group-based mentalisation, once a month for 12 months) with probation-as-usual for male offenders who have a history of violent behaviour. The primary outcome is frequency of aggressive acts. Secondary outcomes include changes in psychometric assessment of clinical outcomes, anger, social functioning, impulsiveness, alcohol and drug use, service engagement, client satisfaction and suicidal/self-harm behaviour.
- ISRCTN14994755 compared a flexible intervention (six to 10 sessions of psychological support for personality delivered over three to six months) with TAU for adults using secondary care mental health services. The primary outcomes of the trial were social functioning, mental well-being, suicidal thoughts, health-related quality of life, satisfaction with care, resources use/costs, and change in mental health. The secondary outcome was participant confidence in their ability to 'get yourself through difficult times and situations'.
- Van Dijk 2019 compared 18-week, group schema-focussed therapy enriched with psychomotor therapy with TAU for older adults (60 years or older) with personality disorder. The primary

outcomes of the study were psychological distress, quality of life and cost-effectiveness. The secondary outcomes were life satisfaction, mental well-being, personality functioning, interoceptive body awareness, substance use and mental state.

- NCT04033835 is comparing 18 months of introductory mentalisation-based treatment with TAU for male sentenced prisoners with borderline or antisocial personality disorder (or both). The primary outcome of the study is successful completion of the study. The secondary outcomes of the study are change in interpersonal functioning, impulsivity, mental state, depressive symptoms, anxiety symptoms, social functioning, global functioning, challenging behaviour and satisfaction with treatment.

Risk of bias in included studies

There was considerable variation in how the included studies were reported. We attempted to contact the investigators wherever the available trial reports provided insufficient information for decisions to be made about the likely risk of bias.

We summarise below the risk of bias for the 19 included studies. Studies with data that could be extracted for the antisocial or dissocial personality disorder subgroup (10 studies: made up of 100% AsPD subgroup (eight studies: Messina 2003; Huband 2007; Woodall 2007; Neufeld 2008; Davidson 2009; Priebe 2012; Asmand 2015; Thylstrup 2015); or > 75% AsPD in sample (2 studies: Bernstein 2012 and Nathan 2019)) are summarised separately from those for which data were unavailable (nine studies: Woody 1985; McKay 2000; Tyrer 2004; Ball 2005; Havens 2007; Marlowe 2007; Tarrier 2010; Feigenbaum 2012; McMurran 2016). This allows the reader to make a separate judgement about possible bias associated with the quantitative data from which conclusions are drawn in this review. Full details of our assessment of the risk of bias in each included study are tabulated within the 'Risk of bias' tables in the 'Characteristics of included studies' section. Graphical summaries of the risk of bias in each included study are presented in Figure 2 and Figure 3.

Figure 2. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.

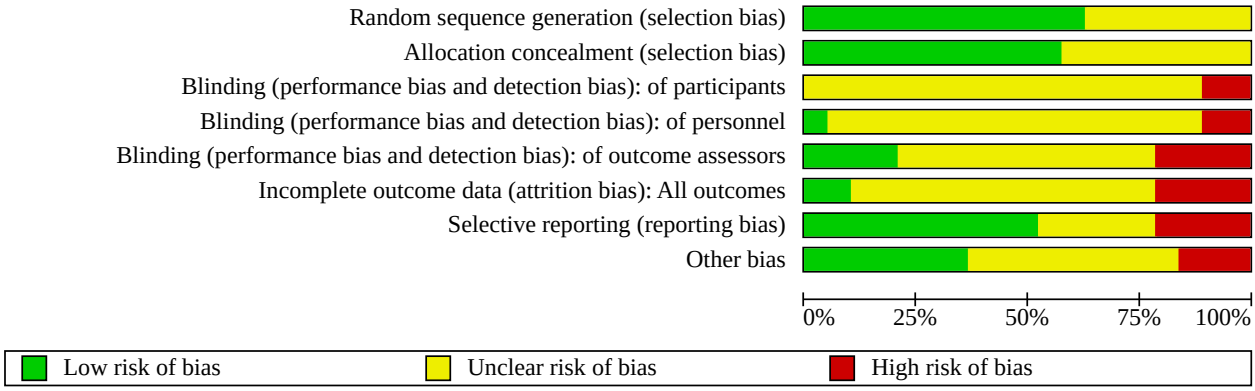
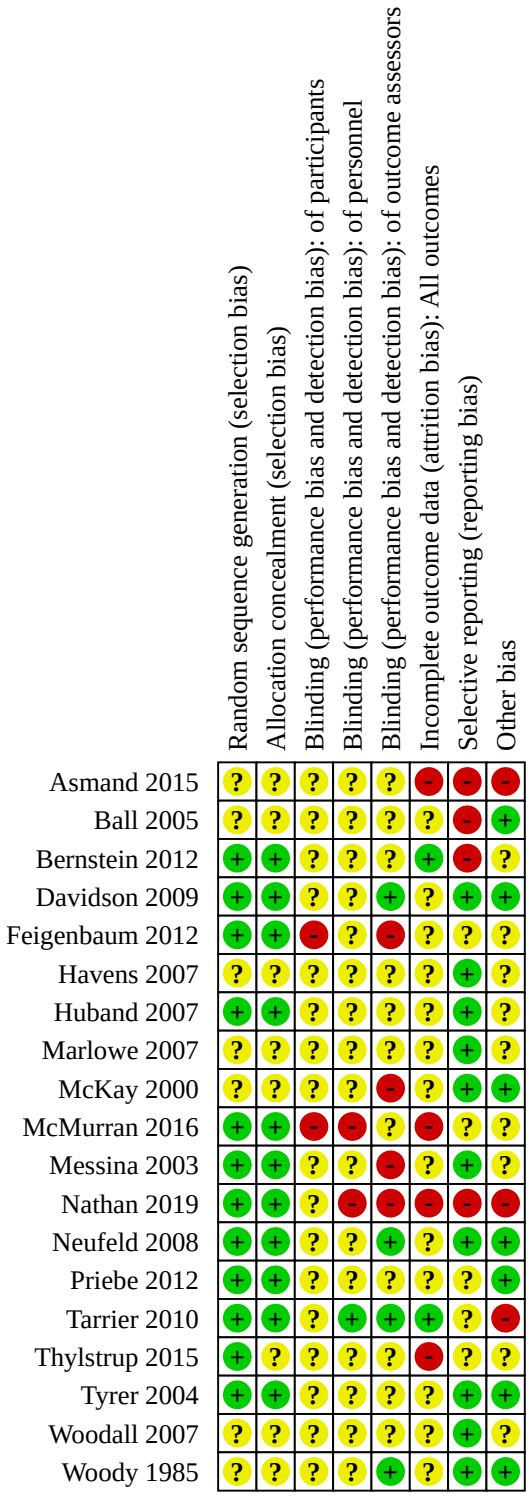


Figure 3. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.



Allocation

Sequence generation

With data (10 studies)

We considered the generation of allocation sequence to be adequate in eight studies where allocation was by random numbers that were: computer-generated (Huband 2007; Davidson 2009; Bernstein 2012; Priebe 2012; Thylstrup 2015; Nathan 2019); derived from a table (Messina 2003); or used the toss of coin (Neufeld 2008). We classified the adequacy of the sequence generation as unclear in the remaining two studies: Woodall 2007, where the investigators reported that participants had been allocated at random but provided no further information on how this had been achieved; and Asmand 2015 where use of a random number table was indicated in the study protocol, but not reported in the paper.

Without data (nine studies)

We classified sequence generation as adequate for four studies: Tyrer 2004 and McMurran 2016 (computer-generated random numbers); and Tarrier 2010 and Feigenbaum 2012 (telephone randomisation process). We rated the sequence generation as unclear for the remaining five studies (Woody 1985; McKay 2000; Ball 2005; Havens 2007; Marlowe 2007). In each case, the investigators reported that participants had been allocated at random, but provided no further information on how this had been achieved.

Allocation concealment

With data (10 studies)

We considered concealment of the allocation sequence adequate for seven studies (Messina 2003; Huband 2007; Neufeld 2008; Davidson 2009; Bernstein 2012; Priebe 2012; Nathan 2019), where we considered that there was sufficient evidence that the person enrolling participants could not have foreseen assignment. We classified the adequacy of sequence concealment as unclear in three studies (Woodall 2007; Asmand 2015; Thylstrup 2015), because the information available was insufficient to allow a judgment to be made.

Without data (nine studies)

We considered concealment of the allocation sequence adequate for four studies due to stated methodology: Tyrer 2004; Tarrier 2010; Feigenbaum 2012; and McMurran 2016. We classified the adequacy of sequence concealment as unclear in the remaining five studies (Woody 1985; McKay 2000; Ball 2005; Havens 2007; Marlowe 2007), again because the information available was insufficient to allow a judgement to be made.

Blinding

Performance bias

We judged 17 studies to be an unclear risk of performance bias for participants because it was not clear whether or not participants could have foreseen treatment allocation. We considered two studies, Feigenbaum 2012 and McMurran 2016, to be at high risk of bias because participants were not blinded to treatment allocation.

We judged that blinding of personnel involved in the delivery of the intervention was not practical in the design of trials of psychological interventions summarised in this review. For this reason, we judged 16 studies to be at an unclear risk of performance bias for personnel. We considered two studies, McMurran 2016 and Nathan 2019, to be at high risk of bias because personnel were not blinded to treatment allocation. We judged only one study, Tarrier 2010, to be at low risk of bias for blinding of personnel because the evaluation was conducted by an independent team.

Detection bias

With data (10 studies)

We considered the adequacy of blinding of outcome assessors to be adequate in two studies and that it was unlikely that this blinding could have been broken (Neufeld 2008; Davidson 2009). Two studies did not blind the outcome assessors and so we rated these at high risk of detection bias (Messina 2003; Nathan 2019). We classified the six remaining studies at unclear risk of detection bias because the information available was insufficient to allow a judgment to be made (Huband 2007; Woodall 2007; Bernstein 2012; Priebe 2012; Asmand 2015; Thylstrup 2015).

Without data (nine studies)

We judged the adequacy of blinding of outcome assessors to be adequate for two studies due to stated methodology (Woody 1985; Tarrier 2010), and not adequate for two studies as assessors were informed of the treatment condition (McKay 2000), or could mostly identify the treatment group of the patient (Feigenbaum 2012). In the remaining five studies (Tyrer 2004; Ball 2005; Havens 2007; Marlowe 2007; McMurran 2016), there was insufficient information to allow a judgement to be made.

Incomplete outcome data

With data (10 studies)

We judged a single study to have adequately addressed attrition bias (Bernstein 2012). We classified three studies as inadequately addressing attrition bias (Asmand 2015; Thylstrup 2015; Nathan 2019) and the remaining six studies at unclear risk of attrition bias because, although numbers were balanced approximately between treatment conditions, the reasons for attrition were not available (Messina 2003; Huband 2007; Woodall 2007; Neufeld 2008; Davidson 2009; Priebe 2012). This generally arose because participants failed to complete endpoint measures without providing a reason. Three of these six studies reported undertaking an intention-to-treat analysis for at least one primary or secondary outcome (Huband 2007; Davidson 2009; Priebe 2012), and four provided analysis for those participants classed by the investigators as 'completers' (Messina 2003; Woodall 2007; Neufeld 2008; Priebe 2012).

Without data (nine studies)

We judged a single study, Tarrier 2010, to have adequately addressed attrition bias. We classed seven studies at unclear risk of attrition bias because it was not possible, in the absence of data from the subgroup with antisocial or dissocial personality disorder, to judge the extent and nature of any missing data and whether the reasons for such missing data were balanced across intervention groups. We judged a single study, McMurran 2016, at high risk of attrition bias. This study was terminated early due to safety concerns and reported the use of multiple data imputation.

Selective reporting

With data (10 studies)

We judged five studies at low risk of reporting bias as they appeared to have reported on all the measures they set out to use, and at all time scales, in as far as could be discerned from the published reports without access to the original protocols (Messina 2003; Huband 2007; Woodall 2007; Neufeld 2008; Davidson 2009). We classified two studies at unclear risk of reporting bias as there was insufficient information on which to make a judgement (Priebe 2012; Thylstrup 2015). We assessed three studies as having a high risk of reporting bias due to non-reporting of stated outcomes (Bernstein 2012; Asmand 2015; Nathan 2019) . Bernstein 2012 acknowledged selective reporting as a consequence of the publication of preliminary and incomplete trial data.

Without data (nine studies)

We judged five studies at low risk of reporting bias as they appeared to have reported on all the measures they set out to use, and at all time scales, in as far as could be discerned from the published reports without access to the original protocols (Woody 1985; McKay 2000; Tyrer 2004; Havens 2007; Marlowe 2007). We classified three studies at unclear risk of reporting bias as there was insufficient information on which to make a judgement (Tarrier 2010; Feigenbaum 2012; McMurran 2016). We assessed one study as having a high risk of reporting bias due to the non-reporting of endpoint or follow-up data for three stated outcomes (Ball 2005).

Other potential sources of bias

With data (10 studies)

We considered two studies to be at high risk of other potential sources of bias (Asmand 2015; Nathan 2019). Asmand 2015 was judged to be at high risk of language or comprehension bias due to the poor quality of the English-language translation and the numerous typographical errors in the report. Nathan 2019 was considered to be at high risk of allegiance bias and 'vested interest' bias due to funding and commissioning issues, and also to have an unclear risk of publication bias due to the long period of time between the study's completion and publication of results.

We assessed five studies to have an unclear risk of other sources of bias (Messina 2003; Huband 2007; Woodall 2007; Bernstein 2012; Thylstrup 2015). Messina 2003 reported providing a reduction of US $40 per month (representing a discount of between 22% and 29%) in the cost of methadone maintenance treatment as an incentive for participation in the study; we classed this study at an unclear risk of bias because of uncertainty about whether or not this could have introduced bias. Huband 2007 reported measurements at two time points (baseline and endpoint) and may be subject to bias from those participants in either a very optimistic or pessimistic state of mind; this study may also have potential bias arising from a baseline imbalance as those in the intervention group were significantly more likely to have had psychiatric hospitalisation at some time in their life in comparison with the controls. Woodall 2007 reported a baseline imbalance where the intervention group was significantly more likely to have histories of drinking and driving in comparison with the controls, although it was unclear if this applied to the AsPD subgroup. We assessed Bernstein 2012 as potentially having 'vested interests' in the development of the intervention under investigation and the development of tools/instruments used in the study. Lastly, Thylstrup 2015 was partially funded by manufacturers of an opioid replacement drug and participants may have received an opioid replacement as part of their treatment-as-usual regimen; however, it is uncertain whether or not this could have introduced bias.

We judged the remaining three studies to be free of other potential sources of bias (Neufeld 2008; Davidson 2009; Priebe 2012).

Without data (nine studies)

We classed one study, Tarrier 2010, at high risk of allegiance bias as funding had been secured to develop a service delivering the experimental intervention and there was a long delay in the publication of the study results in a peer-reviewed journal. We also had concerns regarding adherence to the treatment protocol, as participants in the control condition reportedly received more therapy than the intervention group.

We assessed four studies as having an unclear risk of other sources of bias (Havens 2007; Marlowe 2007; Feigenbaum 2012; McMurran 2016). We classed Havens 2007 as unclear risk of bias because, as the trial investigators acknowledged, bias may have been present because only those completing the one-month follow-up were eligible for psychiatric assessment and participants in the case management arm were significantly less likely to have been followed up. We classed Marlowe 2007 at unclear risk of bias because of uncertainty about possible risk of bias arising from a diagnosis of AsPD using an 'antisocial personality disorder interview' derived from SCID-II by the trial investigators, but with no information on its validation. We classed Feigenbaum 2012 at unclear risk of bias for both attention and allegiance bias, as treatments offered in the TAU condition were not examined as carefully as the experimental condition; the investigators provided most, but not all, of the components of the experimental intervention; the intervention was provided through a newly-established clinical service; and there was a significant time lapse between the study completion and publication in a peer-reviewed journal. We classed McMurran 2016 at unclear risk of bias as there was potential allegiance bias from the intervention, and warnings provided about the study may have impacted on the study management and ongoing treatment delivery, though it is unclear whether this could have introduced bias.

We judged the remaining four studies to be free of other potential sources of bias (Woody 1985; McKay 2000; Tyrer 2004; Ball 2005).

Effects of interventions

See: **Summary of findings 1** Cognitive behaviour therapy + treatment-as-usual versus treatment-as-usual alone for antisocial personality disorder; **Summary of findings 2** Impulsive lifestyle counselling + treatment-as-usual versus treatment-as-usual alone for antisocial personality disorder; **Summary of findings 3** Contingency management + standard maintenance versus standard maintenance alone for antisocial personality disorder; **Summary of findings 4** 'Driving whilst intoxicated' programme + incarceration versus incarceration alone for antisocial personality disorder; **Summary of findings 5** Schema therapy versus treatment-as-usual for antisocial personality disorder; **Summary of findings 6** Social problem-solving therapy + psychoeducation versus treatment-as-usual for antisocial personality disorder; **Summary of findings 7** Dialectical behaviour therapy versus treatment-as-usual for antisocial personality disorder; **Summary of findings 8** Psychosocial risk management

('Resettle' programme) versus treatment-as-usual for antisocial personality disorder

Data on participants with AsPD were available, either in the study report or directly from the study authors, for 10 of the 19 included studies (Messina 2003; Huband 2007; Woodall 2007; Neufeld 2008; Davidson 2009; Bernstein 2012; Priebe 2012; Asmand 2015; Thylstrup 2015; and Nathan 2019). Data on the subgroup of participants with antisocial or dissocial personality disorder from the other nine studies were not available at the time this review was prepared and thus these studies are not discussed any further in this section (Woody 1985; McKay 2000; Tyrer 2004; Ball 2005; Havens 2007; Marlowe 2007; Tarrier 2010; Feigenbaum 2012 McMurran 2016).

A significant proportion of the quantitative data available from the studies included in this review met our criteria for skewed data, as described in the section on 'Measures of treatment effect'. Consequently, in the absence of raw data from the trial investigators, we presented all skewed data in 'Additional tables' and reported statistics on comparisons between conditions as calculated by the trial investigators, rather than performing our own analyses.

We did not carry out any syntheses of primary or secondary outcome data using meta-analyses (other than for the outcome of 'leaving the study early') because (a) data for an outcome were available from only one study, or (b) we wanted to minimise the risk of applying parametric statistics to skewed data that was not normally distributed.

Comparison 1: cognitive behavioural therapy + treatment-as-usual versus treatment-as-usual alone

We included one study in this comparison: Davidson 2009 (male outpatients with AsPD and recent verbal/physical violence; six and 12 months treatment; n = 52). See Summary of findings 1.

Primary outcomes

Aggression

Davidson 2009 found no difference between the treatment and control conditions at 12 months post-intervention in numbers reporting any act of verbal aggression (OR 1.25, 95% CI 0.40 to 3.94, P = 0.70, 52 participants, 1 study, low-certainty evidence Analysis 1.1) or physical aggression (OR 0.92, 95% CI 0.28 to 3.07, P = 0.90, 52 participants, 1 study, low-certainty evidence, Analysis 1.2), assessed with the MacArthur Community Violence Screening Instrument. Davidson 2009 also found no significant difference between the treatment and control conditions from baseline to endpoint (at 12 months) in the change (reduction) in number reporting any act of verbal aggression (OR 0.94, 95% CI 0.29 to 3.00, P = 0.92, 52 participants, 1 study, low-certainty evidence, Analysis 1.3) or of physical aggression (OR 1.20, 95% CI 0.40 to 3.62, P = 0.75, 52 participants, 1 study, low-certainty evidence, Analysis 1.4). The trial investigators observed, however, that "incidents of any acts of verbal or physical aggression decreased in both groups over the year of the study" (p 574).

Social functioning

Davidson 2009 found no clear difference between the treatment and control conditions in mean scores on the Social Functioning Questionnaire (SFQ; eight items, rated on four-point scale (anchors vary across items) by responders who indicate the extent to which they experienced problems over past two weeks; scores range from 0 to 24; higher scores indicate greater social dysfunction) at 12 months/last recorded assessment (MD −1.60 points, 95% CI −5.21 to 2.01, P = 0.39, 39 participants, 1 study, very low-certainty evidence, Analysis 1.5). Davidson 2009 also found no clear difference between the treatment and control conditions in the 'difference between baseline and last value' of total scores on the SFQ (MD 1.70, 95% CI −1.80 to 5.10, P = 0.33; analysis by trial investigators; analysis not shown).

The study did not report data on any of our other primary outcomes: reconviction; global state/functioning; or adverse events.

Secondary outcomes

Satisfaction with treatment

Davidson 2009 found no significant difference between the treatment and control conditions in mean scores for 'satisfaction with taking part in the study' (rated on a six-point Likert scale ranging from one (not at all) to seven (very much); higher scores indicate greater satisfaction) (MD 0.70, 95% CI −0.22 to 1.62, P = 0.14, 25 participants, Analysis 1.6).

Leaving the study early

Davidson 2009 found no significant difference between the treatment and control conditions for number of participants leaving the study early by three months (OR 0.63, 95% CI 0.19 to 2.13, P = 0.46, 52 participants, 1 study, low-certainty evidence, Analysis 1.7), six months (OR 0.96, 95% CI 0.31 to 2.96, P = 0.94, 52 participants, 1 study, low-certainty evidence, Analysis 1.8), nine months (OR 1.84, 95% CI 0.61 to 5.57, P = 0.28, 52 participants, 1 study, low-certainty evidence, Analysis 1.9), or by 12 months (OR 0.88, 95% CI 0.23 to 3.33, P = 0.84, 52 participants, 1 study, low-certainty evidence, Analysis 1.10).

Substance misuse - alcohol

Davidson 2009 reported skewed summary data (see Table 8) that indicated no significant difference between the treatment and control conditions at 12 months for mean overall scores (MD (change from baseline) 4.1, 95% CI −0.6 to 8.9, P = 0.08; last-observation-carried-forward by the trial investigators) and total unit scores (MD (change from baseline) 0.6, 95% CI −7.6 to 8.8, P = 0.88; intention-to treat-analysis by the trial investigators in each case) on the AUDIT (Alcohol Use Disorders Identification Test; 10-items, rated on five-point scale (ranging from zero to four; response anchors vary across item content); a score of eight or more indicates harmful alcohol use).

Economic outcomes

Davidson 2009 provided data on the total cost of health, social work and criminal justice services received over 12 months, and the average cost per participant for NHS services alone over 12 months (see Table 9), but with no statistics.

Anger

Davidson 2009 found no significant difference between the treatment and control conditions at 12 months in mean scores on the Novaco Anger Scale (25-item scale, rated on four-point scale ranging from zero (little to no annoyance) to three (very angry),

total score range = 0 to 100; higher scores indicate greater problems with anger) (MD −1.30 points, 95% CI −13.97 to 11.37, P = 0.84, 39 participants, Analysis 1.11), or in mean scores on the Novaco Provocation Inventory (80 items, rated on four-point scale, ranging from one (very little) to five (very much), total score range = 80 to 400; higher scores indicate greater problems with anger) (MD −2.60 points, 95% CI −11.51 to 6.31, P = 0.57, 39 participants, Analysis 1.12).

Mental state

Davidson 2009 found no significant difference between the treatment and control conditions at 12 months in mean anxiety scores (MD −0.30 points, 95% CI −2.70 to 2.10, P = 0.81, 43 participants, 1 study, low-certainty evidence, Analysis 1.13) and depression scores (MD −1.30 points, 95% CI −4.38 to 1.78, P = 0.41, 43 participants, 1 study, low-certainty evidence, Analysis 1.14), assessed with the Hospital Anxiety and Depression Rating Scale (14-item, self-rating scale comprising two comprising two subscales (anxiety (seven items) and depression (seven items)), rated on a four-point severity scale (ranging from zero (not at all) to three (all of the time); total score range = 0 to 21, with scores equal to 11 or above on either scale indicate a definite case).

Other outcomes

Davidson 2009 reported skewed summary data (see Table 10; intention-to treat-analysis by the trial investigators in each case), which indicated no significant difference between the treatment and control conditions at 12 months for mean scores on the following subscales of the Brief Core Schema Scales (24-item, self-report questionnaire comprising four scales measuring positive and negative beliefs about self and others; each scale comprises six statements with which the participant rates agreement (yes/no); if agree, they rate the strength of their belief from one (slightly) to four (totally); total item scores range from zero to four and total subscale scores from zero to 24).

- 'self-as-positive' belief scores (MD (change from baseline) −0.2, 95% CI −3.6 to 3.1, P = 0.89).
- 'self-as-negative' belief scores (MD (change from baseline) −0.8, 95% CI −4.3 to 2.7, P = 0.64).
- 'others-as-positive' belief scores (MD (change from baseline) −2.6, 95% CI −5.8 to 0.5, P = 0.10).
- 'others-as-negative' belief scores (MD (change from baseline) −2.4, 95% CI −5.8 to 0.9, P = 0.15).

Neither study reported data on any of our other secondary outcomes: quality of life; engagement with services; employment status; housing/accommodation status; impulsivity; mental state; or prison and service outcomes.

Comparison 2: impulsive lifestyle counselling (ILC) + treatment-as-usual versus treatment-as-usual alone

We included one study in this comparison: Thylstrup 2015 (male and female adults with AsPD receiving outpatient treatment for drug and alcohol problems; intervention delivered over six sessions; n = 176). See Summary of findings 2.

Primary outcomes

Aggression

Thylstrup 2015 reported scores on the 12-item short-form of the Buss-Perry Aggression Questionnaire (scored on a five-point Likert scale ranging from one (extremely uncharacteristic) to five (extremely characteristics), at baseline, and three and nine months post-intervention (Table 11). There was no difference between ILC + treatment-as-usual (TAU) and TAU alone for trait aggression at three months (MD 0.18, 95% CI −0.22 to 0.58; 131 participants, 1 study, very low-certainty evidence; Analysis 2.1) or at nine months (MD 0.07, CI −0.35 to 0.49, 118 participants, 1 study, very low-certainty evidence; Analysis 2.2).The study authors also reported scores − skewed data (Table 12) − on the Self-Report of Aggression and Social Behavior Measure (SRASBM) at baseline, and three and nine months post-intervention. Although aggression decreased from baseline to both three and nine months, the study authors reported that "No differences were found between ILC and TAU at any point, but across both groups considerable reductions in interpersonal aggression were observed at both follow-up waves" (p 8, column 1).

Adverse events

Thylstrup 2015 reported the number of participant deaths between the three- and nine-month follow-up period. There was no significant difference between the ILC intervention and control group (OR 0.40, 95% CI 0.04 to 4.54, P = 0.46, 142 participants, 1 study, very low-certainty evidence, Analysis 2.3). Thylstrup 2015 also reported on the number of participants incarcerated during the follow-up period. Again, there was no significant difference between the ILC intervention and control group (OR 0.70, 95% CI 0.27 to 1.86, P = 0.48, 142 participants, 1 study, very low-certainty evidence, Analysis 2.4).

The study did not report data on our other primary outcomes: reconviction; global state/functioning; and social functioning.

Secondary outcomes

Leaving the study early

Thylstrup 2015 reported the number of participants leaving the study early at three months and at nine months post-intervention. There was no significant difference between the ILC +TAU intervention group and the TAU control group at both three months (OR 1.54, 95% CI 0.72 to 3.30, P = 0.27, 167 participants, 1 study, very low-certainty evidence, Analysis 2.5) and nine months (OR 1.38, 95% CI 0.70 to 2.72, P = 0.35, 167 participants, 1 study, very low-certainty evidence, Analysis 2.6) post-intervention.

Substance misuse

Thylstrup 2015 reported on the percentage of participants using drugs or alcohol daily at three months post-intervention (ILC intervention + TAU group = 37%; TAU control group = 36%) and at nine months post-intervention (ILC intervention + TAU group = 31%; TAU control group = 33%). Thylstrup 2015 also reported skewed data (from a mixed-effects regression analysis) for the drug composite score and alcohol composite score of the ASI (comprising 1) severity ratings (10-point assessment of lifetime and current problem severity) in seven problem areas affected by substance use disorder by interviewer, and 2) composite scores (range from zero = no problems to one = severe problems) for each domain based on client responses to items measuring behaviour in

the 30 days prior to interview. The results for the drug composite score favoured the experimental ILC + TAU condition at three months post-intervention but not at nine months post-intervention (Table 12). There was no difference between the groups in terms of alcohol composite scores at three and nine months post-intervention (Table 12).

Thylstrup 2015 reported the percentage of participants abstinent of drugs or alcohol at three months post-intervention (ILC intervention + TAU group = 17%; TAU control group = 13%) and at nine months post-intervention (ILC intervention + TAU group = 21%; TAU control group = 13%). Thylstrup 2015 also reported skewed data (from a mixed-effects regression analysis) for the number of days abstinent in the previous 30 days, which favoured the experimental ILC + TAU condition at three months post-intervention, and favoured neither condition at nine months post-intervention (Table 12).

The trial investigators concluded that "(m)oderate short-term improvements in substance use were associated with randomization to Impulsive Lifestyle Counselling. The findings support the usefulness of providing psycho-education to outpatients with antisocial personality disorder" (quote from Abstract, p 1, Thylstrup 2015).

The study did not report data on our other secondary outcomes: quality of life; engagement with services; satisfaction with treatment; employment status; housing/accommodation status; economic outcomes; impulsivity; anger; mental state; prison and service outcomes; or other outcomes.

Comparison 3: contingency management + standard maintenance versus standard maintenance alone

We included two studies in this comparison: Neufeld 2008 (outpatients with AsPD and opioid dependence; six months treatment; n = 100); and Messina 2003 (outpatients with cocaine dependence; AsPD subgroup; 16 weeks treatment; n = 26). See Summary of findings 3.

Primary outcomes: social functioning

Neufeld 2008 found a significant difference between the groups at six months post-intervention in (adjusted) composite family/social domain scores, assessed with the Addiction Severity Index (ASI; severity ratings (10-point assessment of lifetime and current problem severity) in seven problem areas affected by substance use disorder by interviewer; and composite scores (range from zero = no problems to one = severe problems) for each domain (based on client responses to items measuring behaviour in the 30 days prior to interview)), which favoured the treatment condition (MD −0.08 points, 95% CI −0.14 to −0.02, P = 0.005, 83 participants, 1 study, low-certainty evidence, Analysis 3.1). This analysis is based on summary data of completers supplied by the trial investigators and derived from a mixed regression model that included time-specific random effects and an interaction term (see Table 13).

The study did not report data on our other primary outcomes: aggression; reconviction; global state/functioning; or adverse events.

Secondary outcomes

Leaving the study early

Both Neufeld 2008 and Messina 2003 reported data on leaving the study early. A meta-analysis of data from these two studies indicated no significant difference between the treatment and control conditions (OR 0.59, 95% CI 0.28 to 1.24, P = 0.16, I^2 = 0%, P value for heterogeneity = 0.69, 127 participants, 2 studies, low-certainty evidence, Analysis 3.2).

Substance misuse

Drugs

Messina 2003 found significant differences between the groups in numbers of patients with cocaine-negative specimens by week 17 (OR 8.56, 95% CI 1.33 to 54.95, P = 0.02, 24 participants, 1 study, low-certainty evidence, Analysis 3.3), week 26 (OR 11.67, 95% CI 1.53 to 89.12, P = 0.02, 22 participants, 1 study, low-certainty evidence, Analysis 3.4), and week 52 (OR 10.00, 95% CI 1.44 to 69.26, P = 0.02, 24 participants, 1 study, low-certainty evidence, Analysis 3.5), in favour of the treatment condition in each case. Messina 2003 also reported skewed summary data (see Table 14), which indicated a significant, greater mean number of cocaine-negative specimens for the treatment condition compared to the control condition, by 16 weeks (P < 0.05; two-way analysis of variance (ANOVA) with Tukey-Kramer post hoc test; analysis of completers by the trial investigators).

Neufeld 2008 found no significant difference between the groups in (adjusted) mean composite drug domain scores, assessed with the ASI (10-point assessment of lifetime and current problem severity) in seven problem areas affected by substance use disorder by the interviewer; and composite scores (range from zero = no problems to one = severe problems) for each domain (based on client responses to items measuring behaviour in the 30 days prior to interview), at six months post-intervention (data presented graphically; hierarchical regression model with variables at one, two, three and six months, including condition, time, time-by-condition interaction and polydrug use at baseline; analysis of completers by the trial investigators, see Table 13). Neufeld 2008 also reported summary data (see Table 15; each being an analysis of completers carried out by the trial investigators), which indicated no significant difference between the treatment and control conditions at six months post-intervention for overall percentage of: opioid-negative urine specimens (OR 1.31, 95% CI 0.71 to 2.42, P = 0.39); cocaine-negative urine specimens (OR 1.59, 95% CI 0.86 to 2.96, P = 0.14); sedative-negative urine specimens (OR 1.82, 95% CI 0.72 to 4.42, P = 0.18); and negative urine specimens for any drug (OR 1.70, 95% CI 0.94 to 3.07, P = 0.08).

Alcohol

Neufeld 2008 found no significant difference between the treatment and control conditions in (adjusted) mean composite alcohol domain scores, assessed with the ASI (10-point assessment of lifetime and current problem severity) in seven problem areas affected by substance use disorder by the interviewer; and composite scores (range from zero = no problems to one = severe problems) for each domain (based on client responses to items measuring behaviour in the 30 days prior to interview), at six months post-intervention (data presented graphically; hierarchical regression model with variables at one, two, three and six months, including condition, time, time-by-condition interaction

and polydrug use at baseline; analysis of completers by the trial investigators, see Table 13).

Employment status

Neufeld 2008 found no significant difference between the treatment and control conditions in (adjusted) mean composite employment domain scores, assessed with the ASI (10-point assessment of lifetime and current problem severity) in seven problem areas affected by substance use disorder by the interviewer; and composite scores (range from zero = no problems to one = severe problems) for each domain (based on client responses to items measuring behaviour in the 30 days prior to interview), at six months post-intervention (data presented graphically; hierarchical regression model with variables at one, two, three and six months, including condition, time, time-by-condition interaction and polydrug use at baseline; analysis of completers by the trial investigators, see Table 13).

Other outcomes

Neufeld 2008 reported summary data (see Table 16) that indicated a significant difference in the overall number of counselling sessions attended (in relation to the total number of sessions offered) for the active treatment condition compared to the control condition, by six months post-intervention (OR 4.00, 95% CI 2.39 to 6.70, P < 0.0001, analysis of completers by the trial investigators). The trial investigators concluded that "subjects in the experimental group had significantly better counselling attendance. . . compared to the control group. The experimental intervention increased attendance in subjects with low and high levels of psychopathy and with and without other psychiatric co-morbidity." (Neufeld 2008, quote from Abstract, p 101).

Neufeld 2008 found no significant difference between the treatment and control conditions in the proportion of participants transferred to routine care due to poor or partial treatment response by six months post-intervention (OR 0.42, 95% CI 0.17 to 1.04, P = 0.06; 100 participants, 1 study, low-certainty evidence, Analysis 3.6).

Neither study reported data on our other secondary outcomes: quality of life; engagement with services; satisfaction with treatment; housing/accommodation status; economic outcomes; impulsivity; anger; mental state; or prison and service outcomes.

Comparison 4: 'driving whilst intoxicated' programme + incarceration versus incarceration

We included one study in this comparison: Woodall 2007 (incarcerated drink-driving offenders with AsPD; 28 days treatment; n = 52). See Summary of findings 4.

Primary outcomes: reconviction

Woodall 2007 found no evidence of a difference between treatment and control conditions in reconviction for drink-driving (Cox regression of re-arrest rates) over 24 months (hazard ratio 0.56, 95% CI −0.19 to 1.31, P = 0.15, 52 participants, 1 study, very low-certainty evidence, Analysis 4.1).

The study did not report data on our other primary outcomes: aggression; global state/functioning; social functioning; or adverse events.

Secondary outcomes

Substance misuse - alcohol

Woodall 2007 provided descriptive and graphical summaries (p 983, column 1) of analyses of self-reported alcohol use assessed using the Form 90 measure (a time-line follow-back method to assess drinking over the previous 90 days). These showed a significant difference between the groups (group x AsPD x time interaction) over the 24-month period for both total standard ethyl-alcohol consumption units and number of drinking days, in favour of the treatment condition in each case (P < 0.05; omnibus test; repeated measures ANOVA, mixed-factorial design with Geisser-Greenhouse adjustment; analysis of completers by the trial investigators). A similar analysis for average blood alcohol content did not indicate significant differences (P = 0.05). Woodall 2007 concluded that "participants randomized to receive the first offender incarceration and treatment [DWI] programme reported greater reductions in alcohol consumption from baseline levels when compared with participants who were only incarcerated. AsPD participants reported heavier and more frequent drinking but showed significantly greater decline in drinking from intake to post-treatment assessments." (quote from Abstract, p 974).

Other outcomes

Woodall 2007 reported skewed summary data that indicated no significant difference between treatment and control conditions for mean number of days driving after drinking in past 30 days (see Table 17) and for mean number of days driving after five or more drinks in past 30 days (see Table 18) at six, 12 and 24 months post-incarceration (P values not provided, but not significant for the group-by-time interaction; ANOVA mixed-factorial design; completer analysis by the trial investigators). However, the trial investigators reported a significant overall main effect of time for the whole sample (P < 0.001), "indicating a decline in self-reported drinking and driving from intake to post-incarceration assessments" (p 982, column 2), and a "significant AsPD-by-time interaction (P < 0.001) resulting from the fact that, contrary to expectations, the AsPD participants showed a greater improvement over time than the non-AsPD participants on both these self-reports of drinking and driving." (p 982, column 2).

The study did not report data on our other secondary outcomes: quality of life; engagement with services; satisfaction with treatment; leaving the study early; employment status; housing/accommodation status; economic outcomes; impulsivity; anger; mental state; or prison and service outcomes.

Comparison 5: schema therapy versus treatment-as-usual

We included one study in this comparison: Bernstein 2012 (male forensic patients with personality disorder; 26 of the 30 completers (87%) had a diagnosis of AsPD; we included the total sample data in the analyses as the proportion of AsPD was greater than 75%). See Summary of findings 5.

Bernstein 2012 reported preliminary results only and outcome data for the following 'mental state' variables were not provided: personality disorder symptoms (assessed with Structured Interview for DSM-IV Personality Disorders (SIDP-IV)); scores on patient version of the Schedule for Nonadaptive and Adaptive Personality (SNAP); scores on the informant version of the Schedule for Nonadaptive and Adaptive Personality (SNAP-I): early maladaptive schemas and schema modes (assessed with the Young

Schema Questionnaire-Short Version (YSQ) and Schema Mode Inventory (SMI)); and general psychopathology (assessed with the Symptom-Checklist 90 (SCL-90)) .

Primary outcomes

Reconviction

Bernstein 2012 reported data on the number of participants reconvicted at three years. They found no difference between the groups for this outcome (OR 2.81, 95% CI 0.11 to 74.56, P = 0.54, 30 participants (87% AsPD diagnosis), 1 study, very low-certainty evidence, Analysis 5.1).

Social functioning

Bernstein 2012 reported data on the number of patients obtaining supervised and unsupervised leave at two and three years follow-up, and found no differences between the groups:

- supervised leave at two years (OR 3.00, 95% CI 0.68 to 13.31, P = 0.15, 30 participants (87% ASPD diagnosis), 1 study, very low-certainty evidence; Analysis 5.2);
- unsupervised leave at two years (OR 5.91, 95% CI 0.60 to 58.48, P = 0.13, 30 participants (87% ASPD diagnosis), 1 study, very low-certainty evidence; Analysis 5.3);
- supervised leave at three years follow-up (OR 1.18, 95% CI 0.20 to 7.08, P = 0.85, 30 participants (87% ASPD diagnosis), 1 study, very low-certainty evidence; Analysis 5.4); and
- unsupervised leave at three years follow-up (OR 1.25, 95% CI 0.29 to 5.41, P = 0.77, 30 participants (87% ASPD diagnosis), 1 study, very low-certainty evidence; Analysis 5.5).

Bernstein 2012 reported skewed data for the mean number of days for patients to gain supervised leave and found no difference between the groups (Table 19; study investigators reported t-test (degrees of freedom (df) = 22) = 1.07, P > 0.05). Bernstein 2012 also reported the mean number of days for patients to gain unsupervised leave and found a difference between the groups in favour of the treatment condition (OR −137.33, 95% CI −271.31 to −3.35, P = 0.04, 30 participants (87% ASPD diagnosis), 1 study, very low-certainty evidence, Analysis 5.6). We chose to report this last result as the measure of social functioning in Summary of findings 5, as 'days to unescorted leave' reflects the person gaining a higher level of independence and progress than 'days to escorted leave'.

Bernstein 2012 concluded that "(t)he observation that ST patients moved through the resocialization process more rapidly than the TAU patients, receiving leave on average about 4.5 months faster for both unsupervised and supervised leave, raises the possibility that it may be a cost-effective form of treatment" (quote from Discussion, p 321, column 1).

Adverse events

Bernstein 2012 classified adverse events, such as dropping out of therapy, recidivism or being transferred to another facility due to poor treatment response as global negative outcomes. They reported data on the number of participants with global negative outcomes overall and found no difference between the groups (OR 0.42, 95% CI 0.08 to 2.19, P = 0.30, 30 participants (87% ASPD diagnosis), 1 study, very low-certainty evidence Analysis 5.7).

The study did not report data on our other primary outcomes: aggression; or global state/functioning.

Secondary outcomes: other outcomes

Bernstein 2012 reported the recidivism risk score on the Historical Clinical Risk Management-20. There was no difference between the groups in a repeated-measures ANOVA (interaction of treatment by time (linear effect): F (1, 20) = 0.12, P = 0.73; interaction of treatment by time (curvilinear effect): F (1, 20) = 3.24, P = 0.09).

In addition to the number of patients who recidivated (Analysis 5.1), Bernstein 2012 provided four additional reasons that would lead to a patient receiving a global negative outcome. They found no difference between the groups for any of these four reasons:

- number of patients transferred to other clinics due to lack of treatment response (OR 0.40, 95% CI 0.03 to 4.96, P = 0.48, 30 participants (87% ASPD diagnosis), 1 study, very low-certainty evidence, Analysis 5.8);
- number of patients terminating therapy due to worsening of psychiatric condition (OR 0.27, 95% CI 0.01 to 7.25, P = 0.44, 30 participants (87% ASPD diagnosis), 1 study, very low-certainty evidence, Analysis 5.9);
- number of patients that terminated therapy due to lack of treatment response (OR 0.27, 95% CI 0.01 to 7.25, P = 0.44, 30 participants (87% ASPD diagnosis), 1 study, very low-certainty evidence, Analysis 5.10); and
- number of patients terminated due to lack of co-operation with the research (OR 0.87, 95% CI 0.05 to 15.28, P = 0.92, 30 participants (87% ASPD diagnosis), 1 study, very low-certainty evidence, Analysis 5.11).

The study did not report data on our other secondary outcomes: quality of life; engagement with services; satisfaction with treatment; leaving the study early; substance misuse; employment status; housing/accommodation status; economic outcomes; impulsivity; anger; mental state; or prison and service outcomes.

Comparison 6: social problem-solving therapy + psychoeducation versus treatment-as-usual alone

We included one study in this comparison: Huband 2007 (community-living adults with personality disorder; AsPD subgroup; 24 weeks treatment; n = 24). The authors of Huband 2007 were able to provide data on the AsPD subgroup, however the investigators noted that their trial was not designed to have sufficient power to detect significant changes in subgroups of this size, and also that 20 of the 24 had at least one other Axis II diagnosis. See Summary of findings 6.

Primary outcomes: social functioning

Huband 2007 found no clear difference between the treatment and control conditions in mean scores on the SFQ (eight items, rated on a four-point scale (anchors vary across items) by responders who indicated the extent to which they experienced problems over the past two weeks, scores range from 0 to 24; higher scores indicate greater social dysfunction) at six months post-intervention (MD −1.60 points, 95% CI −5.43 to 2.23, P = 0.41, 17 participants, 1 study, very low-certainty evidence, Analysis 6.1).

The study did not report data on our other primary outcomes: aggression; reconviction; global state/functioning; or adverse events.

Secondary outcomes

Leaving the study early

Huband 2007 found no significant difference between treatment and control conditions for the outcome 'leaving the study early' (OR 1.19, 95% CI 0.20 to 6.99, P = 0.85, 24 participants, 1 study, very low-certainty evidence, Analysis 6.2).

Impulsivity

Huband 2007 found no significant difference between treatment and control conditions in mean scores on the Barrett Impulsiveness Scale (BIS; 30 items scored on a four-point Likert scale ranging from one (rarely or never) to four (almost always/always); higher scores indicate greater impulsivity) at six months post-intervention (MD 6.58 points, 95% CI −4.81 to 17.97, P = 0.26, 14 participants, 1 study, very low-certainty evidence, Analysis 6.3).

Anger

Huband 2007 found no significant difference between treatment and control conditions in mean scores on the Anger Expression Index (overall measure of total anger expression, calculated by subtracting the summed scores on the 16-item anger control scale from the summed scores on the 16-item anger expression scale (both scales rated on four-point Likert scale from one (not at all/almost never) to four (very much so/almost always)) and adding 48 to eliminate the possible of negative numbers; higher scores indicate greater levels of overall anger expression) of the State-Trait Anger Expression Inventory-2 (STAXI-2) at six months follow-up (MD −1.74 points, 95% CI −12.64 to 9.16, P = 0.75, 14 participants, 1 study, very low-certainty evidence, Analysis 6.4).

Other outcomes

Huband 2007 found no significant differences between the treatment and control conditions at six months follow-up in mean social problem-solving ability scores on the Social Problem Solving Inventory-Revised (SPSI-R; 5 subscales; total scores range 0 to 20 with higher scores indicating greater problem-solving ability) (MD 0.18 points, 95% CI −2.57 to 2.93, P = 0.90, 16 participants, 1 study, very low-certainty evidence, Analysis 6.5), mean shame scores on the Experience of Shame Scale (25-item questionnaire assessing characterological shame and behavioural shame over the past year, each item scored on a four-point scale ranging from one (not at all) to four (very much), yielding a total score between 25 and 100; higher scores indicate greater shame) (MD 14.64 points, 95% CI −12.70 to 41.98, P = 0.29, 14 participants, 1 study, very low-certainty evidence, Analysis 6.6), and mean dissociation scores on the Dissociative Experiences Scale (28-item questionnaire asking about percentage of time (range = 0% to 100%) that a particular symptom is experienced, overall score = average of all individual scores; scores of 20 or more consistent with post-traumatic or dissociative disorders) (MD 4.30 %, 95% CI −21.19 to 29.79, P = 0.74, 13 participants, 1 study, very low-certainty evidence, Analysis 6.7).

The study did not report data on any of our other secondary outcomes: quality of life; engagement with services; satisfaction with treatment; substance misuse; employment status; housing/accommodation status; economic outcomes; mental state; or prison and service outcomes.

Comparison 7: dialectical behaviour therapy versus treatment-as-usual

We included two studies in this comparison: Asmand 2015 (adult male prisoners in Iran with AsPD; n = 32); and Priebe 2012 (mixed gender community outpatients with personality disorder; n = 14; AsPD subgroup data available). The description of the DBT intervention provided by Asmand 2015 was very poor, and for participants in the control condition of this study, TAU was standard incarceration rather than the psychiatric outpatient treatment offered in Priebe 2012. See Summary of findings 7.

Primary outcomes: adverse events

Priebe 2012 reported skewed data for the mean number of self-harm days in the past two months for five AsPD participants in the intervention group and nine AsPD participants in the control condition (Table 20; data provided by the study authors; baseline data, data at month two and change between these is shown in the table; no statistics were provided by the study authors for this extracted data). Priebe 2012 concluded that "DBT can be effective in reducing self-harm in patients with personality disorder, possibly incurring higher total treatment costs. The effect is stronger in those who complete treatment" (quote from Abstract, p 356).

The study did not report data for any of the other primary outcomes: aggression; reconviction; global state/functioning; or social functioning.

Secondary outcomes

Mental state

Priebe 2012 reported total scores on the Brief Psychiatric Rating Scale (BPRS; 24 items rated by an observer, total scores ranging from 24 to 168) at two months follow-up. There was a difference between the groups in mean BPRS total scores, in favour of the treatment condition (MD −15.32 points, 95% CI −27.55 to −3.09, P = 0.01, 11 participants, 1 study, very low-certainty evidence, Analysis 7.1).

Asmand 2015 reported data on changes in anxiety, measured by the Beck Anxiety and Depression Scale (BADS; 21 items rated on four-point scale, ranging from zero (never) to three (I can't stand it), overall score range = 0 to 63; higher scores indicate more severe anxiety symptoms). There was no difference between the groups in mean BADS total scores at follow-up (MD −0.50 points, 95% CI −10.35 to 9.35, P = 0.92, 32 participants, 1 study, very low-certainty evidence, Analysis 7.2).

Other outcomes

Asmand 2015 (32 participants, 1 study, very low-certainty evidence) reported the results of comparisons between the treatment and control conditions on 10 subscales of the Jones' Illogical Beliefs Questionnaire [(sic), query Irrational Beliefs Test (Jones 1969)]. This is a 100-item questionnaire, comprising 10 subscales, each with 10 questions rated on a five-point Likert scale ranging from one (quite disagree) to five (quite agree); subscale scores are summed to give a total score, and the higher the score the more severe the illogical belief. Using the 10 subscale names reported by Asmand 2015, the results favoured neither condition and were as follows:

- need for high degree of confirmation (MD −0.22 points, 95% CI −6.06 to 3.62, P = 0.62, 32 participants, 1 study, very low-certainty evidence Analysis 7.3);

- high expectations of self (MD −1.31 points, 95% CI −5.16 to 2.54, P = 0.50, 32 participants, 1 study, very low-certainty evidence, Analysis 7.4);
- tend to blame (MD 0.25 points, 95% CI −4.20 to 4.70, P = 0.91, 32 participants, 1 study, very low-certainty evidence, Analysis 7.5);
- reaction to failure (MD 0.44 points, 95% CI −3.04 to 3.92, P = 0.80, 32 participants, 1 study, very low-certainty evidence, Analysis 7.6);
- emotional irresponsibility (MD −3.44 points, 95% CI −7.04 to 0.16, P = 0.06, 32 participants, 1 study, very low-certainty evidence, Analysis 7.7);
- anxiety and stress (MD −1.44 points, 95% CI −3.75 to 0.87, P = 0.22, 32 participants, 1 study, very low-certainty evidence, Analysis 7.8);
- avoidance of exposition to the pitfalls (MD −3.31 points, 95% CI −7.15 to 0.53, P = 0.09, 32 participants, 1 study, very low-certainty evidence, Analysis 7.9);
- dependence (MD 0.31 points, 95% CI −2.79 to 3.41, P = 0.84, 32 participants, 1 study, very low-certainty evidence, Analysis 7.10);
- helplessness to changes (MD −1.87 points, 95% CI −5.21 to 1.47, P = 0.27, 32 participants, 1 study, very low-certainty evidence, Analysis 7.11); and
- perfectionism (MD −0.25 points, 95% CI −4.10 to 3.60, P = 0.90, 32 participants, 1 study, very low-certainty evidence Analysis 7.12).

None of the studies provided data on our other secondary outcomes: quality of life; engagement with services; satisfaction with treatment; leaving the study early; substance misuse; employment status; housing/accommodation status; economic outcomes; impulsivity; anger; or prison and service outcomes.

Comparison 8: cognitive behavioural therapy + standard maintenance versus standard maintenance alone

We included one study in this comparison: Messina 2003 (outpatients with cocaine dependence; AsPD subgroup; 16 weeks treatment; n = 27).

Primary outcomes

Messina 2003 did not report data on our primary outcomes: aggression; reconviction; global state/functioning; social functioning; or adverse events.

Secondary outcomes

Leaving the study early

Messina 2003 found no difference between treatment and control conditions for the outcome of 'leaving the study early' (OR 0.38, 95% CI 0.03 to 4.87, P = 0.46, 26 participants, 1 study, very low-certainty evidence, Analysis 8.1).

Substance misuse - drugs

Messina 2003 found no significant difference between treatment and control conditions in numbers of participants with cocaine-negative specimens by week 17 (OR 2.72, 95% CI 0.48 to 15.47, P = 0.26; 23 participants, 1 study, very low-certainty evidence; Analysis 8.2), or by week 26 (OR 5.60, 95% CI 0.81 to 38.51, P = 0.08, 22 participants, 1 study, very low-certainty evidence, Analysis 8.3). However, Messina 2003 did find a significant difference between treatment and control conditions in numbers of participants with cocaine-negative specimens by week 52, in favour of the treatment condition (OR 8.00, 95% CI 1.13 to 56.79, P = 0.04, 22 participants, 1 study, very low-certainty evidence, Analysis 8.4). Messina 2003 also reported skewed summary data (see Table 21) that indicated a significant difference in mean number of cocaine-negative specimens in the groups by 16 weeks (P < 0.05, two-way ANOVA with Tukey-Kramer post hoc test, analysis of completers by the trial investigators), again in favour of the treatment condition.

Messina 2003 did not report data on any of our other secondary outcomes: quality of life; engagement with services; satisfaction with treatment; employment status; housing/accommodation status; economic outcomes; impulsivity; anger; mental state; or prison and service outcomes.

Comparison 9: contingency management + cognitive behavioural therapy + standard maintenance versus standard maintenance alone

We included one study in this comparison: Messina 2003 (outpatients with cocaine dependence; AsPD subgroup; 16 weeks treatment; n = 19).

Primary outcomes

The study did not report data on any of our primary outcomes: aggression; reconviction; global state/functioning; social functioning; or adverse events.

Secondary outcomes

Leaving the study early

Messina 2003 found no significant difference between the treatment and control conditions for the outcome 'leaving the study early' (OR 0.28, 95% CI 0.01 to 6.72, P = 0.43, 19 participants, 1 study, very low-certainty evidence, Analysis 9.1).

Substance misuse - drugs

Messina 2003 found no significant difference between the treatment and control conditions in numbers with cocaine-negative specimens by week 17 (OR 3.11, 95% CI 0.41 to 23.39, P = 0.27, 17 participants, 1 study, very low-certainty evidence, Analysis 9.2) or by week 26 (OR 7.00, 95% CI 0.69 to 70.74, P = 0.10, 15 participants, 1 study, very low-certainty evidence, Analysis 9.3). However, Messina 2003 did find a significant difference between the groups in numbers with cocaine-negative specimens by week 52, in favour of the treatment condition (OR 16.00, 95% CI 1.09 to 234.25, P = 0.04, 15 participants, 1 study, very low-certainty evidence, Analysis 9.4). Messina 2003 also reported skewed summary data (see Table 22) that indicated a difference in mean number of cocaine-negative specimens between the groups by 16 weeks, again in favour of the treatment condition (P < 0.05, two-way ANOVA with Tukey-Kramer post hoc test, completer analysis by the trial investigators).

The study did not report data on any of our other secondary outcomes: quality of life; engagement with services; satisfaction with treatment; employment status; housing/accommodation status; economic outcomes; impulsivity; anger; mental state; or prison and service outcomes; or other outcomes.

Comparison 10: rational emotive behaviour therapy (REBT) versus treatment-as-usual

We included one study in this comparison: Asmand 2015 (adult male prisoners in Iran with AsPD; n = 32). The description of the REBT intervention provided by Asmand 2015 was very poor.

Primary outcomes

The study did not report data on any of our primary outcomes: aggression; reconviction; global state/functioning; social functioning; or adverse events.

Secondary outcomes

Mental state

Asmand 2015 reported data on changes in anxiety, measured by the Beck Anxiety Depression Scale (BADS; 21 questions, rated on a four-point scale, ranging from zero (never) to three (I can't stand it); overall score range = 0 to 63; higher scores indicate more severe anxiety symptoms). There was no difference between REBT treatment and control conditions at follow-up in mean BADS total scores (MD −4.00 points, 95% CI −12.34 to 4.34, P = 0.35, 32 participants, 1 study, very low-certainty evidence, Analysis 10.1).

Other outcomes

Asmand 2015 reported differences between the groups in four of the 10 subscales of the Jones' Illogical Beliefs Questionnaire [(sic), query Irrational Beliefs Test (Jones 1969)]. This is a 100-item questionnaire, comprising 10 subscales, each with 10 questions rated on a five-point Likert scale ranging from one (quite disagree) to five (quite agree); subscale scores are summed to give a total score and the higher the score, the more severe the illogical belief. Using the subscale names reported by Asmand 2015, the results were as follows:

- high degree of confirmation (MD −4.47 points, 95% CI −10.06 to 1.12, P = 0.12, 32 participants, 1 study, very low-certainty evidence, Analysis 10.2, favours neither condition);
- high expectations of self (MD −5.31 points, 95% CI −9.86 to −0.76, P = 0.02, 32 participants, 1 study, very low-certainty evidence, Analysis 10.3, favours intervention condition);
- tend to blame (MD −2.12 points, 95% CI −7.17 to 2.93, P = 0.41, 32 participants, 1 study, very low-certainty evidence, Analysis 10.4, favours neither condition);
- reaction to failure (MD −4.13 points, 95% CI −8.78 to −0.52, P = 0.08, 32 participants, 1 study, very low-certainty evidence, Analysis 10.5, favours neither condition);
- emotional irresponsibility (MD −6.25 points, 95% CI −10.35 to −2.15, P = 0.003, 32 participants, 1 study, very low-certainty evidence, Analysis 10.6, favours the intervention condition);
- anxiety and stress (MD −2.69 points, 95% CI −6.03 to 0.65, P = 0.11, 32 participants, 1 study, very low-certainty evidence, Analysis 10.7, favours neither condition);
- avoidance of exposition to the pitfalls (MD −4.31 points, 95% CI −8.85 to 0.23, P = 0.06, 32 participants, 1 study, very low-certainty evidence, Analysis 10.8, favours neither condition);
- dependence (MD −1.94 points, 95% CI −5.94 to 2.06, P = 0.34, 32 participants, 1 study, very low-certainty evidence, Analysis 10.9, favours neither condition).
- helplessness to changes (MD −5.62 points, 95% CI −9.78 to −1.46, P = 0.008, 32 participants, 1 study, very low-certainty evidence, Analysis 10.10, favours the intervention condition); and
- perfectionism (MD −5.07 points, 95% CI −9.51 to −0.63, P = 0.03, 32 participants, 1 study, very low-certainty evidence, Analysis 10.11 , favours the intervention condition).

The study did not provide data on any of our other secondary outcomes: quality of life; engagement with services; satisfaction with treatment; employment status; housing/accommodation status; economic outcomes; impulsivity; anger; or prison and service outcomes.

Comparison 11: psychosocial risk management ('Resettle programme') versus treatment-as-usual

We included one study in this comparison: Nathan 2019 (adult male prisoners in UK; AsPD; n = 65; whole sample data included (n = 72) as over 90% of participants had AsPD diagnosis).

Primary outcomes

Recidivism

Nathan 2019 provided raw study data that allowed us to extract summary statistics (skewed data) for the total number of official offences recorded after release from prison (Table 23). These showed there were no differences between total number of offences recorded in the first year (35 participants) and second year (non-cumulative; 16 participants) after release from prison (Table 23).

Nathan 2019 reported the results of an intention-to-treat regression analysis to predict the total offences committed in the two years following release, which favoured the control condition (OR 1.188, 95% CI −0.042 to 2.334, P = 0.042, 72 participants (90% AsPD), 1 study, very low-certainty evidence; Analysis 11.1); however, this effect disappeared when the analysis was corrected for time in the community (OR 1.204, 95% CI −0.014 to 2.423, P 0 = 0.053, 72 participants (90% AsPD), 1 study, very low-certainty evidence; Analysis 11.2). The study authors noted that "one offender in the intent-to-treat group had nine offences and that was the maximum score in the entire cohort" (p 6, column 2). Nathan 2019 also reported the results of an intention-to-treat analysis (72 participants, 90% AsPD) to predict the binary outcome (no offences versus 1 or more offences) for official offences at two years post-release, which favoured the PSRM Resettle intervention (OR 2.371, 95% CI 0.464 to 4.278, P = 0.015, 72 participants (90% AsPD), 1 study, very low-certainty evidence, Analysis 11.3); however, this effect disappeared when the analysis was corrected for time in the community (OR 2.077, 95% CI −0.188 to 4.201, P = 0.073, 72 participants (90% AsPD), 1 study, very low-certainty evidence, Analysis 11.4). The study authors noted that "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" (p 6, column 2).

Nathan 2019 provided raw study data that allowed us to extract summary statistics (skewed data) for the total number of self-reported antisocial acts, reported using an adapted Self-reported Delinquency Scale (SRD; 32-item, self-report measure), to record the frequency (ranging from 0 (low delinquency) to 32 (high delinquency)) in the first year (35 participants) and second year

(non-cumulative; 17 participants) after release from prison (Table 23).

Nathan 2019 reported the results of an intention-to-treat regression analysis (20 participants, 90% AsPD), to predict the total number of self-reported antisocial acts reported by the SRD, which favoured neither condition (OR 1.534, 95% CI −0.210 to 3.277, P = 0.085, 20 participants (90% AsPD), 1 study, very low-certainty evidence, Analysis 11.5).

Adverse events

Nathan 2019 reported the number of participants that died during the study period, with results favouring neither condition (OR 0.89, 95% CI 0.05 to 14.83, P = 0.94, 72 participants (90% AsPD), 1 study, very low-certainty evidence, Analysis 11.6).

The study did not report data on any of our other primary outcomes: aggression; global state/functioning; or social functioning.

Secondary outcomes

Leaving the study early

Nathan 2019 incidentally reported the number of participants who did not contribute data to the ITT analysis of the primary outcome (number of official offences recorded at two years after release from prison), with results favouring neither condition (OR 2.07, 95% CI 0.63 to 6.83, P = 0.23, 72 participants (90% AsPD), 1 study, very low-certainty evidence, Analysis 11.7).

The study did not provide data on any of our other secondary outcomes: quality of life; engagement with services; satisfaction with treatment; employment status; housing/accommodation status; economic outcomes; impulsivity; anger; or prison and service outcomes.

DISCUSSION

Antisocial personality disorder (AsPD) is a prevalent condition associated with considerable negative consequences for both the person with AsPD (including poor mental health, substance abuse, relationship difficulties, premature death) and society (including criminality and unemployment). Given the combination of its prevalence and widespread negative impact, it might be expected that the identification of effective interventions for this condition would be a research priority. Unfortunately, the conclusion of this review is similar to previous reviews (Gibbon 2010; NICE 2010), and it remains the case that there is little evidence as to what might (or might not) be effective for this condition.

The first point to make is how few studies there were to consider. The second concerns the design and methodological quality of the 19 included studies. The participant populations, attrition statistics, wide range of interventions investigated, choice of assessment tools (e.g. using measures designed for static 'trait' outcomes) and low quality of data, hinder the ability of this review to make meaningful comparisons between groups and draw conclusions from the evidence.

Disappointingly, few of the included studies addressed the primary outcomes defined in this review. While the underlying personality structure of AsPD comprises disparate traits, such as impulsivity, lack of remorse and irritability, its most common behavioural manifestation is persistent rule-breaking (NICE 2015). Although the focus on behaviour, rather than on the underlying personality structure, has been frowned upon by some commentators (e.g. Livesley 2007), we argue that persistent rule-breaking is akin to a final, common pathway manifestation of the underlying personality structure. If one accepts this argument, it is surprising that only four of the 19 included studies had reconviction as an outcome (Marlowe 2007; Woodall 2007; Bernstein 2012; Nathan 2019). Additionally, only five studies used self-reported or institutional reports of aggression (Davidson 2009; Tarrier 2010; Bernstein 2012; Feigenbaum 2012; Thylstrup 2015). In the light of the important, adverse cost consequences of the condition, and likely need for complex and expensive interventions, it was also disappointing that only six studies considered the economic impact of their intervention directly or indirectly (Tyrer 2004; Davidson 2009; Bernstein 2012; Feigenbaum 2012; Priebe 2012; McMurran 2016).

Of the 19 included studies, nearly half (n = 9) were focussed on reducing substance misuse (Woody 1985; McKay 2000; Messina 2003; Ball 2005, Havens 2007; Marlowe 2007; Woodall 2007; Neufeld 2008; Thylstrup 2015). As many within the sample of substance misusers also satisfied the criteria for AsPD, there was an opportunity to report on these separately. Hence, strictly speaking, these were not interventions for AsPD; rather, they were interventions to reduce substance misuse in a sample, some of whom also satisfied criteria for AsPD. While these studies were not without their limitations, there is evidence that contingency management is effective in reducing substance misuse in people with AsPD. This finding is in keeping with NICE guidance on opioid detoxification (NICE 2007), and it suggests that this principle of intervention is also effective in those with AsPD.

Summary of main results

The focus of this review was relatively broad, since it sought evidence on the effectiveness of any psychological intervention in the treatment of AsPD or dissocial PD. We found considerable differences between the studies in terms of participants, sample sizes, interventions and outcome measures.

There were significant limitations in the certainty of the evidence (which was generally low), which limits the certainty of any conclusions we can draw from this review. The conclusions that we can draw may be subject to change with the addition of future research. Whist we did not find clear evidence of benefit from psychological interventions for this condition, we cannot tell if this is due to an absence of effective interventions or an absence of trials of a sufficient quality to detect this benefit (i.e. the absence of evidence is not evidence of absence of effect).

We identified eight interventions (primarily developed for people with substance abuse) that reported evidence for our primary outcomes.

Cognitive behaviour therapy (CBT) + treatment-as-usual (TAU) versus TAU

One study (52 participants, low-certainty evidence) found no evidence of a difference between CBT + TAU and TAU alone for physical aggression for outpatients at 12 months post-intervention.

One study (39 participants, very low-certainty evidence) found no evidence of a difference between CBT + TAU and TAU alone for social

functioning measured by the Social Functioning Questionnaire (SFQ) for outpatients at 12 months post-intervention.

Impulsive lifestyle counselling (ILC) + TAU versus TAU

One study (118 participants, very low-certainty evidence) found no evidence of a difference between ILC + TAU and TAU alone for trait aggression (assessed with Buss-Perry Aggression Questionnaire-Short Form) for outpatients at nine months.

One study (142 participants, very low-certainty evidence) found no evidence of a difference between ILC + TAU and TAU alone for the adverse event of death or incarceration for outpatients between three and nine months follow-up.

Contingency management (CM) + standard maintenance (SM) versus SM

One study (83 participants, low-certainty evidence) found evidence that, compared to SM alone, CM + SM may improve social functioning, measured by family/social scores on the Addiction Severity Index for outpatients at six months.

'Driving whilst intoxicated' programme (DWI) + incarceration versus incarceration

One study (52 participants, very low-certainty evidence) found no evidence of a difference between DWI + incarceration and incarceration alone on reconviction (re-arrest) rates for prisoner participants at 24 months.

Schema therapy (ST) versus TAU

One study (30 participants, of whom 87% had AsPD diagnosis, very low-certainty evidence) found no evidence of a difference between ST and TAU for the number of participants reconvicted as patients in a secure psychiatric hospital at three years. This study also found evidence that ST, compared to TAU, may improve for social functioning (assessed by the number of days for patients to gain unsupervised leave at three years) and that there was no evidence of a difference between ST and TAU for overall adverse events classified globally as negative outcomes at three years, but the evidence is very uncertain.

Social problem-solving therapy (SPS) + psychoeducation (PE) versus TAU.

One study (17 participants, very low-certainty evidence) found no evidence of a difference between SPS + PE and TAU for participants' level of social functioning assessed with the SFQ at six months post-intervention.

Dialectical behaviour therapy versus TAU

One study (skewed data, 14 participants, very low-certainty evidence) provided narrative evidence that DBT, compared to TAU, may reduce adverse events (number of self-harm days) for outpatients at two months post-intervention

Psychosocial risk management (PSRM; 'Resettle' programme) versus TAU

One study (skewed data, 35 participants, very low-certainty evidence) found no evidence of a difference between PSRM and TAU for participants' number of officially recorded offences at one year after release from prison. The same study also found no evidence of difference between the PSRM and TAU for the adverse event of death at two years after release from prison, but the evidence is very uncertain.

Of these eight interventions, five (CBT + TAU; ILC + TAU; DWI programme + incarceration; SPS; and PSRM ('Resettle' programme)) demonstrated little or no difference compared to control for the primary outcomes considered in this review. Two interventions (CM + SM; and ST) showed some benefit over the control condition in terms of social functioning, although these findings were based only on single study data with small numbers of participants (83 and 30 participants, respectively). For the remaining intervention (DBT), narrative evidence suggested that DBT may be more effective than control at reducing the adverse event of self-harm, although this was also based on findings from a single study with skewed data.

For the CM intervention, two studies produced contrasting results in terms of the secondary outcome 'substance misuse' (Messina 2003; Neufeld 2008). The Addiction Severity Index results for substance misuse (drugs and alcohol) favoured the intervention over the control in the Messina 2003 study but not in the Neufeld 2008 study. However, CM was superior in terms of social functioning and attendance at counselling sessions in the Neufeld 2008 study. These differences may have arisen because of differences in the nature of the behavioural intervention. Both studies described CM but the positive reinforcements available in the Messina 2003 study for participants who stayed drug-free seem considerably more attractive. For example, a participant in the Messina 2003 study who managed to stay drug-free for the whole 16 weeks of the trial could earn redeemable vouchers worth a total of US$1277. In contrast, the positive reinforcement in the Neufeld 2008 trial comprised greater control over methadone clinic attendance and dosage in reward for drug abstinence and attendance at counselling sessions.

Overall completeness and applicability of evidence

The evidence obtained from the included studies is relevant and applicable to the review question, but is incomplete for the following reasons.

- Although 18 different psychological interventions were compared, none of the studies evaluated therapeutic community treatment, cognitive analytic therapy, mentalisation-based therapy or nidotherapy.
- The majority of studies did not focus primarily on the treatment of AsPD; only four recruited samples where all participants had this diagnosis.
- Nine studies focussed on participants with difficulties with substance misuse. Although drug or alcohol misuse (or both) is often relevant to people with AsPD, having a substance misuse problem is not part of the diagnostic criteria for AsPD.
- The findings in two studies may not fully generalise to the population of interest: the sample in Woodall 2007 was drawn mainly from a Native American community; and Marlowe 2007 found that women were significantly over-represented in their sample, and that individuals with more severe drug problems and less severe criminal histories were significantly more likely to have participated.
- Many of the included studies did not address the primary outcomes specified in this review. Of the 19 included studies,

only five reported on aggression and only four reported on reconviction. Five of the included studies did not report any of the primary outcomes.

The review only considered effectiveness trials, where interventions were compared with either TAU, waiting-list, or a 'no treatment' control group, rather than head-to-head trials comparing two or more psychological interventions without an adequate control condition.

The review identified three ongoing RCTs of psychological interventions for individuals with a diagnosis of AsPD that may represent different interventional approaches to the treatment of AsPD in future updates of this review. One RCT is examining the effectiveness of moral reconation therapy (NCT02524171) and two other trials are assessing the effectiveness of mentalisation-based therapy (ISRCTN32309003; NCT04033835). Three further ongoing studies have samples that may include participants with AsPD: one examining the impact of low-intensity psychological support for people with personality disorder (ISRCTN14994755); one examining group schema-focussed therapy enriched with psychomotor therapy for older adults with personality disorder (Van Dijk 2019); and one examining mindfulness for alcohol-abusing female offenders (NCT03883646).

Quality of the evidence

The 19 studies that met the criteria for inclusion in this review involved a total of 848 participants with AsPD. Of these 19 studies, only 10 provided suitable data, involving 605 participants with AsPD.

All of the included studies were RCTs; however, as Guyatt 2011 acknowledges, even RCTs can be limited by problems such as failure to conceal allocation, failure to blind, loss to follow-up, failure to use the intention-to-treat principle, stopping early for apparent benefit, and selective reporting of outcomes. Such issues increase the risk of bias, which, in turn, can overestimate the benefits and underestimate the harms identified (Moher 1998; Moher 2010). We used the GRADE approach to assess the certainty of the reported evidence (Schünemann 2013), and considered the risk of bias, inconsistency, indirectness, imprecision of the evidence and publication bias. We assessed the certainty of the evidence from all included studies with data for AsPD participants separately for individual outcomes. In every case, the evidence was downgraded due to a combination of issues with risk of bias (high or possible risk of bias), indirectness (e.g. due to use of self-reported questionnaire), or imprecision (due to small sample size/optimal information size criteria not being met or non-reporting of outcome data).The largest risk of bias in the included studies came from inadequate blinding of outcome assessors, incomplete outcome data (attrition bias) and selective reporting bias. We rated the certainty of the evidence for all primary outcomes as low or very low (i.e. we have very little confidence in the effect estimate, and the true effect is likely to be substantially difference from the estimate of effect). None of the outcome effect estimates assessed using the GRADE approach received a rating of moderate certainty (i.e. the true effect is likely to close to the estimate of the effect, but there is a possibility that it is substantially different), or a rating of high certainty (i.e. that we could be confident that the true effect lies close to that of the estimate of the effect).

We judged the overall certainty of the evidence from the included trials to be poor for the following reasons.

- The review relied on data from only 10 of the 19 included studies despite attempts to contact the trial investigators for information on the AsPD subgroups.
- The study samples were heterogeneous; they encompassed, for example, both prisoners, inpatients and outpatients. In addition, AsPD (or dissocial personality disorder) was diagnosed under four similar but not identical rubrics (DSM-III, DSM-III-R, DSM-IV and ICD-10).
- Where the completion rate was reported, it was high (mean = 83.5%). This may be misleading because of the custodial element of some interventions. For example, Woodall 2007 had a 100% completion rate, which might be expected given that one component of the intervention was incarceration.
- There was inconsistency in the way studies measured and reported the primary and secondary outcomes.

Although Guyatt 2011 suggests that a single, very large, rigorously planned and conducted multicentre RCT may provide high-certainty evidence, others suggest that there should be at least two independent, well-conducted RCTs or single-case experiments for a treatment to be considered effective (Chambless 1998). The majority of studies reported small sample sizes and provided evidence for individual comparisons; it was not possible to pool data given the heterogeneity of the interventions and participants. In light of this, we considered that the body of evidence summarised in this review is insufficient to allow any conclusion to be drawn about the use of psychological interventions in the treatment of AsPD.

A further limitation with the certainty of the evidence arises from an acknowledgement that personality disorder, in general, is a complex condition and clinical outcomes are best measured across multiple domains (see Gibbon 2010). A broad approach to outcome evaluation in personality disorder has been recognised by international experts in the field (e.g. Crawford 2007).

Potential biases in the review process

As Lieb 2016 discuss, we were aware of a potential for bias that might be seen as arising because two of the authors in the original review (CD and NH) were investigators in one of the studies included in this review (Huband 2007). We minimised this risk by ensuring that neither author took part in the extraction of data, summarising the risk of bias for this trial or assessing the certainty of the evidence using GRADE. When it became necessary to request additional data from this study's lead investigator, correspondence was handled via Cochrane Developmental, Psychosocial and Learning Problems (DPLP). These requests were referred by NH to the trial's research committee who responded via Cochrane DPLP. There were no such conflicts of interest in this update.

We acknowledge that a small number of decisions taken during the review process may have introduced 'selective reporting bias' to the review. First, the decision to include studies with two treatment conditions where the trial investigators randomised ‘at least five people with AsPD’ may have resulted in the exclusion of a small number of studies. In this case, we considered that the potential for bias was minimal, as any excluded studies with very small numbers were usually not RCTs. Second, the 12-week cut-off period for receiving missing data from study authors could have resulted in

relevant data being omitted from the review. In this way, it could be interpreted that we selectively reported the missing data and that the review is open to reporting bias. However, this is not the case, as no missing data were excluded. Third, we decided to include only studies where at least 75% of participants were diagnosed with AsPD. Although this appeared clinically and scientifically appropriate, this decision may have introduced reporting bias to the review.

Agreements and disagreements with other studies or reviews

It remains the case that the most recent and widest ranging relevant review with which to compare our findings is that carried out in the development of the NICE clinical guideline on antisocial personality disorder (NICE 2010). In reporting their systematic review, the NICE guideline authors observed that there had been little formal development of psychological interventions specifically for the treatment of AsPD, whereas there had been "considerable development of interventions aimed at reducing offending behaviour" (p 171, section 7.2.1, NICE 2010). In recognition of this, they chose to consider not only interventions that targeted AsPD itself, but also those that targeted the symptoms or behaviours associated with the diagnosis (such as anger, impulsivity and aggression), as well as interventions specifically for offenders regardless of diagnosis. Thus, the review described by NICE 2010 is broader than our current review, which focuses solely on studies of participants with a diagnosis of antisocial or dissocial personality disorder.

Although our original review (Gibbon 2010) and the NICE 2010 review identified four of the same studies (Woody 1985; McKay 2000; Messina 2003 and Davidson 2009), there were several differences between them.

- Gibbon 2010, identified one study, Neufeld 2008, which was a later and more complete summary of the trial initially reported by Brooner 1998, which was included in the NICE 2010 review.
- Gibbon 2010, identified two additional studies with data that were not included in the NICE 2010 review: Huband 2007 and Woodall 2007.
- NICE 2010 considered three additional studies that we excluded from our original review (Gibbon 2010): Hesselbrock 1991 on hospitalisation for alcohol dependence, which we excluded because it was not an RCT and had no control condition; Wölwer 2001 on CBT versus coping skills training versus TAU in alcohol dependence, which we excluded because too few participants had AsPD; and Vannoy 2004 on anger management versus waiting-list TAU in offenders, which we excluded because no participants had AsPD.
- NICE 2010 additionally considered a further 21 studies of treatments for offending behaviour in young people (n = 11), in adults (n = 5) and in offenders with substance misuse problems (n = 5). These studies were not eligible for inclusion in this review (neither in the original review (Gibbon 2010) nor this update), because the participants had no formal diagnosis of antisocial or dissocial personality disorder.

In their conclusions, NICE 2010 considered that the evidence for the psychological treatment of antisocial personality disorder was limited to one community trial (Davidson 2009), that the quality of the evidence varied between low and moderate, and that the limited economic evidence from that trial suggested that CBT may not be cost saving in the short term. They considered, however, that there was modest evidence for the effectiveness of cognitive and behavioural interventions, primarily delivered in groups, in reducing offending for adults with substance misuse problems and that this effect has been found in variety of settings, including institutional, outpatient and probation settings.

The current review concludes that good-quality evidence in favour of any psychological intervention for AsPD continues to be virtually non-existent.

AUTHORS' CONCLUSIONS

Implications for practice

This review concludes that there is insufficient evidence to support or refute the effectiveness of any psychological intervention for AsPD. There are particular difficulties with conducting trials in this area and the limited number of studies limits the extent to which useful conclusions can be drawn. In the absence of good-quality trial data, the use of psychological interventions to treat people with AsPD in clinical practice remains a matter for the clinician, who will wish to weigh the limited evidence of effectiveness against any risk of possible harm; it should ideally be based on consultation with the patient, their family and carers (subject to their consent) and the multidisciplinary team involved in the individual's care.

Implications for research

Given the very few studies that could be considered in this review, there is clearly an imperative to conduct further well-designed trials. These trials should be of an active psychological treatment against treatment-as-usual (effectiveness trials) rather than head-to-head trials. It would be helpful if future studies could provide more detail about the interventions that were delivered.

Future trials should use assessment tools that are designed to identify clinical change rather than static traits. We are also mindful of the issues described in the DSM-5 (p 659): “Because deceit and manipulation are central features of antisocial personality disorder, it may be especially helpful to integrate information acquired from systematic clinical assessments with information collected from collateral sources”. In deciding outcomes for future trials, consideration should also be given to those that are measurable by a number of means such as self-report, psychometrics, observed behaviour, informant information and official records. It is also notable that there have not been any studies focussing on women with AsPD.

A major problem in carrying out trials involving AsPD participants is that this is a challenging group to retain in treatment, as people with AsPD are often treatment-rejecting rather than treatment-seeking (NICE 2010). However, this caveat does not apply to those in prison, where there are a large number of individuals incarcerated with AsPD. This may also help to address the difficulties that previous studies have encountered regarding small sample size. If a prison population was chosen, then reconviction on release ought to be the outcome of choice, as this is, unfortunately, a relatively common outcome in many with AsPD, with approximately two-thirds of those being released from prison reoffending within two years (Kershaw 1999; ONS 2004). The major negative impact of aggression and reconviction (which could represent a final common pathway encompassing a variety of

traits, including failure to confirm to social norms, deceitfulness, impulsivity, recklessness, irresponsibility and lack of remorse) makes this outcome particularly important. Hence, we suggest that reconviction is chosen as the primary outcome in such a trial, preferably in conjunction with an economic evaluation.

If there was a consensus on a single outcome measured across studies, then it would be possible to make cross-study comparisons, a task that is difficult to perform at present because of the wide range of outcomes and measures that are used.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by year]

Woody 1985

Study characteristics	
Methods	Design: parallel randomised controlled trial
Participants	Participants: methadone-maintained male outpatients with AsPD and opioid dependence[a] Sex: all males Age: (for whole sample[a]) mean = 29 years (SD = 6) Unit of allocation: individual participant Number randomised: 50 with AsPD (breakdown by treatment group not available[a]) Number completing: not available[a] Setting: outpatient; single site; urban; USA (Philadelphia) Inclusion criteria: male; aged 18 to 55 years; meeting Food and Drug Administration requirements for methadone maintenance treatment; had been receiving methadone for at least 2 weeks but not more than 6 months during their current treatment episode; subgroup met DSM-III criteria for AsPD (obtained via MPI and SADS) Exclusion criteria: psychosis; persistent or clinically significant organic brain syndrome; serious medical, legal or personal problems that would require movement from local area within 1 year Ethnicity: (for whole sample[a]) black (62%); white (38%) Baseline characteristics: (for whole sample[a]) lifetime major depressive disorder (35%); lifetime anxiety disorder, any (20%); lifetime alcoholism (19%); antisocial personality disorder (45%)
Interventions	Three conditions: supportive-expressive psychotherapy (SE) + standard maintenance (SM); cognitive behavioural therapy (CBT) + SM; or SM only • Experimental group 1 (number = not reported[a]): SE + SM • Experimental group 2 (number = not reported[a]): CBT + SM • Control group (number = not reported [a]): SM

Woody 1985 *(Continued)*

	Details of conditions: • SE is an analytically-oriented focal psychotherapy. • CBT is cognitive behavioural psychotherapy. • SM is an individual counselling intervention focussed on providing external services rather than dealing with intra-psychic processes, plus methadone maintenance. Duration of intervention: 24 weeks Duration of trial: 28 weeks Length of follow-up: participants were not followed up after the end of treatment.
Outcomes	Primary outcomes • None Secondary outcomes • Leaving the study early: proportion of participants discontinuing treatment • Substance misuse (drugs): data from the Addiction Severity Interview Other outcomes • Psychiatric symptoms: mean scores on the SCL90 • Depression: mean scores on the Beck Depression Inventory (BDI)
Notes	[a]Although the study recruited a subgroup with antisocial personality disorder (50/110 had DSM-III AsPD), investigators did not provide pre/post data nor effect sizes for AsPD participants in the control condition. They reported "(t)he DC group was not included in the present analysis as our major interest was in comparing response to psychotherapy among the various diagnostic subgroups" (p 1083, column 2). Thus, no data extractable on any AsPD subgroup Study funding: National Institute of Drug Abuse and the National Institute of Mental Health Declaration of interests: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients were randomly assigned to three treatment conditions. . ." (p 1082, column 1). Comment: No further information given. Insufficient reporting to permit judgement of Yes or No. Clarification has been requested from the trial investigators, but no further information was available at the time this review was prepared.
Allocation concealment (selection bias)	Unclear risk	Comment: No information provided. Insufficient reporting to permit judgement of Yes or No. Clarification has been requested from the trial investigators, but no further information was available at the time this review was prepared.
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind participants in this type of study. We found no indication of any specific additional measures taken to reduce the risk of bias that might result from differential behaviours by participants.

Woody 1985 *(Continued)*

Blinding (performance bias and detection bias) of personnel	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because personnel would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind personnel in this type of study.
Blinding (performance bias and detection bias) of outcome assessors	Low risk	Quote: "Addiction Severity Interviews were done by independent technicians who were not part of the treatment staff and were not aware of patients group assignments" (p 1082, column 2). Comment: Review authors judged that blinding of outcome assessors was adequate for this outcome and that it was unlikely that this blinding could have been broken.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: Unclear whether there were missing outcome data for the AsPD control condition and, if so, whether the numbers of and reasons for such missing data were balanced across intervention groups. Review authors unable to make a judgement unless data from AsPD control condition become available
Selective reporting (reporting bias)	Low risk	Comment: Review authors judged that the published report included all expected outcomes, including those that were prespecified.
Other bias	Low risk	Comment: The study appeared to be free of other sources of bias. Review authors noted that, although participants were not paid for attending sessions, they could receive up to USD 55 for completing all the measures required over the course of the project. The case for this was argued in the paper. Review authors considered that this is unlikely to have introduced a source of bias.

McKay 2000

Study characteristics	
Methods	Design: parallel randomised controlled trial
Participants	Participants: male outpatients with cocaine dependence Sex: all males Age: (for AsPD subgroup[a]) mean = 41.2 years (SD = 6.8) Unit of allocation: individual participant Number randomised: (for AsPD subgroup) 46 (no details on numbers randomised to each condition[a]) Number completing: no details for AsPD subgroup[a] Setting: outpatient; single sites; urban; USA (Philadelphia) Inclusion criteria: male; diagnosis of cocaine dependence (DSM-III-R; SCID); cocaine use in the 6 months before entrance into the IOP[b]; willingness to participate in research; literacy at approximately the fourth-grade level; not homeless Exclusion criteria: history of psychotic disorder requiring antipsychotic medication; current severe dementia Ethnicity: (for AsPD subgroup) African-American (89.1%); white (6.5%); other (4.3%)

McKay 2000 *(Continued)*

	Baseline characteristics: (for AsPD subgroup[a]) veterans = 100%; in education for a mean of 12.6 (SD = 1.5) years; lifetime alcohol dependence = 84.8%; lifetime major depression = 46.7%; mean duration regular cocaine use = 7.9 (SD = 5.6) years; mean duration of regular drinking = 17.6 (SD = 9.1) years
Interventions	Two conditions: individualised relapse prevention (IRP); or treatment-as-usual (TAU) • Experimental group (n = not reported[a]): IRP • Control group (n = not reported[a]): TAU (standard continuing care treatment) Details of conditions: • IRP is a manualised modular intervention developed for substance users who are in the maintenance phase of recovery. Modules deal with identifying risky situations in the past, self-monitoring current risky situations, learning to anticipate further risky situations, and improving coping responses in these situations. Clients allocated to the IRP condition received 1 individual relapse prevention session and 1 group session per week for up to 20 weeks. • Participants in the TAU condition received standard continuing care comprising 2 group therapy sessions per week where the orientation was a mix of addictions counselling and 12-step recovery practices. Duration of intervention: mean = 20 weeks Duration of trial: 17 months Length of follow-up: follow-up at 3, 6 and 12 months following treatment
Outcomes	Primary outcomes • None Secondary outcomes • Substance misuse (drugs): data from Addiction Severity Interview (ASI) and Time-Line Follow-Back, including days of drug use, days any drug use, any criminal activity; data from the Cocaine Relapse Interview; drug screen by urinalysis • Substance misuse (alcohol): days alcohol intoxication from ASI • Leaving the study early: proportion of participants discontinuing treatment; mean number of continuing care sessions attended Other outcomes • None
Notes	[a]46 participants out of 127 (36.2%) who were randomised had AsPD under DSM-III-R. Details on characteristics of, and outcomes for, this subgroup have been requested from trial investigators. [b]Before entering aftercare, trial investigators reported that most patients participated in a 4-week Intensive Outpatient Program (IOP; 5 days/week, 3 hours/day) at the Philadelphia Veterans Administration Medical Center. Treatment was focussed on overcoming denial, fostering participation in self-help groups, and providing information about the process of addiction and cues to relapse. Study funding: National Institute on Drug Abuse Declaration of interests: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "An urn randomization procedure was used. . . which balanced the groups on five potential prognostic factors (marital status, employment sta-

McKay 2000 *(Continued)*

		tus, race, site of initial treatment, and completion of the IOP within the standard 4-week period)" (p 289). Comment: Insufficient reporting to permit judgement of Yes or No. Clarification has been requested from the trial investigators, but no further information was available at the time this review was prepared.
Allocation concealment (selection bias)	Unclear risk	Comment: Insufficient reporting to permit judgement of Yes or No. Clarification has been requested from the trial investigators, but no further information was available at the time this review was prepared.
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind participants in this type of study. We found no indication of any specific additional measures taken to reduce the risk of bias that might result from differential behaviours by participants.
Blinding (performance bias and detection bias) of personnel	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because personnel would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind personnel in this type of study.
Blinding (performance bias and detection bias) of outcome assessors	High risk	Comment: Outcome assessors not blinded Quote: "Baseline and follow-up interviews were conducted by research personnel who had received extensive training in the use of the assessment instruments. . . these interviewers had not been informed of the study hypotheses but they had been informed of treatment condition" (McKay 1997, p 781, column 1).
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: Unclear whether there were missing outcome data for the AsPD subgroup and, if so, whether the numbers of and reasons for such missing data were balanced across intervention groups. Review authors unable to make a judgement unless data from AsPD subgroup were available
Selective reporting (reporting bias)	Low risk	Comment: Review authors judged that the published report included all expected outcomes, including those that were prespecified.
Other bias	Low risk	Comment: The study appeared to be free of other sources of bias. In terms of baseline imbalance, a significantly lower percentage of those in the intervention group were married compared to the controls, but as the groups were equivalent on percentages of those living with a romantic partner for 2 years or more, the risk of bias from this source was judged not to be significant.

Messina 2003

Study characteristics	
Methods	Design: parallel randomised controlled trial
Participants	Participants: cocaine-dependent outpatients (with AsPD subgroup) receiving methadone maintenance treatment Sex: (for AsPD subgroup) 34/48 (71%) males; 14/48 (29%) females

Messina 2003 *(Continued)*

Age: (for AsPD subgroup) mean = 43.5 years (SD = 8.1)

Unit of allocation: individual participant

Number randomised: 48 (n = 14 CBT; n = 15 CM; n = 7 CM + CBT; n = 12 MM only)

Number completing: 44 at 17 weeks; 41 at 26 weeks; 41 at 52 weeks

Setting: outpatient, multisite (2 sites), urban, USA (Los Angeles)

Inclusion criteria: cocaine dependence (DSM-IV); receiving methadone maintenance treatment at 1 of 2 clinics for at least 90 days[a]; urine sample testing positive for cocaine use during month prior to study enrolment; antisocial personality disorder (DSM-IV, SCID-II) for AsPD subgroup

Exclusion criteria: alcohol or benzodiazepine dependence requiring withdrawal medication; received specific treatment for cocaine dependency in past 30 days; court mandated to treatment

Ethnicity: (for AsPD subgroup) 31% white; 21% black; 48% Hispanic/other

Baseline characteristics: described by investigators as having "relatively low motivation" (quote; p 322, column 2); 60% had completed at least 12 years of schooling; 13% had been in steady employment over last 3 years; self-reported drug/alcohol use in the 30 days prior to admission to the study was: 60% alcohol use, 35% alcohol use to intoxication, 27% marijuana use, 79% heroin use, 31% other opiate use, 96% cocaine use and 8% amphetamine use

Interventions	Four conditions: cognitive behavioural therapy (CBT); contingency management (CM); CBT + CM; and standard maintenance (SM) • Experimental group 1 (n = 14 randomised): CBT + SM • Experimental group 2 (n = 15 randomised): CM + SM • Experimental group 3 (n = 7 randomised): CBT + CM + SM • Control group (n = 12 randomised): SM only Details of conditions: • CBT + SM comprised 48 group sessions of 90 minutes (3 per week for 16 weeks) with typically 4 to 8 participants in each group. Format of sessions was: topic introduced, worksheet read out, discussion of relevance of topic to participants, participants reported their own use of illicit drugs since the last session (with positive verbal reinforcement of decreased or no use of illicit drugs, or for prosocial behaviour), participants described a behavioural plan for the time up to the next session (with positive verbal reinforcement of activities based on the CBT principles presented in the group). Participants continued on standard maintenance treatment (including methadone, mean 72 mg/day). • In CM + SM, participants required to provide 3 urine samples each week and briefly meet (2 to 5 minutes) with a contingency management technician. If urine sample negative for stimulants, participants given a voucher of escalating value and praise/encouragement. Voucher rewards could be increased by subsequent negative samples to a maximum (if the participant was drug-free for all of the 16 week trial) of redeemable vouchers worth USD 1277.50. If urine sample positive, voucher was withheld but participant not rebuked/punished. Participants continued on standard maintenance treatment (including methadone, mean 62 mg/day). • In CBT + CM + SM, participants received all 3 interventions. Participants continued on standard maintenance treatment (including methadone, mean 68 mg/day). • In standard maintenance only, participants continued on methadone maintenance treatment (mean 71 mg/day) with daily clinic visits for methadone, twice-monthly counselling sessions, plus medical care and case management visits as required. Duration of intervention: 16 weeks Duration of trial: 52 weeks (16-week intervention + 36 weeks of follow-up) Length of follow-up: participants were followed up at weeks 17, 26 and 52 (i.e. weeks 1, 10 and 36 following end of intervention)

Messina 2003 *(Continued)*

	Dose adjustment: none
Outcomes	Primary outcomes • None Secondary outcomes • Leaving the study early: proportion of participants discontinuing post-treatment follow-up • Substance misuse (drugs): cocaine use by urinalysis
Notes	[a]All participants were paying for their methadone maintenance treatment (either USD140 or USD180/month depending upon centre) but received a discount of USD40/month for participating in the study. Prior to the introduction of this incentive, only 4 participants had volunteered for the study after 60 days of recruitment. Study funding: National Institute on Drug Abuse Declaration of interests: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: Information received from trial investigators (email received 19 October 2009 confirmed that a random numbers table was used to prepare numbered sealed envelopes. Review authors judged this adequate to minimise bias.
Allocation concealment (selection bias)	Low risk	Comment: Information received from trial investigators (email received 19 October 2009) confirmed that allocation codes were sealed within envelopes that were opened in turn at each site at time of allocation. Only the principal investigator and project co-ordinator had access to these envelopes. Review authors considered it unlikely that participants or any investigator enrolling participants could foresee assignment.
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind participants in this type of study. We found no indication of any specific additional measures taken to reduce the risk of bias that might result from differential behaviours by participants.
Blinding (performance bias and detection bias) of personnel	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because personnel would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind personnel in this type of study.
Blinding (performance bias and detection bias) of outcome assessors	High risk	Comment: Information received from trial investigators (email received 19 October 2009) confirmed that outcome assessors were not blinded to participant allocation. This may have introduced bias.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: The actual number of participants with AsPD failing to complete treatment (at 17 weeks) and to provide data relating to the key outcome (substance misuse - cocaine, by urinalysis) was broadly balanced between the treatment conditions (1/14 for CBT condition; 1/15 for the CM condition, 0/7 for the CBT + CM condition, and 2/12 for the control (SM) condition).

Messina 2003 *(Continued)*

Selective reporting (reporting bias)	Low risk	Comment: Study protocol was not available but it seemed clear that the published report included all expected outcomes. No evidence of selective reporting. All prospectively stated outcomes were reported.
Other bias	Unclear risk	Comment: Trial investigators acknowledged the presence of other psychiatric disorders in the sample; review authors did not judge this to introduce a significant risk of bias. However, whilst all participants were paying for their methadone maintenance treatment (either USD 140 or USD 180/month depending upon centre), they received a discount of USD 40/month for participating in the study. Prior to the introduction of this incentive, only 4 subjects had volunteered for the study after 60 days of recruitment. Review authors were unclear whether this payment would introduce bias.

Tyrer 2004

Study characteristics	
Methods	Design: parallel randomised controlled trial
Participants	Participants: patients with recurrent self-harm presenting at hospital emergency departments Sex: (for whole sample) 154 males; 326 females Age: (for whole sample) mean = 31.0 years (SD = 11.0) Unit of allocation: individual participant Number randomised: 480 (for whole sample); no details for dissocial PD subgroup[a] Number completing: no details for dissocial PD subgroup[a] Setting: outpatient; 5 sites; urban; UK (Glasgow, Edinburgh, Nottingham, West London, South London) Inclusion criteria: recent episode of self-harm and presenting at hospital emergency department; at least 1 previous episode of self-harm; willing to provide written consent Exclusion criteria: requiring inpatient psychiatric treatment after self-harm episode; primary diagnosis of substance dependence; psychotic or bipolar disorder Ethnicity: no information provided Baseline characteristics: (for whole sample[a]) any personality disorder (ICD-10; PAS-Q) (42.1%); paranoid PD (7.5%); schizoid PD (1.0%); dissocial PD (3.1%); impulsive PD (12.9%); borderline PD (14.0%); histrionic PD (6.7%); anankastic PD (4.0%); anxious PD (14.2%); dependent PD 11.3%
Interventions	Two conditions: manual-assisted cognitive behaviour therapy (MACT); or treatment-as-usual (TAU) • Experimental group (n = not reported[a]): MACT • Control group (n = not reported[a]): TAU Details of conditions: • In MACT, participants were allocated a therapist from the existing services and previously trained in MACT according to a pre-planned rota arrangement. Each was sent a 70-page booklet and offered up to 7 treatment sessions. • In TAU, participants were seen by another designated therapist and offered the standard treatment in the area concerned or the continuation of current therapy. Duration of intervention: up to 7 treatment sessions (total duration not specified)

Tyrer 2004 *(Continued)*

	Duration of trial: one year Length of follow-up: 6 months and 12 months post-treatment
Outcomes	Primary outcomes • Social functioning: scores on the Social Functioning Questionnaire • Global functioning: scores on the Global Assessment of Functioning • Quality of life: scores on the EuroQOL Secondary outcomes • Economic outcomes: total costs per patient over one year Other outcomes • Frequency of self-harm episodes: via Parasuicide History Interview • Anxiety and depressive symptoms (HADS) • Number of completed suicides
Notes	[a]15 participants out of 480 (3.1%) who were randomised had dissocial PD. Details of characteristics of, and outcomes for, this subgroup have been requested from trial investigators. Study funding: Medical Research Council Declaration of interests: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The Stata software was used to generate allocation using randomly permuted blocks. . ." (Tyrer 2003, p 60) Comment: Review authors judged that an appropriate computer-generated randomisation method was used for random sequence generation.
Allocation concealment (selection bias)	Low risk	Comment: Participants were randomly allocated by telephone or fax from the trial's co-ordinating centre. Review authors judged that concealment was achieved by use of central allocation so that neither participants nor any investigator enrolling participants could foresee assignment.
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind participants in this type of study. We found no indication of any specific additional measures taken to reduce the risk of bias that might result from differential behaviours by participants.
Blinding (performance bias and detection bias) of personnel	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because personnel would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind personnel in this type of study.
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	Comment: Insufficient information to allow a judgement to be made. Clarification has been requested from the trial investigators, but no further information was available at the time this review was prepared.

Tyrer 2004 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: Unclear whether there were missing outcome data for the dissocial PD subgroup and, if so, whether the numbers of and reasons for such missing data were balanced across intervention groups. Review authors unable to make a judgement unless data from dissocial PD subgroup become available
Selective reporting (reporting bias)	Low risk	Comment: Review authors judged that the published report included all expected outcomes, including those that were prespecified.
Other bias	Low risk	Comment: The study appeared to be free of other sources of bias.

Ball 2005

Study characteristics	
Methods	Design: parallel randomised controlled trial
Participants	Participants: homeless adults with substance abuse difficulties and personality disorder Sex: (for whole sample[a]) 49/52 (94%) males; 3/52 (6%) females Age: (for whole sample[a]) mean 38.3 = years (SD = 10.4, range = 19 to 57) Unit of allocation: individual participant Number randomised: 52 (for whole sample; no details for AsPD subgroup[a]) Number completing: no details for AsPD subgroup[a] Setting: outpatient; single site; urban; USA (Manhattan) Inclusion criteria: at least 18 years old; alcohol or drug use in past 30 days; diagnosis of PD (DSM-IV; PDQ[b]); able to read and comprehend consents and assessments; willingness to be a research participant Exclusion criteria: acute schizophrenia; bipolar disorder; organic syndrome; acute violence or suicidality; incarceration pending; actively participating in counselling at another substance abuse or mental health clinic whilst in active treatment phase Ethnicity: (for whole sample[a]) white (23%); Hispanic (26%); African American (49%) Baseline characteristics: (for whole sample[a]) never married (58%); currently married (4%); separated/divorced (33%); high school education (67%); essentially unemployed for prior 3 years (26%); some full-time or part-time work in prior 3 years (49%); alcohol as primary misuse substance (50%); illicit drugs as primary misuse substance (50%); average age of diagnosis onset for alcohol abuse 23.5 (SD = 7.8, median = 22) years; average age of diagnosis onset for drug abuse 21.0 (SD = 5.8, median = 19) years; cluster A PD diagnosis (88%); cluster B PD diagnosis (74%); cluster C PD diagnosis (85%); no period of stable living arrangements over last 3 years (27%)
Interventions	Two conditions: dual focus schema therapy (DFST); or treatment-as-usual (TAU) • Experimental group (n = not reported[a]): DFST • Control group (n = not reported[b]): TAU Details of conditions: • DFST is individual psychotherapy focussed on PD and substance abuse relapse prevention. It is a 24-week manual-guided individual therapy that integrates symptom-focussed relapse prevention coping skills techniques for interpersonal, affective and craving experiences, and schema-focussed techniques for early maladaptive schemas and coping styles and is delivered weekly.

Ball 2005 *(Continued)*

	• TAU is standard group substance abuse counselling as normally provided at the drop-in centre where clients are typically offered a total of 3 opportunities per week to attend group psychoeducation and counselling sessions. Duration of intervention: 24 weeks Duration of trial: 9 months Length of follow-up: 3 months following end of treatment (although investigators reported "successful follow up in the sample proved to be extraordinarily difficult to achieve"; quote, p 374, column 1)
Outcomes	Primary outcomes • Social functioning: mean scores on the Addiction Severity Index social/family domain Secondary outcomes • Leaving the study early: proportion of participants discontinuing treatment Other outcomes • Therapy retention: total weeks in treatment • Therapy utilisation: number weeks in which sessions attended • Severity of PD: scores on the Personality Diagnostic Questionnaire [b] • Psychiatric symptoms: mean scores on the Brief Symptom Inventory • Early maladaptive schemas: mean scores on the Early Maladaptive Schema Questionnaire - Research • Interpersonal problems: means scores on the Inventory of Interpersonal Problems
Notes	[a]24 participants out of 52 (47%) who were randomised had AsPD. Details of characteristics of, and outcomes for, this subgroup have been requested from trial investigators. [b]Trial investigators noted significant missing data for PDQ scores: “because of a major computer malfunction, the personality disorder profiles of 16 of the participants could not be recovered” (quote; p 373, column 1) Study funding: Jacob and Valeria Langeloth Foundation Declaration of interests: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "after completion of baseline assessments, subjects were randomly allocated to 1 of 2 study treatments" (p 374, column 1). Comment: no further details reported. Clarification about method of sequence generation has been requested from the trial investigators, but no further information was available at the time this review was prepared.
Allocation concealment (selection bias)	Unclear risk	Comment: Insufficient information to allow a judgement to be made. Clarification about method of allocation concealment has been requested from the trial investigators, but no further information was available at the time this review was prepared.
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not that they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind participants in this type of study. We found no indication of any specific

Ball 2005 *(Continued)*

		additional measures taken to reduce the risk of bias that might result from differential behaviours by participants.
Blinding (performance bias and detection bias) of personnel	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because personnel would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind personnel in this type of study.
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	Comment: Insufficient information to allow a judgement to be made. Clarification about blinding of outcome assessors has been requested from the trial investigators, but no further information was available at the time this review was prepared.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: The trial investigators noted significant missing data for PDQ scores "because of a major computer malfunction, the personality disorder profiles of 16 of the participants could not be recovered" (quote; p 373, column 1). Although review authors considered this could have introduced bias for one outcome (severity of PD), this was not one of the primary or secondary outcomes addressed in this review. Unclear whether there were missing outcome data for the AsPD subgroup and, if so, whether the numbers of and reasons for such missing data were balanced across intervention groups. Review authors unable to make a judgement unless data from AsPD subgroup become available
Selective reporting (reporting bias)	High risk	Comment: Investigators did not report endpoint or follow-up data for 3 outcomes, measured with the Early Maladaptive Schema Questionnaire, the Inventory of Interpersonal Problems and the Addiction Severity Index.
Other bias	Low risk	Comment: The study appeared to be free of other sources of bias.

Havens 2007

Study characteristics	
Methods	Design: cluster-randomised controlled trial
Participants	Participants: intravenous drug users (subgroup with AsPD) attending an outpatient needle exchange programme Sex: 68% males (for whole sample, including non-AsPD) Age: median = 38 years (for whole sample, including non-AsPD) Unit of allocation: site[a] Number randomised: 10 sites, 254 participants (for whole sample, including non-AsPD) (breakdown by treatment condition not supplied) Number completing: 162 (n = 74 intervention group; n = 88 control group) (for whole sample, including non-AsPD[b]) Setting: outpatient; multisite (10 sites); urban; USA (Baltimore) Inclusion criteria: diagnosis of AsPD (DSM-IV, SCID-II); intravenous drug user participating in the Baltimore needle exchange programme Exclusion criteria: none reported Ethnicity: (for whole sample, including non-AsPD) 76% black

Havens 2007 *(Continued)*

	Baseline characteristics: 19% current major depressive disorder; 14% current generalised anxiety disorder; Addiction Severity Index mean score 0.23; 28% HIV positive; 31% had entered opiate agonist treatment
Interventions	Two conditions: strengths-based case management (SBCM-subsequently split in to SBCM of 5 to 24 minutes duration, or SBCM of at least 25 minutes duration); or control • Experimental group[c] (n = 128) (SBCM of 5 to 24 minutes duration, and SBCM of at least 25 minutes duration) • Control group[c] (n = 117) passive referral or SBCM of 0 to 4 minutes duration Details of conditions: • SBCM activities included engagement, strengths assessment, personal case planning, and resource acquisition. Services provided by case managers included referrals to health and social services, transportation and employment. • Control condition was passive referral or SBCM of 0 to 4 minutes duration Duration of intervention: median treatment duration of SBCM was 25 minutes Duration of trial: 1 month Length of follow-up: 1 month Dose adjustment: n/a
Outcomes	Primary outcomes • None Secondary outcomes • Engagement with services: entry into treatment
Notes	[a]Random allocation was by site. Havens 2007 did not clarify this, but an earlier report of the same study (Strathdee 2006) stated "To limit contamination participants were randomised by NEP site. Specifically, at the beginning of the study NEP site was randomised to receive the intervention (case management) or control condition (passive referral). Approximately halfway through the recruitment period, a 1 month washout period was scheduled during which time no participants were recruited. After washout, sites originally randomised to case management received the control intervention and vice versa until the end of enrolment." (quote; p 226, column 1) [b]Figures given for AsPD subgroup not provided, except that 37 of those completing 1-month follow up had AsPD. Clarification has been requested from the trial investigators, but no further information was available at the time this review was prepared. [c]Whole sample only, no AsPD subgroup Study funding: National Institute on Drug Abuse Declaration of interests: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: No information given. Insufficient reporting to permit judgement of Yes or No. Clarification has been requested from the trial investigators, but no further information was available at the time this review was prepared.

Havens 2007 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Comment: No information given. Insufficient reporting to permit judgement of Yes or No. Clarification has been requested from the trial investigators, but no further information was available at the time this review was prepared.
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind participants in this type of study. We found no indication of any specific additional measures taken to reduce the risk of bias that might result from differential behaviours by participants.
Blinding (performance bias and detection bias) of personnel	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because personnel would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind personnel in this type of study.
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	Comment: Insufficient information to allow a judgement to be made. Clarification about blinding of outcome assessors has been requested from the trial investigators, but no further information was available at the time this review was prepared.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: Unclear whether there were missing outcome data for the AsPD subgroup and, if so, whether the numbers of and reasons for such missing data were balanced across intervention groups. Review authors unable to make a judgement unless data from AsPD subgroup become available.
Selective reporting (reporting bias)	Low risk	Comment: Review authors judged that the published report included all expected outcomes, including those that were prespecified.
Other bias	Unclear risk	Comment: There is the possibility of bias arising from baseline imbalance in that the median age of first injection (of drugs) was greater in the control group than in the intervention group.

Neufeld 2008

Study characteristics	
Methods	Design: parallel randomised controlled trial
Participants	Participants: outpatients with AsPD and opioid dependency Sex: 77/100 (77%) males; 33/100 (33%) females Age: mean = 39 years (SD = 7.1) Unit of allocation: individual participant Number randomised: 100 (n = 51 experimental group; n = 49 control group) Number completing: 86 (n = 42 experimental group; n = 44 control group) Setting: outpatient, single site, urban, USA (Baltimore) Inclusion criteria: antisocial personality disorder (DSM-III-R; SCID-II); opioid dependence (DSM-III-R; SCID-I)

Neufeld 2008 *(Continued)*

	Exclusion criteria: pregnancy; bipolar disorder; schizophrenia Ethnicity: 40/100 (40%) Caucasian Baseline characteristics: all participants recruited from local addiction treatment programme; 75/100 (75%) were new admissions to the programme and 25/100 (25%) were already in treatment and responding poorly; 12/100 (12%) married; 34/100 (34%) employed; mean = 10.7 years (SD = 2.1) in education; 72/100 (72%) income less than USD 500 per month; all participants met criteria for both lifetime and current opioid use disorder (includes both dependence and abuse); 95/100 (95%) met criteria for lifetime cocaine use disorder and 49/100 (49%) current cocaine use disorder; 82/100 (82%) met criteria for lifetime alcohol use disorder and 18/100 (18%) current alcohol use disorder; 58/100 (58%) met criteria for lifetime sedative use disorder and 11/100 (11%) current sedative use disorder; 74/100 (74%) met criteria for lifetime cannabis use disorder and 12/100 (12%) current cannabis use disorder; 41/100 (41%) met criteria for lifetime other stimulants use disorder and 0/100 (0%) current other stimulants use disorder; 38/100 (38%) met criteria for lifetime hallucinogen use disorder and 1/100 (1%) current hallucinogen use disorder; 35/100 (35%) met criteria for lifetime axis I diagnosis and 25/100 (25%) current axis I diagnosis; 28/100 (28%) met criteria for axis II diagnosis (presumably other than AsPD); 46/100 (46%) met criteria for any axis I or II diagnosis
Interventions	Two conditions: contingency-based behavioural programme; or standard maintenance • Experimental group (n = 51 randomised): contingency-based behavioural programme • Control group (n = 49 randomised): standard maintenance Details of conditions: • The contingency-based behavioural programme is a highly structured contingency-based, adaptive treatment protocol. It is based on counselling sessions and behavioural interventions of rewarding/punishing participants with greater/lesser control over their methadone maintenance based on their compliance with counselling attendance and drug abstinence. Participants gained greater control over methadone clinic attendance and dosage in reward for drug abstinence and attendance at counselling sessions. Negative reinforcers were reduction in methadone dosage and staff determining when and what dosage administered, or being given split dosing. • Standard maintenance comprised standard methadone substitution treatment in which participants started at methadone dosage of 55 mg/day and attended 2 individual counselling sessions per week. Methadone dosage reviewed every 2 weeks and changes determined clinically. Methadone doses also monitored monthly to ensure they remained comparable to mean dose in experimental group. Methadone take-home doses could be earned but only after 12 weeks of consecutive illicit drug negative urine samples and participants could not select the specific day of the week on which they received take-home methadone. Duration of intervention: 6 months Duration of trial: 7 months (initial 4-week baseline evaluation period followed by 6 months of randomised treatment) Length of follow-up: none Dose adjustment: dose of methadone was adjusted according to protocol as determined by group membership (see above)
Outcomes	Primary outcomes • Social functioning: mean scores on the Addiction Severity Index (ASI) social/family domain Secondary outcomes • Leaving the study early: proportion of participants discontinuing treatment • Substance misuse (drugs): drug-related problem severity (adjusted mean ASI composite scores); urinalysis • Substance misuse (alcohol): mean ASI scores • Employment status: mean ASI employment domain scores

Neufeld 2008 *(Continued)*

- Engagement with services: adherence to counselling sessions

Other outcomes

- Proportion transferred due to poor/partial treatment response

Notes	Study funding: National Institute on Drug Abuse Declaration of interests: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: Information received from trial investigators (email to NH received 17 November 2009) confirmed that sequence generation was by coin toss.
Allocation concealment (selection bias)	Low risk	Comment: Information received from trial investigators (email to NH, received 17 November 2009) indicated that the nature of the allocation process was such that allocation status could not have been predicted or foreseen by the participants or any investigator enrolling participants.
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind participants in this type of study. We found no indication of any specific additional measures taken to reduce the risk of bias that might result from differential behaviours by participants.
Blinding (performance bias and detection bias) of personnel	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because personnel would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind personnel in this type of study.
Blinding (performance bias and detection bias) of outcome assessors	Low risk	Comment: Information received from trial investigators (email to NH, received 17 November 2009) confirmed that the laboratory technicians who tested the urines were not privy to the study design or group assignment, that the data entry people who collated attendance did not know the assignment of the patient, and that the research staff who collected the ASI questionnaire data over the course of the study did not know to which arm of the study the patient was assigned. Review authors judged that blinding of outcome assessors was adequate and that it was unlikely that this blinding could have been broken.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: For urinalysis results, 31% of data missing from experimental group and 33% of data missing from control group. Investigators reported that missing data were equally distributed across study conditions, but reasons were not given. For ASI results, 9/51 (18%) data missing from experimental group and 5/49 (10%) missing from control group. Review authors unable to judge whether reasons for missing data differed substantially across the groups or if reasons for missing outcome data were likely to be related to true outcome. Clarification has been requested from the trial investigators, but no further information was available at the time this review was prepared.
Selective reporting (reporting bias)	Low risk	Comment: Review authors judged that the published report included all expected outcomes, including those that were prespecified.
Other bias	Low risk	Comment: The study appeared to be free of other sources of bias. Investigators commented that the presence of a therapeutic transfer procedure may

Neufeld 2008 *(Continued)*

	have reduced drug abuse in order to avoid transfer to a more intensive routine treatment allocation, although investigators reported that this dropout rate is comparable to other studies of opioid-dependent subjects.

Woodall 2007

Study characteristics	
Methods	Design: parallel randomised controlled trial
Participants	Participants: incarcerated drink-driving offenders with AsPD sentenced to a Driving While Intoxicated (DWI) treatment programme Sex: (for AsPD subgroup) 45/52 (87%) males; 7/52 (13%) females Age: (for AsPD subgroup) mean = 26.5 years (SD = 7.9) Unit of allocation: individual participant Number randomised: 52 (n = 36 intervention group; n = 16 control group) Number completing: 52 (n = 36 intervention group; n = 16 control group) Setting: prison, single site, USA (New Mexico) Inclusion criteria: court-defined first offenders sentenced to the Driving While Intoxicated (DWI) treatment programme whilst in prison; diagnosis of AsPD (DSM-III-R, Diagnostic Interview Schedule) Exclusion criteria: none reported Ethnicity: (for AsPD subgroup) 37/52 (71%) Native American; 12/52 (23%) Non-Hispanic white; 3/52 (6%) Hispanic or other Baseline characteristics: 42/52 (89%) met DSM-III-R criteria for alcohol dependency using the Diagnostic Interview Schedule; mean DrinC score = 23.8 (SD 9.9); mean number of days drinking in past 30 days = 9.2 (SD 8.4) days; mean number of days in last 30 days when had drank and then driven = 3.9 (SD 5.3) days; mean number of drinks per drinking day = 5.9 (SD 5.1); mean number of days with 5 or more drinks = 5.9 (SD 6.9); mean number of days driving after 5 or more drinks = 2.9 (SD 4.3); Form 90 measures of drinking over past 90 days: total standard ethyl-alcohol consumption (SEC) = 328.0 (SD 431.3), drinking days = 25.7 (SD 26.3), mean blood alcohol content (BAC) = 0.043 (SD 0.058)
Interventions	Two conditions: 'driving whilst intoxicated' programme (DWI) + incarceration; or incarceration only • Experimental group (n = 36 randomised): DWI + incarceration • Control group (n = 16 randomised): incarceration only Details of conditions: • In the DWI condition, the programme was non-confrontational and utilised motivational interviewing principles. Components included: alcohol use, abuse and dependence; health and nutrition; psychological effects of alcohol; drinking and driving awareness; stress-management; goal-setting and action-planning for the future; family issues and alcohol; domestic violence; HIV/AIDS prevention; work release programme for those in employment. Also incorporated culturally appropriate elements such as sweat lodges and talking circles (71% of participants were native American). The DWI programme was delivered whilst participants were subject to 28 days incarceration. • The control condition was 28 days incarceration Duration of intervention: 28 days Duration of trial: 25 months (1 month of intervention and 24 months of follow-up)

Woodall 2007 *(Continued)*

	Length of follow-up: 6, 12 and 24 months Dose adjustment: n/a
Outcomes	Primary outcomes • Reconviction: recidivism data Secondary outcomes • Substance misuse (alcohol): number of drinks, number of drinking days and mean blood alcohol content; mean number of days driving after drinking in past 30 days; mean number of days driving after 5 or more drinks in past 30 days (via Form 90 and DrInC-2R questionnaires) Other outcomes • None
Notes	Study funding: National Institute on Alcohol Abuse and Alcoholism Declaration of interests: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: No information provided. Insufficient reporting to permit judgement of Yes or No. Clarification has been requested from the trial investigators, but no further information was available at the time this review was prepared.
Allocation concealment (selection bias)	Unclear risk	Comment: No information provided. Insufficient reporting to permit judgement of Yes or No. Clarification has been requested from the trial investigators, but no further information was available at the time this review was prepared.
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind participants in this type of study. We found no indication of any specific additional measures taken to reduce the risk of bias that might result from differential behaviours by participants.
Blinding (performance bias and detection bias) of personnel	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because personnel would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind personnel in this type of study.
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	Comment: Insufficient information to allow a judgement to be made. Clarification about blinding of outcome assessors has been requested from the trial investigators, but no further information was available at the time this review was prepared.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: For the outcome of self-reported drink-driving behaviour, data missing for 6/36 (17%) of the intervention group and for 3/16 (19%) of control group. Although these numbers appear similar, reasons for this missing data were not provided. For the outcome of alcohol use, the amount of missing self-report data was not reported but review authors judged it reasonable to assume that the above figures also applied to this as it was measured similarly. For the outcome of drink-driving recidivism, it was unclear what numbers of missing data occurred in the AsPD subgroup, although for the entire sample

Woodall 2007 *(Continued)*

		missing data on this item was reported as 31/305 (10%). Clarification has been requested from the trial investigators, but no further information was available at the time this review was prepared.
Selective reporting (reporting bias)	Low risk	Comment: Study protocol was not available but it seemed clear that the published report included all expected outcomes. No evidence of selective reporting. All prospectively stated outcomes were reported.
Other bias	Unclear risk	Comment: In terms of baseline imbalance, the intervention group was significantly more likely to have histories of drinking and driving in comparison with the controls, although it was unclear if this applied to the AsPD subgroup.

Huband 2007

Study characteristics	
Methods	Design: parallel randomised controlled trial
Participants	Participants: community living adults with personality disorder Sex: (for AsPD subgroup[a]) 18 males; 6 females Age: (for AsPD subgroup[a]) mean = 34.4 years (SD = 8.4) Unit of allocation: individual participant Number randomised: (for AsPD subgroup) 24 (13 = intervention, 11 = control) Number completing: not reported; used last-observation-carried-forward Setting: outpatient; 5 sites; urban and rural; UK (East Midlands) Inclusion criteria: presence of at least one personality disorder (DSM-IV; IPDE); age 18 to 65 years; literacy and cognitive functioning sufficient to allow engagement with the intervention; able to provide written informed consent Exclusion criteria: major functional psychosis Ethnicity: no information on ethnicity reported for AsPD subgroup Baseline characteristics: for whole sample, including non-AsPD participants: 49/176 (27.8%) visited Accident and Emergency (A + E) for any reason in the previous 6 months; 25/176 (14.2%) visited A + E due to self-harm in the previous 6 months; 21/176 (11.9%) psychiatric hospital admission in the previous 6 months; mean number of contacts with a psychiatrist/month in the last 6 months 0.21 (intervention) and 0.27 (control group); mean number of contacts with other mental health staff/month in the last 6 months 0.63 (intervention) and 0.83 (control group). For the AsPD subgroup[a]: 4/24 (16.7%) AsPD as the only personality disorder; 20/24 (83.3%) AsPD comorbid with at least one other personality disorder
Interventions	Two conditions: brief individual psychoeducation plus problem-solving group sessions; or treatment-as-usual (TAU) • Experimental group (n = 13 randomised): brief individual psychoeducation plus problem-solving group sessions • Control group (n = 11 randomised): TAU whilst on waiting list Details of conditions: • Participants in the intervention condition attended an individual psychoeducation programme where they learned about personality disorder and nature of own personality disorder diagnosis. This was followed by 16 weekly group-based problem-solving sessions (lasting approximately 2 hours) based

Huband 2007 *(Continued)*

	on the 'Stop and Think!' method. Each group was facilitated by 2 facilitators, experienced in working with patients with personality disorder. Groups started with no more than 8 participants in each and were single gender. • In TAU, participants were placed on a waiting list Duration of intervention: mean = 24 weeks (range = 21 to 28) Duration of trial: mean = 24 weeks (range = 21 to 28) Length of follow-up: none
Outcomes	Primary outcomes • Social functioning: scores on Social Functioning Questionnaire Secondary outcomes • Anger: scores on State-Trait Anger Expression Inventory-2 • Impulsivity: scores on Barrett Impulsivity Scale Other outcomes • Social problem-solving ability: mean scores on the Social Problem Solving Inventory - Revised • Shame: mean scores on the Experience of Shame Scale • Dissociation: mean scores on the Dissociative Experiences Scale
Notes	[a]24 (13.6%) of all 176 participants in the sample had AsPD. Of these, 13 were allocated to intervention and 11 to control conditions. Data from this AsPD subgroup supplied by trial investigators Study funding: National Programme for Forensic Mental Health R&D and the Home Office Declaration of interests: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: Research investigators described a block randomisation procedure using computer-generated random numbers provided by an independent statistician. Review authors judged this adequate to minimise bias.
Allocation concealment (selection bias)	Low risk	Comment: Allocation codes pre-sealed into identical, sequentially numbered, opaque envelopes that were opened in sequence by research staff with trial coordinator masked to allocations. Review authors considered it unlikely that participants or any investigator enrolling participants could foresee assignment.
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind participants in this type of study. We found no indication of any specific additional measures taken to reduce the risk of bias that might result from differential behaviours by participants.
Blinding (performance bias and detection bias) of personnel	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because personnel would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind personnel in this type of study.

Huband 2007 *(Continued)*

Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	Outcome measures were self-report questionnaires completed by participants who were not blind to their own allocation status and were scored by research assistants who could have been aware of this allocation status in some cases. In view of this uncertainty, review authors considered a judgement of 'unclear' to be appropriate as some possibility of bias remains.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: Data from the AsPD subgroup supplied by trial investigators indicated that at the end of the trial 4 of 13 (30.8%) were missing from the intervention condition and 3 of 11 (27.3%) were missing from the TAU condition (all outcomes). Reasons for missing data (and any differences in the reasons between conditions) were not available. Feedback from trial investigators confirmed that missing data occurred where clients declined to complete endpoint questionnaires. Although no further information was available on why these clients declined to participate in this task, review authors considered the reasons for missing data were reasonably likely to be balanced across the treatment conditions.
Selective reporting (reporting bias)	Low risk	Comment: Review authors judged that the published report included all expected outcomes, including those that were prespecified.
Other bias	Unclear risk	Comment: Trial investigators noted that outcomes were based on measurements at just two time points (baseline and endpoint) so may be open to bias from those participants in either a very optimistic or pessimistic state of mind. They also noted that 20 of 24 (83.3%) participants had at least one other personality disorder. There was also the possibility of bias arising from baseline imbalance in that those in the intervention group were significantly more likely to have had psychiatric hospitalisation at some time in their life in comparison with the controls (although they were not significantly more likely to have been hospitalised in the previous 6 months).

Marlowe 2007

Study characteristics	
Methods	Design: parallel randomised controlled trial
Participants	Participants: adults charged with a drug-related offence and admitted to a pre-adjudication court Sex: (for whole sample[a]) 75% males; 25% females Age: (for whole sample[a]) mean = 25.1 years (SD = 8.4) Unit of allocation: individual participant Number randomised: 279 (for sample as a whole; no details for AsPD subgroup[a]) Number completing: no details for AsPD subgroup[a] Setting: outpatient; single site; urban; USA (Wilmington, Delaware) Inclusion criteria: at least 18 years old; admitted to a misdemeanour (pre-adjudication) drug court located in Wilmington, Delaware, USA; having pleaded guilty to the initial charge (the plea of guilty was held in abeyance pending graduation or termination from the programme); charged with possession or consumption of cannabis, possession of drug paraphernalia, possession of hypodermic syringes, or driving under the influence; resident in New Castle County, Delaware or committed his/her offence there Exclusion criteria: having a history of a violent offence involving serious injury to a victim or use of a deadly weapon

Marlowe 2007 *(Continued)*

	Ethnicity: (for whole sample[a]) white (60%); African American (35%) Baseline characteristics: (for whole sample[a]) unmarried (94%); employed (66%); currently abusing cannabis (68%); currently abusing alcohol to intoxication (47%); currently abusing stimulants or cocaine (14%), opiates (13%) or hallucinogens (3%)
Interventions	Two conditions: optimal ('matched') schedule of court hearings; or standard ('unmatched') schedule court hearings • Experimental group (n = 137 randomised for whole sample; n = not reported for AsPD subgroup[a]): optimal ('matched') schedule of court hearings • Control group (n = 142 randomised for whole sample; n = not reported for AsPD subgroup[a]): standard ('unmatched') schedule of court hearings Details of conditions: • Optimal ('matched') schedule of court hearings in which frequency of court attendance was matched with risk, so that high-risk offenders (those with AsPD and a history of drug treatment) attended with greater frequency. Group sessions were psychoeducational and covered a range of topics including relapse prevention strategies. Minimum requirements for graduation from the programme were attending at least 12 weekly group counselling sessions, providing at least 14 consecutive weekly drug-negative urine specimens, remaining arrest-free, obeying programme rules and paying a USD 200 court fee. • Standard ('unmatched') schedule of court hearings required attendance every 4 to 6 weeks. Duration of intervention: minimum 14 weeks, although clients required on average approximately 9 months to satisfy all the conditions for graduation Duration of trial: 15 months (9 months to graduation plus 6 months post-discharge) Length of follow-up: 6 months post-discharge
Outcomes	Primary outcomes • Reconviction: as recorded in Criminal Justice System databases up to 24 months post-admission to programme • Adverse events: "no study-related adverse event was reported to date" (quote; p 56, column 1) Secondary outcomes • Substance misuse (drugs): data from Addiction Severity Interview, including days of drug use, days any drug use, days alcohol intoxication; any criminal activity; drug screen by urinalysis • Leaving the study early: proportion of participants discontinuing treatment
Notes	[a]Investigators used diagnosis of AsPD as one criterion in the assessment of risk. Diagnosis of AsPD was via an antisocial personality disorder interview derived from SCID-II. Characteristics of, and outcomes for, this subgroup have been requested from trial investigators. Study funding: National Institute on Drug Abuse Declaration of interests: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: No information given. Insufficient reporting to permit judgement of Yes or No. Clarification has been requested from the trial investigators, but no further information was available at the time this review was prepared.

Marlowe 2007 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Comment: No information given. Insufficient reporting to permit judgement of Yes or No. Clarification has been requested from the trial investigators, but no further information was available at the time this review was prepared.
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind participants in this type of study. We found no indication of any specific additional measures taken to reduce the risk of bias that might result from differential behaviours by participants.
Blinding (performance bias and detection bias) of personnel	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because personnel would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind personnel in this type of study.
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	Comment: Insufficient information to allow a judgement to be made. Clarification about blinding of outcome assessors has been requested from the trial investigators, but no further information was available at the time this review was prepared.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: Unclear whether there were missing outcome data for the AsPD subgroup and, if so, whether the numbers of and reasons for such missing data were balanced across intervention groups. Review authors unable to make a judgement unless data from AsPD subgroup were available
Selective reporting (reporting bias)	Low risk	Comment: Review authors judged that the published report included all expected outcomes, including those that were prespecified.
Other bias	Unclear risk	Comment: Review authors unable to judge unless data from the AsPD subgroup become available. It is important to note, however, that the diagnosis of AsPD was via an 'antisocial personality disorder interview' derived from SCID-II by the trial investigators, but with no evidence that this has been validated. This may have introduced bias.

Davidson 2009

Study characteristics	
Methods	Design: parallel randomised controlled trial
Participants	Participants: male outpatients with AsPD and recent verbal/physical violence Sex: all males Age: mean = 37.9 years (SD = 10.4) Unit of allocation: individual participant Number randomised: 52 (n = 25 CBT + TAU; n = 27 TAU only) Number completing: 41 (n = 20 CBT + TAU; n = 21 TAU only) at 12 months Setting: outpatient; multisite (2 sites); urban; UK (Glasgow and London)

Davidson 2009 *(Continued)*

	Inclusion criteria: male; aged 18 to 65 years; diagnosis of AsPD (DSM-IV; SCID); living in community; endorsement of at least one item on MacArthur Community Violence Screening Instrument (MCVSI); interviewed in 6 months prior to baseline; able to provide written informed consent Exclusion criteria: currently receiving a systematic psychological therapy; insufficient knowledge of English to participate/understand; diagnosis of psychosis (schizophrenia or bipolar-affective disorder); currently receiving inpatient treatment[a] Ethnicity: 35/52 (67%) white Baseline characteristics: 51/52 (98%) reported verbal aggression in previous six months; 45/52 (87%) reported physical aggression against others in previous 6 months; mean = 4.9 (SD = 20.4) days in psychiatric hospital in previous 12 months; mean age at first contact with psychiatric services = 19.8 (SD = 12.5) years; mean age at first trouble with law = 14.3 (SD = 7.6) years; mean total Drug and Alcohol Screening Test score = 5.7 (SD = 4.4); mean age at leaving school = 15.6 (SD = 1.4) years; mean number of months in work during last 5 years = 16.5 (SD = 22.9) months; 38/52 (73%) unemployed at entry into study; 37/52 (71%) assessed as at least below average literacy on Test of Word Reading Efficacy
Interventions	Two conditions: cognitive behavioural therapy plus treatment-as-usual (CBT + TAU); or treatment-as-usual (TAU) • Experimental group (n = 25 randomised): CBT + TAU • Control group (n = 27 randomised): TAU Details of conditions: • CBT intervention defined as “structured, time-limited, psychosocial intervention developed to treat those with borderline and antisocial personality disorder within National Health Service settings”. Participants were encouraged to engage in treatment through a cognitive formulation of their problems. The therapy focuses on beliefs about self and others that impair social functioning. CBT was delivered by 7 therapists who had relevant experience and training and who were supported with weekly case supervision. Therapist adherence/competence was assessed for a random selection (30%) of sessions by audio recording and found to be “within the 'competent' range” (quote; p 571, column 1) • In TAU “All participants received whatever treatment they would have received had the trial not taken place” (quote; p 570, column 2) Duration of intervention: 6 months or 12 months (see note 2). Participants who were randomised to CBT + TAU were further randomly allocated to treatment over either 6 months as 15 x 1-hour sessions (n = 12) or 12 months as 30 x 1-hour sessions (n = 13) Duration of trial: 12 months[b] Length of follow-up: Participants were not followed up beyond end of trial at 12 months.

Outcomes	Primary outcomes
	
	• Aggression: number reporting incidents of physical aggression; number reporting incidents of verbal aggression
	• Social functioning: mean scores on Social Functioning Questionnaire
	
	Secondary outcomes
	
	• Leaving the study early: proportion of participants discontinuing treatment
	• Anger: mean scores on Novaco Anger Scale and Provocation Inventory
	• Satisfaction with treatment: satisfaction with taking part in study (via questionnaire)
	• Substance misuse (alcohol): scores on AUDIT questionnaire
	• Economic outcomes: costs per patient
	• Mental state
	  ◦ Depression: mean scores on the Hospital Anxiety and Depression Rating Scale (HADS) depression subscale
	  ◦ Anxiety: mean scores on HADS anxiety subscale

Davidson 2009 *(Continued)*

	Other outcomes • Shame: mean Brief Core Schema Scale, shame scores
Notes	[a]Investigators did not list substance dependency as an exclusion criterion. Trial investigators have, however, confirmed (telephone conversation between SG and Prof Davidson on 14 August 2009) that 3 participants who were obviously physically dependent on drugs or alcohol (or both) to such an extent that they were unable to co-operate with the trial were excluded and referred on to appropriate substance abuse services. [b]Feedback from trial investigators (telephone conversation between SG and Prof Davidson on 14 August 2009) confirmed that one aim in this feasibility study was to determine whether clients would comply best with a 6- or 12-month intervention. Investigators reported no difference at baseline between those who received the 6-month and those who received the 12-month intervention, and that the two groups were not analysed separately. Study funding: Medical Research Council Declaration of interests: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: Web-based system used to generate the allocation sequence with stratification by centre Quote: "randomisation schedule was constructed using the method of randomised permuted blocks of size four. Randomisation was conducted using a web-based system" (p 570). After contacting the investigators (telephone conversation between SG and Prof Davidson on 14 August 2009), review authors judged that an appropriate computer-generated randomisation method was used for random sequence generation.
Allocation concealment (selection bias)	Low risk	Quote: "the randomisation schedules were generated by the study data centre. . . and kept securely and confidentially by the trial coordinator at the study coordinating centre in Glasgow. The trial coordinator informed the referring agent of the result of the randomisation immediately and in writing, and then contacted the CBT therapists in each area with the participants details so that CBT could be initiated" (p 570). Comment: Review authors judged that concealment achieved by use of central allocation so that participants and any investigator enrolling participants could not foresee assignment.
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind participants in this type of study. We found no indication of any specific additional measures taken to reduce the risk of bias that might result from differential behaviours by participants.
Blinding (performance bias and detection bias) of personnel	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because personnel would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind personnel in this type of study.

Davidson 2009 *(Continued)*

Blinding (performance bias and detection bias) of outcome assessors	Low risk	Quote: "the research assistants on each site carried out all the assessments at 3-monthly intervals until the participant exited the trial (after 12 months) and were blind to allocation" (p 571). Comment: Review authors judged that blinding of outcome assessors was adequate and that it was unlikely that this blinding could have been broken.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: Number missing varied across the 4 time points for all outcomes, although at each time point the numbers missing were approximately balanced across the groups. At the final time point (i.e. endpoint at 12 months), there were 5/25 (20%) missing from the CBT group and 6/27 (22%) missing from the TAU group. Reasons for missing data (and any differences in the reasons between groups) were not reported. Feedback from trial investigators (telephone conversation between SG and Prof Davidson on 14 August 2009) confirmed that missing data occurred where clients declined to participate and did not attend. Although no further information was available on why these clients declined to participate, review authors considered the reasons for non-participation were reasonably likely to be balanced across the treatment conditions.
Selective reporting (reporting bias)	Low risk	Comment: Investigators noted that three additional behaviours were assessed ('shouting angrily at others'; 'threatening to harm others'; 'causing damage to property'), but the published report did not appear to fully report the results of these besides noting that "overall, no differences were found between those randomised to CBT or TAU on any of the measures at 12-month follow-up" (quote; p 574). However, feedback from trial investigators (telephone conversation between SG and Prof Davidson on 14 August 2009) confirmed that 'shouting angrily at others' and 'threatening to harm others' were reported together as 'verbal aggression', and that 'causing damage to property' was included in outcome 'number reporting any act of physical aggression'.
Other bias	Low risk	Comment: Review authors judged study to be free of other forms of bias despite the analysis being partial rather than true intention-to-treat.

Tarrier 2010

Study characteristics	
Methods	Design: parallel randomised control trial
Participants	Participants: male patients aged 18-70 from the personality disorder service of a UK high secure hospital Sex: 100% male Age: (for whole sample[a]) schema modal therapy (SMT) + treatment-as-usual (TAU) (mean = 41.8 years, SD = 9.92); treatment-as-usual (TAU) (mean = 42.74 years, SD = 12.44) Unit of Allocation: individual Number randomised: 63 for whole sample (AsPD subsample = 43)[a]; schema modal therapy + TAU group (n = 29; AsPD subgroup = 18); TAU group (n = 34; AsPD subgroup = 25) Number completing: 35[a]; Schema modal therapy + TAU group (n = 15, 51.7%); TAU group (n = 20, 58.8%) Setting: high secure psychiatric hospital; Ashworth Hospital, National Health Service, England, UK

Tarrier 2010 *(Continued)*

Inclusion criteria: at least one diagnosis on Structured Clinical Interview for DSM-IV Axis II personality disorder (SCID-II); consent from clinical team; consent from patient

Exclusion criteria: current symptoms of psychotic illness or an organic brain syndrome; IQ of less than 80; patient due to be transferred; patient in seclusion

Ethnicity:[a] white Caucasian: schema modal therapy + TAU n = 26/29 (89.7%); TAU n = 29/34 (85.3%)

Baseline characteristics:[a])

- Schema modal therapy + TAU group: past convictions (mean = 7.2, SD = 5.86); length of stay in days (mean = 5259, SD = 3012); psychopathy (PCL-R total score; mean = 23.8, SD = 7.58): psychiatric symptoms (BPRS total score; mean = 31.83, SD = 7.13); risk (HCR-20 total score; mean = 25.86, SD = 7); risk of violence (VRS total score; mean = 51.35, SD = 11.14); participants on legal section 37/41 (n = 14/29, 48%); participants with violent incidents in past month* (n = 8/29, 28%); participants with self-harm incidents in month before baseline (n = 6/29, 21%)
- TAU group: past convictions (mean = 7.5, SD = 6.95); length of stay in days (mean = 4678, SD = 3835); psychopathy (PCL-R total score; mean = 25.3, SD = 6.24); psychiatric symptoms (BPRS total score; mean = 34.26, SD = 7.51); risk (HCR-20 total score; mean = 26.12, SD = 5.07); risk of violence (VRS total score; mean = 53.77, SD = 10.39); participants on legal section 37/41 (n = 16/34, 38%); participants with violent incidents in past month (n = 6/34, 18%); participants with self-harm incidents month before baseline (n = 5/34, 15%)

Interventions	Two conditions: schema modal therapy (SMT); or treatment-as-usual (TAU) • Experimental group = SMT + TAU (n = 18 randomised) • Control group = TAU (n = 25 randomised) Details of conditions:[b] • Intervention group treatment described as "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." (quote; p 7). The intervention treatment was provided for a minimum of 18 months. • Control group: treatment-as-usual (TAU) comprised: "Group-based enhanced thinking skills and sex offender treatment were the most frequently provided therapies recorded on the TAU logs." (quote; p 14). Other noted TAU therapies included: social therapy and resettlement work; review of clinical or psychology reports; discussion of therapy; neurorehabilitation; review of previous assessments; end of therapy meeting support work; and ″talking sessions" (quote; p 14). Duration of intervention: 24 months Duration of trial: 36 months Length of follow-up: 6, 12, 24 and 36 months after baseline
Outcomes	Primary outcomes • Aggression; Modified Overt Aggression Scale (MOAS) • Social functioning; interpersonal style assessed by Chart of Interpersonal Reactions in Close Living Environments (CIRCLE) Secondary outcomes • Leaving the study early; proportion of participants discontinuing treatment • Impulsivity (trait); Barratt Impulsiveness Scale-II (BIS-II) • Anger; Novaco Anger Scale (NAS) • Mental state; psychiatric symptoms using the Brief Psychiatric Rating Scale (BPRS); schema modes using Young Schema Questionnaire (YSQ); antisocial personality traits assessed by Anti-social Personality Questionnaire (APQ) Other outcomes

Tarrier 2010 *(Continued)*

- Risk: measured by scores on the HCR-20 (version 2); Violence Risk Scale (VRS); Institutional Behaviour Rating Scale (IBRS)

Notes	[a]18/29 (62%) patients randomised to SMT, and 25/34 (74%) of patients randomised to TAU had a diagnosis of AsPD; no data for AsPD subsample [b]Participants in both groups also received social, occupational and recreational activities that were not classed as formal therapy. Study funding: Ministry of Justice Declaration of interests: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "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." (p 6)
Allocation concealment (selection bias)	Low risk	Quote: "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." (p 7)
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not that they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind participants in this type of study. We found no indication of any specific additional measures taken to reduce the risk of bias that might result from differential behaviours by participants.
Blinding (performance bias and detection bias) of personnel	Low risk	Quote: "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." (p 7)
Blinding (performance bias and detection bias) of outcome assessors	Low risk	Quote: "The Evaluation Team were independent of the Treatment Team who provided the SMT intervention." (p 6)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "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." (p 9)
Selective reporting (reporting bias)	Unclear risk	Comment: Review authors judged that the published reports did not include data on all expected outcomes; e.g. data for the Institutional Behaviour Rating Scale was not reported.
Other bias	High risk	Comment: Review authors identified a number of additional sources of potential bias. Allegiance bias: funding had been secured to develop an SMT service within the personality disorder service. Publication bias; the trial was conducted in 2004-08, reported initially in a Ministry of Justice paper in 2010 and then

Tarrier 2010 *(Continued)*

	in a peer review publication in 2016; the delay in publication of this trial could be a result of the null findings of the impact of SMT. Treatment bias: treatment adherence in terms of competence of therapists in the SMT condition was reported as poor; additionally, participants in the TAU group received more therapy than the intervention group: "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." (quote; p 14)

Bernstein 2012

Study characteristics	
Methods	Design: parallel randomised controlled trial
Participants	Participants: male forensic patients with personality disorder Sex: male Age: (for sample as a whole[a]) mean = 41.3 years (SD = 8.5) Unit of Allocation: individual Number randomised: 33 (for sample as a whole[a]); schema therapy = 16; control group = 14; unknown = 3 Number completing: 30; schema therapy = 16; control = 14 Setting: seven government-run forensic psychiatric clinics (terbeschikkingstelling (TBS)) in Netherlands Inclusion criteria: male patients with antisocial, borderline, narcissistic or paranoid personality disorder; personality disorder-not otherwise specified, if patient had at least five cluster B symptoms and no other Axis II PD diagnosis Exclusion criteria: other personality disorders (e.g. histrionic personality disorder); presence of current psychotic symptoms, schizophrenia or bipolar disorder; current drug or alcohol dependence; low intelligence (full scale IQ < 80); serious neurological impairment (e.g. dementia); autistic spectrum disorder; paedophilia Ethnicity: not reported Baseline characteristics: (for sample as a whole[a]) • Nationality: Dutch (n = 27, 91%); Morocco (n = 1, 3%); Surinam (n = 1, 3%); other European Union countries (n = 1, 3%) • DSM-IV personality disorder diagnosis: antisocial (n = 26, 86.7%); borderline (n = 9, 30%); narcissistic (n = 10, 33.3%); paranoid (n = 1, 33.3%); 15 patients had more than one personality disorder diagnosis
Interventions	Two conditions: schema therapy (ST); or treatment-as-usual (TAU) • Experimental group: ST (n = 16 randomised but unknown how many of these were AsPD[a]) • Control group = TAU (n = 14 randomised bit unknown how many of these were AsPD[a]) Details of conditions: • Intervention group: schema therapy (ST) is an integrative therapy for personality disorders combining cognitive, behavioural, psychodynamic object relations, and humanistic/experiential approaches; individual therapy delivered twice a week according to adapted procedures for forensic patients

Bernstein 2012 *(Continued)*

set out in a practitioner's guide; treatment lasts from two to three years, with frequency reduced to one session per week in the third year of treatment

- Control group: treatment-as-usual (TAU) is the standard treatment that patients receive at each clinic; usually another (non-ST) form of individual psychotherapy, such as cognitive-behaviour therapy, psychodynamic therapy, or client-centred therapy; clinics are free to choose the type of therapy that they provide to patients and therapy is typically delivered once per week; cognitive-behaviour therapy is the most common form of 'treatment-as-usual' offered in TBS clinic

Both groups also received concomitant therapy such as: individual or group psychotherapy, art therapy, relapse prevention programmes for addiction and aggression, pharmacological interventions, vocational training, milieu therapy

Duration of intervention: 3 years

Duration of trial: 6 years[b]

Two phases: 3-year treatment phase (3-year follow-up phase = not reported)

Length of follow-up: none[b]

Outcomes

Primary outcomes [b]

- Aggression; institutional violence was a stated outcome measure but data was not reported
- Recidivism; reported as negative global outcome
- Global state/functioning; outcomes classified globally as positive, neutral, or negative
- Social functioning; continuous resocialisation outcome based on days to first supervised and unsupervised leave; % patients receiving supervised and unsupervised leave

Secondary outcomes

- Engagement with services; Treatment Engagement Rating Scale for Forensic Outpatient Treatment (TER), but data was not reported
- Leaving the study early; proportion of participants discontinuing treatment
- Economic outcomes: direct costs of TAU and cost estimations of Intervention (ST) provided in the discussion section only
- Mental state: personality disorder symptoms on Structured Interview for DSM-IV Personality Disorders (SIDP-IV) and patient and informant versions of Schedule for Nonadaptive and Adaptive Personality (SNAP-I); early maladaptive schemas and schema modes using Young Schema Questionnaire-Short Version (YSQ) and the Schema Mode Inventory (SMI); general psychopathology measured using Symptom-Checklist 90 (SCL-90)

Other outcomes

- Recidivism risk measured using risk assessments Historical Clinical Risk Management-20 (HCR-20); Sexual Violence Risk-20 (SVR-20); Short-Term Assessment of Risk and Treatability (START)

Notes

[a]26/30 (87%) of trial completing participants had AsPD; no data for AsPD sub-sample

[b]The authors only reported preliminary results as follow-up phase is ongoing.

Study funding: Netherlands Ministry of Justice, the Expertise Center for Forensic Psychiatry, Maastricht University's Faculty of Psychology and Neuroscience, and the participating forensic hospitals

Declaration of interests: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Random assignment is accomplished using an "adapted biased urn procedure"(Schouten, 1995), which randomly assigns patients to treatment

Bernstein 2012 *(Continued)*

		conditions at each site using an algorithm that assures that the overall proportion of patients in the experimental and control condition will be in equal balance." (p 317, column 2)
Allocation concealment (selection bias)	Low risk	Quote: "Patients are assigned by a central research assistant who is blind to any information about the patient." (p 317, column 2)
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind participants in this type of study.We found no indication of any specific additional measures taken to reduce the risk of bias that might result from differential behaviours by participants.
Blinding (performance bias and detection bias) of personnel	Unclear risk	Quote: "Raters were not kept blind to treatment condition, as this was not feasible in a three-year study in clinical settings." (p 319, column 1)
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	Quote: "...that research assistants were not blind to the patients' treatment conditions." (p 322, col.1). Inter-rater agreement between blind and non-blind ratings were provided for risk assessment scores for a subsample: "In a subsample of 16 patients, the interrater reliability (intra-class correlation (ICC) for the average of two raters) for the HCR-20 overall judgment of the risk level within the hospital was.81; there was perfect agreement for ratings of risk level outside of the hospital (ICC = 1.0). The interrater reliability for the PCL-R total score was ICC = .88; ratings were also internally consistent (Cronbach's alpha = .80)." (p 319, column 1)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "We did not use intention-to-treat analysis, as there were no missing data for these analyses." (p 319, column 2)
Selective reporting (reporting bias)	High risk	Comment: Stated outcome measures including aggression (institutional violence) and engagement with treatment (TER) were not reported, however the trial investigators reported "Finally, as this report is preliminary in nature, we did not provide full information about all aspects of the research design (e.g., number of sessions of ST versus TAU) or the results; we will provide further details when we publish our complete findings." (quote; p 322, column 2).
Other bias	Unclear risk	Comment: The review authors considered that there was a potential risk of allegiance bias in this study as ST for forensic patients was developed by D. Bernstein and T. Kersten (unclear risk). Vested interest bias: unvalidated instruments developed by DB were used in the study (unclear risk).

Feigenbaum 2012

Study characteristics	
Methods	Design: randomised control trial
Participants	Participants: referrals to a new specialist personality disorder service Sex: (for sample as a whole[a]) female (n = 30/41, 73%); male (n = 11/41, 27%) Age: (for sample as a whole[a]).

Feigenbaum 2012 *(Continued)*

- Intervention group, dialectical behaviour therapy (DBT): mean 35.4 years (SD = 7.8, range = 23 - 56 years)
- Control group, treatment-as-usual (TAU): mean = 34.6 years (SD = 7.4, range = 23 - 45 years)

Unit of Allocation: cluster (balancing for geographic, demographic (gender) and diagnostic criteria (presence of borderline personality disorder)); for every 3 patients randomised, 2 assigned to DBT and 1 to TAU

Number randomised: 41 (for sample as a whole[a]). DBT group n = 25; TAU group n = 16

Number completing: 31 (for sample as a whole[a]). DBT group n = 17; TAU group n = 14

Setting: National Health Service (NHS) specialist personality disorder service; London, UK

Inclusion criteria: diagnosis of cluster B personality disorder; aged 18-65 years old; provide written consent

Exclusion criteria: currently in long-term psychotherapeutic treatment; meet DSM-IV criteria for comorbid psychotic disorder or bipolar disorder; opiate dependence requiring specialist treatment; mental impairment; evidence of organic brain disorder

Ethnicity: not stated

Baseline characteristics (for sample as a whole[a])

- Relationship status: single (83%); currently married (5%); co-habiting (2%); separated/divorced (10%)
- Education status: comprehensive education (15%); no formal education (37%); A-level (15%); first degree (7%); second degree (2%); vocational training (22%)
- Years of education; DBT group mean = 12.38 (SD = 1.8, range = 8-17 years); TAU group mean = 13.4 (SD = 2.5, range = 10-18 years)
- Employment status: unemployed (90%); full-time or part-time paid work (5%); homemaker (5%)
- Substance use: alcohol as comorbid misuse substance (27%); illicit drugs as comorbid misuse substance (20%)
- Cluster A personality disorder diagnosis: DBT group (10/25, 40% paranoid PD); TAU group (3/16, 19% had paranoid, schizotypal or schizoid PD)
- Cluster B personality disorder diagnosis:[b] DBT group 23/25 (92%) borderline PD, 7/25 (28%) antisocial PD, 1/25 (4%) narcissistic PD; TAU group 15/16 (94%) borderline PD, 4/16 (25%) antisocial PD, 2/16 (13%) narcissistic PD
- Cluster C personality disorder diagnosis: DBT group 9/25 (36%) avoidant PD, 2/25 (8%) dependent PD, 1/25 (4%) obsessive compulsive PD; TAU group 6/16 (38%) avoidant PD

Interventions	Two conditions: dialectical behaviour therapy (DBT); or treatment-as-usual (TAU) (2:1 allocation) • Experimental group: DBT (n = 25 randomised) • Control group: TAU (n = 16 randomised) Details of conditions: • Intervention group: DBT pretreatment phase of 3-6 weeks of goal-setting and commitment-building followed by offer of 1 year DBT treatment contract; DBT treatment consists of 1 hour of individual therapy and 2.5 hours of group skills training per week plus out-of-hours telephone consultation as required • Control group: TAU consists of a range of individualised service provision including outpatient psychiatric review, case management, psychoanalytic psychotherapy, cognitive behaviour therapy, supportive structured counselling, inpatient admission, drug and alcohol treatment and crisis management. TAU provision for personality disorder within the region may include schema therapy. Duration of intervention: 55-58 weeks Duration of trial: 20 months

Feigenbaum 2012 *(Continued)*

	Length of follow-up: 12 months after baseline
Outcomes	Primary outcomes • Aggression**:** Overt Aggression Scale (OAS) • Adverse events: Self-harm and suicide attempts from semi-structured interview (SASII); ratings of suicidality (OAS) Secondary outcomes • Economic outcomes: service use (indirect economic outcome) • Anger: State Trait Anger Expression Inventory (STAXI) • Mental state: Clinical Outcomes in Routine Evaluation-Outcome Measure (CORE-OM) total score and PTSD symptoms Other outcomes • Dissociative experiences: Dissociative Experiences Scale (DES)
Notes	[a]11/41 of randomised participants (27%) had a diagnosis of AsPD; no data for AsPD subsample [b]Due to comorbidity of personality disorders, percentages summed to more than 100%. Study funding: Camden and Islington Health Authority and North Thames Regional Health Authority Declaration of interests: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Treatment allocation was made offsite via telephone randomization using a stochastic minimization programme (MINIM) balancing for sector within the regions to avoid differences in terms of differential referral practices, gender, and presence of BPD." (p 124)
Allocation concealment (selection bias)	Low risk	Quote: "Treatment allocation was made offsite via telephone randomization using a stochastic minimization programme (MINIM) balancing for sector within the regions to avoid differences in terms of differential referral practices, gender, and presence of BPD. Clients were randomized so that two of three entered DBT and one of three TAU in order to build the caseloads for staff, as this was a new service with no existing clients." (p 124)
Blinding (performance bias and detection bias) of participants	High risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not that they were participating in a psychological intervention and may also be aware of the nature of this intervention. Quote: "Patients in the TAU group were informed that they would receive DBT in 1 year, if they still wished for this therapy." (p 125) Comment:The review authors considered that this statement increased the risk of bias that might result from differential behaviours by participants in the TAU and DBT groups.
Blinding (performance bias and detection bias) of personnel	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because personnel would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind personnel in this type of study.

Feigenbaum 2012 *(Continued)*

Blinding (performance bias and detection bias) of outcome assessors	High risk	Quote: "...while we attempted blinding of assessments, as is often the case with psychosocial treatment trials, those carrying out the research assessments could mostly identify the treatment group of the patient." (p 137)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment:The trial investigators reported DBT data withdrawal (n = 1) and conducted an ITT analysis. The paper did not provide adequate information on statistical processes to make a judgement of Yes or No.
Selective reporting (reporting bias)	Unclear risk	Comment: It was unclear if the study was subject to selective reporting as no protocol was available. It should be noted however that there was considerable time between the study completion and publication of the results in a peer-reviewed journal.
Other bias	Unclear risk	Comment: • Attention bias: treatment offered in TAU was not carefully examined - unlike the DBT condition. • Allegiance bias: the trial investigators provided components of DBT (individual, group, generalisation – through phone coaching – and consultation to the environment), but this was not fully adherent to the DBT programme, since telephone consultation was not provided for the full 24-hr day for all clients. Also, potential allegiance bias of author (JF) for DBT treatment. • Other: extensive use of self-report measures (little or no opportunity for cross-referencing validation checks); especially problematic for suicide/service use.

Priebe 2012

Study characteristics	
Methods	Design: parallel randomised control trial
Participants	Participants: individuals who self-harm and have a diagnosis of at least one personality disorder referred from primary, secondary and tertiary health services to dialectical behaviour therapy (DBT) service Sex: (for whole sample[a]) female (n = 70/80, 87.5%); male (n = 10/80, 12.5%) Age: (for whole sample[a]) Intervention group, dialectical behaviour therapy (DBT) (mean age = 33.0 years, SD = 10.7); control group, treatment-as-usual (TAU) (mean age = 31.3 years, SD = 11.0) Unit of Allocation: individual Number randomised: 80 (for whole sample[a]) DBT group (n = 40; AsPD subgroup n = 6); TAU group (n = 40; AsPD subgroup n = 9) Number completing: 74 (for whole sample) (AsPD subgroup n = 14) DBT group (n = 38; AsPD subgroup n = 5); TAU group (n = 36; AsPD subgroup n = 9) Setting: outpatient; National Health Service DBT service; London Borough of Newham, England, UK Inclusion criteria: five days or more with self-harm in the year prior to treatment; age 16 years or over; diagnosis of at least one personality disorder (DSM-IV criteria using SCID-II) Exclusion criteria: severe learning difficulties; inability to read or write English

Priebe 2012 *(Continued)*

Ethnicity: (for whole sample[a]) DBT group: white (n = 26, 65%); black (n = 4, 10%); Asian (n = 8, 20%), mixed/other (n = 2, 5%). TAU group: white (n = 20, 50%): black (n = 8, 20%); Asian (n = 9, 22.5%); mixed/other (n = 3, 7.5%)

Baseline characteristics: (for whole sample[a]) Employment: unemployed (n = 43/80, 56%); voluntary/protected/sheltered work (n = 8/80, 10%); regular employment (n = 29/80, 37%). Accommodation: homeless or 24-hour supervised accommodation (n = 6/80, 8%); sheltered/supported accommodation (n = 6/80, 8%), independent accommodation (n = 68/80, 84%). Psychiatric diagnoses: number of patients with Axis I disorder (n = 63/80); number of Axis 1 disorders (mean 8.0, SD 3.1); number of patients with Axis II disorders (n = 80/80, 100%); number of Axis II disorders (mean 3.5, SD 1.6). Self-harm and suicide: number of patients with suicide attempts in past 12 months (n = 79/80, 98.8%); number of suicide attempts in past 12 months (mean 2.2, SD 6.0); number of patients with self-harm days in past 2 months (n = 78/80, 97.5%); number of self-harm days in past 2 months (mean 13.9, SD 18.4).

Interventions	Two conditions: dialectical behaviour therapy (DBT) or treatment-as-usual (TAU) • Experimental group: DBT • Control group: TAU Details of conditions: • DBT intervention: "Patients randomised to the intervention group received 12 months of DBT delivered according to Linehan's [1,2] treatment and skills training manuals....It consists of weekly hour-long individual therapy sessions, a weekly 2-hour skills training group, and out-of-hours skills coaching over the telephone as needed." (quote; p 357). • Control/treatment-as-usual: "Participants allocated to the TAU condition were referred back to the referrer and encouraged to engage in any kind of treatment other than DBT; this may have included treatment from psychotherapists, psychiatrists, community mental health teams, counsellors, general practitioners or user-run support groups, all of which were offered free of charge under the NHS." (quote; p 358) Duration of intervention: 12 months Duration of trial: 26 months (March 2008 to May 2010) Length of follow-up: follow-up every 2 months until 12 months after baseline
Outcomes	Primary outcomes • Adverse events; days of self-harm; type of deliberate self-harm Secondary outcomes • Quality of Life; Manchester Short Assessment of Quality of Life (MANSA) • Leaving the study early; number of patients dropping out of treatment/lost to follow-up • Economic outcomes; service and total costs measured using modified Client Service Receipt Inventory (CSRI) • Mental state; borderline personality disorder symptoms using Zanarini Rating Scale for Borderline Personality Disorder (ZAN-BPD); psychiatric symptoms using Brief Symptom Inventory (BSI) and Brief Psychiatric Rating Scale (BPRS)
Notes	[a]Email correspondence with Kirsten Barnicot on 24 January 2017 established that 15/80 participants (18.75%) who were randomised had a diagnosis of AsPD; limited data for AsPD sub-sample at baseline and 2-month follow-up (number of days self-harm; BPRS total score; BSI total score) provided by KB on 02 March 2017. Study funding: National Institute for Health Research Declaration of interests: None

Risk of bias

Priebe 2012 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomisation was computer generated with a 1: 1 allocation by an independent statistician, using 6 blocks of 12 randomly permuted treatment allocation sequences, with a final block of 8." (p 358)
Allocation concealment (selection bias)	Low risk	Quote: "Randomisation was computer generated with a 1: 1 allocation by an independent statistician, using 6 blocks of 12 randomly permuted treatment allocation sequences, with a final block of 8." (p 358)
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not that they were participating in a psychological intervention and may also be aware of the nature of this intervention. Quote: "Participants allocated to the TAU condition were referred back to the referrer and encouraged to engage in any kind of treatment other than DBT..." (p 358). "...referring those allocated to TAU back to their original referral sources following randomisation may have had a negative impact on participants, which may have augmented any negative outcomes observed in this group..." (p 362). Comment: The review authors found no indication of any specific additional measures taken to reduce the risk of bias that might result from differential behaviours by participants.
Blinding (performance bias and detection bias) of personnel	Unclear risk	Quote: "Due to the nature of the questions researchers asked regarding service use, coupled with the frequency of contact between researchers and participants (every 2 months) it was impractical to blind researchers to allocation; this may have biased the way in which the interviews were conducted." (p 362)
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	Quote: "The cost assessment included questions on service use which revealed the patients' allocation to the DBT or TAU group. Interviewers were therefore not masked to treatment allocation. However, the data analyst remained masked throughout the study period." (p 358)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: The trial investigators reported using an ITT analysis based on 38/40 DBT and 36/40 TAU participants; baseline data is missing for 2 TAU, follow-up data is missing for 2/40 DBT and 2/40 TAU, however the investigators reported that they "...conducted a sensitivity analysis with last observation carried forward." (quote; p 358). The investigators anticipated a high treatment dropout and planned a priori subgroup analyses of completers vs. dropouts; they note an effect of treatment completion on their primary outcome of self-harm: .."..only 48% of patients allocated to the DBT group completed the envisaged 1-year treatment period, and the reduction of self-harm was substantially greater for those who completed the intervention than for those who did not." (quote; p 362).
Selective reporting (reporting bias)	Unclear risk	Comment: The review authors were unable to locate a published protocol for this study and therefore there was insufficient information to allow a judgement to be made. All outcomes measures described in the method section were reported by the trial investigators.
Other bias	Low risk	Comment: The study appeared to be free of other sources of bias.

Thylstrup 2015

Study characteristics	
Methods	Design: parallel, randomised control trial

Participants	Participants: new and existing patients with AsPD receiving outpatient treatment for drug or alcohol problems
	
	Sex: male (n = 124/142, 87%); female (n = 18/142, 13%); data only for the participants who completed the study; no data provided for the 176 randomised patients[a]
	
	Age: (for sample as a whole[a]) mean age = 32.2 years (SD = 8.9)
	
	Unit of Allocation: cluster; stratified by clinic; randomised permuted blocks or randomly varying size with ratio 1:1 (4 or 6 per block)
	
	Number randomised: 176; impulsive lifestyle counselling (ILC) + treatment-as-usual (TAU) = 96; TAU = 80
	
	Number completing: 142 patients completed at least 1 follow-up; ILC + TAU = 78; TAU = 64
	
	Setting: community-based substance abuse treatment centres across 13 municipalities of Denmark
	
	Inclusion criteria: outpatients aged 18 to 65; meet AsPD criteria using Mini International Neuropsychiatric Interview (MINI); able to provide written informed consent; seeking/already in treatment for a substance use disorder
	
	Exclusion criteria: patient has plans that would interfere with participation in psychoeducation in next 3 months (e.g. moving away, prison, residential rehab); participating in group treatment with another subject in trial; known to suffer from acute psychosis; severe brain damage; does not speak Danish
	
	Ethnicity: no information given
	
	Baseline characteristics:
	
	• Conduct disorder criteria: ILC + TAU group mean = 4.04 (SD = 0.83); TAU group mean = 3.90 (SD = 0.80)
	• Adult antisocial behaviours: ILC + TAU group mean = 5.14 (SD = 0.98); TAU group mean = 4.87 (SD = 1.07)
	• Days of substance use in previous 30-day period:
	  ○ ILC + TAU group: alcohol use (mean = 4.81, SD = 6.97); alcohol intake + 5 units per day (mean = 3.16, SD = 5.61); heroin (mean = 0.49, SD = 2.75); methadone (mean = 7.73, SD = 12.87); other opioids (mean = 0.83, SD = 3.26); tranquillisers (mean = 7.42, SD = 11.93); cocaine (mean = 1.31, SD = 4.38); amphetamines (mean = 1.43, SD = 3.83); cannabis (mean = 24.26, SD = 13.09); hallucinogens (mean = 0.04, SD = 0.26); inhalants (mean = 0.01, SD = 0.12); buprenorphine (mean = 1.64, SD = 6.70); poly-substance (mean = 7.57, SD = 11.58)
	  ○ TAU group: alcohol use (mean = 6.46, SD = 8.45); alcohol intake + 5 units per day (mean = 3.44, SD = 5.92); heroin (mean = 1.48, SD = 5.15); methadone (mean = 7.20, SD = 12.83); other opioids (mean = 0.92, SD = 4.27); tranquillisers (mean = 8.00, SD = 12.26); cocaine (mean = 1.31, SD = 3.91); amphetamines (mean = 0.36, SD = 0.83); cannabis (mean = 13.54, SD = 12.86); hallucinogens (mean = 0.14, SD = 0.71); buprenorphine (mean = 2.78, SD = 8.44); poly-substance (mean = 6.77, SD = 10.52)

Interventions	Two conditions[b]: impulsive lifestyle counselling (ILC); or treatment-as-usual (TAU) • Experimental group: ILC + TAU (n = 96 randomised) • Control group = TAU (n = 80 randomised) Details of conditions: • Impulsive lifestyle counselling (ILC): treatment was described as "...a brief psycho-educational intervention..." (quote; p 2); patients randomised to ILC were offered up to six ILC sessions by a specially trained counsellor; the ILC programme is a manualised intervention; sessions cover specific topics and include mandatory questions, printed handouts and worksheets for the patient. Duration of session was not reported.

Thylstrup 2015 *(Continued)*

	• TAU always included: access to opioid substitution treatment (if required); psychosocial support such as casework, counselling, or referral to residential rehabilitation; referral to 'off-site' psychiatrist for treatment of other psychiatric conditions, such as attention-deficit/hyperactivity disorder, anxiety or depression. Duration of intervention: 6 sessions, time period not reported Duration of trial: 31 months; January 2012 to July 2014. Length of follow-up: follow-up at 3 months and 9 months
Outcomes	Primary outcomes • Aggression: trait aggression scores on the 12 item (short-form) Buss-Perry Aggression Questionnaire (BPAQ-SF); scores on the Self-Report of Aggression and Social Behaviour Measure (SRASBM) • Adverse events: number of deaths, incarceration Secondary outcomes • Leaving the study early: attrition at 3 and 9 month follow-up • Substance use: scores on Addiction Severity Index (ASI) for drugs and alcohol; days abstinent; % participants reporting complete abstinence; % participants reporting daily use Other outcomes • None
Notes	[a]Data analysed for the 142 participants who completed at least one follow-up (79% of whole group). [b]36.5% of whole group received opioid substitution treatment at the point of randomisation. Study funding: Trygfonden, and Reckitt-Benckiser Declaration of interests: None

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The randomization schedules were generated by the trial coordinator and kept secure and confidential at the study coordinating center in Copenhagen. The randomization schedule was constructed using the method of randomized permuted blocks of randomly varying size with a ratio of 1:1 (4 or 6 per block)." (p 3)
Allocation concealment (selection bias)	Unclear risk	Quote: "The trial coordinator informed the referring clinician of the result of randomization immediately after being notified that the patient had been assessed and was found to be eligible for study participation. After this, the clinician informed the patient of the result. In the cases in which patients were randomized to the ILC treatment, the clinician then contacted one of the ILC counsellors at the uptake unit with the participants' details so that the sessions could be initiated as quickly as possible. Because the randomization had to take place immediately after the assessment interview, the trial coordinator was unable to check whether the baseline assessment was complete before randomizing, and patients with incomplete data at baseline had to be excluded after randomization." (p 3).
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: Participants were not blind. The trial investigators reported that patients were informed of the result of the randomisation by the clinician undertaking the baseline eligibility assessments.

Thylstrup 2015 *(Continued)*

Blinding (performance bias and detection bias) of personnel	Unclear risk	Quote: "The trial coordinator informed the referring clinician of the result of randomization immediately after being notified that the patient had been assessed and was found to be eligible for study participation... ... In the cases in which patients were randomized to the ILC treatment, the clinician then contacted one of the ILC counsellors at the uptake unit with the participants' details so that the sessions could be initiated as quickly as possible." (p 3)
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	Quote: "Research technicians not affiliated with the clinics carried out all assessments at the 3 and 9-month follow-up interviews and were blind to treatment group allocation." (p 5). Comment: The review authors noted that there was no reference to the blinding of the data analysts and therefore insufficient information to allow a judgement to be made.
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: Authors reported it was an ITT analysis but it was not clear that this was the case as 176 were randomised but they only analysed data for subjects who completed baseline data (167) and then completed at least one follow-up (142).
Selective reporting (reporting bias)	Unclear risk	Comment: Trial information on the ISRCTN register indicated additional secondary outcome measures that are not reported in the 2015 paper: perceived help for antisocial personality disorder (reported in 2017 post hoc secondary analysis only); readiness to change antisocial behaviour measured using the adapted readiness ruler; and staff-rated improvement in in-clinic antisocial behaviour, general antisocial behaviour and substance use.
Other bias	Unclear risk	Comment: Vested interest bias (funding and/or author affiliations): although not a pharmacological trial, the study was partially funded by grant from Reckitt-Benckiser who manufacture an opioid replacement drug. Some subjects in the trial were administered opioid substitution treatment.

Asmand 2015

Study characteristics	
Methods	Design: parallel randomised control trial
Participants	Participants: adult prisoners with antisocial personality disorder Sex: all male Age: in the DBT group 37.5% were aged 20-25 years; REBT group 50% were aged 20-25 years; control group range 18-40 years Unit of Allocation: individual Number randomised: 48 (DBT = 16, REBT = 16, control = 16) Setting: Ilam Prison, Iran[a] Inclusion criteria: AsPD diagnosis; aged 18-40 years; conviction length > 1 year Exclusion criteria: two episodes of non-compliance Ethnicity: not stated Baseline characteristics:

Asmand 2015 *(Continued)*

- DBT: 100% of the group were single; 56.2% were employed
- REBT: 75% of the group were single; 50% were employed
- Both DBT and REBT groups: more than 80% were in prison for the second time; 37.5% educated to diploma level; 31% drug addicts
- No details provided for the control group

Interventions	Three conditions: dialectical behavioural therapy (DBT); rational emotive behavioural therapy (REBT); or control • Experimental group 1: DBT (n = 16 randomised) • Experimental group 2: REBT (n = 16 randomised) • Control group: TAU (n = 16 randomised) Details of conditions: • Dialectical Behaviour Therapy (DBT) delivery described by the authors as ''...the application of treatments based on the original protocol DBT for borderline personality disorder, were little changed..." (quote; p 2, column 2). • Rational Emotional Behaviour Therapy (REBT) described by authors as "...REBT thought process orientation with a focus on cognitive distortions has been performed." (quote; p 2, column 2). • Control/TAU received no special training[b] Duration of intervention: 16 sessions over 20 days[c] Duration of trial: 20 weeks Length of follow-up: 20 days after initial therapy session[c]
Outcomes	Primary outcomes • None Secondary outcomes • Mental state: anxiety; scores on the Beck Anxiety and Depression Scale Other outcomes • Scores on the "Jones Illogical Beliefs questionnaire" (sic)
Notes	[a]The review authors have concerns about possible ethical issues, given the particular setting and circumstances of the prisoners in this study. [b]The authors provided a very poor description of the two interventions offered and their mode of delivery; the TAU control group may have received individual work but no details were provided. [c]The intervention duration was unclearly reported, possibly 16 sessions of 1 hour, possibly over 20 days (1 day per week over a 20-week period) Study funding: none Declaration of interests: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: Investigators reported use of random number table in the study protocol, however the randomisation process was not reported in the paper. Insufficient reporting to permit judgement of Yes or No

Asmand 2015 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Comment: We found no indication of any specific measures taken to address allocation concealment. Insufficient reporting to permit judgement of Yes or No
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not that they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind participants in this type of study. We found no indication of any specific additional measures taken to reduce the risk of bias that might result from differential behaviours by participants.
Blinding (performance bias and detection bias) of personnel	Unclear risk	Comment: In a study such as this, full blinding is difficult to achieve because personnel would be aware whether or not they were participating in a psychological intervention and may also be aware of the nature of this intervention. The review authors judged that it would thus not be possible to fully blind personnel in this type of study.
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	Comment: The review authors found no evidence of any measures taken to address blinding of outcome assessors.
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: Attrition from dropouts/other reasons was not reported in the paper, however there was reference to noncompliance and "...lack of co-operation of some samples and absent prison and more than two sessions..." (quote; p 2, column 2).
Selective reporting (reporting bias)	High risk	Comment: The trial authors reported four primary outcomes in the study protocol; irrational belief ('irrational beliefs questionnaire'), anxiety ('beke Anxiety questionnaire' [sic]), depression ('Beck Depression questionnaire') and aggression ('agrretion questionnaire' [sic]). Outcomes for depression and aggression were not reported in the paper.
Other bias	High risk	Comment: The review authors considered there was a high risk for language/comprehension bias as the quality of the translation into English was exceptionally poor. The review authors also had concerns regarding the recruitment and coercion of participants as all were incarcerated in prison and no ethics approvals were reported; "The specimens were randomly assigned to treatment groups of 16 persons consisted [sic] of DBT and REBT group and one control group." (quote; p 2, column 2)

McMurran 2016

Study characteristics	
Methods	Design: multisite, parallel randomised control trial
Participants	Participants: community-living adults with a diagnosis of one (or more) personality disorder Sex:[a]Intervention group, psychoeducation and problem-solving (PEPS): male (n = 39/154, 25%); female (n = 115/154, 75%). Control group, treatment-as-usual (TAU): male (n = 37/152, 24%); female (n = 115/152, 76%) Age:[a] intervention group (PEPS) mean age 38.6 years (SD 10.9); control group (TAU) mean 37.8 years (SD 11.0)

McMurran 2016 *(Continued)*

Unit of allocation: block stratified by recruiting centre and sex; intervention to control allocation ratio was 1:1

Number randomised: 306; PEPS (n =154); TAU (n = 152)

Number completing: 306 (for sample as a whole) (see notes 1 and 2)

PEPS (n = 154); TAU (n = 152)

Setting: multisite; community National Health Service (NHS) mental health services; United Kingdom

Inclusion criteria: one or more personality disorders (this could include Personality Disorder Not Otherwise Specified, PD-NOS); aged 18 years or over; living in the community; proficient in spoken English; capacity to provide informed consent

Exclusion criteria: insufficient degree of literacy, comprehension or attention to allow engagement in therapy and assessments; currently undertaking psychological treatment for personality disorder or likely to start such treatment during the trial period; participation in any other trial

Ethnicity: PEPS group: white (n = 129, 84%); mixed (n = 6, 4%); black Caribbean (n = 5, 3%); black African (n = 2, 1%); other (n = 12, 8%).

TAU group: white (n = 127, 83%); mixed (n = 9, 6%); black Caribbean (n = 6, 4%); black other (n = 2, 1%); Asian Indian (n = 1, 2%); Asian other (n = 1, 1%); other (n = 6, 4%)

Baseline characteristics: (for sample as a whole) (see note [a])

PEPS group: age left full-time education (mean 17·2 years, SD 3·7); highest educational attainment, none (n = 24, 16%), GCSE (n = 22,14%), A-level (n = 35, 23%), vocational (n = 10, 7%), degree (n = 36, 23%), other (n = 25, 16%), missing (n = 2, 1%); socioeconomic status, never worked and long-term unemployed (n = 105, 68%), routine and manual occupations (n = 20, 13%), intermediate occupations (n = 9, 6%), managerial and professional occupations (n = 20, 13%); personality disorder diagnosis using International Personality Disorder Examination (IPDE), [participants may have more than one type] paranoid PD (n = 13, 8%), schizoid PD (n = 4, 3%), antisocial PD (n = 23, 15%), borderline PD (n = 93, 60%), histrionic PD (n = 2, 1%), narcissistic PD (n = 1, 1%), avoidant PD (n = 57, 37%), dependent PD (n = 4, 3%), obsessive-compulsive PD (n = 14, 9%), personality disorder not otherwise specified (n = 14, 9%); personality disorder classification, simple PD (n = 61, 40%); complex PD (n = 93, 60%)

TAU group: age left full-time education (mean 16·9 years, SD 3·3); highest educational attainment, none (n = 29, 19%), GCSE (n = 16, 10%), A-level (n = 45, 30%), vocational (n = 10, 7%), degree (n = 32, 21%), other (n = 20, 13%); socioeconomic status, never worked and long-term unemployed (n = 96, 63%), routine and manual occupations (n = 28, 18%), intermediate occupations (n = 13, 9%), managerial and professional occupations (n = 15, 10%); personality disorder diagnosis using International Personality Disorder Examination (IPDE), [participants may have more than one type] paranoid PD (n = 16, 11%), schizoid PD (n = 1, 1%), antisocial PD (n = 31, 20%), borderline PD (n = 90, 59%), histrionic PD (n = 6, 4%), narcissistic PD (n = 3, 2%), avoidant PD (n = 56, 37%), dependent PD (n = 7, 5%), obsessive-compulsive PD (n = 20, 13%), personality disorder not otherwise specified (n = 10, 7%); personality disorder classification, simple PD (n = 77, 51%), complex PD (n = 75, 49%)

Interventions	Two conditions: psychoeducation and problem solving (PEPS); or treatment-as-usual (TAU) • Intervention: PEPS + TAU (n = 23 randomised) • Control group:TAU (n = 31 randomised) Details of conditions: • Psychoeducation with problem-solving (PEPS) therapy is a cognitive–behavioural intervention that integrates individual and group therapies with optional individual support sessions; up to four individual psychoeducation sessions; 12 x 2-hour group sessions of problem-solving therapy; individual support sessions offered every 2 weeks through the 12-week problem-solving group (optional); patients also receive treatment-as-usual

McMurran 2016 *(Continued)*

	• TAU is provided by participants' usual-care teams; TAU includes assessment, care-planning, risk assessment and psychological interventions; participants excluded at baseline if accessing/likely to access psychological treatment programme specifically designed for personality disorder Duration of intervention: ~16 weeks (4 weeks of psychoeducation + 12 weeks of social problem-solving) Duration of trial: 28 months[b] (August 2010 to November 2012) Length of follow-up:intended follow-up period of 72 weeks[b]
Outcomes	Primary outcomes • Global state/functioning**:** Global Assessment of Functioning (GAF) • Social functioning: Social Functioning Questionnaire (SFQ) • Adverse events: death; self-harm; hospitalisation Secondary outcomes • Quality of Life: European Quality of Life-5 Dimensions (EQ-5D) a health status measure used to generate Quality-Adjusted Life-Years (QALYs) • Engagement with services: numbers of completers and non-completers; mean number of weeks in trial • Leaving the study early: proportion of participants discontinuing treatment • Employment status: number of days in employment over the assessment period; number of days lost from work as a result of health problems (absenteeism) • Economic outcomes: cost of services (direct and indirect) for health and social care service utilisation using Client Service Receipt Inventory (CSRI); cost impact of absence from work • Mental state: Hospital Anxiety and Depression Scale (HADS) Other outcomes • Strength of the therapeutic alliance: Working Alliance Inventory (WAI) • Social problem-solving ability: Social Problem Solving Inventory-Revised (SPSI-R)
Notes	[a]The intervention group (PEPS) had 23/154 (15%) participants with a diagnosis of AsPD; the control group (TAU) had 31/152 (20%) of participants with an AsPD diagnosis; no data for the AsPD subsample [b]Trial stopped in month 30 of the recruitment phase due to safety concerns (recruitment due to be 32 months duration); no more patients were randomised after this point; patients receiving PEPS had treatment stopped and were informed of possibility of harm; all patients followed up as per trial protocol Study funding: National Institute for Health Research Health Technology Assessment Programme Declaration of interests: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomisation was based on a computer generated pseudo-random code using random permuted blocks of randomly varying size created by the Nottingham Clinical Trials Unit (NCTU) in accordance with their standard operating procedure and held on a secure server. The randomisation was stratified by recruiting centre and sex. The sequence of treatment allocations was concealed until recruitment, data collection, and all other trial-related assessments were complete. The investigator, or an authorised designee, accessed the treatment allocation for each participant by means of a remote, internet-based randomisation system developed and maintained by the NCTU.

McMurran 2016 *(Continued)*

		Allocation was therefore fully concealed from recruiting staff." (HTA report, p xxiv)
Allocation concealment (selection bias)	Low risk	Quote: "Randomisation was based on a computer-generated pseudo-random code using random permuted blocks of randomly varying size, created by the Nottingham Clinical Trials Unit in accordance with their standard operating procedure and held on a secure server. Allocation was stratified by recruiting centre and sex." (quote from HTA report, p xxiv)
Blinding (performance bias and detection bias) of participants	High risk	Comment: In a study such as this, full blinding is difficult to achieve because participants would be aware whether or not that they were participating in a psychological intervention and may also be aware of the nature of this intervention. Quote: "Participants, mental health workers delivering the interventions, and participants' usual care teams were aware of the treatment allocation." (HTA report, p 16) Comment: The review authors noted that most of the outcome data were obtained from self-report questionnaires from participants who were not blind to treatment allocation.
Blinding (performance bias and detection bias) of personnel	High risk	Comment: The trial investigators reported that both the mental health workers who delivered the interventions, and the usual-care teams of participants, were aware of the participant's treatment allocation.
Blinding (performance bias and detection bias) of outcome assessors	Unclear risk	Quote: "...outcome measures were administered by research assistants blinded to treatment allocation in order to reduce assessment bias as far as possible. Data analysts remained blinded to allocation during the study by having access to only aggregate data and no access to data that could reveal treatment arm, such as course attendance. Final analyses were conducted using treatment labels A/B, with allocation decodes released only after completion of analyses. Data that could reveal allocation were analysed following release of allocation decodes." (p 16)
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "The pattern of missing data was investigated by examining variables recorded at baseline that were associated with 'missingness' of SFQ score at the 72-week follow-up. Multiple imputation and analysis of multiple imputed data sets were conducted using 'mi' procedures in Stata. The imputation model contained site, age, sex, ethnicity, social status, PD category (simple or complex), SFQ at baseline and 24 weeks, baseline EQ-5D health state score, baseline HADS score, baseline SPSI-R score and baseline three main problems score, and 20 data sets were imputed." (p 12)
Selective reporting (reporting bias)	Unclear risk	Comment: The trial investigators reported 'a priori' minimum completion rates for a valid analysis ("...80% completion rate at baseline and 50% completion at follow-up..." (quote; p 36)). Two proposed outcomes were not reported as data completion rates did not reach the prespecified level required for a valid analysis; Global Assessment of Functioning (GAF) and Working Alliance Inventory – Short Revised (WAI).
Other bias	Unclear risk	Comment: • Allegiance bias; trial authors MM and CD may be considered to have allegiance to the development of PEPS therapy (high risk). • Vested interest: the National Institute for Health Research (NIHR) Health Technology Assessment programme funded this study. Hywel Williams is the Deputy Director of this programme but was not involved in the funding decision for this programme (low risk). Publication bias; protocol and peer-reviewed journal article, publicly available HTA report (low risk). Language

McMurran 2016 *(Continued)*

	bias; English language papers (low risk). Other; warnings provided before the study was halted prematurely may have impacted on study management and ongoing treatment delivery (unclear risk)

Nathan 2019

Study characteristics	
Methods	Design: multisite, parallel, randomised control trial
Participants	Participants: male prisoners with personality disorder (whole sample, see note[a]) Sex: all male Age: (see note[a]) intervention group ('Resettle') mean age = 35.8 years (SD = 11.3); control group (treatment-as-usual; TAU) mean age = 32.6 years (SD = 11.6); total sample mean age = 34.3 years (SD = 11.5) Unit of allocation: individual participant Number randomised: (see note[a]) intervention (n = 38); control (n = 34) Number completing: (see note [a]) intervention group (Resettle: primary outcome - intention-to-treat (ITT), n = 28; secondary outcome at y1, n = 25; secondary outcome at y2, n = 12); control group (TAU: primary outcome ITT, n = 29; secondary outcome at y1, n = 24; secondary outcome at y2, n = 11) Setting: prison and community in the North West of England Inclusion criteria: male prisoners over 18 years of age, likely to have personality disorder and identified as 'high risk' and in need of multi-agency risk management arrangements (MAPPA) Exclusion criteria: severe intellectual impairment or psychotic mental illness identified from a review of the records or from the initial baseline assessment Ethnicity: (see note [a]) intervention (Resettle) group (white British - 34 (89.5%); white Irish - 1 (2.6%); white & black Caribbean - 0; African - 1 (2.6%); other mixed backgrounds - 2 (5.3)); control (TAU) group (white British - 33 (97.1%); white Irish - 0; white & black Caribbean - 1 (2.9%); African - 0; other mixed backgrounds - 0) Baseline characteristics: (see note [a]) *Intervention (Resettle) group* Age at first conviction: 'before age 15': n = 13 (34.2%); 'age 15-17': n = 11 (28.9%); 'age 18 +': n = 14 (36.8%) Number of previous convictions: 13.3 (SD = 9.6) Number of previously convicted offences: 32.5 (SD = 25.4) Index offence: violent (n = 25, 65.8%), sexual (n = 10, 26.3%), burglary (n = 1, 2.6%), robbery (n = 7, 18.4%), other (n = 7, 18.4%) Psychopathy Checklist-Screening Version (PCL-SV): total mean score = 16.2 (SD = 4.6), facet 1 mean = 7.1 (SD = 3.0), facet 2 mean = 9.0 (SD = 3.3) Number of days from release to follow-up: mean = 882.5 (SD = 187.1) SCL-90 Global Severity Index: mean score = 0.85 (SD = 0.66)

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DSM-IV personality disorders definite diagnosis: paranoid (n = 5, 12.2%); schizoid (n = 0); schizotypal (n = 0); antisocial (n = 34, 89.5%); borderline (n = 9, 23.7%); narcissistic (n = 1, 2.6%); avoidant (n = 1, 2.6%); obsessive compulsive (n = 0); not otherwise specified (n = 3, 7.9%)
DSM-IV personality disorders probable diagnosis: paranoid (n = 3, 7.9%); schizoid (n = 3, 7.9%); schizotypal (n = 0); antisocial (n = 2, 5.3%); borderline (n = 7, 18.4%); narcissistic (n = 0); avoidant (n = 3, 7.9%); obsessive compulsive (n = 1, 2.6%); not otherwise specified (n = 0)

Control (TAU) group

Age at first conviction: 'before age 15': n = 13 (38.2%); 'age 15-17': n = 12 (35.5%); 'age 18 +': n = 9 (26.5%)

Number of previous convictions: n = 14.2 (SD = 10.9)

Number of previously convicted offences: n = 30.2 (SD = 27.2)

Index offence: violent (n = 25, 73.5%), sexual (n = 5, 14.7%), burglary (n = 3, 8.8%), robbery (n = 7, 20.6%), other (n = 5, 14.7%)

Psychopathy Checklist-Screening Version (PCL-SV): total mean score = 15.7 (SD = 4.5), facet 1 mean = 6.5 (SD = 3.5), facet 2 mean = 9.2 (SD = 2.4)

Number of days from release to follow-up: mean = 832.6 (SD = 144.1)

SCL-90 Global Severity Index: mean score = 0.82 (SD = 0.78)

DSM-IV personality disorders definite diagnosis: paranoid (n = 1, 2.9%); schizoid (n = 0); schizotypal (n = 1, 2.9%); antisocial (n = 31, 91.2%); borderline (n = 4, 11.8%); narcissistic (n = 2, 5.9%); avoidant (n = 1, 2.9%); obsessive compulsive (n = 2, 5.9%); not otherwise specified (n = 3, 8.8%)

DSM-IV personality disorders probable diagnosis: paranoid (n = 1, 2.9%); schizoid (n = 2, 5.9%); schizotypal (n = 0); antisocial (n = 2, 5.9%); borderline (n = 5, 14.7%); narcissistic (n = 0); avoidant (n = 1, 2.9%); obsessive compulsive (n = 1, 2.9%); not otherwise specified (n = 3, 8.8%)

Interventions	Two conditions: Resettle programme; TAU • Intervention (n = 34 definite AsPD participants randomised): Resettle programme • Control group (n = 31 definite AsPD participants randomised): TAU Details of conditions: • Resettle intervention programme is an individual and group-based psychosocial intervention consisting of 3 levels; (i) the therapeutic milieu generated by appropriate and prosocial relationships with a focus on enhancing social learning within a safe and boundaried environment; (ii) regular group work aimed at developing enhanced capacities for self-reflection and understanding of others; and (iii) individually-tailored psychosocial interventions, with a focus on risk management, well-being and social integration. All Resettle participants are subject to detailed case formulations which form the basis of individual risk management and intervention plans. Participants initially attend the programme 6 days per week and there are 2 key-worker sessions a week. Following a period of familiarisation, less frequent weekly attendance is negotiated on the basis of individualised assessments of need and risk. • The control condition is TAU; standard probation supervision following release from prison. TAU comprises regular meetings (weekly initially) with the offender manager and engagement with other services where specified in the licence conditions. Duration of intervention: at least 2 years 6 months (6 months prior to release, then 2 years after release) Duration of trial: variable but approximately 30-36 months Length of follow-up: 2 years following discharge from prison; outcomes measured at 1 year and 2 years after release
Outcomes	Primary outcomes

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- Recidivism: number and type of officially recorded offending according to the Police National Computer (PNC) (data were obtained for every offence recorded on the PNC between the point of initial release until the completion of the study) (see note[c])
- Recidivism: non-convicted offences identified by self-report or incident reporting of antisocial behaviour using the Self-Reported Delinquency (SRD) scale[b] over the previous year (see note[c])
- Adverse events: death (reported incidentally)

Secondary outcomes

- Leaving the study early: number of participants not included in ITT analysis of primary outcome (reported incidentally)

Other outcomes

- None

Notes

[a]In the intervention group (n = 38), 34 participants had a definite AsPD diagnosis and 2 had a probable AsPD diagnosis. In the control group (n = 34), 31 participants had a definite AsPD diagnosis and 2 had a probable AsPD diagnosis. Reported participant demographic data are for the whole intervention group (n = 38) and control group (n = 34)

[b]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 1986), amended for use in an adult group (Palmer 2000).

[c]Raw study data was provided by the study authors, allowing data extraction for the primary outcome to be undertaken for a 100% AsPD subsample

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "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 utilized 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." (p 3, column 1)
Allocation concealment (selection bias)	Low risk	Quote: "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." (p 3, column 1)
Blinding (performance bias and detection bias) of participants	Unclear risk	Comment: Due to the nature of the intervention, it is not possible to blind participants to their allocation; the impact of this on risk of bias is unclear. In the intervention arm: "Participants initially attended Resettle for 6 days each week. In this phase, there were two key-worker sessions a week...." (quote, p 3, column 1) In the control arm: "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." (quote, p 3, column 1)

Nathan 2019 *(Continued)*

Blinding (performance bias and detection bias) of personnel	High risk	Comment: This is an open-label study: the offender manager was aware of group allocation. Resettle practitioners only worked with the participants randomised to the intervention. Quote: "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." (p 3, column 1)
Blinding (performance bias and detection bias) of outcome assessors	High risk	Quote: "Follow-up was not conducted blindly because assignment to the treatment and control groups was evident from the contact process." (p 4)
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: The attrition rate was high for the intervention and control groups. ITT was utilised in the analysis but numbers were still smaller than would be expected in the ITT and reasons for the missing numbers were unclear. E.g. Resettle: n = 38 randomised, ITT primary outcome reported as n = 28; TAU: n = 34 randomised, ITT primary outcome reported as n = 29
Selective reporting (reporting bias)	High risk	Comment: primary outcome measures reported in protocol as of 13 June 2013 were significantly different from those reported in the paper. The trial register indicated that several outcome measures were administered (e.g. Inventory of Interpersonal Problems (IIP); Barratt Impulsivity Scale (BIS)) but the study only reported data for reoffending and self-reported antisocial behaviour. Protocol primary outcomes of 13 June 2013: 1. Reoffending data (Records from Police National Computer (PNC); Probation records) Nathan 2019 primary outcome: "The primary outcome was number and type of officially recorded offending according to the Police National Computer (PNC)." (quote, p 3-4). Secondary outcomes reported in the protocol as of 13 June 2013: 1. Antisocial behaviour (Self-Report Delinquency (SRD) scale). 2. Personality functioning (Inventory of Interpersonal Problems (IIP); Barratt Impulsivity Scale (BIS)). 3. Psychiatric illness/symptom and substance abuse/dependency (Structured Clinical Interview for DSM-IV (SCID I); Symptom Check List-90-Revised (SCL-90-R)) Nathan (2019) secondary outcome: "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)." (quote, p 4 column 1)
Other bias	High risk	Comment: • Allegiance bias: high risk of bias. 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. Author V Baker is described as 'Associate Director, Resettle Project, Speke, Liverpool, UK' in the Miller 2010 publication. This allegiance to the Resettle programme was not declared in Nathan 2019.

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- Vested interest bias (funding and/or author affiliations): high risk of bias. This work was supported by the 'Dangerous and Severe Personality Disorder' (DSPD) programme established by the UK Home Office and the Department of Health (DoH) 1999. The Resettle programme (formerly known as the Community Risk Assessment and Case Management Service) was jointly funded by the Ministry of Justice and the DoH as part of the DSPD services. The intervention was therefore developed by DoH, and this study was funded in part by the DoH.
- Publication bias: unclear risk of bias. Though the study was published in a peer reviewed journal, there has been a long period of time between study commencement (2008) and publication of results (2019).

A + E = accident and emergency
AIDS = acquired immune deficiency syndrome
APQ = Antisocial Personality Questionnaire
ASI = Addiction Severity Index
AsPD = antisocial personality disorder
AUDIT = Alcohol Use Disorders Identification Test
BCSS = Brief Core Schema Scales
BDI = Beck Depression Inventory
BIS = Barratt Impulsivity Scale
BPAQ-SF = Buss-Perry Aggression Questionnaire-12-Item Short-Form
BPD = borderline personality disorder
BPRS = Brief Psychiatric Rating Scale
BSI = Brief Symptom Inventory
CBT = cognitive behavioural therapy
CIRCLE = Chart of Interpersonal Reactions in Close Living Environments
CM = contingency management
CORE-OM = Clinical Outcomes in Routine Evaluation-Outcome Measure
CRACMS = community risk assessment and case management service
CSRI = Client Service Receipt Inventory
DAST = Drug and Alcohol Screening Test
DBT = dialectical behaviour therapy
DC = drug counseling
DES = Dissociative Experiences Scale
DFST = dual-focus schema therapy
DoH = Department of Health (England and Wales)
DSM (III, IV) = *Diagnostic and Statistical Manual of Mental Disorders* (*Third Edition, Fourth Edition*)
DrinC = Drinker Inventory of Consequences
DSPD = dangerous and severe personality disorder
DWI = driving while intoxicated
EQ-5D = European Quality of Life-5 dimensions
ESS = Experience of Shame Scale
EUROQOL = EuroQol Research Foundation
GAF = Global Assessment of Functioning
GCSE = General Certificate of Secondary Education
HADS = Hospital Anxiety and Depression Scale
HCR-20 = Historical Clinical Risk Management-20
HIV = human immunodeficiency virus
HTA = Health Technology Assessment
IBRS = Institutional Behaviour Rating Scale
ICC = intra-class correlations
ICD-10 = *International Classification of Diseases-Tenth Revision*
IIP = Inventory of Interpersonal Problems
ILC = impulsive lifestyle counselling
IOP = intensive outpatient programme
IPDE = International Personality Disorder Examination
IQ = intelligence quotient
IRP = individualised relapse prevention
ITT = intention-to-treat analysis

MACT= manual-assisted cognitive behaviour therapy
MANSA = Manchester Short Assessment of Quality of Life
MAPPA = multi-agency public protection arrangements
MCVSI = MacArthur Community Violence Screening Instrument
MINI = Mini International Neuropsychiatric Interview
MINIM = randomisation program for running minimisation in clinical trials
MOAS = Modified Overt Aggression Scale
n/a = not applicable
NAS = Novaco Anger Scale
NCTU = Nottingham Clinical Trials Unit
NEP = needle exchange programme
NHS = National Health Service
OAS = Overt Aggression Scale
PAS-Q = Quick Personality Assessment Schedule
PCL-R = Psychopathy Checklist-Revised
PCL-SV = Psychopathy Checklist-Screening Version
PD = personality disorder
PD-NOS = personality disorder-not otherwise specified
PDQ = Personality Diagnostic Questionnaire
PEPS = psychoeducation and problem-solving
PNC = Police National Computer
PTSD = post-traumatic stress disorder
QALY = quality-adjusted life year
QOL = quality of life
REBT = rational emotional behaviour therapy
Resettle = programme of psychosocial interventions for high risk personality disordered offenders
SASII = Suicide Attempt Self-Injury Interview
SBCM = strengths-based case management
SCID = Structured Clinical Interview for DSM [*Diagnostic and Statistical Manual of Mental Disorders*]
SCL-90-R = Symptom Checklist 90
SD = standard deviation
SE = standard error
SFQ = Social Functioning Questionnaire
SIDP = Structured Interview for DSM-IV Personality Disorders
SM = standard maintenance
SMI = schema mode inventory
SMT = schema modal therapy
SNAP = Schedule for Nonadaptive and Adaptive Personality
SPSI-R = Social Problem Solving Inventory-Revised
SRASBM = Self-Report of Aggression and Social Behaviour Measure
SRD = Self-Reported Delinquency Scale
ST = schema therapy
START = Short-Term Assessment of Risk and Treatability
STAXI = State-Trait Anger Expression Inventory
SVR-20 = Sexual Violence Risk-20
TAU = treatment-as-usual
TBS = Terbeschikkingstelling
TER = Treatment Engagement Rating Scale for Forensic Outpatient Treatment
USD = United States Dollar
VRS = Violence Risk Scale
WAI = Working Alliance Inventory
YSQ = Young Schema Questionnaire-Short Version
ZAN-BPD = Zanarini Rating Scale for Borderline Personality Disorder

Characteristics of excluded studies [ordered by year]

Study	Reason for exclusion
Sloane 1976	Randomised trial comparing psychoanalytically-oriented psychotherapy, behaviour therapy and waiting-list controls in outpatients. Excluded because diagnosis of AsPD not attempted

Study	Reason for exclusion
Liberman 1981	Randomised trial comparing BT with insight-oriented therapy for repeated suicide attempters. Excluded because no participants had a diagnosis of AsPD and there was no control condition that could be classified as TAU, waiting list or no treatment
Hesselbrock 1991	Outcome study of inpatients with alcohol dependency. Excluded because participants were not randomised
Longabaugh 1994	Randomised trial comparing CBT and relationship-enhancement therapy for alcohol abusers. Investigators reported that 48 of 229 participants recruited had AsPD. Excluded because there was no control condition that could be classified as TAU, waiting list or no treatment
Winston 1994	Randomised trial comparing brief adaptive psychotherapy with short-term dynamic psychotherapy and with waiting-list controls in outpatients. Excluded because there was no AsPD subgroup (trial excluded participants with history of violent behaviour or destructive impulse control problems)
Springer 1996	Randomised trial comparing DBT-derived CBT group therapy with discussion control group for inpatients with PD, assessed using MCMI-II. Excluded because no indication that any participant had a diagnosis of AsPD
Wölwer 2001	Randomised trial comparing CBT and coping skills training against treatment as usual in outpatients with alcohol dependency. Excluded because only 10 participants had a diagnosis of AsPD. Review authors judged the numbers of participants randomised to each of the 3 conditions to be too small for extraction of means and SDs for each condition.
Messina 2002	Study comparing 2 therapeutic community treatments. PD assessed using MCMI-II. Excluded because the participants were not randomised and there was no control condition that could be classified as TAU, waiting list or no treatment
Kool 2003	Randomised trial comparing psychodynamic supportive therapy plus pharmacotherapy with pharmacotherapy for depressive disorder in depressed patients with and without AsPD. Excluded because only 4 participants had a diagnosis of AsPD (confirmed by study investigators via email to J Dennis on 29 May 2009, Kool 2003)
Chiesa 2003	Prospective study comparing 2 specialist psychosocial interventions (therapeutic community-based inpatient treatment and step-down). Excluded because participants were not randomised
Colom 2004	Randomised trial comparing a group psychoeducation intervention with a non-structured control intervention in patients with PD and bipolar disorder. Only 2 participants had a diagnosis of AsPD. Excluded because participants had bipolar disorder in addition to AsPD
Vannoy 2004	Randomised trial comparing anger management with a waiting-list control condition. Excluded because there was no AsPD subgroup
Vinnars 2005	Randomised trial comparing manualised supportive-expressive psychotherapy with non-manualised community-delivered psychotherapy. Excluded because there was no control condition that could be classified as TAU, waiting list or no treatment
Mörtberg 2007	Randomised trial comparing group cognitive therapy, individual cognitive therapy and TAU in outpatients with social phobia. Investigators used the SCID-II screener but made no formal diagnostic assessment of PD. Excluded because no indication that any participant had a diagnosis of AsPD
Weertman 2007	Randomised trial comparing present-focused and past-focused cognitive therapy in outpatients. Excluded because no participant had a diagnosis of AsPD, and there was no control condition that could be classified as TAU, waiting list or no treatment
Zorn 2007	Randomised trial comparing schema-focused emotional behaviour therapy and classical social skills training. Excluded because no participant had a diagnosis of AsPD

Study	Reason for exclusion
Lynch 2007	Randomised trial comparing medication plus a DBT-based intervention with medication only in older adults with comorbid PD and depression. Excluded because only 1 participant had a diagnosis of AsPD
Milrod 2007	Randomised trial comparing psychodynamic psychotherapy with relaxation for individuals with panic disorder. Excluded because no participant had a diagnosis of AsPD, and there was no control condition that could be classified as TAU, waiting list or no treatment
Kallert 2007	Randomised trial comparing acute day hospital care with inpatient care. Excluded because no participant had a diagnosis of AsPD (confirmed by study authors via email on 2 June 2009, see Kallert 2007)
Kool 2007	Randomised trial comparing psychodynamic supportive therapy plus pharmacotherapy with pharmacotherapy alone for depressive disorder in depressed patients with and without AsPD (article in Dutch). Excluded because only 3 participants had a diagnosis of AsPD
Ball 2007	Randomised trial comparing dual-focus schema therapy with 12-step facilitation therapy in opioid-dependent outpatients. Excluded because there was no control condition that could be classified as TAU, waiting list or no treatment
Easton 2007	Study aggregating results from two RCTs (Carroll 1998; Carroll 2004) to compare CBT, interpersonal psychotherapy, 12-step facilitation therapy, supportive psychotherapy and disulfiram in outpatients with alcohol and cocaine dependence. Both trials had a subgroup with AsPD. Excluded because neither trial had a control condition that could be classified as TAU, waiting list or no treatment
Fournier 2008	Randomised trial comparing antidepressants with cognitive therapy in patients with and without PD. Excluded because no participant had a diagnosis of AsPD (confirmed by investigators via email on 3 June 2009, see Fournier 2008). Placebo control condition only in the follow-up of treatment responders
Petersen 2008	Randomised trial comparing a specialised, psychotherapeutic day treatment programme with a waiting-list control condition for adults with personality disorder. Excluded because a diagnosis of AsPD was an exclusion criterion
Bagby 2008	Analyses the aggregated results of two randomised trials comparing CBT and pharmacotherapy for adults with major depression. Excluded because a diagnosis of AsPD was an exclusion criterion, and because there was no control condition that could be classified as TAU, waiting list or no treatment
Daughters 2008	Study examining the interactive effects of court-mandated treatment and AsPD on treatment dropout in a sample of male substance users who were receiving residential substance-abuse treatment. Excluded because participants were not randomised, and there was no control condition that could be classified as TAU, waiting list or no treatment
Abbass 2008	Randomised trial comparing intensive short-term dynamic psychotherapy with TAU in outpatients. Excluded as insufficient number of observations; only one participant had a diagnosis of AsPD
Vera 2008	Study describing a cognitive behavioural group treatment for adults with OCD symptoms plus comorbid personality disorder. Excluded because there was no random allocation and no control condition that could be classified as TAU, waiting list or no treatment
Bowen 2009	Randomised trial comparing mindfulness-based relapse prevention for substance disorders with TAU. Excluded as participants were not assessed for PD

Study	Reason for exclusion
Frisman 2009	Secondary analysis of data from a randomised trial of assertive community treatment and clinical case management in participants with substance disorders (Essock 2006). Excluded as participants also had axis I disorders such as schizophrenia
Tyrer 2009	Randomised trial of early versus late assessment of dangerous and severe PD in a sample of prisoners. Excluded because there was no psychological treatment in either allocated condition
Bateman 2009	Randomised superiority trial of mentalisation-based treatment and structured clinical management for patients with AsPD and comorbid borderline PD. Excluded as the trial did not have a control condition that could be classified as TAU, waiting list or no treatment
Kelly 2009	Randomised trial comparing individual problem-solving, group depression prevention and TAU with a European sample of adults with depressive disorder (the ODIN [Outcome of Depression International Network] study). Investigators reported that 93 of the 301 participants who were fully assessed met criteria for at least 1 PD. Excluded because no AsPD subgroup was identified and because a proportion of the sample had a diagnosis of bipolar disorder
Muran 2009	Randomised trial comparing CBT, brief relational therapy and short-term dynamic psychotherapy in fee-paying outpatients. Excluded because the primary inclusion criterion was a diagnosis of cluster C PD or PD-NOS, with no indication of any AsPD subgroup. In addition, there was no control condition that could be classified as TAU, waiting list or no treatment
Arnevik 2009	Randomised trial comparing short-term, day hospital psychotherapy and outpatient individual psychotherapy for adults with PD. Excluded because a diagnosis of AsPD was an exclusion criterion, and because there was no control condition that could be classified as TAU, waiting list or no treatment
Holmqvist 2009	Superiority trial comparing aggression replacement training and a relationally-orientated treatment for young offenders. Excluded as the trial was not randomised and used juvenile participants
Hesse 2010	Randomised trial of psychoeducation as an addition to substance abuse treatment vs attention placebo. Excluded as only participants in the treatment arm were formally assessed for PD
Bartak 2010	Superiority trial comparing 3 treatments (outpatient, day hospital and inpatient) for patients with cluster B personality disorders. Excluded as participants were not randomised to treatment conditions, and there was no control condition that could be classified as TAU, waiting list or no treatment
McGauley 2011	Pilot study of mentalisation-based treatment for men with AsPD delivered in 1 site of a multisite trial. Excluded as the participants were not randomised and there was no control condition that could be classified as TAU, waiting list or no treatment
Høglend 2011	Randomised superiority trial of dynamic psychotherapy with or without transference interpretation in patients with predominately cluster C personality disorders (1 patient with AsPD was reported in the transference treatment group). Excluded as there was no control condition that could be classified as TAU, waiting list or no treatment
Korrelboom 2011	Randomised trial comparing memory training therapy and TAU in patient participants with low self-esteem. Excluded as borderline PD was the predominant diagnosis and patients with AsPD were treated in another clinical department to where the study was conducted
Ball 2011	Randomised study comparing manual-guided individual dual-focus schema therapy or individual drug counselling as an addition to standard residential therapeutic community treatment. Excluded as there was no control condition that could be classified as TAU, waiting list or no treatment

Study	Reason for exclusion
Easton 2012	Randomised superiority trial comparing 4 cognitive-behavioural interventions for substance-dependent participants with or without AsPD. Excluded as there was no control condition that could be classified as TAU, waiting list or no treatment
Rees-Jones 2012	Trial of a cognitive-behavioural programme (reasoning and rehabilitation mental health programme) for mentally disordered offenders treated in forensic mental health setting. Excluded as participants were not randomised
Young 2013	Controlled trial of a cognitive skills programme for personality-disordered offenders (Reasoning and Rehabilitation ADHD program). Excluded as participants were not randomised to the experimental treatment or waiting-list control groups
McMurran 2013	Randomised trial comparing a specialist treatment for PD with or without a goal-based motivational interview. Excluded as the specialist nature of the intervention meant that no condition could be classified as TAU, waiting list or no treatment
Rademacher 2013	Controlled trial of individual systemic therapy (voluntary participation vs participation mandated by conditions of probation, vs waiting-list control), to reduce aggressiveness. Excluded as participants were not randomised
Johnson 2013	Double-blind RCT comparing topiramate + CBT with placebo + CBT in cocaine-dependent adults. Excluded because no diagnosis of PD was made
Lorentzen 2013	Randomised trial of short- and long-term group analytic psychotherapy for patients with mood, anxiety or PD. Excluded as insufficient number of observations; only 2 patients with AsPD were reported in the study (none in the short-term group, 2 in the long-term group)
De Jong 2013	Randomised trial comparing group and individual treatment in participants with personality problems. Excluded as the trial did not have a control condition that could be classified as TAU, waiting list or no treatment
Doyle 2013	Controlled trial to assess the effectiveness of enhanced thinking skills in offenders with AsPD traits. Excluded as participants were not randomised
Dean 2013	Randomised trial of a cognitive skills programme (Reasoning and Rehabilitation) for mentally disordered offenders. Excluded as participants were described as having a "psychotic disorder"
Davidson 2014	Randomised trial of manual-assisted cognitive therapy to promote engagement in services and address self-harm in patients admitted to hospital following an episode of self-harm. Excluded as no AsPD reported in paper; author (Kate Davidson) was contacted by email (28 February 2017, see Davidson 2014) and confirmed she is unable to access and check the original study data.
Witkiewitz 2014	Randomised superiority trial of mindfulness-based relapse prevention and standard relapse prevention for substance-addicted women offenders. Excluded as there was no control condition that could be classified as TAU, waiting list or no treatment
Chen 2014	Randomised study comparing a CBT training programme plus routine intervention (TAU) vs TAU in young male violent offenders. Excluded because some participants were juveniles and no reported diagnosis of PD
Hakvoort 2015	Randomised trial of 'cognitive-behavioral music therapy' vs TAU for anger management and coping skills in a forensic psychiatric setting. Email correspondence with the author on 21 November 2017 confirmed all participants had a diagnosis of AsPD (Hakvoort 2015). Excluded as intervention was not a specific psychological therapy as defined in this review

Study	Reason for exclusion
Suszek 2015	Protocol for a randomised trial of 2 group interventions (intensive psychodynamic therapy and CBT) vs waiting-list control for patients with anxiety disorders and comorbid depressive or PD. Excluded as this was a study protocol
Brazão 2015	Randomised controlled study of a CBT group intervention (Growing Pro-Social) for male offenders. Excluded as no diagnosis of PD reported
Crane 2015	Randomised study comparing a brief motivational interview with a control intervention on treatment compliance in violent offenders. Excluded as no diagnosis of PD was reported
Urban 2015	Randomised cross-over trial of animal-assisted (dog) therapy for patients undergoing drug withdrawal. Excluded after email from author on 14 February 2017 confirmed that there were no participants with AsPD comorbidity in the sample (Urban 2015)
Wupperman 2015	Trial of individual mindfulness and modification therapy vs TAU for women with substance use and aggression difficulties. Excluded as the participants were not randomised and PD was not reported
Swogger 2016	RCT comparing a brief motivational intervention for substance-using offenders. Psychopathic traits were assessed; however, the study was excluded as there was no formal assessment of PD
Keefe 2016	Secondary analysis of randomised trial of cognitive therapy, antidepressants and placebo for major depressive disorder (DeRubeis 2005). Excluded as AsPD was an exclusion criteria in the original trial
Leichsenring 2016	Controlled trial of manualised psychoanalytical and psychodynamic therapy for cluster B PD. Excluded as the study was not a RCT as participants were randomised to the 2 treatment conditions but not the control condition
Elsner 2016	Controlled parallel trial of schema-orientated psychotherapy vs TAU with personality-disordered forensic patients. Excluded as the study was not a randomised trial
Gysin-Maillart 2016	Randomised trial of a suicide prevention intervention vs TAU. Excluded as author confirmed by email that no participants had a diagnosis of AsPD (22 March 2017, Gysin-Maillart 2016)
Blattman 2017	Randomised study of CBT (designed to foster self-regulation, patience, and a noncriminal identity and lifestyle), with or without cash grants of USD 200, for criminally engaged men in Liberia. Excluded as no diagnosis of AsPD/dissocial PD
Välimäki 2017	Protocol for a cluster-randomised trial comparing the impact of an educational programme for staff or standard care on the outcomes of inpatients with a diagnosis of schizophrenia. Excluded as participants had a diagnosis of major mental illness, and it was the staff members who were randomised in the study, not the patients
Shaw 2017	Randomised trial comparing the completion of collaborative case formulations (CFs) and usual practice, on the relationships between offender managers and high-risk offenders with PD. Excluded as it was the offender managers, rather than the offenders, who were randomised into the intervention and control groups
Tomlinson 2017	Randomised, waiting-list controlled trial of DBT for forensic psychiatric patients. Excluded after correspondence with the study author (email from MT on 9 November 2018, Tomlinson 2017), which confirmed that of the 4 participants with a diagnosis of AsPD, 3 also had a serious mental illness (schizophrenia; delusional disorder; schizoaffective disorder)
NCT03382808	Ongoing, parallel randomised trial of emotional recognition training (behavioural SEE training versus behavioural GAZE training) for antisocial violent offenders with psychopathic traits. Excluded as this study did not have a true control condition; GAZE training was described as an "active comparator"

Study	Reason for exclusion
Pearce 2017	Randomised trial comparing democratic therapeutic community treatment with crisis planning plus TAU for adults with PD. 7 participants diagnosed with AsPD (5 in intervention group; 2 in control group). Excluded as the addition of 'crisis planning' to the control group intervention was not TAU
Conrad 2017	Pre/post-treatment evaluation of the effectiveness of a 10-week group psychological intervention based on DBT skills with patients diagnosed with either cluster B PD or a mood disorder. Excluded as the study was not an RCT
DRKS0001326	Trial registry citation of a pre-post study of schema therapy for adult inpatients with PD randomised to different baseline lengths. Excluded from classification as an 'on-going' study in this review as it was not an RCT and AsPD was an exclusion criterion
Nitschke 2018	Study documented a violence-prevention treatment based on psychoeducation, group training, and individual treatment on violence risk co-management for forensic psychiatry outpatients. Excluded as the study was not an RCT
Lay 2018	Randomised trial of a psychoeducation intervention (focusing on behaviours prior to and during illness-related crises) and TAU in a sample of psychiatric inpatients with compulsory admission to hospital. Excluded after email correspondence with the study author (B Lay) on 21 November 2018 confirmed that no participants had a diagnosis of AsPD (Lay 2018)
NCT03677037	Randomised trial of mentalisation-based therapy (20 weeks/short-term compared with 14 months/long-term) for outpatients with subthreshold or diagnosed borderline PD. Excluded as AsPD was an exclusion criterion and there was no control condition that could be classified as TAU, waiting list or no treatment
Davis 2018	Randomised trial of multi-systemic therapy (MST-EA) for young adults (17-20 years) with serious mental health conditions referred for state vocational rehabilitation services. Excluded as the study included juveniles and AsPD was not assessed/recorded
Kool 2018	Randomised trial of therapy dosage (25 compared to 50 sessions in a year) and type of therapy (schema therapy compared to short-term psychodynamic supportive psychotherapy) for patients with comorbid depressive disorder and PD. Excluded as there was no control condition that could be classified as TAU, waiting list or no treatment
Larden 2018	Nonrandomised comparison of a cognitive-behavioural intervention (aggression-replacement training) in adult offenders within the Swedish prison and probation service. Excluded as the study was not an RCT
Kingston 2018	Randomised trial comparing a cognitive skills programme (Reasoning and Rehabilitation 2: Short version for Adults) and TAU in a sample of offenders with mental illness. Excluded as participants were diagnosed with serious mental illnesses such as bipolar disorder and psychosis. We contacted the study authors to confirm if any participants had comorbid AsPD and anxiety/trauma-related diagnoses but received no response (Kingston 2018)
Klein Tuente 2018	Protocol for an ongoing, waiting-list controlled trial of a virtual reality intervention for aggressive forensic psychiatric inpatients with any DSM-5 diagnosis (virtual reality aggression-prevention training). Excluded because the intervention could not be described as a purely psychological intervention, as the training was delivered using virtual reality technology headsets
Haeyen 2018	Randomised, waiting-list control trial of a group-based, art therapy intervention for adult participants diagnosed with a cluster B/C PD. The intervention used theoretical elements of DBT, schema-focused therapy, gestalt art therapy and creative problem-solving. Excluded as there were no reported participants with a diagnosis of AsPD

Study	Reason for exclusion
Keefe 2018	Secondary analysis of a randomised trial of 3 psychotherapies for people with panic disorder (with or without agoraphobia) comparing CBT, panic-focused psychodynamic psychotherapy and applied relaxation training (ART). Excluded as there was no control condition that could be classified as TAU, waiting list or no treatment, and ART data were not presented
De Jong 2018	Randomised trial of outcome-monitoring feedback (to therapist or patients and therapists or no feedback) with day treatment patients and inpatients with PD. Excluded as there were no patients with AsPD reported
Grenyer 2018	Cluster-RCT of a stepped-care model of psychological therapy compared with TAU for inpatients with PD. Excluded as the study recruited people aged 12 years or over
Deng 2019	RCT of a five-week intervention for male violent prisoners comparing 3 conditions: gratitude-sharing, blessing-counting, and control. Excluded as AsPD was not assessed
Sewall 2019	Long-term, community follow-up of men completing sexual offender treatment in a Canadian prison. Excluded as the study was not an RCT
Bianchini 2019	Randomised trial of 12 months DBT plus standard REMS treatment (TAU) versus TAU for male forensic psychiatric patients with borderline PD. Pre and post-assessments included BIS-11, DERS and TAS-20. Excluded as there was no information regarding AsPD or other diagnoses such as psychosis and bipolar disorder

ADHD = attention deficit hyperactivity disorder
ART = applied relaxation training
AsPD = antisocial personality disorder
BIS-11 = Barratt Impulsiveness Scale Version 11
BT = behaviour therapy
CBT = cognitive behavioural therapy
CF = case formulation
DBT = dialectical behaviour therapy
DERS = Difficulties in Emotion Regulation Scale
DSM-5 = *Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition*
GAZE = GAZE training sequence comprises four weekly sessions using a modified dote-probe paradigm (averted vs directed gaze)
MCMI-II = Millon Clinical Multiaxial Inventory II
MST-EA = multi-systemic therapy for emerging adults
OCD = obsessive-compulsive disorder
ODIN = Outcome of Depression International Network
PD = personality disorder
PD-NOS = personality disorder not otherwise specified
RCT = randomised controlled trial
REMS = 'Residenze per l'Esecuzione delle Misure di Sicurezza' Italian high intensity therapeutic facility treatment
SCID-II = Structured clinical Interview for DSM-IV [*Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition*]
SD = standard deviation
SEE = SEE training sequence comprises four weekly sessions using a modified dote-probe paradigm (fearful vs neutral expression)
TAS-20 = Toronto Alexithymia Scale 20
TAU = treatment as usual
USD = United States Dollars
vs = versus

Characteristics of studies awaiting classification [ordered by year]

Evans 1999

Methods	Design: parallel randomised controlled trial

Evans 1999 *(Continued)*

Participants	Participants: individuals with recent self-harm episode and personality disturbance within ICD-10 'flamboyant' cluster[a] Sex: mixed (breakdown not provided, although treatment groups similar in terms of male:female ratio) Age: range = 16 to 50 years Unit of allocation: individual participant Number randomised: for whole sample n = 34 (n = 18 intervention group; n = 16 control group; data not extractable for any AsPD subgroup)[a] Number completing: data not extractable for any AsPD subgroup[a] Setting: outpatient; 2 sites; urban; United Kingdom (London) Inclusion criteria: aged 16 to 50 years; recent episode of self-harm; at least one other episode of self-harm in past 12 months; minimum score of personality disturbance (i.e. one level below personality disorder) within the ICD-10 flamboyant cluster (antisocial, histrionic or emotionally unstable) on the Personality Assessment Schedule (PAS) Exclusion criteria: primary ICD-10 diagnosis within the organic (F0), alcohol or drug dependence (F1) or schizophrenia (F2) groups Ethnicity: no details given Baseline characteristics: (for whole sample[a]) groups very similar in age, sex ratio, marital status and employment with no important differences in baseline assessments apart from scores on the Social Functioning Questionnare (manual assisted cognitive behavioural therapy (MACT) mean = 11.9; TAU mean = 15.6)
Interventions	Two conditions: brief manual assisted cognitive behavioural therapy (MACT); or treatment-as-usual (TAU) • Experimental group (number randomised unknown for AsPD subgroup[a]): MACT • Control group (number randomised unknown for AsPD subgroup[a]): TAU Details of conditions: • MACT lasted 2 to 6 sessions, with first chapter of manual given by therapists and remaining 5 chapters sent by post. • TAU was standard psychiatric treatment. Duration of intervention: between 2 and 6 sessions Duration of trial: to 6 months post-treatment Length of follow-up: Participants were followed up for 6 months after end of treatment.
Outcomes	Primary outcomes • Social functioning: scores on the Social Functioning Questionnaire Secondary outcomes • Leaving the study early: proportion of participants discontinuing treatment • Economic outcomes: cost of care Other outcomes • Time to next parasuicidal act, rate of parasuicidal acts per month, anxiety/depression symptoms

Evans 1999 *(Continued)*

Notes	[a]Study may have recruited a subgroup with AsPD since all participants had scores at least to the level of personality disturbance within the flamboyant cluster of ICD-10 (which includes dissocial personality disorder). However, numbers of formal axis II diagnoses were not described in the paper. No data extractable on any AsPD subgroup. Awaiting clarification from investigators

Linehan 2006

Methods	Design: parallel randomised controlled trial
Participants	Participants: women with recent suicidal and self-injurious behaviours meeting criteria for BPD[a] Sex: all female Age: mean = 29.3 years (SD = 7.5) Unit of allocation: individual participant Number randomised: for whole sample n = 101 (n = 52 intervention group; n = 49 control group); data not extractable for any AsPD subgroup[a] Number completing: data not extractable for any AsPD subgroup[a] Setting: outpatient; single site; urban; USA (Washington) Inclusion criteria: aged 18 to 45 years; meeting criteria for BPD (DSM-IV, IPDE); current or past suicidal behaviour (2 suicide attempts or self-injuries in past 5 years, with at least 1 in past 8 weeks) Exclusion criteria: lifetime diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder, psychotic disorder, psychotic disorder not otherwise specified, mental retardation; seizure disorder requiring medication; a mandate to treatment; needing primary treatment for another debilitating condition Ethnicity: (for whole sample[a]) white (87%), African American (4%), Asian American (2%), native American (1%), other (5%) Baseline characteristics: (for whole sample[a]) single, divorced or separated (87.2%); median number suicide attempts in past 5 years 1.0 (IQR 0.5 to 4.0); median number self-injuries in past 5 years 10.0 (interquartile range = 2.0 to 47.0); college graduate (23.8%); current major depressive disorder (72.3%); current anxiety disorder (78.2%); current substance use disorder (29.7%); current eating disorder (23.8%); current panic disorder (40.6%); comorbid cluster A personality disorder (3.0%); comorbid cluster B personality disorder other than BPD (10.9%), cluster C PD (25.7%)
Interventions	Two conditions: dialectical behaviour therapy (DBT); or community treatment by experts (CTBE) • Experimental group (number randomised unknown for AsPD subgroup[a]): DBT • Control group (number randomised unknown for AsPD subgroup[a]): CTBE Details of conditions: • DBT is standard manualised dialectical behaviour therapy. • CTBE was developed to maximise internal validity by controlling for sex of therapist, availability, expertise, allegiance, training and experience, consultation availability and institutional prestige. Duration of intervention: 12 months Duration of trial: 12 months Length of follow-up: Participants were followed up for 12 months after end of treatment.
Outcomes	Primary outcomes

Linehan 2006 *(Continued)*

	• None Secondary outcomes • Leaving the study early: proportion of participants discontinuing treatment Other outcomes • Number and severity of self-harm incidents; level of suicidal ideation, reasons for living, depression
Notes	[a]Study may have recruited a subgroup with AsPD since 11 of 101 participants (10.9%) had a cluster B personality disorder other than BPD. No data extractable on any AsPD subgroup. Awaiting clarification from investigators (Linehan 2006)

Berget 2008

Methods	Design: parallel randomised controlled trial
Participants	Participants: adult psychiatric inpatients and outpatients with various diagnoses[a] Sex: (for whole sample) 59 women; 31 men Age: (for whole sample) mean = 34.7 years (SD = 10.7, range = 18 to 58) Unit of allocation: individual participant Number randomised: for whole sample n = 90 (n = 60 intervention group; n = 30 control group; data not extractable for any AsPD subgroup[a]) Number completing: data not extractable for any AsPD subgroup[a] Setting: community; 15 sites (farms); rural; Oslo (Norway) Inclusion criteria: adults currently receiving psychiatric care (both inpatients and outpatients) Exclusion criteria: aged less than 18 years; acute psychotic disorder; mental retardation; serious drug addiction; being in a job during the 6 months prior to start of intervention Ethnicity: no information Baseline characteristics: (for whole sample[a]) current inpatients = 14/90 (15.5%); current outpatients = 76/90 (84.5%); ill for more than 5 years (> 50%); treated in psychiatric institutions for > 3 years (72%); receiving daily medication (83%)
Interventions	Two conditions: animal-assisted therapy with farm animals plus treatment-as-usual (AAT + TAU); or treatment-as-usual (TAU) • Experimental group (number randomised unknown for AsPD subgroup[a]): AAT + TAU • Control group (number randomised unknown for AsPD subgroup[a]): TAU Details of conditions: • AAT comprised farm visit for 3 hours twice a week for 12 weeks to work with farm animals • TAU comprised 'standard therapy' and stable medical treatment Duration of intervention: 12 weeks Duration of trial: 9 months

Berget 2008 *(Continued)*

	Length of follow-up: Participants were followed up for 6 months after end of treatment.
Outcomes	Primary outcomes • None Secondary outcomes • Leaving the study early: proportion of participants discontinuing treatment • Quality of life: scores on the Quality of Life Scale Other outcomes • Self-efficacy: scores on the Generalised Self-Efficacy Scale • Coping ability: scores on the Coping Strategies Scale
Notes	[a]Study may have recruited a subgroup with AsPD since 22 of 90 participants had an ICD-10 F60-69 disorder (disorder of adult personality and behaviour). No data extractable on any AsPD subgroup. Awaiting clarification from investigators (Berget 2008)

Clarke 2013

Methods	Design: randomised control trial
Participants	Participants: individuals with personality disorder referred to a specialist outpatient service Sex:[a] 28 men, 71 women Age:[a] mean age = 36.0 years (SD = 9.5, range = 19-59) Unit of allocation: individual, stratified by cluster Number randomised: experimental group (n = 50); control/TAU group (n = 49) Number completing: experimental group (n = 38), control/TAU group (n = 40) Setting: specialist outpatient clinic of public health service (NHS, UK) Inclusion criteria: participants met diagnostic criteria for a personality disorder; participants had completed at least one previous episode of therapy (see note 2) Exclusion criteria: diagnosis of psychotic illness, substance dependence or intellectual disability based on DSM-IV criteria; participant reports self-harming behaviour on at least a monthly basis Ethnicity: not stated Baseline characteristics:[a] 88% of the sample had a diagnosis of two or more personality disorders; 53% displayed diagnoses across two clusters; 28% across all three clusters; 68% of participants had a diagnosis of borderline personality disorder
Interventions	Two conditions: cognitive analytic therapy (CAT); or treatment-as-usual (TAU) • Experimental group: CAT + TAU • Control group: TAU Details of conditions: • CAT described as following the principles outlined by Ryle 2002 and guidelines developed by the Association of Cognitive Analytic Therapy (ACAT); participants in the CAT condition were offered 24 sessions of CAT and 3 follow-up sessions at 3, 6 and 12 months after termination of weekly therapy plus usual care.

Clarke 2013 *(Continued)*

	• TAU described as usual NHS standard care including "...care from community mental health team, clinical services and contact with a general practitioner." (quote; p 130) Duration of intervention: 24 sessions Duration of trial: 10 months Length of follow-up: 12 months
Outcomes	Secondary outcomes • Satisfaction with treatment: Service Satisfaction Scale • Mental state: symptoms of personality disorder (Structured Clinical Interview for DSM-IV Axis II); global distress (Clinical Outcomes in Routine Evaluation); Dissociation (Dissociative Questionnaire; Dissociative Experiences Scale); Symptom Checklist-90-Revised • Prison and service outcomes, treatment of people in the community • Frequency and duration of all accident and emergency attendances • Frequency and duration inpatient admissions including those for general health difficulties Other outcomes • Interpersonal problems: Inventory of Interpersonal Problems (32 items)
Notes	[a]For all of those randomised (n = 99) at least 18 participants had a cluster B personality disorder. Author (Susan Clarke) contacted by email on 19 January 2017 with request to identify the number of participants with AsPD; no data for AsPD subset. No response received (Clarke 2013)

Jochems 2015

Methods	Design: cluster-randomised control trial
Participants	Participants: patients receiving individual outpatient treatment for a mental disorder Sex: (for sample as a whole[a,b]) Intervention group: motivation feedback (MF) + treatment-as-usual (TAU): male (n = 98/148, 66%); female (n = 50/148, 34%). Control group: treatment-as-usual group (TAU): male (n = 81/146, 55%); female (n = 65/146, 45%) Age: (for sample as a whole[a,b]) MF + TAU group: mean age = 45.47 years (SD = 10.4, range = 18-65). TAU group: mean age = 42.5 years (SD = 10.0, range = 18-65) Unit of allocation: cluster Number randomised: 294 for sample as a whole[a,b]; MF + TAU group (n) = 148; TAU group (n) = 146 Number completing: 254 for sample as a whole[a,b]; MF+ TAU group (n) = 127; TAU group (n) = 127 Setting: 12 community mental health care teams affiliated with two mental health institutions in the Netherlands Inclusion criteria: patients with a primary diagnosis of psychotic disorder or personality disorder (DSM-TR VI); aged between 18-65 years old; receiving outpatient treatment for their mental disorder Exclusion criteria: insufficient command of the Dutch language; documented diagnosis of dementia or chronic toxic encephalopathy Ethnicity: (for sample as a whole[a,b]) MF + TAU group: Dutch ethnicity (n = 116, 78.4%); other ethnicity (n = 32, 21.6%). TAU group: Dutch ethnicity (n = 92, 63%); other ethnicity (n = 54, 37%) Baseline characteristics: (for sample as a whole[a,b])

Jochems 2015 *(Continued)*

	Education level: MF + TAU group: no education/elementary (n = 57, 38.5%); secondary school (n = 57, 38.5%); upper high school (n = 32, 21.6%). TAU group: no education/elementary (n = 51, 34.9%); secondary school (n = 67, 45.9%); upper high school (n = 27, 18.5%) Living situation: MF + TAU group: living alone (n = 88, 59.5%); with partner or children or both (n = 49, 33.1%); mental health centre facility (n = 10, 6.8%); homeless (n = 1, 0.7%). TAU group: living alone (n = 59, 40.4%); with partner or children or both (n = 70, 47.9%); mental health centre facility (n = 16, 11%); homeless (n = 1, 0.7%) Primary diagnosis: MF + TAU group: psychotic disorder (n = 104, 70.2%); personality disorder (n = 44, 29.7%); comorbid substance use problems (n = 42, 28.4%). TAU group: psychotic disorder (n = 95, 65.1%); personality disorder (n = 51, 34.9%); comorbid substance use problems (n = 32, 21.9%) Prescribed medication: MF + TAU group: classical antipsychotics (n = 37, 25%); atypical antipsychotics (n = 63, 42.6%); combination of typical and atypical antipsychotics (n = 12, 8.1%); benzodiazepines (n = 42, 28.4%); antidepressants (n = 40, 27%). TAU group: classical antipsychotics (n = 26, 17.8%); atypical antipsychotics (n = 67, 45.9%); combination of typical and atypical antipsychotics (n = 15, 10.3%); benzodiazepines (n = 39, 26.7%); antidepressants (n = 53, 36.3%) Age of first contact with mental health: MF + TAU group: mean age = 27.16 years (SD = 10.34); TAU group: mean age = 24.95 years (SD = 10.24). Number of patient participants with one or more previous hospitalizations: MF + TAU group: n = 113 (76.4%); TAU group: n = 114 (78.1%) Number of patient participants with a legal mandate: MF + TAU group: n = 11 (7.4%); TAU group: n = 13 (8.9%).
Interventions	Two conditions: motivational feedback (MF); or treatment-as-usual (TAU) • Experimental group (148 participants[a]): MF + TAU • Control group (146 participants[a]): TAU Details of conditions: • MF was provided in addition to TAU in patients randomised to the MF intervention. Patients and clinicians in the intervention group fill in a Short Motivation Feedback List every month for up to 12 months after baseline assessment to provide clinicians with feedback on the patient's level of external, introjected and identified motivation. • TAU was provided by multidisciplinary assertive outreach community mental health teams. TAU was guided by the patient's individual symptoms and needs for care and could include assertive outreach, medication, social and financial management, job counselling, crisis interventions, cognitive behavioural therapy, strengths-based approach, and/or supportive structured therapy. Individual case management was offered to patients who were more stable and needed long-term care. Duration of intervention: 12 months Duration of trial: May 2011 and September 2012 (16 months) Length of follow-up: 12 months
Outcomes	Primary outcomes • Adverse events: number of deaths Secondary outcomes • Quality of life: Manchester Short Assessment of Quality of Life • Engagement with services: Service Engagement Scale scores recorded for engagement; number of missed appointments; patient-reported motivation; clinician-reported motivation • Leaving the study early: number of patient withdrawals • Mental state: psychosocial functioning measured by Dutch version of the Health of the Nation Outcome Scale

Jochems 2015 *(Continued)*

	Other outcomes • Medication Adherence: Morisky Medication Adherence Scale (no data reported) • Motivation for treatment: Treatment Entry Questionnaire
Notes	[a]Whole sample: number of patients with a diagnosis of personality disorder at baseline: intervention group (n = 44, 29.7%); control group (n = 51, 34.9%) [b]Number of patients with a diagnosis of AsPD: at baseline (n = 25/294, 8%); at follow-up (n = 12/254, 5%), data on group allocation was not provided; no data are currently available for the AsPD subsample [c]This study would meet the review exclusion criteria of including patients with psychotic disorders; however, an interaction effect of personality disorder on outcomes was reported. Email correspondence with Eline Jochems (EJ) confirmed n = 25 AsPD at baseline and n = 12 AsPD at follow-up. Email contact on 7 February 2017 from EJ "In the meanwhile, I will ask my project members for their approval to share data" (quote from email correspondence; Jochems 2015)

Black 2016

Methods	Design: secondary analysis of randomised control trial[a]
Participants	Participants: patients with borderline PD and comorbid AsPD recruited to previous RCT of systems training + TAU vs TAU (Blum 2008) Sex: [b] 7 males and 9 females Age: over age 18 years Unit of Allocation: not stated Number randomised: unclear; 16 participants with AsPD randomised to the intervention group; no data available for the control group in the original RCT Number completing: not stated Setting: inpatient and outpatient settings of University of Iowa and local Iowa psychiatric services Inclusion criteria: original RCT; DSM-IV borderline personality disorder diagnosis, with other DSM-IV diagnoses assessed Exclusion criteria: not English speaker; psychotic or primary neurological disorder; cognitive impairment; current (past month) substance abuse or dependence; previously participated in Systems Training for Emotional Predictability and Problem Solving (STEPPS) programme Ethnicity [b]: Caucasian (n = 15); other (n = 1) Baseline characteristics [b] Marital status: never married (n = 10), married/living together (n = 4), divorced/separated (n = 2) Education: < high school (n = 1), high school (n = 2), some college (n = 11), college degree (n = 1), graduate degree (n = 1) Employment: employed (n = 8), disabled (n = 4), other (e.g. student) (n = 4) Mental health: 9 (69%) participants had a prior psychiatric hospitalisation; 14 (88%) had prior suicide attempts; 12 (75%) had prior self-harm; 7 (44%) had current major depressive disorder; mean number of lifetime Structured Clinical Interview for DSM-IV (SCID) disorders = 10.3 (SD = 5.0); mean

Black 2016 *(Continued)*

	number of Structured Interview for DSM-IV Personality (SIDP-IV) disorders = 4.5 (SD = 1.4); mean number of SIDP-IV BPD criteria = 7.6 (SD = 1.1)
Interventions	Two conditions: Systems Training for Emotional Predictability and Problem Solving (STEPPS) + treatment-as-usual (TAU); or TAU • Experimental group (16 AsPD randomised): STEPPS + TAU • Control group (n = unknown): TAU Details of conditions • STEPPS is a 20-week, manual-based group treatment programme for outpatients with borderline personality disorder, combining cognitive behavioural and skills training with a systems component; plus TAU. • TAU consists of individual psychotherapy, medication, and case management. Participants assigned to treatment-as-usual alone could not attend any STEPPS group until they completed the 20-week trial. Duration of intervention: 20 weeks Duration of trial: 72 weeks Length of follow-up: 1 year (assessments at month 1, 3, 6, 9 and 12)
Outcomes	Primary outcomes [a,c]: • Global state/functioning: Global Assessment Scale • Social functioning: Social Adjustment Scale Secondary outcomes [a,c]: • Impulsivity (trait): Barratt Impulsiveness Scale • Mental state: Zanarini Rating Scale for Borderline Personality Disorder; Borderline Evaluation of Severity Over Time; Symptom Checklist-90-R; Clinical Global Impressions - Severity scale; Beck Depression Inventory; Positive and Negative Affect Schedule Other outcomes • None
Notes	[a]Paper reported a secondary analysis of previously unpublished data from two studies, one of which was an RCT (Blum 2008). Review authors contacted the study author (Donald Black) to request data for the AsPD participants in the intervention and control groups from the original RCT study described (Blum 2008). An email was received from DB on 16 February 2017 indicating that these data are potentially available but subject to contact with the original project statistician (Black 2016). [b]Demographic data available only for the 16 AsPD participants randomised to the intervention (STEPPS + TAU); data requested for the participants with AsPD in the control group (TAU) [c]Published data were provided only for AsPD participants in the intervention group.

Buric 2019

Methods	Design: randomised controlled study (see notes[ab])
Participants	Participants: prisoners with personality disorder (see note[c]) Sex: all male

Buric 2019 *(Continued)*

	Age: whole sample (see note[c]): 41 years (SD = 8.00) Unit of allocation: individual (stratified random sampling) Number randomised: 30 (see note[a]) Number completing: 21 (see note [c]) (7/10 mindfulness group; 5/10 yoga group; 9/10 control group) (intention-to-treat analysis) Setting: prison; clinical unit in high-security prison, for prisoners with severe personality disorder Inclusion criteria: aged 18-65 years; willing to participate and able to provide informed consent Exclusion criteria: major neurological disorders (not specified) that compromise completion of the interventions or assessments; difficulty understanding English Ethnicity: not stated Baseline characteristics:(see note[c]) Age: mindfulness group mean = 37.60 (SD = 3.24); yoga group mean = 41.60 (SD = 7.15); control group mean = 42.60 (SD = 6.79) Psychopathy Checklist-Revised score: mindfulness group mean = 31.75 (SD = 4.12); yoga group mean = 29.32 (SD = 4.99); control group mean = 33.16 (SD = 6.98) Diagnosis (definite or probable) of personality disorder: paranoid PD (mindfulness group = 60%; yoga group = 65%; control group = 60%); schizoid PD: (mindfulness group = 5%; yoga group = 10%; control group = 10%); schizotypal PD: (mindfulness group = 0%; yoga group = 25%; control group = 10%); AsPD (mindfulness group = 100%; yoga group = 85%; control group = 90%); borderline PD (mindfulness group = 85%; yoga group = 75%; control group = 85%); histrionic PD (mindfulness group = 25%; yoga group = 10%; control group = 25%); narcissistic PD (mindfulness group = 40%; yoga group = 45%; control group = 40%); avoidant PD (mindfulness group = 20%; yoga group = 40%; control group = 20%); dependent PD (mindfulness group = 0%; yoga group = 0%; control group = 5%); obsessive-compulsive PD (mindfulness group = 15%; yoga group = 10%; control group = 10%) Number of psychotherapy sessions: mindfulness group mean = 392.10 (SD = 366.90); yoga group mean = 403.20 (SD = 344.55); control group mean = 380.40 (SD = 293.68)
Interventions	Three conditions: mindfulness meditation programme; yoga programme; or waiting-list control • Experimental group 1 (10 participants, 10 with AsPD): mindfulness meditation programme • Experimental group 2 (10 participants, 8 with AsPD): yoga programme • Control group (10 participants, 9 with AsPD): waiting-list control (see note[d]) Details of conditions • Mindfulness meditation: 10 sessions of mindfulness (each session 1.5 hours) over 5 consecutive days (i.e. 3 hours per day, for 5 days) • Yoga: 10 sessions of yoga (each session 1.5 hours) over 5 consecutive days (i.e. 3 hours per day, for 5 days) • Control: waiting list Duration of intervention: 10 sessions (15 hours) over 5 days Duration of trial: 4-5 weeks but unclear (pre-intervention assessments = 2 weeks; intervention = 1 week; post-intervention = 10 days) Length of follow-up: up to 2 weeks but unclear (follow-up commenced 3 days after intervention was complete and lasted for 10 days)
Outcomes	Primary outcomes

Buric 2019 *(Continued)*

- None

Secondary outcomes

- Mental state: perceived stress (assessed with the Perceived Stress Scale)
- Emotion regulation (assessed with the Difficulties in Emotion Regulation Scale)
- Mindfulness (assessed with the Mindful Attention Awareness Scale)

Other outcomes

- Inflammation-related gene expression (using blood sample)
- Neural measures (resting state brain activity with electroencephalography, electroculography, heart rate, eye movements)
- Attention (using Attention Nework Test and event-related potentials (ERP) related to the attention task)
- Risk-taking (using Risk-Ambiguity Task)

Notes

[a]Email correspondence sent to I Buric on 12 September 2019 requesting full text of study. Further email sent to both I Buric and M Farias on 3 December 2019 and 17 December 2019 requesting confirmation of whether the study was an RCT. Response received on 17 December 2019 confirming randomisation procedure and that the paper is currently under review with the International Journal of Offender Therapy and Comparative Criminology (Buric 2019). Given that the study has not been though a peer-review process (and data may be subject to amendment), the review authors considered that this study should remain in the 'awaiting assessment' until the peer-review process has taken place.

[b]Participants were stratified by the amount of therapy received (from 0 to 5 years), dominant cluster of personality disorders (A, B, C or equally dominant A and B, and B and C), comorbid psychiatric disorder (7 had ADHD, 2 had major depressive disorder, and 21 had no other psychiatric diagnosis), and previous experience in meditation or yoga (5 had experience in meditation, 2 had experience in yoga).

[c]Whole sample data only. 90% of recruited participants had a diagnosis of AsPD (mindfulness group: 100% definite diagnosis of AsPD; yoga group: 85% definite AsPD; control group: 90% definite AsPD). No data for AsPD subgroup. No details of assessment method for AsPD diagnosis provided, though all participants were recruited from a specialist clinical service for personality disordered offenders

[d]The trial authors noted that "all prisoners attend a 5-year trauma-informed treatment programme that consists of group and individual therapy, and aims to improve mental well-being, emotional self-regulation, and consequently reduce risk of reoffending" (p 9, pre-publication manuscript; Buric 2019).

AAT = animal-assisted therapy
ACAT = Association of Cognitive Analytic Therapy
ADHD = attention deficit hyperactivity disorder
AsPD = antisocial personality disorder
BPD = borderline personality disorder
CAT = cognitive analytic therapy
CTBE = community treatment by experts
DBT = dialectical behaviour therapy
DSM-IV (-TR) = *Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition* (*-Text Revision*)
ERP = event-related potentials
F0 = diagnoses F00-F09 in the *International Classification of Diseases-Tenth Edition*
F1 = diagnoses F10-F19 in the *International Classification of Diseases-Tenth Edition*
F2 = diagnoses F20-F29 in the *International Classification of Diseases-Tenth Edition*
ICD-10 = *International Classification of Diseases-Eleventh Edition*
IPDE = International Personality Disorder Examination
IQR = inter-quartile range
MACT= manual-assisted cognitive behaviour therapy

MF = motivation feedback
NHS = National Health Service
PAS = Personality Assessment Schedule
PD = personality disorder
RCT = randomised controlled trial
SCID = Structured Clinical Interview for DSM-IV [*Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition*]
SD = standard deviation
SFQ = Social Functioning Questionnaire
SIDP-IV = Structured Interview for DSM-IV Personality
STEPPS = systems training for emotional predictability and problem solving
TAU = treatment as usual
USA = United States of America

Characteristics of ongoing studies [ordered by year]

NCT03883646

Study name	Mindfulness for Alcohol Abusing Offenders
Methods	Design: single-blind, parallel assignment, randomised control study
Participants	Participants: female prisoners with alcohol use disorders (see note[a]) Sex: female Age:18 years to 65 years Unit of allocation: not stated Target sample size: 480 Blinding: outcomes assessor blinding only Inclusion criteria: 18-65 years of age; alcohol use disorder; female (biological sex at birth); time to release from incarceration > 3 months to < 24 months; 5th grade or higher reading level; able to speak and understand English Exclusion criteria: uncorrectable auditory or visual deficits; intelligence quotient score below 70; history of serious head injury with loss of consciousness and ongoing soft signs, or positive radiology magnetic resonance imaging (MRI) reading for significant brain damage; history of dementia or other cognitive disability; current psychotic disorder; currently taking antipsychotic medication; major medical illness or central nervous system disease; MRI incompatibility (e.g. metal in body)
Interventions	4 conditions: mindfulness; relapse prevention; waiting-list control; or treatment as usual (TAU) • Experimental: mindfulness • Experimental: relapse prevention • Control: waiting-list control • Control: TAU Details of conditions: • Mindfulness: mindfulness-based relapse prevention consists of group sessions of guided meditation and discussion • Relapse prevention: consists of group sessions using cognitive behavioural principles and strategies • Waiting-list control: no further details provided • TAU: no further details provided Duration of intervention: not stated (see note[b]) Duration trial: not stated (see note[b])

NCT03883646 *(Continued)*

	Length of follow-up: one year after release from prison
Outcomes	Primary outcomes of trial • Change from baseline alcohol craving [time frame: 4 weeks, 8 weeks, and after release from incarceration (up to one year)]; Penn Alcohol Craving Scale (5-item, self-report measure assessing frequency, intensity, and duration of craving, and overall rating of craving for the previous week. Total score range = 0-30. Higher scores indicate higher craving) • Change from baseline daily alcohol consumption [time frame: up to one year after release from incarceration]; assessed by Timeline Follow Back interview • Change from baseline temptation to drink alcohol [time frame: 4 weeks, 8 weeks, and after release from incarceration (up to one year)]; Abstinence Self-Efficacy Scale (40-item, self-report measure assessing how tempted the participant found themselves to drink under various circumstances. Total score range = 0-160. Higher scores indicate higher temptation to drink) • Criminal Behavior [time frame: an average of six months after release from incarceration]; Crime Inventory Secondary outcomes of trial • None Other outcomes of trial • None
Starting date	1 July 2018 (estimated completion date is 30 April 2023)
Contact information	Kent Kiehl, Professor of Psychology, Neuroscience and Law, Executive Science Officer, The Mind Research Network, Albuquerque, New Mexico, United States, 87106 Carla Harenski (charenski@mrn.org)
Notes	[a]Email correspondence from Carla Harenski: 'We assess personality disorders using the SCID-5-PD. We also assess psychopathic personality using the Psychopathy Checklist-Revised (PCL-R), given the important differences between psychopathy and ASPD' (quote from email correspondence; NCT03883646). [b]Assessments reported to be at 4 weeks, 8 weeks, and up to one year after release from prison

NCT02524171

Study name	Improving treatment engagement and outcomes among justice-involved veterans
Methods	Design: parallel randomised trial
Participants	Participants: veterans with antisocial personality disorder and/or substance use disorder Sex: all Age: not clear - child, adult, senior all included on clinical trial register (CTR) protocol Unit of allocation: not stated Target sample size: 365 Blinding: single-blind (research assistants conducting the 6- and 12-month outcome assessments are blinded to condition assignment)

NCT02524171 *(Continued)*

	Inclusion criteria: veterans who (a) are entering a mental health residential rehabilitation treatment programme (MH RRTP) at one of three study sites (Palo Alto, Little Rock, or Bedford, Veterans Affairs), and (b) had been arrested and charged and/or released from incarceration in the past 5 years prior to MH RRTP admission will be eligible for participation. Exclusion criteria: only exclusion criterion is being too cognitively impaired to understand the informed consent process and other study procedures.
Interventions	Two conditions: moral reconation therapy (MRT); or usual care (UC) • Experimental: MRT + UC • Control: UC Details of conditions: • MRT is a group-based cognitive-behavioural intervention to restructure antisocial thinking. Patients will receive two groups per week of this intervention for approximately 12 weeks, in addition to the usual care they receive in the mental health residential rehabilitation treatment programme • UC provided by the mental health residential rehabilitation treatment programmes, which patients in both groups are in Duration of intervention: 12 weeks Duration trial: April 4, 2016 to estimated finish date of 31st December 2019 Length of follow-up: 12 months
Outcomes	Primary outcomes of trial [a] • Risk for criminal recidivism • Changes in patients' self-reported levels of antisocial attitudes and cognitions since the baseline assessment Secondary outcomes of trial • Substance use (quantity and frequency of patients' self-reported alcohol and drug use since the baseline assessment) • Mental health problems (changes in the severity of patients' self-reported psychiatric distress since the baseline assessment) • Housing problems (changes in the severity of patients' self-reported problems with securing stable housing since the baseline assessment) • Employment problems (severity of patients' self-reported problems with securing stable employment) • Substance use problems (changes in the severity of patients' self-reported problems with alcohol and drug use since the baseline assessment)
Starting date	4 April 2016
Contact information	Daniel M Blonigen (email: Daniel.Blonigen@va.gov) Christine Timko (email: Christine.Timko@va.gov)
Notes	[a] Time frame: 12 months for all outcome measures Clinical trial registry: clinicaltrials.gov/ct2/show/record/NCT02524171 ClinicalTrials.gov identifier: NCT02524171 Sponsor: Veterans Affairs Office of Research and Development

ISRCTN32309003

Study name	A national randomised controlled trial to evaluate mentalisation based therapy for antisocial personality disorder
Methods	Design: parallel randomised controlled trial
Participants	Participants: male offenders who have a history of violent behaviour, are subject to statutory provision by the National Probation Service and have at least 6 months remaining on their licence Age: 21 years or above Unit of allocation: multicentre trial; 1:1 allocation Target sample size: 302 Inclusion criteria: participants subject to statutory provision by the National Probation Service; aged 21 or over; at least 6 months remaining of their license or community sentence; adequate level of English; evidence of a history of violent behaviour, that may include verbal assault, assaults against objects and/or assault against others; DSM-IV-R diagnosis of AsPD (using SCID-II); and evidence of recent aggressive acts (using OAS-M) Exclusion criteria: conviction for child sexual offences (including child pornography); current diagnosis for schizophrenia or bipolar disorder; neurodevelopmental disorder or significant cognitive impairment; severe substance or alcohol dependency
Interventions	Two conditions: mentalisation-based therapy for anti-social personality disorder (MBT-ASPD); or probation as usual (PAU) • Experimental group: MBT-ASPD • Control group: PAU Details of conditions: • MBT-ASPD is described as a programme of group and individual psychotherapy; all participants randomised to MBT-ASPD will have an allocated psychiatrist, a therapist who will provide individual therapy and two group therapists (one of whom will be their individual therapist). The therapist will provide a monthly 1-hour individual mentalisation-based therapy session. Participants will also attend weekly group mentalisation-based therapy for 75 minutes. • Participants randomised to PAU remain under the supervision of their probation trust for the duration of their licence or community sentence. Duration of intervention: 2 months, after which patients will be reassessed by a member of the trial clinical team and referred for further management if required, for up to 12 months Duration of trial: 24 months (assessment at baseline, month 6 and 12 (in-treatment), month 18 and 24 (post-treatment) Length of follow-up: 12 months
Outcomes	Primary outcomes of trial • Aggression: frequency of aggressive acts measured using a self-report, 5-item version of the Overt Aggression Scale Modified Secondary outcomes of trial • Global state/outcomes:assessed with Clinical Outcomes in Routine Evaluation–Outcome Measure (CORE-OM); EuroQoL 5 dimensions (EQ-5D); Brief Symptom Inventory (BSI) • Mental state: assessed with Psychopathic Personality Inventory- Revised (PPI-R); assessed with State Trait Anger Expression Inventory 2 (STAXI-2); Suicidal Behaviours Questionnaire–Revised (SBQ–R); Self Harm Inventory (SHI)

ISRCTN32309003 *(Continued)*

- Violent behaviour: assessed with MacArthur Community Violence Screening Instrument (MCVSI)
- Offending: offending behaviour
- Social functioning: assessed with Social Functioning Questionnaire (SFQ)
- Impulsivity: assessed with Barratt Impulsiveness Scale (BIS)
- Substance use: assessed with Alcohol Use Disorders Identification Test (AUDIT); Drug Use Disorders Identification Test (DUDIT)
- Service use: assessed using Secure Facilities Service Use Schedule (SFSUS); Service Engagement Scale (SES)
- Satisfaction with treatment: assessed with Client Satisfaction Questionnaire (CSQ)

Other outcomes of trial

- Reflective Functioning Questionnaire-54 (RFQ54)
- Movie for the Assessment of Social Cognition (MASC)
- Social hierarchy game
- Investor trustee game

Starting date	01 January 2016
Contact information	Ms Elizabeth Simes (email: MOAM@ucl.ac.uk) Address: Research Department of Clinical Educational & Health Psychology, University College London, 1-19 Torrington Place, London, United Kingdom, WC1E 7HB
Notes	Sponsor: project funded by the National Institute for Health Research HTA (14/186/01)

ISRCTN14994755

Study name	Low intensity psychological support for people with personality disorder: randomised controlled trial
Methods	Design: parallel randomised controlled trial
Participants	Participants: adults using secondary care mental health services in London, UK[a] Age: 18 years or over Unit of allocation: 1:1, stratified by referring team and gender Target sample size: 60 Inclusion criteria: clinical diagnosis of personality disorder; positive screening result using the International Personality Disorder Examination self-administered questionnaire; competent and willing to provide written, informed consent Exclusion criteria:current clinical diagnosis of a coexisting organic or psychotic mental disorder (dementia, bipolar affective disorder (type I and II), delusional disorder, schizophrenia, schizoaffective disorder or schizotypal disorder; cognitive or language difficulties that would preclude subjects providing informed consent or compromise participation in study procedures; currently receiving psychological treatment for personality disorder
Interventions	Two conditions: psychological support for personality (PSP); or treatment-as-usual (TAU) • Experimental group: PSP • Control group: TAU Details of conditions:

ISRCTN14994755 *(Continued)*

	• PSP is described as a 'flexible' intervention delivered by clinical staff who receive regular supervision and have experience in working with people with PD. Sessions last between 45-60 minutes and are delivered on an individual basis over a three to six-month period; the total number of sessions can be between six and ten. Telephone support is also provided. Session content includes information on personality, personality disorder, validation and acceptance, tailored psychological support aimed at promoting mentalising and distress tolerance • TAU is delivered by staff working in community mental health teams. TAU comprises assessment, care planning, review, and may involve pharmacotherapy and referral to other services including access to inpatient care at times of crisis Duration of intervention: flexible (6 to 10 sessions, delivered over 3 to 6 months) Duration of trial: six months Length of follow-up: 24 weeks after baseline
Outcomes	Primary outcomes of trial • Social functioning: assessed using Work and Social Adjustment Scale (WSAS) • Mental state: assessed by Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) • Suicidal thoughts: National Household Survey of Psychiatric Morbidity (NHSPM) • Health-related quality of life: EuroQol 5 dimension, 5 levels instrument (EQ-5D-5L) • Satisfaction with care: Client Satisfaction Questionnaire (CSQ) • Resource use and costs; modified version of the Adult Service Use Schedule (ASUS) • Change in global mental health; Clinical Global Impression (CGI) scale Secondary outcomes of trial • Participants will be asked to state how confident they are in their ability to “get yourself through difficult times and situations" (quote; p 7, column 2) on a five-point Likert scale (ranging from totally confident to totally unconfident) *Other outcomes of trial* • Following completion of the six-month follow-up interview, up to 20 participants will be invited to take part in a separate interview about their experience of taking part in the study and any ways improve the design of a future definitive trial.
Starting date	13 July 2017
Contact information	Ms Amy Claringbold (email a.claringbold@imperial.ac.uk) Address: Personality Disorder Research Unit, Centre for Psychiatry, Imperial College London, London, UK Tel: +44 20 8383 4134 Sponsor: Central and North West London NHS Foundation Trust Funder: National Institute for Health Research
Notes	[a]Recruitment from community mental health teams, home treatment teams, and other community-based mental health services

Van Dijk 2019

Study name	Group schema-focussed therapy enriched with psychomotor therapy for older adults with personality disorders in specialised mental health care: a (cost-)effectiveness study

Van Dijk 2019 *(Continued)*

Methods	Design: multicentre randomised trial
Participants	Participants: older persons, with a cluster B or C personality disorder or meeting the general criteria for a personality disorder, treated in specialised mental health care settings Age: 60 years or older Unit of allocation: stratified block randomisation to assign participants evenly (1:1) over the two conditions (stratified by presence of a full versus subthreshold cluster B or C personality disorder) Target sample size: 140 Inclusion criteria: age of 60 years or above; cluster B or C personality disorder (or falling one content criterion short) as confirmed by the Structured Clinical Interview for DSM-5 for personality disorders (SCID-5-PD); mentally able to adhere to the group SFT treatment schedule and to fill out the schema questionnaires; able to give informed consent after having received oral and written information Exclusion criteria: severe current mental illness, including bipolar I disorder, psychosis, or substance abuse disorders needing clinical detoxification; an established neurodegenerative disorder; cognitive impairment defined as a sum score below 23 points on the Montreal Cognitive Assessment (MoCA) battery; having received schema-focussed therapy in the previous year or during the current illness episode; suicide risk interfering with adequate treatment delivery
Interventions	Two conditions: group schema-focussed therapy enriched with psychomotor therapy (group SFT + PMT); or treatment-as-usual (TAU) • Experimental group: group SFT + PMT • Control group: TAU Details of conditions: • Group schema-focussed therapy with psychomotor therapy is delivered in 18 weekly and 2 follow-up sessions (at weeks 22 and 26); consists of 2-hour group schema-focussed therapy and 1-hour psychomotor therapy; group schema-focussed therapy focuses on the cognitive behavioural techniques of schema therapy; psychomotor therapy uses physical exercises to facilitate the experience of patients' typical cognitions and behaviours • TAU is unrestricted. Duration of intervention: 18 weeks (plus 2 individual pre-treatment sessions without PMT, to make a personal treatment plan and explain the concept of group SFT + PMT in more detail) Duration of trial: 26 weeks Length of follow-up: unclear: the protocol reports follow-up at 6 months and 12 months; the clinical trials register reports there are two follow-up sessions, 1 at week 22 and 1 at week 26, i.e. 8 weeks post-intervention
Outcomes	Primary outcomes of trial: • Psychological distress: assessed with the Brief Symptom Inventory-53-item version (BSI-53) • Cost-effectiveness analysis: health-related quality of life is assessed with the EuroQoL (EQ-5D-5L) • Cost-effectiveness: medical consumption and other cost data gathered by structured patient interview Secondary outcomes of trial: • Life satisfaction: Cantril's Ladder - a single self-report question to rate one's current life situation on a scale (from 0 to 10), where a score of 0 indicates 'the worst possible life for you' and 10 'the best possible life for you' • Mental well-being: assessed using Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)

Van Dijk 2019 *(Continued)*

	• Personality functioning: assessed using Severity Indices of Personality Problems–Short Form (SIPP-SF) • Interoceptive body awareness: assessed using Multidimensional Assessment of Interoceptive Awareness (MAIA) • Substance use: psychotropic drug use and treatment received • Mental state (mood variability): using Mood-Zoom, an experience sampling method for real-time mood assessment on a smart-phone Other outcomes of trial: • none
Starting date	2017-08-01
Contact information	Name: M.S.Veenstra Email: m.s.veenstra@umcg.nl Phone: +31 50 3612079 University Medical Center Groningen, Department of Psychiatry, P.O. Box 30.001, 9700 RB, Groningen, The Netherlands
Notes	Current trial ID: NL6443 Old trial ID: NTR6621

NCT04033835

Study name	Mentalisation Based Treatment - Introductory group for male prisoners with borderline and/or antisocial personality disorder in Her Majesty's Prison Barlinnie
Methods	Design:Open label, cross-over, randomised clinical trial
Participants	Participants: Male sentenced prisoners with primary diagnosis of borderline PD and/or anti-social PD Age:18 years and older Unit of allocation: individual Target sample size: 30 participants Inclusion criteria: primary diagnosis of BPD and/or AsPD; comorbidity with other personality disorder is accepted; sentenced prisoners with estimated date of liberation > six months Exclusion criteria: comorbid severe and enduring mental illness (schizophrenia, delusional disorder, bipolar affective disorder, major depressive disorder); comorbid organic brain disorder (acquired brain injury, alcohol-related brain damage); remand prisoners; uncontrolled substance dependence; index offence of sexual offending; repeatedly chaotic, antisocial or violent behaviour in prison; care in segregation and reintegration unit in past 3 months; current individual specialist psychological therapy in prison; English as not first language
Interventions	Two conditions: Mentalisation-Based Treatment-Introductory (MBT-I); or waiting-list control/treatment-as-usual • Experimental group: MBT-I • Control group: TAU (waiting-list control)

NCT04033835 *(Continued)*

	Details of conditions: • MBT-I is not described in the clinical trials record; completion of the intervention is described as attending three cycles of group MBT-I (each cycle of MBT-I has 12 sessions). • TAU is not described in the clinical trials record. Duration of intervention: 18 months Duration of trial: 21 months Length of follow-up: 3 months post-intervention
Outcomes	Primary outcomes of trial • Completion of 3 MBT-I group cycles [time frame = 18 months] • Participants to have attended ≥ 75% (9 or more out of 12) of scheduled sessions to consider this successful completion of the programme • ≥ 50% participants who commenced session one to have completed the intervention as described above to consider the group successful Secondary outcomes of trial (time frame for all secondary outcomes is 21 months; measures administered one week pre-, one week post- and three months post-intervention) • Interpersonal functioning: change in interpersonal functioning using Inventory of Interpersonal Problems-32, pre- and post-intervention • Impulsivity: change in impulsivity using Barrett Impulsiveness Scale (BIS) pre- and post-intervention • Mental state: change in difficulties with reflective functioning using Reflective Functioning Questionnaire (RFQ) pre- and post-intervention • Mental state: change in depressive symptoms using Beck's Depression Inventory (BDI) pre- and post-intervention • Mental state: change in anxiety symptoms using Beck's Anxiety Inventory (BAI) pre- and post-intervention • Social functioning: change in social functioning and satisfaction using Social Adjustment Scale-Self Report (SAS-SR) pre- and post-intervention • Global functioning: quantitative data measuring change in overall symptoms and functioning using Clinical Outcomes in Routine Evaluation-Outcome Measure (CORE-OM) pre- and post-intervention • Challenging behaviour: quantitative data from behavioural proxy measures examining change in the number of challenging behaviours pre- and post-intervention [time frame = 21 months]; number of discipline procedures (reports) and Incentives and Enhanced Privileges (IEPs) will be examined over a 3-month period pre-intervention, 3-month period during the intervention and 3-month period post-intervention to allow a behavioural proxy measure of negative (reports) vs positive (IEPs) behaviours • Satisfaction with treatment: qualitative data from follow-up interviews examining understanding of and overall satisfaction of intervention; semi-structured interview schedule to be completed 1 week post- and 3 months post-intervention; examines participants' understanding of the concepts of the intervention, in addition to their overall satisfaction *Other outcomes of trial* • none
Starting date	1 August 2019[a]; estimated completion date 1 August 2021
Contact information	Stephen Davidson (s.davidson7@nhs.net) Erica Packard (erica.packard@ggc.scot.nhs.uk) NHS Greater Glasgow and Clyde, Glasgow, United Kingdom

NCT04033835 *(Continued)*

Notes	[a]The last update on the clinical trials site [26 July 2019] stated that the study is not yet recruiting.

AsPD = antisocial personality disorder
ASUS = Adult Service Use Schedule
AUDIT = Alcohol Use Disorders Identification Test
BAI = Beck Anxiety Inventory
BDI = Beck Depression Inventory
BIS = Barratt Impulsiveness Scale
BPD = borderline personality disorder
BSI (-53) = Brief Symptom Inventory
CGI = Clinical Global Impression
CORE-OM = Clinical Outcomes in Routine Evaluation–Outcome Measure
CSQ = Client Satisfaction Questionnaire
CTR = Clinical Trial Register
DSM-IV-R = Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition-Revised
DUDIT = Drug Use Disorders Identification Test
EQ-5D (-5L) = EuroQol 5 dimensions, 5 levels instrument
HTA = Health Technology Assessment
IEP = incentives and enhanced privileges
MAIA = Multidimensional Assessment of Interoceptive Awareness
MASC = Movie for the Assessment of Social Cognition
MBT (-I) = mentalization based treatment-introductory
MCVSI = MacArthur Community Violence Screening Instrument
MIH RRTP = mental health residential rehabilitation treatment programme
MoCA = Montreal Cognitive Assessment
MRI = magnetic resonance imaging
MRT = moral reconation therapy
NHSPM = National Household Survey of Psychiatric Morbidity
OAS-M = Overt Aggression Scale-Modified
PAU = probation as usual
PCL-R = Psychopathy Checklist-Revised
PD = personality disorder
PMT = psychomotor therapy
PPI-R = Psychopathic Personality Inventory-Revised
PSP = psychological support for personality
RFQ(54) = Reflective Functioning Questionnaire-54
SAS-SR = Social Adjustment Scale-Self-Report
SBQ-R = Suicidal Behaviours Questionnaire–Revised
SCID-5-PD (-11) = Structured Clinical Interview for DSM-5 [DSM-5 = *Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition*] for Personality Disorders
SES = Service Engagement Scale
SFQ = Social Functioning Questionnaire
SFSUS = Secure Facilities Service Use Schedule
SFT = schema-focussed therapy
SHI = Self Harm Inventory
SIPP-SF = Severity Indices of Personality Problems–Short Form
STAXI 2 = State Trait Anger Expression Inventory 2
TAU = treatment as usual
UC = usual care
vs = versus
WEMWBS = Warwick-Edinburgh Mental Wellbeing Scale
WSAS = Work and Social Adjustment Scale

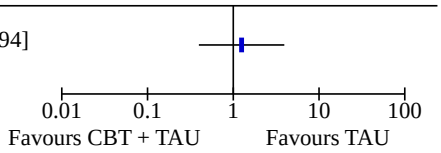
DATA AND ANALYSES

Comparison 1. Cognitive behavioural therapy + treatment-as-usual versus treatment-as-usual alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Aggression: number reporting any act of verbal aggression; MCVSI interview; at 12 months	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.2 Aggression: number reporting any act of physical aggression; MCVSI interview; at 12 months	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.3 Aggression: change in number reporting any act of verbal aggression (high = good); MCVSI interview; baseline to endpoint at 12 months	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.4 Aggression: change in number reporting any act of physical aggression (high = good); baseline to endpoint at 12 months	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.5 Social functioning: mean SFQ scores (high = poor); at 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.6 Satisfaction with treatment: satisfaction with taking part in the study (high = good); at 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.7 Leaving the study early; by 3 months	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.8 Leaving the study early; by 6 months	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.9 Leaving the study early; by 9 months	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.10 Leaving the study early; by 12 months	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.11 Anger: mean Novaco Anger Scale scores (high = poor); at 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.12 Anger: mean Novaco Provocation Inventory scores (high = poor); at 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.13 Other: anxiety; mean HADS score (high = poor); at 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.14 Other: depression; mean HADS score (high = poor); at 12 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

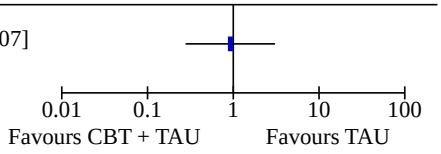
Analysis 1.1. Comparison 1: Cognitive behavioural therapy + treatment-as-usual versus treatment-as-usual alone, Outcome 1: Aggression: number reporting any act of verbal aggression; MCVSI interview; at 12 months

Study or Subgroup	CBT + TAU Events	CBT + TAU Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Davidson 2009	17	25	17	27	1.25 [0.40 , 3.94]



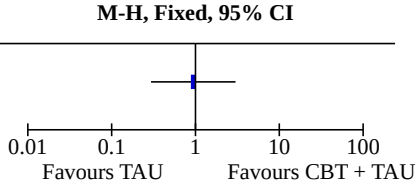
Analysis 1.2. Comparison 1: Cognitive behavioural therapy + treatment-as-usual versus treatment-as-usual alone, Outcome 2: Aggression: number reporting any act of physical aggression; MCVSI interview; at 12 months

Study or Subgroup	CBT + TAU Events	CBT + TAU Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Davidson 2009	7	25	8	27	0.92 [0.28 , 3.07]



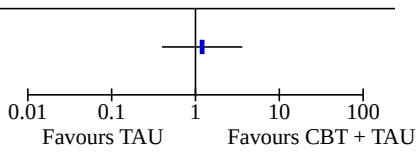
Analysis 1.3. Comparison 1: Cognitive behavioural therapy + treatment-as-usual versus treatment-as-usual alone, Outcome 3: Aggression: change in number reporting any act of verbal aggression (high = good); MCVSI interview; baseline to endpoint at 12 months

Study or Subgroup	CBT + TAU Events	CBT + TAU Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Davidson 2009	8	25	9	27	0.94 [0.29 , 3.00]



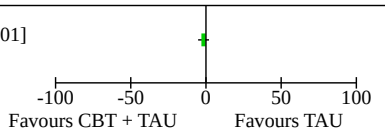
Analysis 1.4. Comparison 1: Cognitive behavioural therapy + treatment-as-usual versus treatment-as-usual alone, Outcome 4: Aggression: change in number reporting any act of physical aggression (high = good); baseline to endpoint at 12 months

Study or Subgroup	CBT + TAU Events	CBT + TAU Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Davidson 2009	15	25	15	27	1.20 [0.40 , 3.62]



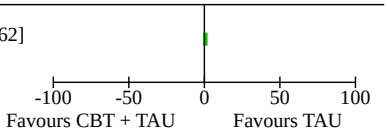
Analysis 1.5. Comparison 1: Cognitive behavioural therapy + treatment-as-usual versus treatment-as-usual alone, Outcome 5: Social functioning: mean SFQ scores (high = poor); at 12 months

Study or Subgroup	CBT + TAU Mean	CBT + TAU SD	CBT + TAU Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Davidson 2009	11.6	5.8	19	13.2	5.7	20	-1.60 [-5.21 , 2.01]	



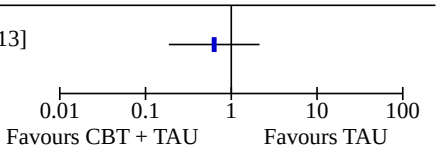
Analysis 1.6. Comparison 1: Cognitive behavioural therapy + treatment-as-usual versus treatment-as-usual alone, Outcome 6: Satisfaction with treatment: satisfaction with taking part in the study (high = good); at 12 months

Study or Subgroup	CBT + TAU Mean	CBT + TAU SD	CBT + TAU Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Davidson 2009	3.9	0.88	10	3.2	1.47	15	0.70 [-0.22 , 1.62]	



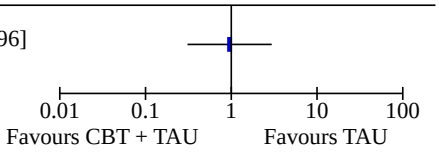
Analysis 1.7. Comparison 1: Cognitive behavioural therapy + treatment-as-usual versus treatment-as-usual alone, Outcome 7: Leaving the study early; by 3 months

Study or Subgroup	CBT + TAU Events	CBT + TAU Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
Davidson 2009	6	25	9	27	0.63 [0.19 , 2.13]	



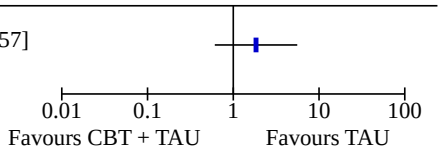
Analysis 1.8. Comparison 1: Cognitive behavioural therapy + treatment-as-usual versus treatment-as-usual alone, Outcome 8: Leaving the study early; by 6 months

Study or Subgroup	CBT + TAU Events	CBT + TAU Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
Davidson 2009	9	25	10	27	0.96 [0.31 , 2.96]	



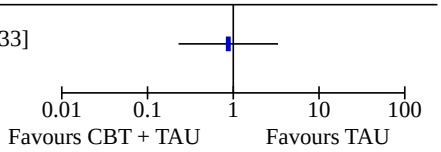
Analysis 1.9. Comparison 1: Cognitive behavioural therapy + treatment-as-usual versus treatment-as-usual alone, Outcome 9: Leaving the study early; by 9 months

Study or Subgroup	CBT + TAU Events	CBT + TAU Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Davidson 2009	13	25	10	27	1.84 [0.61 , 5.57]



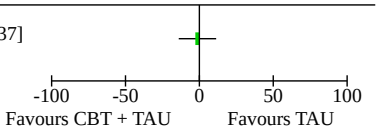
Analysis 1.10. Comparison 1: Cognitive behavioural therapy + treatment-as-usual versus treatment-as-usual alone, Outcome 10: Leaving the study early; by 12 months

Study or Subgroup	CBT + TAU Events	CBT + TAU Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Davidson 2009	5	25	6	27	0.88 [0.23 , 3.33]



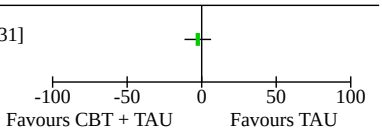
Analysis 1.11. Comparison 1: Cognitive behavioural therapy + treatment-as-usual versus treatment-as-usual alone, Outcome 11: Anger: mean Novaco Anger Scale scores (high = poor); at 12 months

Study or Subgroup	CBT + TAU Mean	CBT + TAU SD	CBT + TAU Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI
Davidson 2009	107.8	20.7	19	109.1	19.6	20	-1.30 [-13.97 , 11.37]



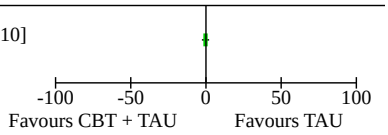
Analysis 1.12. Comparison 1: Cognitive behavioural therapy + treatment-as-usual versus treatment-as-usual alone, Outcome 12: Anger: mean Novaco Provocation Inventory scores (high = poor); at 12 months

Study or Subgroup	CBT + TAU Mean	CBT + TAU SD	CBT + TAU Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI
Davidson 2009	69.8	13.9	19	72.4	14.5	20	-2.60 [-11.51 , 6.31]



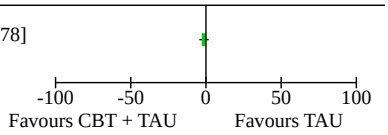
Analysis 1.13. Comparison 1: Cognitive behavioural therapy + treatment-as-usual versus treatment-as-usual alone, Outcome 13: Other: anxiety; mean HADS score (high = poor); at 12 months

Study or Subgroup	CBT + TAU Mean	CBT + TAU SD	CBT + TAU Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI
Davidson 2009	13.3	4.5	22	13.6	3.5	21	-0.30 [-2.70 , 2.10]



Analysis 1.14. Comparison 1: Cognitive behavioural therapy + treatment-as-usual versus treatment-as-usual alone, Outcome 14: Other: depression; mean HADS score (high = poor); at 12 months

Study or Subgroup	CBT + TAU Mean	CBT + TAU SD	CBT + TAU Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI
Davidson 2009	9.7	5.1	22	11	5.2	21	-1.30 [-4.38 , 1.78]

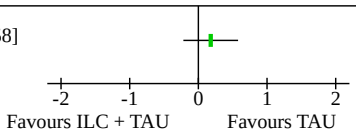


Comparison 2. Impulsive lifestyle counselling + treatment-as-usual versus treatment-as-usual alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Aggression: scores on Buss-Perry Aggression Questionnaire (BPAQ) at 3 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.2 Aggression: scores on Buss-Perry Aggression Questionnaire (BPAQ) at 9 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.3 Adverse events: death between 3-month and 9-month follow-up	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
2.4 Adverse events: incarceration during follow-up period	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
2.5 Leaving the study early: number at 3 months	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
2.6 Leaving the study early: number at 9 months	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected

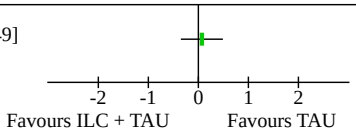
Analysis 2.1. Comparison 2: Impulsive lifestyle counselling + treatment-as-usual versus treatment-as-usual alone, Outcome 1: Aggression: scores on Buss-Perry Aggression Questionnaire (BPAQ) at 3 months

Study or Subgroup	ILC + TAU Mean	ILC + TAU SD	ILC + TAU Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Thylstrup 2015	4.01	1.16	70	3.83	1.16	61	0.18 [-0.22 , 0.58]	



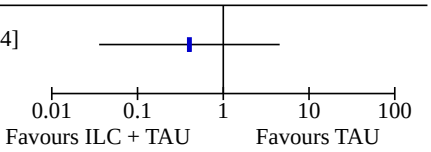
Analysis 2.2. Comparison 2: Impulsive lifestyle counselling + treatment-as-usual versus treatment-as-usual alone, Outcome 2: Aggression: scores on Buss-Perry Aggression Questionnaire (BPAQ) at 9 months

Study or Subgroup	ILC + TAU Mean	ILC + TAU SD	ILC + TAU Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Thylstrup 2015	3.59	1.05	63	3.52	1.25	55	0.07 [-0.35 , 0.49]	



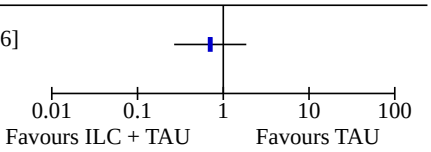
Analysis 2.3. Comparison 2: Impulsive lifestyle counselling + treatment-as-usual versus treatment-as-usual alone, Outcome 3: Adverse events: death between 3-month and 9-month follow-up

Study or Subgroup	ILC + TAU Events	ILC + TAU Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
Thylstrup 2015	1	78	2	64	0.40 [0.04 , 4.54]	



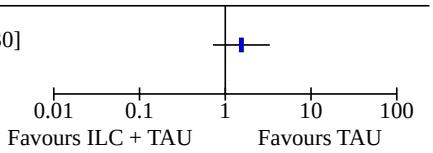
Analysis 2.4. Comparison 2: Impulsive lifestyle counselling + treatment-as-usual versus treatment-as-usual alone, Outcome 4: Adverse events: incarceration during follow-up period

Study or Subgroup	ILC + TAU Events	ILC + TAU Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
Thylstrup 2015	9	78	10	64	0.70 [0.27 , 1.86]	



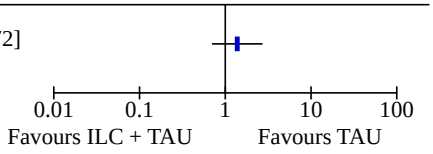
Analysis 2.5. Comparison 2: Impulsive lifestyle counselling + treatment-as-usual versus treatment-as-usual alone, Outcome 5: Leaving the study early: number at 3 months

Study or Subgroup	ILC + TAU Events	ILC + TAU Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Thylstrup 2015	23	93	13	74	1.54 [0.72 , 3.30]



Analysis 2.6. Comparison 2: Impulsive lifestyle counselling + treatment-as-usual versus treatment-as-usual alone, Outcome 6: Leaving the study early: number at 9 months

Study or Subgroup	ILC + TAU Events	ILC + TAU Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Thylstrup 2015	30	93	19	74	1.38 [0.70 , 2.72]

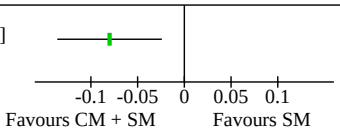


Comparison 3. Contingency management + standard maintenance versus standard maintenance alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Social functioning: mean family/social domain scores (high = poor); ASI; at 6 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.2 Leaving the study early	2	127	Odds Ratio (M-H, Fixed, 95% CI)	0.59 [0.28, 1.24]
3.3 Substance misuse (drugs): numbers with cocaine-negative specimens; at 17 weeks	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
3.4 Substance misuse (drugs): numbers with cocaine-negative specimens; at 26 weeks	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
3.5 Substance misuse (drugs): numbers with cocaine-negative specimens; at 52 weeks	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
3.6 Other: proportion transferred to routine care due to poor treatment response (high = poor); by 6 months	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected

Analysis 3.1. Comparison 3: Contingency management + standard maintenance versus standard maintenance alone, Outcome 1: Social functioning: mean family/social domain scores (high = poor); ASI; at 6 months

Study or Subgroup	CM + SM Mean	CM + SM SD	CM + SM Total	SM Mean	SM SD	SM Total	Mean Difference IV, Fixed, 95% CI
Neufeld 2008 (1)	0.08	0.13	41	0.16	0.13	42	-0.08 [-0.14 , -0.02]



Footnotes

(1) From summary data supplied by the trial investigators (adjusted means from mixed regression model, including time-specific random effects and an interac

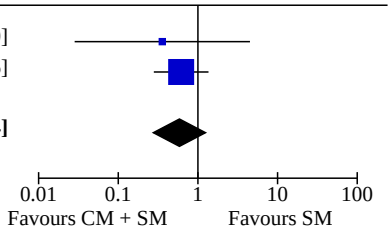
Analysis 3.2. Comparison 3: Contingency management + standard maintenance versus standard maintenance alone, Outcome 2: Leaving the study early

Study or Subgroup	CM + SM Events	CM + SM Total	SM Events	SM Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Messina 2003 (1)	1	15	2	12	11.7%	0.36 [0.03 , 4.50]
Neufeld 2008	23	51	28	49	88.3%	0.62 [0.28 , 1.36]
Total (95% CI)		**66**		**61**	**100.0%**	**0.59 [0.28 , 1.24]**
Total events:	24		30			

Heterogeneity: Chi² = 0.16, df = 1 (P = 0.69); I² = 0%

Test for overall effect: Z = 1.39 (P = 0.16)

Test for subgroup differences: Not applicable

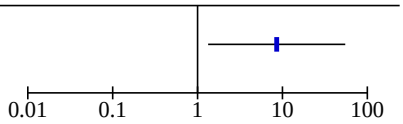


Footnotes

(1) Based on numbers completing, calculated from the percentages reported by trial investigators (p.323, col.1).

Analysis 3.3. Comparison 3: Contingency management + standard maintenance versus standard maintenance alone, Outcome 3: Substance misuse (drugs): numbers with cocaine-negative specimens; at 17 weeks

Study or Subgroup	CM + SM Events	CM + SM Total	SM Events	SM Total	Odds Ratio M-H, Fixed, 95% CI
Messina 2003 (1)	11	14	3	10	8.56 [1.33 , 54.95]

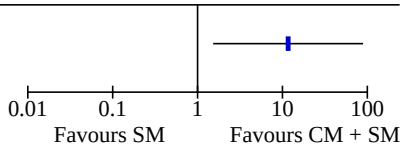


Footnotes

(1) Based on numbers completing, calculated from the percentages reported by trial investigators (p.323, col.1).

Analysis 3.4. Comparison 3: Contingency management + standard maintenance versus standard maintenance alone, Outcome 4: Substance misuse (drugs): numbers with cocaine-negative specimens; at 26 weeks

Study or Subgroup	CM + SM Events	CM + SM Total	SM Events	SM Total	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
Messina 2003 (1)	10	13	2	9	11.67 [1.53 , 89.12]	

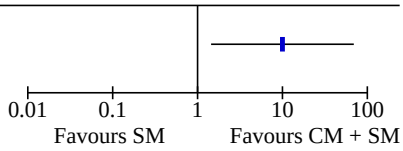


Footnotes

(1) Based on numbers completing, calculated from the percentages reported by trial investigators (p.323, col.1).

Analysis 3.5. Comparison 3: Contingency management + standard maintenance versus standard maintenance alone, Outcome 5: Substance misuse (drugs): numbers with cocaine-negative specimens; at 52 weeks

Study or Subgroup	CM + SM Events	CM + SM Total	SM Events	SM Total	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
Messina 2003 (1)	10	14	2	10	10.00 [1.44 , 69.26]	

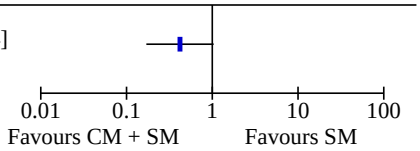


Footnotes

(1) Based on numbers completing, calculated from the percentages reported by trial investigators (p.323, col.1).

Analysis 3.6. Comparison 3: Contingency management + standard maintenance versus standard maintenance alone, Outcome 6: Other: proportion transferred to routine care due to poor treatment response (high = poor); by 6 months

Study or Subgroup	CM + SM Events	CM + SM Total	SM Events	SM Total	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
Neufeld 2008	10	51	18	49	0.42 [0.17 , 1.04]	

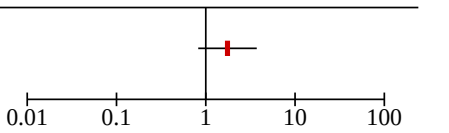


Comparison 4. 'Driving whilst intoxicated' program + incarceration versus incarceration alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Reconviction: reconviction for drink-driving; Cox regression of rearrest rates; at 24 months	1		Hazard Ratio (IV, Fixed, 95% CI)	Totals not selected

Analysis 4.1. Comparison 4: 'Driving whilst intoxicated' program + incarceration versus incarceration alone, Outcome 1: Reconviction: reconviction for drink-driving; Cox regression of rearrest rates; at 24 months

Study or Subgroup	log[Hazard Ratio]	SE	Hazard Ratio IV, Fixed, 95% CI	Hazard Ratio IV, Fixed, 95% CI
Woodall 2007 (1)	0.56	0.385	1.75 [0.82 , 3.72]	



Footnotes

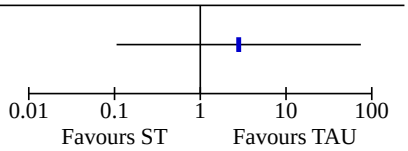
(1) Effect size via generic inverse variance method; SE calculated by review authors from the reported confidence intervals (Cochran

Comparison 5. Schema therapy versus treatment-as-usual

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 Recidivism: number of participants to recidivate, documented as a global negative outcome	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
5.2 Social functioning: number of patients with supervised leave at 2 years	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
5.3 Social functioning: number of patients with unsupervised leave at 2 years	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
5.4 Social functioning: number of patients with supervised leave at 3 years	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
5.5 Social functioning: number of patients with unsupervised leave at 3 years	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
5.6 Social functioning: mean number of days to unsupervised leave	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
5.7 Adverse events: global negative outcomes overall	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
5.8 Adverse events: number of patients transferred to other clinics due to lack of treatment response	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
5.9 Adverse events: number of patients terminating therapy due to worsening of psychiatric condition	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
5.10 Adverse events: number of patients that terminate therapy due to lack of treatment response	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
5.11 Adverse events: number of patients terminated due to lack of co-operation with the research	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected

Analysis 5.1. Comparison 5: Schema therapy versus treatment-as-usual, Outcome 1: Recidivism: number of participants to recidivate, documented as a global negative outcome

Study or Subgroup	ST Events	ST Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Bernstein 2012 (1)	1	16	0	14	2.81 [0.11 , 74.56]

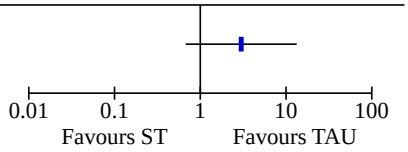


Footnotes

(1) 26/30 (87%) participants has AsPD diagnosis

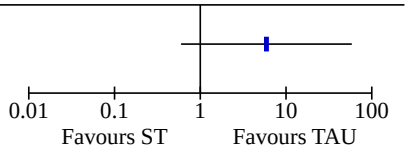
Analysis 5.2. Comparison 5: Schema therapy versus treatment-as-usual, Outcome 2: Social functioning: number of patients with supervised leave at 2 years

Study or Subgroup	ST Events	ST Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Bernstein 2012	10	16	5	14	3.00 [0.68 , 13.31]



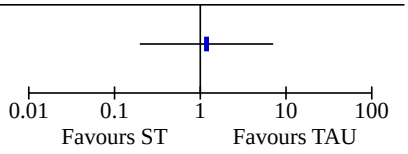
Analysis 5.3. Comparison 5: Schema therapy versus treatment-as-usual, Outcome 3: Social functioning: number of patients with unsupervised leave at 2 years

Study or Subgroup	ST Events	ST Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Bernstein 2012	5	16	1	14	5.91 [0.60 , 58.48]



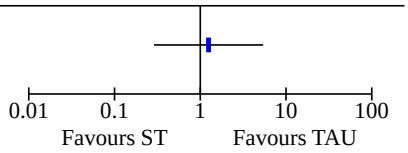
Analysis 5.4. Comparison 5: Schema therapy versus treatment-as-usual, Outcome 4: Social functioning: number of patients with supervised leave at 3 years

Study or Subgroup	ST Events	ST Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Bernstein 2012	13	16	11	14	1.18 [0.20 , 7.08]



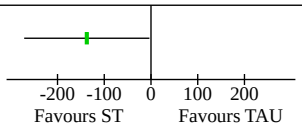
Analysis 5.5. Comparison 5: Schema therapy versus treatment-as-usual, Outcome 5: Social functioning: number of patients with unsupervised leave at 3 years

Study or Subgroup	ST Events	ST Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Bernstein 2012	10	16	8	14	1.25 [0.29 , 5.41]



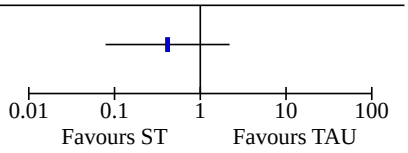
Analysis 5.6. Comparison 5: Schema therapy versus treatment-as-usual, Outcome 6: Social functioning: mean number of days to unsupervised leave

Study or Subgroup	ST Mean	ST SD	ST Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI
Bernstein 2012	679.8	183.17	16	817.13	189.89	14	-137.33 [-271.31 , -3.35]



Analysis 5.7. Comparison 5: Schema therapy versus treatment-as-usual, Outcome 7: Adverse events: global negative outcomes overall

Study or Subgroup	ST Events	ST Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Bernstein 2012 (1)	3	16	5	14	0.42 [0.08 , 2.19]

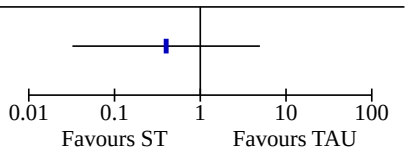


Footnotes

(1) 26/30 (87%) of participants has a AsPD diagnosis

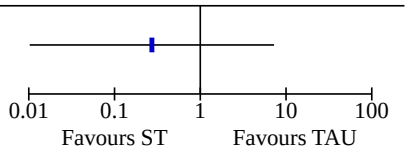
Analysis 5.8. Comparison 5: Schema therapy versus treatment-as-usual, Outcome 8: Adverse events: number of patients transferred to other clinics due to lack of treatment response

Study or Subgroup	ST Events	ST Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Bernstein 2012	1	16	2	14	0.40 [0.03 , 4.96]



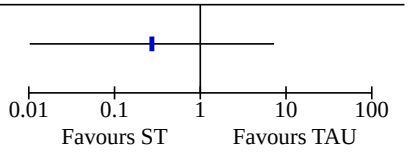
Analysis 5.9. Comparison 5: Schema therapy versus treatment-as-usual, Outcome 9: Adverse events: number of patients terminating therapy due to worsening of psychiatric condition

Study or Subgroup	ST Events	ST Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Bernstein 2012	0	16	1	14	0.27 [0.01 , 7.25]



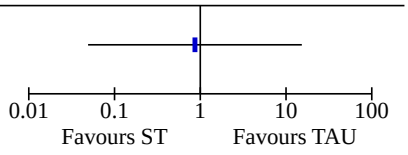
Analysis 5.10. Comparison 5: Schema therapy versus treatment-as-usual, Outcome 10: Adverse events: number of patients that terminate therapy due to lack of treatment response

Study or Subgroup	ST Events	ST Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Bernstein 2012	0	16	1	14	0.27 [0.01 , 7.25]



Analysis 5.11. Comparison 5: Schema therapy versus treatment-as-usual, Outcome 11: Adverse events: number of patients terminated due to lack of co-operation with the research

Study or Subgroup	ST Events	ST Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Bernstein 2012	1	16	1	14	0.87 [0.05 , 15.28]

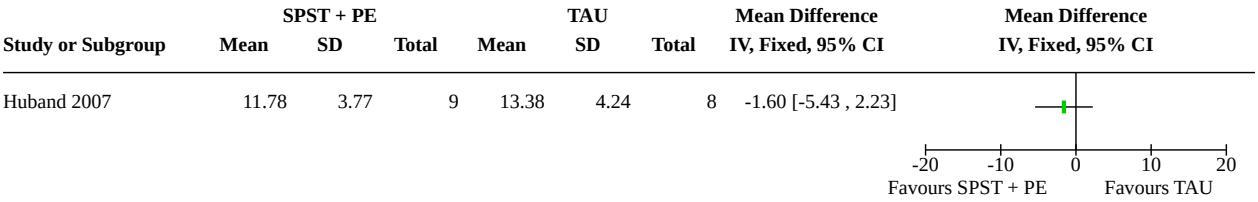


Comparison 6. Social problem-solving therapy + psychoeducation versus treatment-as-usual alone

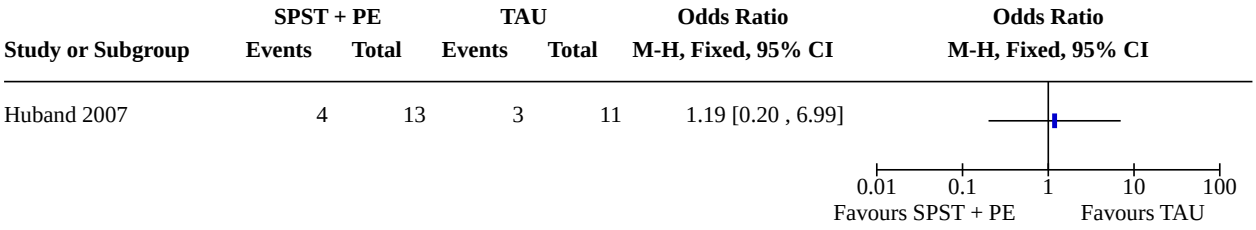
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.1 Social functioning: mean social functioning scores (high = poor); SFQ; at 6 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
6.2 Leaving the study early	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
6.3 Impulsivity: mean impulsiveness scores (high = poor); BIS; at 6 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
6.4 Anger: mean Anger Expression Index scores (high = poor); STAXI-2; at 6 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.5 Other: social problem-solving ability; mean overall scores (high = good); SPSI; at 6 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
6.6 Other: shame; mean overall shame scores (high = poor); ESS; at 6 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
6.7 Other: dissociation; mean dissociation scores (high = poor); DES: at 6 months	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

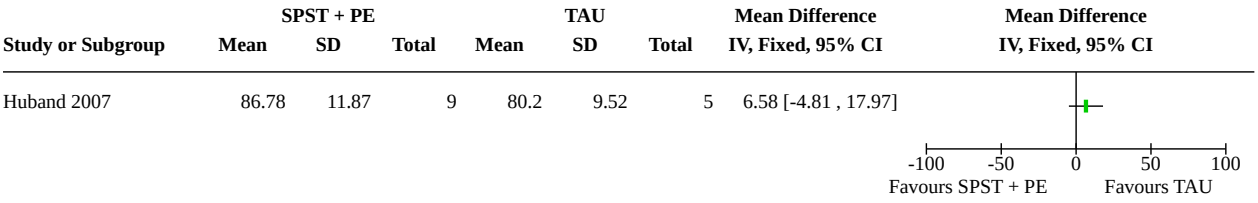
Analysis 6.1. Comparison 6: Social problem-solving therapy + psychoeducation versus treatment-as-usual alone, Outcome 1: Social functioning: mean social functioning scores (high = poor); SFQ; at 6 months



Analysis 6.2. Comparison 6: Social problem-solving therapy + psychoeducation versus treatment-as-usual alone, Outcome 2: Leaving the study early

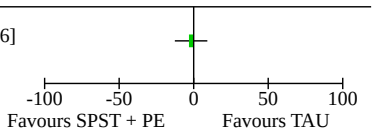


Analysis 6.3. Comparison 6: Social problem-solving therapy + psychoeducation versus treatment-as-usual alone, Outcome 3: Impulsivity: mean impulsiveness scores (high = poor); BIS; at 6 months



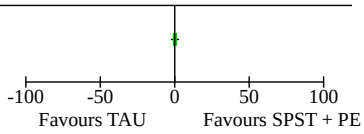
Analysis 6.4. Comparison 6: Social problem-solving therapy + psychoeducation versus treatment-as-usual alone, Outcome 4: Anger: mean Anger Expression Index scores (high = poor); STAXI-2; at 6 months

Study or Subgroup	SPST + PE Mean	SD	Total	TAU Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Huband 2007	56.26	13.12	9	58	7.68	5	-1.74 [-12.64 , 9.16]



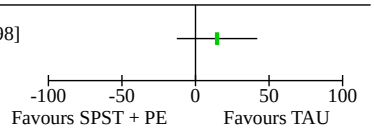
Analysis 6.5. Comparison 6: Social problem-solving therapy + psychoeducation versus treatment-as-usual alone, Outcome 5: Other: social problem-solving ability; mean overall scores (high = good); SPSI; at 6 months

Study or Subgroup	SPST + PE Mean	SD	Total	TAU Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Huband 2007	8.27	3.05	9	8.09	2.56	7	0.18 [-2.57 , 2.93]



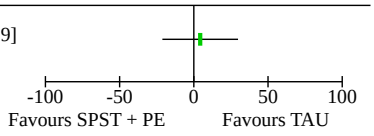
Analysis 6.6. Comparison 6: Social problem-solving therapy + psychoeducation versus treatment-as-usual alone, Outcome 6: Other: shame; mean overall shame scores (high = poor); ESS; at 6 months

Study or Subgroup	SPST + PE Mean	SD	Total	TAU Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Huband 2007	68.44	20.32	9	53.8	27.27	5	14.64 [-12.70 , 41.98]



Analysis 6.7. Comparison 6: Social problem-solving therapy + psychoeducation versus treatment-as-usual alone, Outcome 7: Other: dissociation; mean dissociation scores (high = poor); DES: at 6 months

Study or Subgroup	SPST + PE Mean	SD	Total	TAU Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Huband 2007	39.53	21.43	9	35.23	21.73	4	4.30 [-21.19 , 29.79]



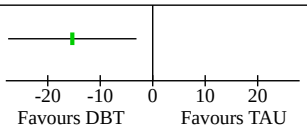
Comparison 7. Dialectical behaviour therapy versus treatment-as-usual

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.1 Mental state: score on Brief Psychiatric Rating Scale (BPRS) (total sum), at month 2	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.2 Mental state: anxiety on Beck Anxiety and Depression Scale (BADS)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
7.3 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test] 'High degree of confirmation' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
7.4 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'High expectations of self' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
7.5 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Tend to blame' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
7.6 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Reaction to failure' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
7.7 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Emotional irresponsibility' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
7.8 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Anxiety and stress' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
7.9 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Avoidance of exposition to the pitfalls' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
7.10 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Dependence' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
7.11 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; ' Helplessness to changes ' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
7.12 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Perfectionism' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

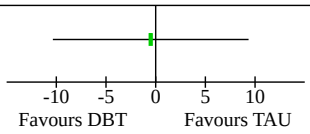
Analysis 7.1. Comparison 7: Dialectical behaviour therapy versus treatment-as-usual, Outcome 1: Mental state: score on Brief Psychiatric Rating Scale (BPRS) (total sum), at month 2

Study or Subgroup	DBT Mean	DBT SD	DBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI
Priebe 2012	46.25	5.85	4	61.57	14.58	7	-15.32 [-27.55 , -3.09]



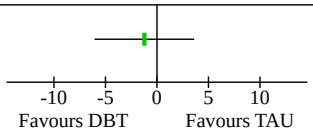
Analysis 7.2. Comparison 7: Dialectical behaviour therapy versus treatment-as-usual, Outcome 2: Mental state: anxiety on Beck Anxiety and Depression Scale (BADS)

	DBT			TAU			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Asmand 2015	33.31	14.74	16	33.81	13.66	16	-0.50 [-10.35 , 9.35]	



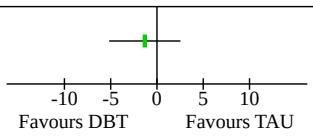
Analysis 7.3. Comparison 7: Dialectical behaviour therapy versus treatment-as-usual, Outcome 3: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test] 'High degree of confirmation' subscale

	DBT			TAU			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Asmand 2015	23.06	6.67	16	24.28	7.28	16	-1.22 [-6.06 , 3.62]	



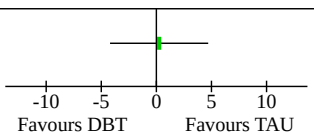
Analysis 7.4. Comparison 7: Dialectical behaviour therapy versus treatment-as-usual, Outcome 4: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'High expectations of self' subscale

	DBT			TAU			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Asmand 2015	21.25	5.96	16	22.56	5.12	16	-1.31 [-5.16 , 2.54]	



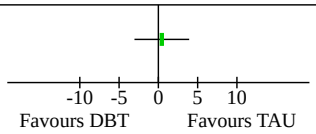
Analysis 7.5. Comparison 7: Dialectical behaviour therapy versus treatment-as-usual, Outcome 5: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Tend to blame' subscale

	DBT			TAU			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Asmand 2015	22.93	6.62	16	22.68	6.23	16	0.25 [-4.20 , 4.70]	



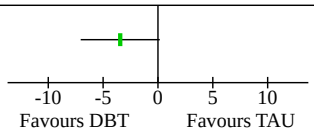
Analysis 7.6. Comparison 7: Dialectical behaviour therapy versus treatment-as-usual, Outcome 6: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Reaction to failure' subscale

Study or Subgroup	DBT Mean	DBT SD	DBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Asmand 2015	22.5	5.57	16	22.06	4.41	16	0.44 [-3.04 , 3.92]	



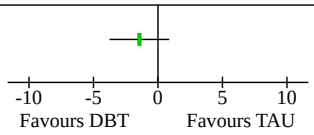
Analysis 7.7. Comparison 7: Dialectical behaviour therapy versus treatment-as-usual, Outcome 7: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Emotional irresponsibility' subscale

Study or Subgroup	DBT Mean	DBT SD	DBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Asmand 2015	21.56	6.12	16	25	4.08	16	-3.44 [-7.04 , 0.16]	



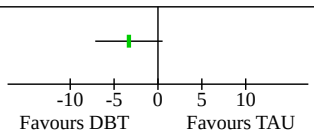
Analysis 7.8. Comparison 7: Dialectical behaviour therapy versus treatment-as-usual, Outcome 8: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Anxiety and stress' subscale

Study or Subgroup	DBT Mean	DBT SD	DBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Asmand 2015	18.81	3.22	16	20.25	3.45	16	-1.44 [-3.75 , 0.87]	



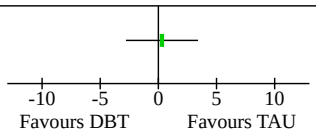
Analysis 7.9. Comparison 7: Dialectical behaviour therapy versus treatment-as-usual, Outcome 9: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Avoidance of exposition to the pitfalls' subscale

Study or Subgroup	DBT Mean	DBT SD	DBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Asmand 2015	19.87	6.18	16	23.18	4.81	16	-3.31 [-7.15 , 0.53]	



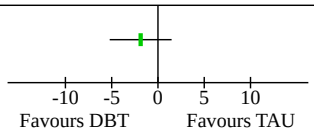
Analysis 7.10. Comparison 7: Dialectical behaviour therapy versus treatment-as-usual, Outcome 10: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Dependence' subscale

Study or Subgroup	DBT Mean	DBT SD	DBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI
Asmand 2015	22.87	4.47	16	22.56	4.47	16	0.31 [-2.79 , 3.41]



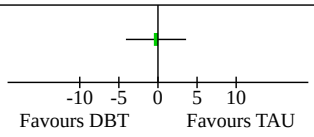
Analysis 7.11. Comparison 7: Dialectical behaviour therapy versus treatment-as-usual, Outcome 11: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; ' Helplessness to changes ' subscale

Study or Subgroup	DBT Mean	DBT SD	DBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI
Asmand 2015	22	4.77	16	23.87	4.88	16	-1.87 [-5.21 , 1.47]



Analysis 7.12. Comparison 7: Dialectical behaviour therapy versus treatment-as-usual, Outcome 12: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Perfectionism' subscale

Study or Subgroup	DBT Mean	DBT SD	DBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI
Asmand 2015	22	5.8	16	22.25	5.29	16	-0.25 [-4.10 , 3.60]

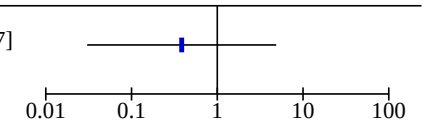


Comparison 8. Cognitive behavioural therapy + standard maintenance versus standard maintenance alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.1 Leaving the study early	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
8.2 Substance misuse (drugs): numbers with cocaine-negative specimens; at 17 weeks	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
8.3 Substance misuse (drugs): numbers with cocaine-negative specimens; at 26 weeks	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
8.4 Substance misuse (drugs): numbers with cocaine-negative specimens; at 52 weeks	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected

Analysis 8.1. Comparison 8: Cognitive behavioural therapy + standard maintenance versus standard maintenance alone, Outcome 1: Leaving the study early

Study or Subgroup	CBT + SM Events	CBT + SM Total	SM Events	SM Total	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
Messina 2003 (1)	1	14	2	12	0.38 [0.03 , 4.87]	

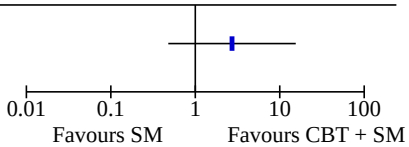


Footnotes

(1) Based on numbers completing, calculated from the percentages reported by trial investigators (p.323, col.1).

Analysis 8.2. Comparison 8: Cognitive behavioural therapy + standard maintenance versus standard maintenance alone, Outcome 2: Substance misuse (drugs): numbers with cocaine-negative specimens; at 17 weeks

Study or Subgroup	CBT + SM Events	CBT + SM Total	SM Events	SM Total	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
Messina 2003 (1)	7	13	3	10	2.72 [0.48 , 15.47]	

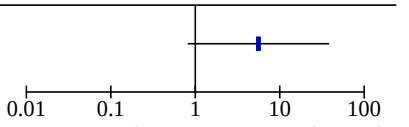


Footnotes

(1) Based on numbers completing, calculated from the percentages reported by trial investigators (p.323, col.1).

Analysis 8.3. Comparison 8: Cognitive behavioural therapy + standard maintenance versus standard maintenance alone, Outcome 3: Substance misuse (drugs): numbers with cocaine-negative specimens; at 26 weeks

Study or Subgroup	CBT + SM Events	CBT + SM Total	SM Events	SM Total	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
Messina 2003 (1)	8	13	2	9	5.60 [0.81 , 38.51]	

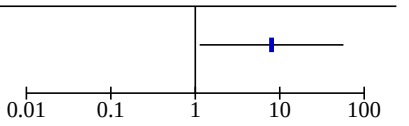


Footnotes

(1) Based on numbers completing, calculated from the percentages reported by trial investigators (p.323, col.1).

Analysis 8.4. Comparison 8: Cognitive behavioural therapy + standard maintenance versus standard maintenance alone, Outcome 4: Substance misuse (drugs): numbers with cocaine-negative specimens; at 52 weeks

Study or Subgroup	CBT + SM Events	CBT + SM Total	SM Events	SM Total	Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
Messina 2003 (1)	8	12	2	10	8.00 [1.13 , 56.79]	



Footnotes

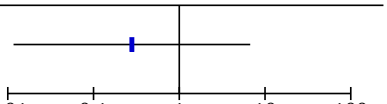
(1) Based on numbers completing, calculated from the percentages reported by trial investigators (p.323, col.1).

Comparison 9. Contingency management + cognitive behavioural therapy + standard maintenance versus standard maintenance alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
9.1 Leaving the study early	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
9.2 Substance misuse (drugs): numbers with cocaine-negative specimens; at 17 weeks	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
9.3 Substance misuse (drugs): numbers with cocaine-negative specimens; at 26 weeks	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
9.4 Substance misuse (drugs): numbers with cocaine-negative specimens; at 52 weeks	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected

Analysis 9.1. Comparison 9: Contingency management + cognitive behavioural therapy + standard maintenance versus standard maintenance alone, Outcome 1: Leaving the study early

	CM + CBT + SM		SM		Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Messina 2003 (1)	0	7	2	12	0.28 [0.01 , 6.72]	

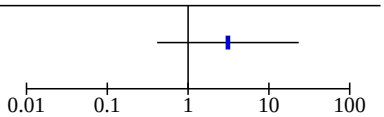


Footnotes

(1) Based on numbers completing, calculated from the percentages reported by trial investigators (p.323, col.1).

Analysis 9.2. Comparison 9: Contingency management + cognitive behavioural therapy + standard maintenance versus standard maintenance alone, Outcome 2: Substance misuse (drugs): numbers with cocaine-negative specimens; at 17 weeks

	CM + CBT + SM		SM		Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Messina 2003 (1)	4	7	3	10	3.11 [0.41 , 23.39]	

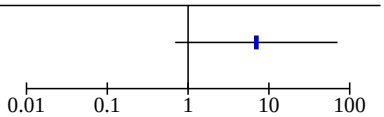


Footnotes

(1) Based on numbers completing, calculated from the percentages reported by trial investigators (p.323, col.1).

Analysis 9.3. Comparison 9: Contingency management + cognitive behavioural therapy + standard maintenance versus standard maintenance alone, Outcome 3: Substance misuse (drugs): numbers with cocaine-negative specimens; at 26 weeks

Study or Subgroup	CM + CBT + SM Events	CM + CBT + SM Total	SM Events	SM Total	Odds Ratio M-H, Fixed, 95% CI
Messina 2003 (1)	4	6	2	9	7.00 [0.69 , 70.74]

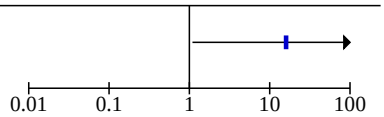


Footnotes

(1) Based on numbers completing, calculated from the percentages reported by trial investigators (p.323, col.1).

Analysis 9.4. Comparison 9: Contingency management + cognitive behavioural therapy + standard maintenance versus standard maintenance alone, Outcome 4: Substance misuse (drugs): numbers with cocaine-negative specimens; at 52 weeks

Study or Subgroup	CM + CBT + SM Events	CM + CBT + SM Total	SM Events	SM Total	Odds Ratio M-H, Fixed, 95% CI
Messina 2003 (1)	4	5	2	10	16.00 [1.09 , 234.25]



Footnotes

(1) Based on numbers completing, calculated from the percentages reported by trial investigators (p.323, col.1).

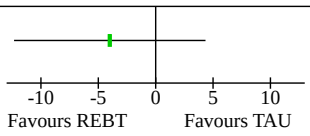
Comparison 10. Rational emotive behaviour therapy versus treatment-as-usual

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
10.1 Mental state: anxiety score on Beck Anxiety and Depression Scale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
10.2 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'High degree of confirmation' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
10.3 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'High expectations of self' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
10.4 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Tend to blame' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
10.5 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Reaction to failure' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
10.6 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Emotional irresponsibility' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
10.7 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Anxiety and stress' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
10.8 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Avoidance of exposition to the pitfalls' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
10.9 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Dependence' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
10.10 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; ' Helplessness to changes ' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
10.11 Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Perfectionism' subscale	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

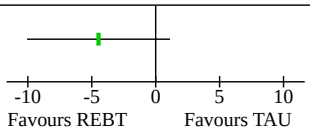
Analysis 10.1. Comparison 10: Rational emotive behaviour therapy versus treatment-as-usual, Outcome 1: Mental state: anxiety score on Beck Anxiety and Depression Scale

	REBT			TAU			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Asmand 2015	29.81	10.16	16	33.81	13.66	16	-4.00 [-12.34 , 4.34]	



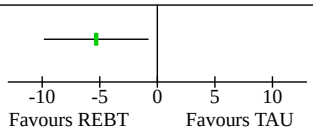
Analysis 10.2. Comparison 10: Rational emotive behaviour therapy versus treatment-as-usual, Outcome 2: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'High degree of confirmation' subscale

	REBT			TAU			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Asmand 2015	19.81	8.79	16	24.28	7.28	16	-4.47 [-10.06 , 1.12]	



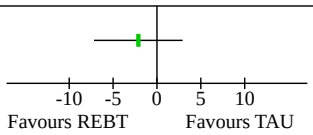
Analysis 10.3. Comparison 10: Rational emotive behaviour therapy versus treatment-as-usual, Outcome 3: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'High expectations of self' subscale

Study or Subgroup	REBT Mean	REBT SD	REBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Asmand 2015	17.25	7.71	16	22.56	5.17	16	-5.31 [-9.86 , -0.76]	



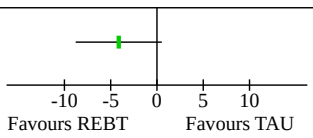
Analysis 10.4. Comparison 10: Rational emotive behaviour therapy versus treatment-as-usual, Outcome 4: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Tend to blame' subscale

Study or Subgroup	REBT Mean	REBT SD	REBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Asmand 2015	20.56	8.21	16	22.68	6.23	16	-2.12 [-7.17 , 2.93]	



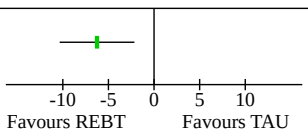
Analysis 10.5. Comparison 10: Rational emotive behaviour therapy versus treatment-as-usual, Outcome 5: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Reaction to failure' subscale

Study or Subgroup	REBT Mean	REBT SD	REBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Asmand 2015	17.93	8.41	16	22.06	4.41	16	-4.13 [-8.78 , 0.52]	



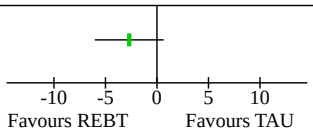
Analysis 10.6. Comparison 10: Rational emotive behaviour therapy versus treatment-as-usual, Outcome 6: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Emotional irresponsibility' subscale

Study or Subgroup	REBT Mean	REBT SD	REBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Asmand 2015	18.75	7.3	16	25	4.08	16	-6.25 [-10.35 , -2.15]	



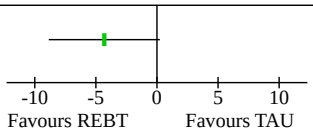
Analysis 10.7. Comparison 10: Rational emotive behaviour therapy versus treatment-as-usual, Outcome 7: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Anxiety and stress' subscale

Study or Subgroup	REBT Mean	REBT SD	REBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Asmand 2015	17.56	5.89	16	20.25	3.45	16	-2.69 [-6.03 , 0.65]	



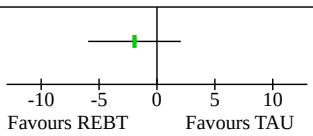
Analysis 10.8. Comparison 10: Rational emotive behaviour therapy versus treatment-as-usual, Outcome 8: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Avoidance of exposition to the pitfalls' subscale

Study or Subgroup	REBT Mean	REBT SD	REBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Asmand 2015	18.87	7.93	16	23.18	4.81	16	-4.31 [-8.85 , 0.23]	



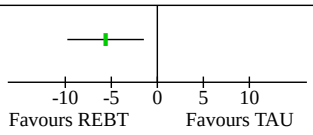
Analysis 10.9. Comparison 10: Rational emotive behaviour therapy versus treatment-as-usual, Outcome 9: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Dependence' subscale

Study or Subgroup	REBT Mean	REBT SD	REBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Asmand 2015	20.62	6.83	16	22.56	4.47	16	-1.94 [-5.94 , 2.06]	



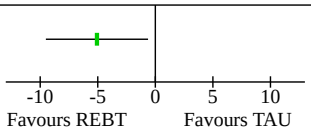
Analysis 10.10. Comparison 10: Rational emotive behaviour therapy versus treatment-as-usual, Outcome 10: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; ' Helplessness to changes ' subscale

Study or Subgroup	REBT Mean	REBT SD	REBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Asmand 2015	18.25	6.94	16	23.87	4.88	16	-5.62 [-9.78 , -1.46]	



Analysis 10.11. Comparison 10: Rational emotive behaviour therapy versus treatment-as-usual, Outcome 11: Other: Jones' Illogical Beliefs Questionnaire (sic), [Irrational Beliefs Test]; 'Perfectionism' subscale

Study or Subgroup	REBT Mean	REBT SD	REBT Total	TAU Mean	TAU SD	TAU Total	Mean Difference IV, Fixed, 95% CI
Asmand 2015	17.18	7.35	16	22.25	5.29	16	-5.07 [-9.51 , -0.63]



Comparison 11. Psychosocial risk management ('Resettle programme') versus treatment-as-usual

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
11.1 Recidivism: total official offences at 2 years post-release	1		Other data	No numeric data
11.2 Recidivism: total official offences at 2 years, corrected for time in the community	1		Other data	No numeric data
11.3 Recidivism: binary outcome (no offences vs 1 or more offences) for official offences at 2 years post release	1		Other data	No numeric data
11.4 Recidivism: binary outcome (no offences vs 1 or more offences) for official offences at 2 years post release, corrected for time in the community	1		Other data	No numeric data
11.5 Recidivism: total antisocial behaviour assessed with the Self-report Delinquency Scale	1		Other data	No numeric data
11.6 Adverse event: death during study period	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected
11.7 Leaving the study early: participants not included in ITT analysis of primary outcome	1		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected

Analysis 11.1. Comparison 11: Psychosocial risk management ('Resettle programme') versus treatment-as-usual, Outcome 1: Recidivism: total official offences at 2 years post-release

Recidivism: total official offences at 2 years post-release

Study	Estimate	SE	95% CI	p	Comments
Nathan 2019	1.188	0.585	-0.042 to 2.334	0.042	Statistical prediction of the number of Poisson-distributed official offences by the ITT Resettle group versus the control group, provided by study investigators (n = 72, 90% AsPD).

Analysis 11.2. Comparison 11: Psychosocial risk management ('Resettle programme') versus treatment-as-usual, Outcome 2: Recidivism: total official offences at 2 years, corrected for time in the community

Recidivism: total official offences at 2 years, corrected for time in the community

Study	Estimate	SE	95% CI	p	Comments
Nathan 2019	1.204	0.621	-0.014 to 2.423	0.053	Statistical prediction of the number of Poisson-distributed official offences by the ITT Resettle group versus the control group, provided by study investigators (n = 72, 90% AsPD)

Analysis 11.3. Comparison 11: Psychosocial risk management ('Resettle programme') versus treatment-as-usual, Outcome 3: Recidivism: binary outcome (no offences vs 1 or more offences) for official offences at 2 years post release

Recidivism: binary outcome (no offences vs 1 or more offences) for official offences at 2 years post release

Study	Estimate	SE	95% CI	p	Comments
Nathan 2019	2.371	0.973	0.464 to 4.278	0.015	Statistical prediction of the zero-inflation binary factor (no offence vs. 1 or more offences) reported by ITT Resettle group versus the control, reported by the study investigators (n = 72, 90% AsPD). The study authors stated (p 5, col 1) "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."

Analysis 11.4. Comparison 11: Psychosocial risk management ('Resettle programme') versus treatment-as-usual, Outcome 4: Recidivism: binary outcome (no offences vs 1 or more offences) for official offences at 2 years post release, corrected for time in the community

Recidivism: binary outcome (no offences vs 1 or more offences) for official offences at 2 years post release, corrected for time in the community

Study	Estimate	SE	95% CI	p	Comments

Nathan 2019	2.077	1.12	-0.188 to 4.201	0.073	Statistical prediction of the zero-inflation binary factor (no offence vs. 1 or more offences) reported by ITT Resettle group versus the control, reported by the study investigators (n = 72, 90% AsPD). The study authors stated (p 5, col 1) "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."

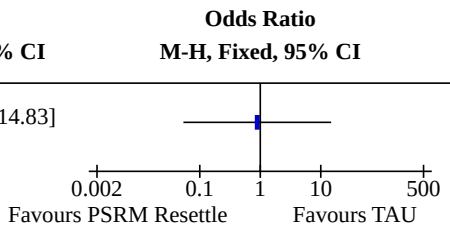
Analysis 11.5. Comparison 11: Psychosocial risk management ('Resettle programme') versus treatment-as-usual, Outcome 5: Recidivism: total antisocial behaviour assessed with the Self-report Delinquency Scale

Recidivism: total antisocial behaviour assessed with the Self-report Delinquency Scale

Study	Estimate	SE	95% CI	p	Comments
Nathan 2019	1.534	0.889	-0.210 to 3.277	0.085	Statistical prediction of number Poisson-distributed self-report of antisocial behaviours (SRS total) by ITT Resettle group versus the control group (20 participants, 90% AsPD)

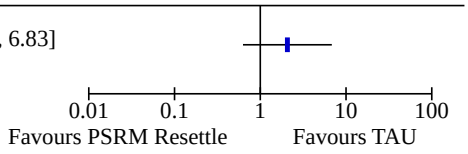
Analysis 11.6. Comparison 11: Psychosocial risk management ('Resettle programme') versus treatment-as-usual, Outcome 6: Adverse event: death during study period

Study or Subgroup	PSRM Resettle Events	PSRM Resettle Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Nathan 2019	1	38	1	34	0.89 [0.05 , 14.83]



Analysis 11.7. Comparison 11: Psychosocial risk management ('Resettle programme') versus treatment-as-usual, Outcome 7: Leaving the study early: participants not included in ITT analysis of primary outcome

Study or Subgroup	PSRM Resettle Events	PSRM Resettle Total	TAU Events	TAU Total	Odds Ratio M-H, Fixed, 95% CI
Nathan 2019	10	38	5	34	2.07 [0.63 , 6.83]



ADDITIONAL TABLES

Table 13. Comparison 3. Contingency management (CM) + standard maintenance (SM) versus SM: Addiction Severity Index scores

Study	Outcome	Experimental group: CM + SM		Control group: SM		Difference of least square means over months 1 to 6	df	P value	Comments
		Adjusted mean	SE	Adjusted mean	SE				
Neufeld 2008	Family/social domain scores	0.08	0.02	0.16	0.02	−0.09	81	0.005	Favours experimental group: CM + SM
Neufeld 2008	Employment domain scores	0.72	0.04	0.72	0.04	0.006	81	0.91	Favours neither group
Neufeld 2008	Alcohol domain scores	0.02	0.01	0.04	0.01	−0.02	81	0.17	Favours neither group
Neufeld 2008	Drug domain scores	0.16	0.01	0.19	0.01	−0.03	81	0.09	Favours neither group

CM: contingency management; **df:** degrees of freedom **SE:** standard error; **SM:** standard maintenance.

Summary data supplied by the trial investigators. Adjusted means obtained from mixed regression model, which included time-specific random effects and an interaction term.

Table 20. Comparison 7. Dialectical behavior therapy (DBT) versus treatment-as-usual (TAU): number of self-harm days (skewed data)

Study	Outcome	Experimental group: DBT			Control group: TAU			Statistic	Comments
		n	Mean	SD	n	Mean	SD		
Priebe 2012	Adverse events: number of self-harm days in past 2 months (averaged), at baseline	5	17.27	25.34	9	10.7	6.31	None reported[a]	DBT range = 0.83 to 60.83; TAU range = 1.0 to 18.67
Priebe 2012	Adverse events: number of self-harm days in past 2 months (averaged), at 2 months	5	3.6	6.95	9	12.22	19.58	None reported[a]	DBT range = 0 to 16; TAU range = 0 to 57

AsPD: antisocial personality disorder; **DBT:** Dialectical Behavior Therapy; **n:** numbers of participants; **SD:** standard deviation; **TAU:** treatment as usual.

[a]Summary data for AsPD subgroup (n = 14) provided by K Barnicot on 2 March 2017; no statistics provided.

Table 23. Comparison 11 Psychosocial Risk Management 'Resettle' programme (PSRM) versus treatment-as-usual (probation supervision): recidivism (skewed data)

Study	Outcome	Experimental group: PSRM			Control group: TAU			Statistic	Comments[a]
		n	Mean	SD	n	Mean	SD		
Nathan 2019	Recidivism: total number of official criminal offences recorded in year 1 (higher = worse outcome)	16	4.13	5.78	19	5.21	3.28	None reported	Experimental group median = 2, range = 0 to 22; control group median = 4, range = 0 to 11
Nathan 2019	Recidivism: total number of official criminal offences recorded in year 2 (higher = worse outcome)	8	3.63	4.10	8	3.25	3.77	None reported	Experimental group median = 2, range = 0 to 11; control group median = 1.5, range = 0 to 9
Nathan 2019	Recidivism: total number of self-report antisocial acts as reported by SRD in year 1 (higher = worse outcome)	16	9.69	19.34	19	7.37	5.17	None reported	Experimental group median = 4, range = 0 to 78; control group median = 7, range = 0 to 17
Nathan 2019	Recidivism: total number of self-report antisocial acts as reported by SRD in year 2 (non-cumulative) (higher = worse outcome)	8	8.75	14.05	9	7.33	9.51	None reported	Experimental group median = 2, range = 0 to 38 ; control group median = 4, range = 0 to 27

AsPD: antisocial personality disorder; **PSRM**: Psychosocial risk management 'resettle' programme **n:** numbers of participants; **SD:** standard deviation; **SRD**: Self-Report Delinquency scale; **TAU:** treatment as usual.

[a]Raw data provided by study authors; all descriptive statistics extracted by review authors for participants with a definite or probable diagnosis of AsPD.

Table 1. DSM-5 general criteria for personality disorder

Criteria	**Description** (DSM-5, p 646-7)
A.	An enduring pattern of inner experience and behaviour that deviates markedly from the expectations of the individual's culture. This pattern is manifested in two (or more) of the following areas. • Cognition (i.e. ways of perceiving and interpreting self, other people, and events). • Affectivity (i.e. the range, intensity, lability, and appropriateness of emotional response). • Interpersonal functioning. • Impulse control.
B.	The enduring pattern is inflexible and pervasive across a broad range of personal and social situations.
C.	The enduring pattern leads to clinically significant distress or impairment in social, occupational, or other important areas of functioning.
D.	The pattern is stable and of long duration, and its onset can be traced back at least to adolescence or early adulthood.
E.	The enduring pattern is not better explained as a manifestation or consequence of another mental disorder.
F.	The enduring pattern is not attributable to the physiological effects of a substance (e.g. a drug of abuse, a medication) or a another medical condition (e.g. head trauma).

DSM-5: *Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition*

Table 2. DSM-5 diagnostic criteria for antisocial personality disorder (301.7)

Criteria	**Description** (DSM-5, p 659)
A.	A pervasive pattern of disregard for and violation of the rights of others, occurring since age 15 years, as indicated by three (or more) of the following. • Failure to conform to social norms with respect to lawful behaviours, as indicated by repeatedly performing acts that are grounds for arrest. • Deceitfulness, as indicated by repeated lying, use of aliases, or conning others for personal profit or pleasure. • Impulsivity or failure to plan ahead. • Irritability and aggressiveness, as indicated by repeated physical fights or assaults. • Reckless disregard for safety of self or others. • Consistent irresponsibility, as indicated by repeated failure to sustain consistent work behavior or honour financial obligations. • Lack of remorse, as indicated by being indifferent to or rationalising having hurt, mistreated, or stolen from another.
B.	The individual is at least 18 years.
C.	There is evidence of conduct disorder with onset before age of 15 years.
D.	The occurrence of antisocial behavior is not exclusively during the course of schizophrenia or bipolar disorder.

DSM-5: *Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition*

Table 3. ICD-10 diagnostic criteria for dissocial personality disorder (F60.2)

Description (ICD-10)
Personality disorder, usually coming to attention because of gross disparity between behaviour and the prevailing social norms, and characterised by: • callous unconcern for the feelings of others; • gross and persistent attitude of irresponsibility and disregard for social norms, rules and obligations; • incapacity to maintain enduring relationships, though having no difficulty in establishing them; • very low tolerance to frustration and a low threshold for discharge of aggression, including violence; • incapacity to experience guilt or to profit from experience, particularly punishment; • marked proneness to blame others, or to offer plausible rationalisations for the behaviour that has brought the patient into conflict with society. There may also be persistent irritability as an associated feature. Conduct disorder during childhood and adolescents, though not invariably present, may further support the diagnosis.

ICD-10: International Classification of Diseases-Tenth Revision

Table 4. Examples of types of psychological interventions and how they might work

Psychological intervention	How the intervention may work
Cognitive behaviour therapy (CBT)	CBT-based treatments place emphasis on encouraging the patient to challenge their core beliefs and thoughts in order to gain insight into how these influence their feelings and behaviour (Bateman 2004a; Henwood 2015).
Cognitive analytic therapy (CAT)	CAT utilises ideas from psychodynamic psychotherapy and cognitive therapy (Denman 2001). CAT encourages patients to identify and change learned attitudes and beliefs about themselves and how these impact on their patterns of relating to others.
Dialectical behavioural therapy (DBT)	DBT is a complex psychological intervention developed using some of the principles of CBT (Linehan 1993). DBT provides individuals with skills training in four modules (i.e. mindfulness, distress tolerance, emotion regulation, interpersonal effectiveness).
Psychoanalytic therapy or dynamic psychotherapy	The British Psychoanalytic Council defines psychoanalytic therapies as "a range of therapeutic treatments derived from psychoanalytic ideas and methods and a critical appreciation of the effect of childhood experiences on adult personality development" (British Psychoanalytical Council 2018; quote, p 2). (see also Piper 1993, Winston 1994, Bateman 2001 and Leichsenring 2003).
Mentalisation-based therapy (MBT)	MBT has developed from attachment theory and aims to help patients identify and reflect on what they, and others are feeling and why, in order to better regulate their behaviour and emotions (Bateman 2004b).
Schema therapy (ST)	In ST, the therapist helps the patient identify long-standing, self-defeating patterns of thinking, feeling and behaving ('schemas') and develop healthier alternatives to replace them (Young 2003).
Nidotherapy	Nidotherapy is a formalised, planned method for achieving environmental change to minimise the effect of the participant's difficulties upon themselves and others. Unlike most other therapies, it aims to fit the immediate environment to the patient, rather than change the patient to cope in the existing environment (Tyrer 2007). In order to achieve this, a detailed psychological formulation is developed for the individual participant (Tyrer 2005a).
Therapeutic community (TC) treatment	TC treatments involve participants engaging in group psychotherapy whilst being involved in a shared, therapeutic environment. This provides them with an opportunity to "explore intrapsychic

Table 4. Examples of types of psychological interventions and how they might work *(Continued)*

	and interpersonal problems and find more constructive ways of dealing with distress" (Campling 2001, quote, p 365). (see also Lees 1999).
Contingency management	Contingency management is based on the psychological principles of behaviour modification and aims to incentivise and reinforce changes in behaviour through the use of financial (or other rewards) that are of value to the patient. (Petry 2011).

CAT = Cognitive analytic therapy
CBT = Cognitive behaviour therapy
DBT = Dialectical behavioural therapy
MBT = Mentalisation-based therapy
ST = Schema therapy
TC = Therapeutic community

Table 5. Additional methods for future updates

Issue	Method
Types of interventions	We will consider widening the range of interventions examined in future reviews to include concepts such as 'Motivation to Change'.
Measures of treatment effect	**Continuous data** We will summarise change-from-baseline ('change score') data alongside endpoint data where these are available. Change-from-baseline data may be preferred to endpoint data if their distribution is less skewed, but both types may be included together in meta-analysis when using the MD (Higgins 2011a, p 270). Where the data are insufficient for meta-analysis, we will report the results of the trial investigators' own statistical analyses comparing treatment and control conditions, using change scores.
Unit of analysis issues	**Cluster-randomised trials** Where trials use clustered randomisation, study investigators may present their results after appropriately controlling for clustering effects (robust standard errors or hierarchical linear models). If, however, it is unclear whether a cluster-randomised trial has used appropriate controls for clustering, we will contact the study investigators for further information. If appropriate controls were not used, we will request individual participant data and re-analyse these using multilevel models that control for clustering. Following this, we will conduct a meta-analysis of effect sizes and standard errors in RevMan 5 (Review Manager 2014), using the generic inverse method (Higgins 2011a). If appropriate controls were not used and individual participant data are not available, we will seek statistical guidance from the Cochrane Methods Group and external experts as to which method to apply to the published results in attempt to control for clustering. If there is insufficient information to control for clustering, we will enter the outcome data into RevMan5 (Review Manager 2014), using the individual as the unit of analysis, and then conduct a sensitivity analysis to assess the potential biasing effects of inadequately controlled clustered trials (Donner 2001).
Dealing with missing data	The standard deviations of the outcome measures should be reported for each group in each trial. If these are not given, we will calculate these, where possible, from standard errors, confidence intervals, t-values, F values or P values using the method described in the *Cochrane Handbook for Systematic Reviews of Interventions*, section 7.7.3.3 (Higgins 2011a). If these data are not available, we will impute standard deviations using relevant data (for example, standard deviations or correlation coefficients) from other, similar studies (Follman 1992), but only if, after seeking statistical advice, to do so is deemed practical and appropriate. Assessment will be made of the extent to which the results of the review could be altered by the missing data by, for example, a sensitivity analysis based on consideration of 'best-case' and 'worst-case' scenarios (Gamble 2005). Here, the 'best-case' scenario is where all participants with missing outcomes in the experimental condition had good outcomes, and all those with missing

Table 5. Additional methods for future updates *(Continued)*

	outcomes in the control condition had poor outcomes; the 'worst-case' scenario is the converse (Higgins 2011a, section 16.2.2). We will report data separately from studies where more than 50% of participants in any group were lost to follow-up. Where meta-analysis is undertaken, we will assess the impact of including studies with attrition rates greater than 50% through a sensitivity analysis. If inclusion of data from this group results in a substantive change in the estimate of effect of the primary outcomes, we will not add the data from these studies to trials with less attrition and will present them separately. Any imputation of data will be informed, where possible, by the reasons for attrition where these are available. We will interpret the results of any analysis based in part on imputed data with recognition that the effects of that imputation (and the assumptions on which it is based) can have considerable influence when samples are small.
Assessment of reporting biases	We will draw funnel plots (effect size versus standard error) to assess small study effects, when there are greater than 10 studies. Asymmetry of the plots may indicate publication bias, although they may also represent a true relationship between trial size and effect size. If such a relationship is identified, we will further examine the clinical diversity of the studies as a possible explanation (Egger 1997; Jakobsen 2014; Lieb 2016).
Data synthesis	For homogeneous interventions, we will group outcome measures by length of follow-up, and use the weighted average of the results of all the available studies to provide an estimate of the effect of specific psychological interventions for people with antisocial personality disorder. We will use regression techniques to investigate the effects of differences in study characteristics on the estimate of the treatment effects. We will seek statistical advice before attempting meta-regression. If meta-regression is performed, it will be executed using a random-effects model as per protocol. Where studies provide both endpoint or change data, or both, for continuous outcomes, we will perform meta-analysis that combines both data types using the methods described by Da Costa 2013. We will consider pooling outcomes reported at different time points where this does not obscure the clinical significance of the outcome being assessed. To address the issue of multiplicity, future reviews should consider the following: • adjusting P values and CIs of outcomes using the method described by (Jakobsen 2014); • adopting a hierarchy of outcome measures to select only one outcome per domain; • using the approaches outlined in point 5 of Table 3.2.c in the Cochrane Handbook (Higgins 2019).
Subgroup analysis and investigation of heterogeneity	We will undertake subgroup analysis to examine the effect on primary outcomes of: • comorbid diagnosis (e.g. other personality disorder, substance misuse disorder); • setting (inpatient, custodial, outpatient/community); • whether intervention was group-based or individual-based; • regression techniques will be used to investigate the effects of differences in study characteristics on the estimate of the treatment effects. We will seek statistical advice before attempting meta-regression; if meta-regression is performed, it will be executed using a random-effects model.
Sensitivity analysis	We will undertake sensitivity analyses to investigate the robustness of the overall findings in relation to certain study characteristics. A priori sensitivity analyses are planned for: • concealment of allocation; • blinding of outcome assessors; • extent of dropouts; • consideration of 'best-case' and 'worst-case' scenarios to assess the extent to which the results of the review could be altered by the missing data; and • the impact of including studies with high attrition rates (25% to 50%).

Table 5. Additional methods for future updates *(Continued)*

- studies with data where at least 75% of participants have a diagnosis of antisocial personality disorder.

MD = Mean difference

Table 6. Details of the psychological interventions examined in the 19 included studies

Study	Intervention	Description
Woody 1985	Supportive-expressive psychotherapy + standard maintenance	Supportive-expressive psychotherapy is an analytically-oriented, focal psychotherapy. Standard maintenance is an individual counselling intervention focused on providing external services rather than dealing with intrapsychic processes, plus methadone maintenance.
McKay 2000	Individualised relapse prevention aftercare	Individualised relapse prevention is a manualised, modular intervention for substance users in the maintenance phase of recovery. Risky situations are identified and improved coping responses encouraged. Clients receive 1 individual relapse prevention session and 1 group session per week for up to 20 weeks.
Messina 2003	Cognitive behaviour therapy (CBT) + standard maintenance	CBT is a structured intervention based on behavioural principles with positive verbal reinforcement of decreased or no use of illicit drugs, or for prosocial behaviour. Comprises 48 group sessions of 90 minutes (3 per week for 16 weeks) with typically 4 to 8 participants in each group. Participants continue on standard maintenance treatment (including methadone, mean = 72 mg/day).
	Contingency management + standard maintenance	Contingency management + standard maintenance comprises a brief meeting (2 to 5 minutes) with a contingency management technician. Clean urine specimens are rewarded with vouchers of escalating value (to a maximum of USD 1277.50 if drug-free for the 16 weeks of the trial) and with praise/encouragement. Positive samples result in the vouchers being withheld but the participant is not rebuked or punished. Participants continue on standard maintenance treatment (including methadone, mean = 62 mg/day).
	Cognitive behavioural therapy (CBT) + contingency management + standard maintenance	CBT + contingency management + standard maintenance is a structured intervention based on behavioural principles with positive verbal reinforcement of decreased or no use of illicit drugs, or for prosocial behaviour. Comprises 48 group sessions of 90 minutes (3 per week for 16 weeks) with typically 4 to 8 participants in each group. Participants continue on standard maintenance treatment (including methadone, mean = 68 mg/day) and meet with a contingency management technician (2 to 5 minutes). Clean urine specimens are rewarded with vouchers of escalating value (to a maximum of USD 1277.50 if drug-free for the 16 weeks of the trial) and with praise or encouragement. Positive samples result in the vouchers being withheld but the participant is not rebuked or punished.
Tyrer 2004	Cognitive behavioural therapy (CBT) + treatment as usual	Manual-assisted CBT (MACT) is a treatment for self-harming behaviour where participants are provided with a booklet based on CBT principles plus an offer of 5 plus 2 booster sessions of CBT in the first 3 months.
Ball 2005	Dual-focus schema therapy	Dual focus schema therapy is a 24-week, manual-guided individual therapy that integrates symptom-focused relapse prevention coping skills techniques with schema-focused techniques for early maladaptive schemas and coping styles.
Neufeld 2008	Contingency management + standard maintenance	Contingency-based behavioural programme is a highly structured contingency-based, adaptive treatment protocol comprising counselling sessions and behavioural interventions. Drug abstinence and counselling attendance

Table 6. Details of the psychological interventions examined in the 19 included studies *(Continued)*

		are rewarded by greater control over methadone management with negative reinforcers being a reduction in methadone dosage and control of the dosage. Standard maintenance comprises standard methadone substitution treatment with 2 individual counselling sessions per week with bi-weekly reviews; negative drug screens are rewarded with methadone take-home doses.
Havens 2007	Strengths-based case management	Strengths-based case management of 5 to 24 minutes duration; includes engagement, strengths assessment, personal case planning, and resource acquisition. Services provided by case managers include advice on referrals to health and social services, and on transportation and employment.
Huband 2007	Social problem-solving therapy with psychoeducation	A brief, individual psychoeducation programme followed by 16 weekly, group-based problem-solving sessions (lasting approximately 2 hours) based on the 'Stop and Think!' method. Groups start with no more than 8 participants in each and are single gender.
Marlowe 2007	Optimal judicial supervision	Optimal ('matched') schedule of court hearings in which frequency of court attendance is matched with risk, so that high-risk offenders (those with antisocial personality disorder and a history of drug treatment) attend with greater frequency. Group sessions are psychoeducational and cover a range of topics including relapse prevention strategies.
Woodall 2007	'Driving whilst intoxicated program' + incarceration	The 'Driving whilst intoxicated program' is nonconfrontational and utilises a psychoeducational approach on the harmful effects of alcohol, stress management, and a work-release programme for those in employment. It also incorporates culturally appropriate elements (71% of participants were native American). The programme was delivered whilst participants were subject to 28 days incarceration.
Davidson 2009	Cognitive behavioural therapy (CBT) + treatment as usual	CBT involves a cognitive formulation of the individual's problems (to promote engagement) and therapy focusing on beliefs about self and others that impair social functioning. Individuals were offered 15 or 30 sessions of CBT (to determine the optimal 'dose') and therapist adherence/competence was assessed for a random selection (30%) of sessions by audio recording and found to be "within the 'competent range'" (quote, p 517)
Bernstein 2012	Schema therapy (ST)	ST is an integrative therapy for personality disorders combining cognitive, behavioural, psychodynamic object relations, and humanistic/experiential approaches; individual therapy delivered twice a week according to adapted procedures for forensic patients set out in a practitioner's guide; treatment lasts from 2 to 3 years, with frequency reduced to 1 session per week in the third year of treatment.
Feigenbaum 2012	Dialectical behavioural therapy (DBT)	DBT pretreatment phase of 3-6 weeks of goal-setting and commitment-building followed by offer of 1 year DBT treatment contract; DBT treatment consists of 1 hour of individual therapy and 2.5 hours of group skills training per week plus out-of-hours telephone consultation, as required.
Priebe 2012	Dialectical behavioural therapy (DBT)	12 months of DBT delivered according to Linehan's treatment and skills training manuals (Linehan 1993); 1 × 1-hour individual therapy session per week; 1 × 2-hour skills training group per week; out-of-hours skills coaching by telephone, as required.
Asmand 2015)	Dialectical behavioural therapy (DBT)	DBT condition and mode of delivery was very poorly described by the study authors; possibly delivered through 16 × 1-hour sessions.
	Rational emotional behaviour Therapy (REBT)	REBT, based on cognitive behaviour therapy principles, was very poorly described by the study authors; possibly delivered through 16 × 1-hour sessions.

Table 6. Details of the psychological interventions examined in the 19 included studies *(Continued)*

McMurran 2016	Psychoeducation with problem-solving (PEPS) + treatment as usual	PEPS therapy is a cognitive–behavioural intervention that integrates individual and group therapies with optional individual support sessions; up to four individual psychoeducation sessions; 12 × 2-hour group sessions of problem-solving therapy; individual support sessions offered every 2 weeks through the 12-week problem-solving group (optional). Patients also received treatment as usual.
Tarrier 2010	Schema modal therapy (SMT) + treatment as usual	SMT followed Young's SMT protocol (Young 2003); 1 60-minute individual session each week for a minimum of 18 months. Participants also received treatment as usual.
Thylstrup 2015	Impulsive lifestyle counselling (ILC) + treatment as usual	ILC is a manualised, psychoeducational intervention; 6 sessions cover specific topics and include mandatory questions, printed handouts and worksheets for the patient.
Nathan 2019	Psychosocial risk management (PSRM)	'Resettle' PSRM is a non-manualised, integrative sociotherapy underpinned by case formulation, risk management, probation supervision and intervention planning. The programme consists of 3 levels: 1) therapeutic milieu generated by appropriate and prosocial relationships; 2) group work to enhance participants' capacity for self-reflection and understanding of others; and 3) individual psychosocial interventions focused on risk management, well-being and social integration. PSRM treatment consists of a 6-month preparatory phase (before individual is released from prison), followed by community-based treatment (time frame = 1-2 years).

CBT = Cognitive behaviour therapy
DBT = Dialectical behavioural therapy
ILC = Impulsive lifestyle counselling
MACT = Manual-assisted CBT
PEPS = Psychoeducation with problem-solving
PSRM = Psychosocial risk management
REBT = Rational emotional behaviour therapy
SMT = Schema modal therapy
ST = Schema therapy

Table 7. Details of the comparator interventions examined in the 19 included studies

Study	Comparator
Woody 1985	SM: an individual counselling intervention focused on providing external services rather than dealing with intrapsychic processes, plus methadone maintenance
McKay 2000	TAU: standard continuing care comprising 2 group therapy sessions per week where the orientation was a mix of addictions counselling and 12-step recovery practices
Messina 2003	SM: methadone maintenance; treatment, with daily clinic visits for methadone, twice-monthly counselling sessions, plus medical care and case management visits, as required
Tyrer 2004	TAU: participants were seen by another designated therapist and offered the standard treatment in the area concerned or the continuation of current therapy.
Ball 2005	TAU: standard group substance abuse counselling as normally provided at the drop-in centre where clients are typically offered a total of 3 opportunities per week to attend group psychoeducation and counselling sessions
Havens 2007	Passive referral: strengths-based case management (SBCM) of 0 to 4 minutes duration

Table 7. Details of the comparator interventions examined in the 19 included studies *(Continued)*

Huband 2007	TAU: placed on waiting list for active intervention
Marlowe 2007	Standard ('unmatched') schedule court hearings requiring attendance every 4 to 6 weeks
Neufeld 2008	SM: standard methadone substitution treatment and participants attended 2 individual counselling sessions per week
Woodall 2007	Incarceration
Davidson 2009	TAU: "all participants received whatever treatment they would have received had the trial not taken place" (quote; p 570, column 2)
Tarrier 2010	TAU: "Group-based enhanced thinking skills and sex offender treatment were the most frequently provided therapies recorded on the TAU logs." (quote; p 14); other noted TAU therapies included: social therapy and resettlement work; review of clinical or psychology reports; discussion of therapy; neurorehabilitation; review of previous assessments; end of therapy meeting support work; and "talking sessions" (quote; p 14)
Bernstein 2012	TAU: standard treatment that patients receive at each clinic usually another (non-ST) form of individual psychotherapy such as cognitive-behaviour therapy, psychodynamic therapy, or client-centred therapy
Feigenbaum 2012	TAU: range of individualised service provision, including outpatient psychiatric review, case management, psychoanalytic psychotherapy, cognitive behaviour therapy, supportive structured counselling, inpatient admission, drug and alcohol treatment and crisis management
Priebe 2012	TAU: participants allocated to the TAU condition were referred back to the referrer and encouraged to engage in any kind of treatment other than DBT; "this may have included treatment from psychotherapists, psychiatrists, community mental health teams, counsellors, general practitioners or user-run support groups, all of which were offered free of charge under the NHS." (quote; p 358)
Asmand 2015	TAU: unclear but TAU control group may have received individual work, but no details were provided
Thylstrup 2015	TAU: access to opioid substitution treatment (if required); psychosocial support such as casework, counselling, or referral to residential rehabilitation; referral to 'off-site' psychiatrist for treatment of other psychiatric conditions
McMurran 2016	TAU: provided by participants' usual-care teams; TAU includes assessment, care planning, risk assessment and psychological interventions; participants excluded at baseline if accessing/likely to access psychological treatment programme specifically designed for personality disorder.
Nathan 2019	TAU: standard probation supervision following release from prison; TAU comprises regular meetings (weekly initially) with the offender manager and engagement with other services where specified in the licence conditions.

SBCM = Strengths-based case management
SM = Standard maintenance
TAU = Treatment as usual

Table 8. Comparison 1. Cognitive behavioural therapy (CBT) + treatment-as-usual (TAU) versus TAU: alcohol abuse scores (skewed data)

Study	Outcome	Experimental group: CBT + TAU			Control group: TAU			Comparison of difference (95% CI)	Notes
		Baseline mean (SD), [n]	Last value mean (SD) [n]	Difference (95% CI)	Baseline mean (SD) [n]	Last value Mean (SD) [n]	Difference (95% CI)		
Davidson 2009	AUDIT scores (high = poor); at 12 months	8.2 (6.8), [25]	5.9 (7.6), [19]	4.1 (0.5 to 7.7), P = 0.03	11.1 (5.9), [27]	11.0 (9.4), [20]	0.3 (−3.1 to 3.7), P = 0.85	4.1 (−0.6 to 8.9), P = 0.08	Favours neither group LOCF analysis[a]
Davidson 2009	AUDIT total units scores (high = poor); at 12 months	8.4 (9.1), [24]	7.9 (10.0), [18]	2.7 (−2.8 to 8.2), P = 0.31	15.7 (12.4), [26]	10.7 (14.7), [20]	5.5 (−1.7 to 12.8), P = 0.12	0.6 (−7.6 to 8.8), P = 0.88	Favours neither group LOCF analysis[a]

AUDIT: Alcohol Use Identification Test;**CBT:** cognitive behavioural therapy; **CI:** confidence interval; **LOCF:** last-observation-carried-forward; **n:** number of participants;**SD:** standard deviation; **TAU:** treatment as usual.

[a]Trial investigators have used a last-observation-carried-forward procedure (i.e. endpoint scores based on last available value).

Table 9. Comparison 1. Cognitive behavioural therapy (CBT) + treatment-as-usual (TAU) versus TAU: costs of services received

Study	Outcome	Experimental group: CBT + TAU (n = 25)	Control group: TAU (n = 27)	Statistic
Davidson 2009	Total cost of health, social work and criminal justice services received; over 12 months	GBP 38,004	GBP 31,097	No statistic available
Davidson 2009	Average cost per participant for NHS services alone; over 12 months	GBP 1295	GBP 1133	No statistic available

CBT: cognitive behavioural therapy; **GBP:** British pound sterling; **n:** number of participants; **TAU:** treatment as usual.

Table 10. Comparison 1: Cognitive behavioural therapy (CBT) + treatment-as-usual (TAU) versus TAU: schema scores; at 12 months (skewed data)

Study	Outcome	Experimental group: CBT + TAU			Control group: TAU			Comparison of difference (95% CI)	Comments
		Baseline mean (SD), [n]	Last value mean (SD), [n]	Difference (95% CI)	Baseline mean (SD), [n]	Last value mean (SD), [n]	Difference (95% CI)		
Davidson 2009	BCSS self-as-positive belief scores; at 12 months	8.6 (5.7), [25]	8.8 (6.3), [19]	0.2 (−1.9 to 2.4), P = 0.84	7.8 (6.1) [27]	7.2 (6.8), [20]	−0.1 (−3.0 to 2.7), P = 0.92	−0.2 (−3.6 to 3.1), P = 0.89	Favours neither group LOCF analysis[a]
Davidson 2009	BCSS self-as-negative belief scores; at 12 months	8.6 (5.5), [25]	7.7 (6.7), [19]	2.2 (−0.4 to 4.8), P = 0.09	10.1 (6.6) [27]	8.6 (6.1), [20]	0.5 (−2.1 to 3.1), P = 0.68	−0.8 (−4.3 to 2.7), P = 0.64	Favours neither group LOCF analysis[a]
Davidson 2009	BCSS others-as-positive belief scores; at 12 months	9.3 (6.1), [25]	9.6 (6.4), [19]	−0.4 (−3.0 to 2.2), P = 0.74	6.6 (4.4) [27]	5.6 (4.4), [20]	1.2 (−1.0 to 3.4), P = 0.28	−2.6 (−5.8 to 0.5), P = 0.10	Favours neither group LOCF analysis[a]
Davidson 2009	BCSS others-as-negative belief scores; at 12 months	12.9 (7.4), [25]	11.9 (8.2), [19]	0.2 (−1.7 to 2.1), P = 0.82	11.8 (7.1) [27]	9.1 (5.3), [20]	2.4 (−0.7 to 5.6), P = 0.12	−2.4 (−5.8 to 0.9), P = 0.15	Favours neither group LOCF analysis[a]

BCSS: Brief Core Schema Scales; **CBT:** cognitive behavioural therapy; **CI:** confidence interval; **LOCF:** last-observation-carried-forward; **n:** number of participants; **SD:** standard deviation; **TAU:** treatment as usual.

[a]Trial investigators have used a last-observation-carried-forward procedure (i.e. endpoint scores based on last available value).

Table 11. Comparison 2. Impulsive lifestyle counselling (ILC) + treatment-as-usual (TAU) versus TAU; additional SMD data for aggression outcomes

Study	Outcome	Experimental group: ILC + TAU		Control group: TAU		Statistic	Comments
		SMD	n	SMD	n		
Thylstrup 2015	Aggression: change in BPAQ-SF from baseline to 3 months	0.34	70	0.50	61	None reported	-

Table 11. Comparison 2. Impulsive lifestyle counselling (ILC) + treatment-as-usual (TAU) versus TAU; additional SMD data for aggression outcomes *(Continued)*

Thylstrup 2015	Aggression: change in BPAQ-SF from baseline to 9 months	0.72	63	0.76	55	None reported	-
Thylstrup 2015	Aggression: change in SRASBM from baseline to 3 months	0.47	70	0.57	61	None reported	-
Thylstrup 2015	Aggression: change in SRASBM from baseline to months	0.75	63	0.31	55	None reported	-

BPAQ-SF: Buss-Perry Aggression Questionnaire - Short Form; **ILC:** impulsive lifestyle counselling; **n:** number of participants; **SMD:** standardised mean difference; **SRASBM:** Self-Report of Aggression and Social Behavior Measure; **TAU:** treatment as usual.

Table 12. Comparison 2. Impulsive lifestyle counselling (ILC) + treatment-as-usual (TAU) versus TAU (skewed data)

Study	Outcome	Experimental group: ILC + TAU			Control group: TAU			Statistic	Comments
		n	Mean	SD	n	Mean	SD		
Thylstrup 2015	Aggression: Self-Report of Aggression and Social Behavior Measure (SRASBM) at 3 months	70	0.64	0.49	61	0.64	0.46	Regression coefficient[a] = 0.083 (95% CI −0.092 to 0.260), P > 0.05	Favours neither group
Thylstrup 2015	Aggression: Self-Report of Aggression and Social Behavior Measure (SRASBM) at 9 months	63	0.47	0.39	55	0.61	0.52	Regression coefficient[b] = 0.026 (95% CI −0.158 to 0.210), P > 0.05	Favours neither group
Thylstrup 2015	Substance misuse: Addiction Severity Index (ASI), drug composite score at 3 months	70	0.17	0.12	61	0.21	0.12	Regression coefficient[c] = −0.052 (95% CI −0.096 to −0.009), P = 0.018.	Favours experimental group: ILC + TAU
Thylstrup 2015	Substance misuse: Addiction Severity Index (ASI), drug composite score at 9 months	63	0.15	0.12	55	0.16	0.13	Regression coefficient[d] = −0.0040 (95% CI −0.049 to 0.042), P > 0.05	Favours neither group
Thylstrup 2015	Substance misuse: Addiction Severity Index (ASI), alcohol composite score at 3 months	72	0.12	0.22	61	0.12	0.22	Regression coefficient[e] = 0.008 (95% CI −0.061 to 0.077), P > 0.05	Favours neither group

Table 12. Comparison 2. Impulsive lifestyle counselling (ILC) + treatment-as-usual (TAU) versus TAU (skewed data) *(Continued)*

Thylstrup 2015	Substance misuse: Addiction Severity Index (ASI), alcohol composite score at 9 months	63	0.12	0.21	55	0.1	0.18	Regression coefficient[f] = 0.049 (95% CI −0.023 to 0.121), P > 0.05	Favours neither group
Thylstrup 2015	Substance misuse: Days abstinent (in previous 30 days) at 3 months	72	13.2	12.7	61	10.8	11.2	Regression coefficient[g] = 4.319 (95% CI 0.183 to 8.456), P < 0.05	Favours experimental group: ILC + TAU
Thylstrup 2015	Substance misuse: Days abstinent (in previous 30 days) at 9 months	63	15.3	13.3	55	13.7	12.7	Regression coefficient[h] = 3.584 (95% CI −0.751 to 7.919), P > 0.05	Favours neither group

ASI: Addiction Severity Index; **CI:** confidence interval; **ILC:** impulsive lifestyle counselling; **n:** number of participants; **SD:** standard deviation; **SRASBM:** Self-Report of Aggression and Social Behaviour Measure; **TAU:** treatment as usual.

[a]Result of mixed effects regression on aggression outcomes (SRASBM as dependent variable), ILC × 3 months.
[b]Result of mixed effects regression on aggression outcomes (SRASBM as dependent variable), ILC × 9 months.
[c]Result of mixed effects regression on substance abuse outcomes (ASI Drugs composite score as dependent variable), ILC × 3 months.
[d]Result of mixed effects regression on substance abuse outcomes (ASI Drugs composite score as dependent variable), ILC × 9 months.
[e]Result of mixed effects regression on substance abuse outcomes (ASI Alcohol composite score as dependent variable), ILC × 3 months.
[f]Result of mixed effects regression on substance abuse outcomes (ASI Alcohol composite score as dependent variable), ILC × 9 months.
[g]Result of mixed effects regression on substance abuse outcomes (Days abstinent in previous 30 days as dependent variable), ILC × 3 months.
[h]Result of mixed effects regression on substance abuse outcomes (Days abstinent in previous 30 days as dependent variable), ILC × 9 months.

Table 14. Comparison 3. Contingency management (CM) + standard maintenance (SM) versus SM alone: cocaine abstinence (skewed data)

Study	Outcome	Experimental group: CM + SM			Control group: SM			Statistic	Comments
		n	Mean	SD	n	Mean	SD		
Messina 2003	Number cocaine-negative specimens; by 16 weeks[a]	15	39.4	11.4	12	9.3	11.3	P < 0.05 (Two-way ANOVA; Tukey-Kramer post hoc test; no further details)	Favours experimental group: CM + SM

ANOVA: analysis of variance; **CM:** contingency management; **n:** participant numbers reported as randomised to each condition; **SD:** standard deviation; **SM:** standard maintenance.

[a]Outcome is mean number of cocaine-negative specimens per participant.

Table 15. Comparison 3. Contingency management (CM) + standard maintenance (SM) versus SM alone: percentage drug-negative specimens

Study	Outcome	Experimental group: CM + SM	Control group: SM	Statistic	Comments
Neufeld 2008	Percentage opioid-negative specimens; at 6 months	80.5%	73.7%	OR 1.31 (95% CI 0.71 to 2.42, P = 0.393)	Favours neither group
Neufeld 2008	Percentage cocaine-negative specimens; at 6 months	77.3%	66.7%	OR 1.59 (95% CI 0.86 to 2.96, P = 0.139)	Favours neither group
Neufeld 2008	Percentage sedative-negative specimens; at 6 months	96.2%	90.8%	OR 1.82 (95% CI 0.715 to 4.42, P = 0.184)	Favours neither group
Neufeld 2008	Percentage (any) drug-negative specimens; at 6 months	68.7%	54.2%	OR 1.70 (95% CI 0.94 to 3.07, P = 0.081)	Favours neither group

CI: confidence interval;**CM:** contingency management; **OR:** odds ratio; **SM:** standard maintenance.

Statistics provided by trial investigators; data relate to proportion of specimens that were negative, rather than proportion of participants who provided negative specimens.

Table 16. Comparison 3. Contingency management (CM) + standard maintenance (SM) versus SM alone: attendance at counselling sessions

Study	Outcome	Experimental group: CM + SM (sessions attended/sessions available)	Control group: SM (sessions attended/sessions available)	Statistic	Comments
Neufeld 2008	Number of counselling sessions attended in proportion to total number of sessions offered by 6 months	83.2%[a] (1285/1545)	53.4%[a] (897/1679)	OR 4.00, 95% CI 2.39 to 6.70, P < 0.0001; statistics provided by trial investigators	Favours experimental group: CM + SM

CI: confidence intervals; **CM:** contingency management; **OR:** odds ratio; **SM:** standard maintenance.

[a]The percentage data relate to the counselling sessions attended, and not to the numbers of participants who attended.

Table 17. Comparison 4. 'Driving whilst intoxicated program' (DWI) + incarceration versus incarceration alone: days drink driving, self-reported (skewed data)

Study	Outcome	Experimental group: DWI + incarceration			Control group: incarceration			Statistic	Comments
		n	Mean	SD	n	Mean	SD		
Woodall 2007	Days driving after drinking in past 30 days; self-reported; at 6 months	30	0.83	3.70	13	0.69	2.50	None provided	Favours neither group Completer analysis[a]
Woodall 2007	Days driving after drinking in past 30 days; self-reported; at 12 months	30	0.63	1.69	13	0.46	0.88	None provided	Favours neither group Completer analysis[a]
Woodall 2007	Days driving after drinking in past 30 days; self-reported; at 24 months	30	0.67	1.75	13	0.38	0.38	None provided	Favours neither group Completer analysis[a]
Woodall 2007	Days driving after drinking in past 30 days; self-reported; mean improvement over baseline; at 24 months	30	4.26	6.32	13	3.03	4.08	None provided	Favours neither group Completer analysis[a]

ANOVA: analysis of variance; **AsPD:** antisocial personality disorder; **DWI:** 'Driving whilst intoxicated program'; **n:** numbers of participants; **SD:** standard deviation.

[a]Trial investigators reported a significant, overall main effect of time (P < 0.001), "indicating a decline in self-reported drinking and driving from intake to post-incarceration assessments" (column 2, p 982) and a significant AsPD-by-time interaction (P < 0.001) "resulting from the fact that the AsPD participants showed a greater improvement over time than the non-AsPD participants" (column 2, p 982), but that the group-by-time interaction was not significant (ANOVA, mixed factorial design).

Table 18. Comparison 4. 'Driving whilst intoxicated program' (DWI) + incarceration versus incarceration alone: days driving after five or more drinks, self-reported (skewed data)

Study	Outcome	Experimental group: DWI + incarceration	Incarceration	Statistic	Comments

Table 18. Comparison 4. 'Driving whilst intoxicated program' (DWI) + incarceration versus incarceration alone: days driving after five or more drinks, self-reported (skewed data) *(Continued)*

		n	Mean	SD	n	Mean	SD		
Woodall 2007	Days driving after 5 or more drinks in past 30 days; self-reported; at 6 months	30	0.87	3.73	13	0.08	0.28	None provided	Favours neither group Completer analysis[a]
Woodall 2007	Days driving after 5 or more drinks in past 30 days; self-reported; at 12 months	30	0.57	1.63	13	0.38	0.77	None provided	Favours neither group Completer analysis[a]
Woodall 2007	Days driving after 5 or more drinks in past 30 days; self-reported; at 24 months	30	0.50	1.25	13	0.31	0.63	None provided	Favours neither group Completer analysis[a]
Woodall 2007	Days driving after 5 or more drinks in past 30 days; self-reported; mean improvement over baseline; at 24 months	30	3.02	4.93	13	2.28	4.22	None provided	Favours neither group Completer analysis[a]

ANOVA: analysis of variance; **AsPD:** antisocial personality disorder; **DWI:** 'Driving whilst intoxicated program';**n:** numbers of participants; **SD:** standard deviation.

[a]Trial investigators reported a significant overall main effect of time (P < 0.001), "indicating a decline in self-reported drinking and driving from intake to post-incarceration assessments" (column 2, p 982) and a significant AsPD-by-time interaction (P < 0.001) "resulting from the fact that the AsPD participants showed a greater improvement over time than the non-AsPD participants" (column 2, p 982), but that the group-by-time interaction was not significant (ANOVA, mixed factorial design).

Table 19. Comparison 5. Schema therapy (ST) versus treatment-as-usual (TAU): continuous data; number of days to supervised leave (skewed data)

Study	Outcome	Experimental group: ST			Control group: TAU			Statistic	Comments
		n	Mean	SD	n	Mean	SD		

Table 19. Comparison 5. Schema therapy (ST) versus treatment-as-usual (TAU): continuous data; number of days to supervised leave (skewed data) *(Continued)*

Bernstein 2012	Social functioning: mean number of days to supervised leave	16	424.38	309.65	14	564.91	317.55	Study author-reported t-test (df = 22), 1.07, P > 0.05	Favours neither group

df: degrees of freedom; **n:** numbers of participants; **SD:** standard deviation; **ST:** Schema Therapy; **TAU:** treatment as usual.

Table 21. Comparison 8. Cognitive behavioural therapy (CBT) + standard maintenance (SM) versus SM: cocaine abstinence (skewed data)

Study	Outcome	Experimental group: CBT + SM			Control group: SM			Statistic	Comments
		n	Mean	SD	n	Mean	SD		
Messina 2003	Number cocaine-negative specimens; by 16 weeks[a]	14	24.8	15.6	12	9.3	11.3	P < 0.05 (Two-way ANOVA; Tukey-Kramer post-hoc test)	Favours experimental group: CBT + SM

ANOVA: analysis of variance; **CBT:** cognitive behavioural therapy; **n:** numbers reported as randomised to each condition; **SD:** standard deviation; **SM:** standard maintenance.

[a]Outcome is mean number of cocaine-negative specimens per participant.

Table 22. Comparison 9. Contingency management (CM) + cognitive behavioural therapy (CBT) + standard maintenance (SM) versus SM: cocaine abstinence (skewed data)

Study	Outcome	Experimental group: CM + CBT + SM			Control group: SM			Statistic	Comments
		n	Mean	SD	n	Mean	SD		
Messina 2003	Number cocaine-negative specimens; by 16 weeks[a]	7	37.7	13.3	12	9.3	11.3	P < 0.05 (Two-way ANOVA; Tukey-Kramer post-hoc test)	Favours experimental group: CM + CBT + SM

ANOVA: analysis of variance; **CBT:** cognitive behavioural therapy; **CM:** contingency management; **n:** numbers reported as randomised to each condition; **SD:** standard deviation; **SM:** standard maintenance.

[a]Outcome is mean number of cocaine-negative specimens per participant.

APPENDICES

Appendix 1. Search strategy

CENTRAL, part of the Cochrane Library

Searched 3 October 2016 [1371 records]
Searched 31 October 2017 [66 records]
Searched 3 October 2018 [359 records]
Searched 5 September 2019 [296 records]

#1[mh "Antisocial Personality Disorder"]
#2[mh ^"personality disorder"]
#3(asocial* or antisocial* or anti next social* or dissocial* or dis next social* or dyssocial* or dys next social*)
#4(self next defeating or masochistic)
#5multi next impulsiv*
#6((moral* or amoral or "a-moral") near/5 (character* or personalit*))
#7[mh ^"Multiple Personality Disorder"]
#8[mh Narcissism]
#9narciss*
#10(sociopath* or socio next path*)
#11(psychopath or psychopaths or psychopathic*)
#12(psycho next path or psycho next paths or psycho next pathic*)
#13[mh sadism]
#14sadis*
#15(self next defeating or masochist*)
#16[mh "Disruptive, Impulse Control, and Conduct Disorders"]
#17[mh Aggression]
#18[mh "Impulsive behavior"]
#19((aggress* or deceitful* or impulsiv* or irritab* or reckless*) near/5 (person* or disorder*))
#20"Cluster B"
#21"F60.2"
#22"301.7"
#23{or #1-#22} Publication Year from 2009 to 2016, in Trials
#24{or #1-#22} Publication Year from 2016 to 2017, in Trials
#25{or #1-#22} Publication Year from 2017 to 2018, in Trials
#26{or #1-#22} Publication Year from 2018 to 2019, in Trials

MEDLINE Ovid

Searched 29 September 2016 [3988 records]
Searched 31 October 2017 [635 records]
Searched 3 October 2018 [614 records]
Searched 5 September 2019 [525 records]

1 Antisocial Personality Disorder/
2 personality disorders/
3 (asocial$ or antisocial$ or anti-social$ or dissocial$ or dis-social$ or dyssocial$ or dys-social$).tw,kf.
4 (self-defeating or masochistic).tw,kf.
5 multi-impulsiv$.tw,kf.
6 ((moral$ or amoral or "a-moral") adj5 (character$ or personalit$)).tw,kf.
7 Multiple Personality Disorder/
8 Narcissism/
9 narciss$.tw,kf.
10 (sociopath$ or socio-path$).tw,kf.
11 (psychopath$2 or psycho-path$2).tw,kf.
12 sadism/
13 sadis$.tw,kf.
14 (self-defeating or masochist$).tw,kf.
15 "Disruptive, Impulse Control, and Conduct Disorders"/
16 Aggression/
17 Impulsive behavior/
18 ((aggress$ or deceitful$ or impulsiv$ or irritab$ or reckless$) adj5 (person$ or disorder$)).tw,kf.

19 Cluster B.tw,kf.
20 "F60.2".tw,kf.
21 "301.7".tw,kf.
22 or/1-21
23 randomized controlled trial.pt.
24 controlled clinical trial.pt.
25 randomi#ed.ab.
26 placebo$.ab.
27 drug therapy.fs.
28 randomly.ab.
29 trial.ab.
30 groups.ab.
31 or/23-30
32 exp animals/ not humans.sh.
33 31 not 32
34 22 and 33
35 limit 34 to yr="2009 -Current"
36 limit 34 to ed=20160901-20171019
37 limit 34 to ed=20171020-20180920
38 limit 34 to ed=20180921-20190829

MEDLINE In-Process & Other Non-Indexed Citations Ovid

Searched 30 September 2016 [840 records]
Searched 31 October 2017 [471 records]
Searched 3 October 2018 [474 records]
Searched 5 September 2019 [514 records]

1 (asocial$ or antisocial$ or anti-social$ or dissocial$ or dis-social$ or dyssocial$ or dys-social$).tw,kf.
2 (self-defeating or masochistic).tw,kf.
3 multi-impulsiv$.tw,kf.
4 ((moral$ or amoral or "a-moral") adj5 (character$ or personalit$)).tw,kf.
5 narciss$.tw,kf.
6 (sociopath$ or socio-path$).tw,kf.
7 (psychopath$2 or psycho-path$2).tw,kf.
8 sadis$.tw,kf.
9 (self-defeating or masochist$).tw,kf.
10 Cluster B.tw,kf.
11 "F60.2".tw,kf.
12 "301.7".tw,kf.
13 ((aggress$ or deceitful$ or impulsiv$ or irritab$ or reckless$) adj5 (disorder$ or person$)).tw,kf.
14 or/1-13
15 (random$ or trial$ or control$ or group$ or placebo$ or blind$ or prospectiv$ or longitudinal$ or meta-analys$ or systematic review $).tw,kf.
16 14 and 15

MEDLINE Epub Ahead of Print Ovid

Searched 30 September 2016 [381 records]
Searched 31 October 2017 [175 records]
Searched 3 October 2018 [171records]
Searched 5 September 2019 [187 records]

1 (asocial$ or antisocial$ or anti-social$ or dissocial$ or dis-social$ or dyssocial$ or dys-social$).tw,kf.
2 (self-defeating or masochistic).tw,kf.
3 multi-impulsiv$.tw,kf.
4 ((moral$ or amoral or "a-moral") adj5 (character$ or personalit$)).tw,kf.
5 narciss$.tw,kf.
6 (sociopath$ or socio-path$).tw,kf.
7 (psychopath$2 or psycho-path$2).tw,kf.
8 sadis$.tw,kf.
9 (self-defeating or masochist$).tw,kf.
10 Cluster B.tw,kf.
11 "F60.2".tw,kf.

12 "301.7".tw,kf.
13 ((aggress$ or deceitful$ or impulsiv$ or irritab$ or reckless$) adj5 (disorder$ or person$)).tw,kf.
14 or/1-13
15 (random$ or trial$ or control$ or group$ or placebo$ or blind$ or prospectiv$ or longitudinal$ or meta-analys$ or systematic review $).tw,kf.
16 14 and 15

Embase OVID

Searched 2009 to 30 September 2016 (3060 records)
Searched 2016 to November 2017 (219 records)
Searched 2017 to 3 October 2018 (344 records)
Searched 2018 to 5 September 2019 (382 records)

1 Antisocial Personality Disorder/
2 *Personality disorder/
3 ((asocial$ or antisocial$ or anti-social$ or dissocial$ or dis-social$ or dyssocial$ or dys-social$) adj5 (person$ or disorder$)).tw,kw.
4 (self-defeating or masochistic).tw,kw.
5 ((moral$ or amoral or "a-moral") adj5 (character$ or personalit$)).tw,kw.
6 multiple personality/
7 narcissism/
8 narciss$.tw,kw.
9 (sociopath$ or socio-path$).tw,kw.
10 psychopathy/
11 (psychopath$2 or psycho-path$2).tw,kw.
12 sadism/
13 sadis$.tw,kw.
14 masochism/
15 (self-defeating or masochist$).tw,kw.
16 impulse control disorder/
17 *impulsiveness/
18 *Aggression/
19 ((aggress$ or deceitful$ or impulsiv$ or irritab$ or reckless$) adj5 (person$ or disorder$)).tw,kw.
20 Cluster B.tw,kw.
21 "F60.2".tw,kw.
22 "301.7".tw,kw.
23 or/1-22
24 Randomized controlled trial/
25 controlled clinical trial/
26 Single blind procedure/
27 Double blind procedure/
28 triple blind procedure/
29 Crossover procedure/
30 (crossover or cross-over).tw.
31 ((singl$ or doubl$ or tripl$ or trebl$) adj1 (blind$ or mask$)).tw.
32 Placebo/
33 placebo.tw.
34 prospective.tw.
35 factorial$.tw.
36 random$.tw.
37 assign$.ab.
38 allocat$.tw.
39 volunteer$.ab.
40 or/24-39
41 23 and 40
42 limit 41 to yr="2009 -Current"
43 remove duplicates from 42
44 exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/
45 human/ or normal human/ or human cell/
46 44 and 45
47 44 not 46
48 43 not 47

CINAHL Plus EBSCOhost

Searched 2009 to 3 October 2016 (2426 records)
Searched 2016 to 2 November 2017 (199 records)
Searched 2017 to3 October 2018 (714 records)
Searched 2018 to 5 September 2019 (422 records)

S1(MH "Antisocial Personality Disorder")
S2(MH "Personality Disorders")
S3(asocial* or antisocial* or anti-social* or dissocial* or dis-social* or dyssocial* or dys-social*)
S4multi-impulsiv*
S5((moral* or amoral or "a-moral") N5 (character* or personalit*))
S6(MH "Multiple-Personality Disorder")
S7(MH "Narcissism")
S8narciss*
S9(sociopath* or socio-path*)
S10(psychopath or psychopaths or psychopathic or psycho-path*)
S11sadis*
S12(MH "Disruptive Behavior")
S13(MH "Aggression")
S14MH social behavior disorders
S15(MH "Deception")
S16((aggress* or deceitful* or impulsiv* or irritab* or reckless*) N5 (person* or disorder*))
S17"Cluster B"
S18"F60.2"
S19"301.7"
S20S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19
S21(MH "Clinical Trials+")
S22MH random assignment
S23(MH "Meta Analysis")
S24(MH "Crossover Design")
S25(MH "Quantitative Studies")
S26PT randomized controlled trial
S27PT Clinical trial
S28(clinical trial*) or (control* N2 trial*)
S29("follow-up study" or "follow-up research")
S30(prospectiv* study or prospectiv* research)
S31(evaluat* N2 study or evaluat* N2 research)
S32(MH "Program Evaluation")
S33(MH "Treatment Outcomes")
S34TI(single N2 mask* or single N2 blind*) OR AB(single N2 mask* or single N2 blind*)
S35TI((doubl* N2 mask*) or (doubl* N2 blind*)) OR AB((doubl* N2 mask*) or (doubl* N2 blind*))
S36TI ((tripl* N2 mask*) or (tripl* N2 blind*)) or ((trebl* N2 mask*) or (trebl* N2 blind*)) OR AB((tripl* N2 mask*) or (tripl* N2 blind*)) or ((trebl* N2 mask*) or (trebl* N2 blind*)
S37random*
S38S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37
S39S20 AND S38

PsycINFO OVID

Searched 2009 to 30 September 2016 (6366 records)
Searched 2016 to 2 November 2017.(1072 records)
Searched 2017 to 3 October 2018 (704 records)
Searched 2018 to 5 September 2019 (684 records)

1 Antisocial Personality Disorder/
2 *Personality Disorders/
3 ((asocial$ or antisocial$ or anti-social$ or dissocial$ or dis-social$ or dyssocial$ or dys-social$) adj5 (person$ or disorder$)).tw,id.
4 (self-defeating or masochistic).tw,id.
5 ((moral$ or amoral or "a-moral") adj5 (character$ or personalit$)).tw,id.
6 Dissociative Identity Disorder/
7 NARCISSISM/
8 narciss$.tw,id.

9 (sociopath$ or socio-path$).tw,id.
10 psychopathy/
11 (psychopath$2 or psycho-path$2).tw,id.
12 Sadism/
13 sadis$.tw,id.
14 MASOCHISM/)
15 Self-Defeating Behavior/
16 (self-defeating or masochist$).tw,id.
17 exp Impulse Control Disorders/
18 Impulsiveness/
19 Aggressiveness/
20 *Aggressive behavior/
21 ((aggress$ or deceitful$ or impulsiv$ or irritab$ or reckless$) adj5 (person$ or disorder$)).tw,id.
22 Cluster B.tw,id.
23 "F60.2".tw,id.
24 "301.7".tw,id.
25 or/1-24
26 clinical trials/
27 longitudinal studies/
28 exp program evaluation/
29 exp Treatment Effectiveness Evaluation/
30 random$.tw.
31 ((singl$ or doubl$ or trebl$ or tripl$) adj (blind$ or mask$)).tw.
32 (crossover$ or "cross over$").tw.
33 trial$.tw.
34 group$.ab.
35 treatment effectiveness evaluation/
36 ((singl$ or doubl$ or tripl$ or trebl$) adj1 (blind$ or mask$)).tw.
37 prospective.tw.
38 factorial$.tw.
39 (assign$ or allocat$).ab.
40 control.ab.
41 placebo.ab.
42 (crossover or cross-over).tw.
43 or/26-42
44 25 and 43

Science Citation Index Web of Science

Searched 2019 to 3 October 2016 (1233 records)
Searched 2016 to 2 November 2017 (198 records)
Searched 2017 to 3 October 2018 (181 records)
Searched 2018 to 5 September 2019 (170 records)

#14 #13 AND #12
DocType=All document types; Language=All languages;
#13 TS=(random* or trial* or control* or group* or placebo* or blind* or prospectiv* or longitudinal* or meta-analys* or systematic review*)
DocType=All document types; Language=All languages;
#12 #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #2 OR #1
DocType=All document types; Language=All languages;
#11 TS="301.7"
DocType=All document types; Language=All languages;
#10 TS="F60.2"
DocType=All document types; Language=All languages;
#9 TS=("Cluster B" and (person* or trait* or character*))
DocType=All document types; Language=All languages;
#8 TS=sadis*
DocType=All document types; Language=All languages;
#7 TS=(psychopath or psychopaths or psychopathic)
DocType=All document types; Language=All languages;
#6 TS=(sociopath* or socio-path*)
DocType=All document types; Language=All languages;
#5 TS=narciss*

DocType=All document types; Language=All languages;
#4 TS=((moral* or amoral or "a-moral") near/5 (character* or personalit*))
DocType=All document types; Language=All languages;
#3 TS=multi-impulsiv*
DocType=All document types; Language=All languages;
#2 TS=(self-defeating or masochistic)
DocType=All document types; Language=All languages;
#1 TS= ((asocial* or antisocial* or anti-social* or dissocial* or dis-social* or dyssocial* or dys-social*) NEAR/5 (person*))
DocType=All document types; Language=All languages;

Social Science Citation Index Web of Science

Searched 2019 to 3 October 2016 (2119 records)
Searched 2016 to 2 November 2017 (386 records)
Searched 2017 to 3 October 2018 (378 records)
Searched 2018 to 5 September 2019 (363 records)

#14 #13 AND #12
DocType=All document types; Language=All languages;
#13 TS=(random* or trial* or control* or group* or placebo* or blind* or prospectiv* or longitudinal* or meta-analys* or systematic review*)
DocType=All document types; Language=All languages;
#12 #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #2 OR #1
DocType=All document types; Language=All languages;
#11 TS="301.7"
DocType=All document types; Language=All languages;
#10 TS="F60.2"
DocType=All document types; Language=All languages;
#9 TS=("Cluster B" and (person* or trait* or character*))
DocType=All document types; Language=All languages;
#8 TS=sadis*
DocType=All document types; Language=All languages;
#7 TS=(psychopath or psychopaths or psychopathic)
DocType=All document types; Language=All languages;
#6 TS=(sociopath* or socio-path*)
DocType=All document types; Language=All languages;
#5 TS=narciss*
DocType=All document types; Language=All languages;
#4 TS=((moral* or amoral or "a-moral") near/5 (character* or personalit*))
DocType=All document types; Language=All languages;
#3 TS=multi-impulsiv*
DocType=All document types; Language=All languages;
#2 TS=(self-defeating or masochistic)
DocType=All document types; Language=All languages;
#1 TS= ((asocial* or antisocial* or anti-social* or dissocial* or dis-social* or dyssocial* or dys-social*) NEAR/5 (person*))
DocType=All document types; Language=All languages;

Conference Proceedings Citation Indexes - Science, and - Social Science & Humanities Wed of Science

Searched 2019 to 3 October 2016 (19 records)
Searched 2016 to 2 November 2017 (17 records)
Searched 2017 to 3 October 2018 (18 records)
Searched 2018 to 5 September 2019 (18 records)

#14 #13 AND #12
DocType=All document types; Language=All languages;
#13 TS=(random* or trial* or control* or group* or placebo* or blind* or prospectiv* or longitudinal* or meta-analys* or systematic review*)
DocType=All document types; Language=All languages;
#12 #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #2 OR #1
DocType=All document types; Language=All languages;
#11 TS="301.7"
DocType=All document types; Language=All languages;
#10 TS="F60.2"
DocType=All document types; Language=All languages;
#9 TS=("Cluster B" and (person* or trait* or character*))

DocType=All document types; Language=All languages;
#8 TS=sadis*
DocType=All document types; Language=All languages;
#7 TS=(psychopath or psychopaths or psychopathic)
DocType=All document types; Language=All languages;
#6 TS=(sociopath* or socio-path*)
DocType=All document types; Language=All languages;
#5 TS=narciss*
DocType=All document types; Language=All languages;
#4 TS=((moral* or amoral or "a-moral") near/5 (character* or personalit*))
DocType=All document types; Language=All languages;
#3 TS=multi-impulsiv*
DocType=All document types; Language=All languages;
#2 TS=(self-defeating or masochistic)
DocType=All document types; Language=All languages;
#1 TS= ((asocial* or antisocial* or anti-social* or dissocial* or dis-social* or dyssocial* or dys-social*) NEAR/5 (person*))
DocType=All document types; Language=All languages;

Sociological Abstracts Proquest

Searched 2009 to 3 October 2016 (878 records)
Searched 2016 to 2 November 2017 (87 records)
Searched 2017 to 3 October 2018 (89 records)
Searched 2018 to 5 September 2019. (86 records)

(SU.EXACT("Personality Disorders") OR SU.EXACT("Sociopathic Personality") OR TI,AB(asocial* or antisocial* or anti-social* or dissocial* or dis-social* or dyssocial* or dys-social*) OR TI,AB(self-defeating or masochistic*) OR TI,AB(narciss* or sociopath* or socio-path* or psychopath* or sadis*) OR TI,AB((aggress* or deceitful* or impulsiv* or irritab* or reckless*) NEAR/5 (person* or disorder*)) OR TI,AB("Cluster B" or "F60.2" or "301.7")) AND (SU.EXACT("Random Samples") OR SU.EXACT("Effectiveness") OR SU.EXACT("Intervention") OR SU.EXACT("Treatment Outcomes") OR SU.EXACT("Evaluation Research") OR SU.EXACT("Program Evaluation") OR SU.EXACT("Comparative Analysis") OR TI,AB(random* OR trial* OR control* OR placebo OR intervention* OR treat* OR evaluat*))

Criminal Justice Abstracts EBSCOhost

Searched 2009 to 3 October 2016 (1104 records)
Searched 2016 to 2 November 2017(144 records)
Searched 2017 to 3 October 2018 (164 records)
Searched 2018 to 5 September 2019 (123 records)

S10 S6 AND S9
S9 S7 OR S8
S8 TI(random* OR control* OR placebo OR intervention* OR treat* OR therap*) OR AB(random* OR control* OR placebo OR intervention* OR treat* OR therap*)
S7 (ZU "randomized controlled trials") or (ZU "randomized controlled trials -- research")
S6 S1 OR S2 OR S3 OR S4 OR S5
S5 ("Cluster B" or "F60.2" or "301.7")
S4 (narciss* or sociopath* or "socio-path*" or psychopath* or sadis*) N5 (person* or disorder*)
S3 (self-defeating or masochistic*)
S2 antisocial or anti-social or dissocial OR "dis-social" OR dys-social OR dyssocial
S1 (ZU "antisocial personality disorders")

Cochrane Database of Systematic Reviews, part of the Cochrane Library

Searched 3 October 2016 (9 records)
Searched 31 October 2017 (1 record)
Searched 3 October 2018 (8 records)
Searched 5 September 2019 (0 records)

#1[mh "Antisocial Personality Disorder"]
#2((asocial* or antisocial* or anti next social* or dissocial* or dis next social* or dyssocial* or dys next social*) next/5 (person* or disorder*)):ti,ab,kw
#3(self next defeating or masochistic):ti,ab,kw
#4multi next impulsiv*:ti,ab,kw

#5((moral* or amoral or "a-moral") near/5 (character* or personalit*)):ti,ab,kw
#6[mh ^"Multiple Personality Disorder"]
#7[mh Narcissism]
#8narciss*:ti,ab,kw
#9(sociopath* or socio next path*):ti,ab,kw
#10(psychopath or psychopaths or psychopathic*):ti,ab,kw
#11(psycho next path or psycho next paths or psycho next pathic*):ti,ab,kw
#12[mh sadism]
#13sadis*:ti,ab,kw
#14(self next defeating or masochist*):ti,ab,kw
#15"Cluster B":ti,ab,kw
#16"F60.2":ti,ab,kw
#17"301.7":ti,ab,kw
#18{or #1-#17}
#19[mh "Disruptive, Impulse Control, and Conduct Disorders"]
#20[mh Aggression]
#21[mh "Impulsive behavior"]
#22((aggress* or conduct* or deceitful* or disruptiv* or impulsiv* or irritab* or reckless*) next/5 (person* or disorder*)):ti,ab,kw in Cochrane Reviews (Reviews and Protocols)
#23{or #19-#22}
#24[mh ^"personality disorders"]
#25(personalit* near/3 disorder*):ti,ab,kw
#26#24 or #25#27#23 and #26
#28#18 or #27 Publication Year from 2009 to 2016, in Cochrane Reviews (Reviews and Protocols)
#29#18 or #27 Publication Year from 2016 to 2017, in Cochrane Reviews (Reviews and Protocols)
#30#18 or #27 Publication Year from 2017 to 2018, in Cochrane Reviews (Reviews and Protocols)
#31#18 or #27 Publication Year from 2018 to 2019, in Cochrane Reviews (Reviews and Protocols)

Database of Abstracts of Reviews of Effects, part of the Cochrane Library

Searched 2009 to 2016 [5 records]. Final issue. No new content added.

#1[mh "Antisocial Personality Disorder"]
#2((asocial* or antisocial* or anti next social* or dissocial* or dis next social* or dyssocial* or dys next social*) next/5 (person* or disorder*)):ti,ab,kw
#3(self next defeating or masochistic):ti,ab,kw
#4multi next impulsiv*:ti,ab,kw
#5((moral* or amoral or "a-moral") near/5 (character* or personalit*)):ti,ab,kw
#6[mh ^"Multiple Personality Disorder"]
#7[mh Narcissism]
#8narciss*:ti,ab,kw
#9(sociopath* or socio next path*):ti,ab,kw
#10(psychopath or psychopaths or psychopathic*):ti,ab,kw
#11(psycho next path or psycho next paths or psycho next pathic*):ti,ab,kw
#12[mh sadism]
#13sadis*:ti,ab,kw
#14(self next defeating or masochist*):ti,ab,kw
#15"Cluster B":ti,ab,kw
#16"F60.2":ti,ab,kw
#17"301.7":ti,ab,kw
#18{or #1-#17}
#19[mh "Disruptive, Impulse Control, and Conduct Disorders"]
#20[mh Aggression]
#21[mh "Impulsive behavior"]
#22((aggress* or conduct* or deceitful* or disruptiv* or impulsiv* or irritab* or reckless*) next/5 (person* or disorder*)):ti,ab,kw in Cochrane Reviews (Reviews and Protocols)
#23{or #19-#22}
#24[mh ^"personality disorders"]
#25(personalit* near/3 disorder*):ti,ab,kw
#26#24 or #25
#27#23 and #26
#28#18 or #27 Publication Year from 2009 to 2016, in Other Reviews

ClinicalTrials.gov (www.clinicaltrials.gov/ct2/home)

Searched 3 October 2016 (14 records)
Searched 3 November 2017 for trials registered between 1 October 2016 and 3 November 2017 (1 record)
Searched 4 October 2018 for trials registered between 3 November 2017 and 4 October 2018(3 records)
Searched 5 September 2019 for trials registered between 4 October 2018 and 5 September 2019 (3 records)

antisocial personality disorder | Interventional Studies

ICTRP (apps.who.int/trialsearch/AdvSearch.aspx)

Searched all years 3 October 2016 (41 records)
Searched 3 November 2017 for trials registered between 1 October 2016 and 3 November 2017 (5 records)
Searched 4 October 2018 for trials registered between 3 November 2017 and 4 October 2018 (10 records)
Searched 5 September 2019 for trials registered between 4 October 2018 and 5 September 2019 (3 records)

antisocial personality OR antisocial AND disorder OR antisocial AND behaviour

WorldCat (theses only; www.worldcat.org)

Searched 3 October 2016 (6 records)
Searched 2016 to 31 October 2017 (3 records)
Searched 2017 to 4 October 2018 (1 record)
Searched 2018 to 5 September 2019 (3 records)

KW: ("ANTISOCIAL PERSONALITY DISORDER" OR "ANTI-SOCIAL PERSONALITY DISORDER ") AND KW:(TREAT* OR RANDOM* OR THERAP* OR INTERVENTION*)

Appendix 2. Data extraction form

Psychological interventions for antisocial personality disorder

Source

Corresponding number on journal article:	Trial ID (e.g. Plizska 2000):
	Trial registry with ID (search www.clinicaltrials.gov from 2008 and apps.who.int/trialsearch/Default.aspx from 2004):
	Full citation:
	Form filled by (date, name):
	Author contact information:
	Other publications on same study:
	Publication type:
	Country of origin:
ID: Identifier	

Eligibility

Confirm eligibility: yes/no/awaiting

(Continued)

At least 5 or more AsPD participants: yes/no
AsPD: Antisocial personality disorder

Correspondence

Correspondence required: yes/no

Method

Corresponding number on journal article:	How randomised (individual/cluster)?:	Participants receiving:
	Location (e.g. hospital, outpatient clinic):	• Intervention = • Control =
	Summary (method):	An X-week trial with X arms:

Methods	Allocation:
	Blinding:
	Duration of trial:
	Duration of participation:
	Setting:
	Phases:
	Intended follow-up period:
	Validated instruments used:
	Unvalidated instruments used:
Participants	Number of participants screened:
	Control group
	Method of recruitment of participants:
	Number of participants included (male, female):
	Number of participants followed up:
	Number of withdrawals (reason):
	Diagnosis of AsPD (DSM/ICD):
	Means of assessment:

(Continued)

	Mean age (range): in years IQ: Ethnicity: Pre-existing substance misuse (specify if drugs/alcohol): Other comorbid diagnoses:
	Experimental group Method of recruitment of participants: Number of participants included (male, female): Number of participants followed up: Number of withdrawals (reason): Diagnosis of AsPD (DSM/ICD): Means of assessment: Mean age (range): in years IQ: Ethnicity: Pre-existing substance misuse (specify if drugs/alcohol): Other comorbid diagnoses:
	Inclusion criteria met
	Exclusion criteria met
Interventions	**Experimental group** Treatment name: Delivery (small/large group vs Individual): Number randomised to experimental condition: Duration (days/weeks/months): Concomitant psychotherapy: Concomitant pharmacotherapy: Adherence to treatment regimen:
	Control/comparison group Comparison name: Number randomised to group: Duration (days/weeks/months): Concomitant psychotherapy: Concomitant pharmacotherapy:

(Continued)

	Adherence to treatment regimen:

Outcomes (if possible, identify if outcomes are immediate (within 6 months), short-term (> 6 months to 24 months), medium-term (> 24 months to 5 years) and long-term (beyond 5 years))	**Primary**
	• **Aggression (state or trait):** reduction in aggressive behaviour or aggressive feelings; continuous outcome or dichotomous outcome, measured through improvement in scores on the Aggression Questionnaire (Buss 1992), the Modified Overt Aggression Scale (Malone 1994), or a similar, validated instrument; or as number of observed incidents
	• **Recidivism:** continuous, dichotomous or time-to-event outcome depending on how these data are reported, measured as reconviction in terms of the overall reconviction rate or numbers reconvicted for the sample (continuous), time to reconviction/reoffending (time-to-event data), recidivism yes/no (dichotomous). Non-convicted offences identified by self-report/incident reporting etc. reported in the same way.
	• **Global state/functioning:** continuous outcome, measured through improvement on the Global Assessment of Functioning numeric scale (DSM-IV-TR)
	  ◦ Relapse
	  ◦ Time to relapse
	  ◦ No clinically important change in global state
	  ◦ Not any change in global state
	  ◦ Average endpoint global state score
	  ◦ Average change in global state scores
	• **Social functioning:** continuous or dichotomous outcome, measured through improvement in scores on the Social Adjustment Scale (Weissman 1976), the Social Functioning Questionnaire (Tyrer 2005b), or a similar, validated instrument; or a proxy measure of social functioning (e.g. decreased level of support required/time taken to achieve leave from hospital)
	• **Adverse events:** dichotomous outcome, measured as incidence of overall adverse events and of the three most common adverse events, measured as numbers reporting:
	  ◦ sudden and unexpected death;
	  ◦ natural causes of death; or
	  ◦ self-harm/injury.
	
	Secondary
	• **Quality of life:** self-reported improvement in overall quality of life; continuous outcome, measured through improvement in scores on the European Quality Of Life instrument (EuroQoL Group 1990), or a similar, validated instrument
	• **Engagement with services:** health-seeking engagement with services; continuous outcome, measured though improvement in scores on the Service Engagement Scale (Tait 2002), or a similar, validated instrument
	• **Satisfaction with treatment:** continuous outcome, measured through improvement in scores on the Client Satisfaction Questionnaire (Attkisson 1982), or a similar, validated instrument
	• **Leaving the study early:** continuous or dichotomous outcome, measured as proportion of participants discontinuing treatment:
	  ◦ for specific reasons (release, parole, move establishment, changes in security); or
	  ◦ for general reasons
	• **Substance misuse:** continuous or dichotomous outcome, measured as improvement on the Substance Use Rating Scale, patient version (Duke 1994), or a similar, validated instrument
	• **Employment status:** continuous outcome, measured as number of days in employment over the assessment period
	• **Housing/accommodation status:** continuous outcome, measured as number of days living in independent housing/accommodation over the assessment period
	• **Economic outcomes:** continuous outcome, reporting direct costs and indirect costs
	• **Impulsivity (state or trait):** self-reported improvement in impulsivity; continuous outcome, measured through reduction in scores on the Barratt Impulsivity Scale (Patton 1995), or a similar, validated instrument

(Continued)

- **Anger:** self-reported improvement in anger expression and control; continuous outcome, measured through reduction in scores on the State-Trait Anger Expression Inventory-2 (Spielberger 1999), or a similar, validated instrument
- **Mental state:** continuous outcome reporting:
  - general mental state;
  - no clinically important change in general mental state;
  - not any change in general mental state;
  - average endpoint general mental state score; or
  - average change in general mental state scores.
- **Prison and service outcomes:** continuous outcome reporting:
  - treatment of people in the community;
  - duration of treatment programme; or
  - changes in services provided by through care/probation teams
- **Other**

Statistical results

Reported means, standard deviation, standard errors, confidence intervals, F values or P values and range for key variables:

Notes	Sample size calculation:
	Power (under/adequately powered):
	Ethics approval:
	Comments from study authors
	Limitations of study
	Strengths of study
	Key conclusion of study authors
	Supplemental information regarding/data received through personal email correspondence with the authors in month/year

Any additional comments you would like to make about this study:

Risk of bias

Item	**Quote to support decision**	**Risk of bias (low, unclear, high)**

(Continued)

Random sequence generation/generation of allocation sequence (selection bias)
Allocation concealment (selection bias)
Blinding of personnel to intervention received (performance bias)
Blinding of participants to intervention received (performance bias)
Blinding of outcome assessment (detection bias)
Incomplete outcome data (ITT, imputation method) (attrition bias)
Selective outcome reporting (according to protocol?) (selection bias)
Treatment adherence
Allegiance bias
Attention bias
Vested interest (funding or author affiliations or both)
Publication bias
Language bias
Other sources of bias

ITT: intention-to-treat

Appendix 3. Detailed outcomes

Primary outcomes

There were five studies that did not report on any of the primary outcomes defined in the protocol for this review (Gibbon 2009): Woody 1985; McKay 2000; Messina 2003; Havens 2007; and Asmand 2015. Of these, only Asmand 2015 and Messina 2003 had data available for participants with antisocial personality disorder (AsPD).

Aggression

Five studies included aggression as an outcome, and used self-report or psychometric questionnaires (or both) to assess levels of state or trait aggression. Two studies included self-reported aggression as an outcome: Davidson 2009 summarised the number of participants reporting any incident of physical or verbal aggression , measured with the MacArthur Community Violence Screening Instrument interview, plus additional questions on four other behaviours (shouting angrily at others; threatening harm to others; causing damage to property; self-harm); while Thylstrup 2015 used scores on the Self-Report of Aggression and Social Behaviour Measure and the 12-item, short-form, Buss-Perry Aggression Questionnaire. Two studies, Tarrier 2010 and Feigenbaum 2012, used the Overt Aggression Scale (OAS) and modified version of the OAS, respectively. One study, Bernstein 2012, assessed levels of institutional violence via aggression and other incident records but did not report aggression data.

Reconviction

Four studies included reconviction as an outcome. Marlowe 2007 assessed re-arrests and convictions using state criminal justice databases (but had no data available for the subgroup of participants with AsPD); Nathan 2019 assessed the number and type of officially recorded offending according to the Police National Computer (PNC) (data were obtained for every offence recorded on the PNC between the point of initial release until the completion of the study; and Woodall 2007 reported drink-driving reconviction using data from the New Mexico State Citation Tracking System. Two studies included recidivism, non-convicted offences or incarceration as an outcome: Bernstein 2012 reported recidivism as a component of an overall 'negative outcome'; and Nathan 2019 assessed non-convicted offences and incident reporting of antisocial behaviour using the Self-Reported Delinquency scale.

Global state functioning

Three studies included global state functioning as an outcome: Bernstein 2012 reported a global outcome for participants as positive, negative or neutral, whereas McMurran 2016 and Tyrer 2004 used the Global Assessment of Functioning scale.

Social functioning

Eight studies included self-reported social functioning as an outcome. Tyrer 2004; Huband 2007; Davidson 2009; and McMurran 2016 reported mean scores on the Social Functioning Questionnaire. Bernstein 2012 reported the number of days to participants gaining supervised and unsupervised leave, while Tarrier 2010 assessed participants' interpersonal style via the Chart of Interpersonal Reactions in Close Living Environments. Neufeld 2008 reported composite scores on the family/social domain of the Addiction Severity Index (ASI), and Ball 2005 reported scores using the same measure but with no data available for the subgroup with antisocial personality disorder. The ASI is a semi-structured interview designed to assess problem severity in seven areas commonly affected by substance misuse difficulties, one of which is termed the family/social domain. Investigators obtained composite scores for this domain, ranging from zero to one, based on problems reported in the last 30 days. Other domains relevant to this review are those concerning alcohol use, drug use and employment problems (see 'Substance misuse' below under 'Secondary outcomes').

Adverse events

Seven studies reported on adverse events: Feigenbaum 2012 reported self-harm and suicide attempts; Marlowe 2007 noted the absence of any study-related adverse events; McMurran 2016 reported incidents of death, self-harm and hospitalisation; Nathan 2019 reported incidents of death ; Priebe 2012 reported the number of days and type of self-harm; Thylstrup 2015 reported number of deaths and incarceration; and Tyrer 2004 reported number of completed suicides and frequency of self-harm episodes via the Parasuicide History Interview.

Secondary outcomes

Studies varied widely in their use of the secondary outcomes considered in this review.

Quality of life

Three studies reported quality of life as an outcome measure: McMurran 2016 used the European Quality of Life-5 Dimensions to calculate quality-adjusted life-years; Priebe 2012 reported scores on the Manchester Short Assessment of Quality of Life; and Tyrer 2004 reported scores on the Euro Quality of Life.

Engagement with services

Four studies reported on engagement with services as an outcome. Bernstein 2012 reported use of the Treatment Engagement Rating Scale for Forensic Outpatient Treatment; Havens 2007 reported numbers entering into drug addiction treatment services; McMurran 2016 reported the number of completers and non-completers, and the mean number of weeks in the trial; and Neufeld 2008 reported adherence to counselling sessions.

Satisfaction with treatment

Only one study, Davidson 2009, examined satisfaction with treatment as an outcome: the investigators used a semi-structured interview to enquire about 'satisfaction with taking part in study' and rated responses on a Likert scale from 1 to 7.

Leaving the study early

Thirteen studies reported on leaving the study early, measuring this as the number/proportion of participants discontinuing treatment before endpoint. Of these 13, only four studies had data available for participants with AsPD (Messina 2003; Neufeld 2008; Davidson 2009; Thylstrup 2015).

Substance misuse

To aid interpretation, we considered 'substance misuse' as two separate outcomes: 'substance misuse - drugs' and 'substance misuse - alcohol' (see section on Differences between protocol and review). Five studies examined 'substance misuse - drugs' using the drug use domain of the ASI (Woody 1985; McKay 2000; Marlowe 2007; Neufeld 2008; Thylstrup 2015), the Cocaine Relapse Interview (McKay 2000), and urinalysis (McKay 2000; Messina 2003; Marlowe 2007; Neufeld 2008). Five studies examined 'substance misuse - alcohol' using the alcohol use domain of the ASI (McKay 2000; Neufeld 2008; Thylstrup 2015), the Alcohol Use Disorders Identification Test (Davidson 2009) , the Form 90 (a time-line follow-back self-report method to assess drinking over the previous 90 days), and the Drinker Inventory of Consequences (Woodall 2007). In addition, Woodall 2007 reported the frequency of drink-driving in 30 days prior to arrest, or in previous 30 days, measured via questionnaire.

Employment status

Two studies considered employment status: McMurran 2016 reported number of days in employment over the assessment period and the number of days lost from work as a result of health problems (absenteeism); while Neufeld 2008 reported mean composite scores on the employment domain of the Addiction Severity Index.

Housing/accommodation status

None of the 19 included studies considered housing/accommodation status as an outcome.

Economic outcomes

Four studies considered direct economic outcomes: Davidson 2009 examined the total cost per participant of healthcare, social care and criminal justice services, measured using case records and the Client Service Receipt Inventory (CSRI); McMurran 2016 and Priebe 2012 reported the cost of services (direct and indirect) for health and social care service utilisation using CSRI, although neither study presented data for the subset with AsPD; McMurran 2016 also examined the cost impact of absence from work ; and Tyrer 2004 calculated total costs per participant, including costs incurred by all service-providing sectors and productivity losses resulting from time off work due to illness, although with no data available for the subgroup with dissocial personality disorder. One additional study, Feigenbaum 2012, provided indirect economic outcomes in the form of service use (e.g. inpatient bed days, accident and emergency department visits) but did not attribute costs to these data, while another study, Bernstein 2012, mentioned economic outcomes in the discussion section of their study only but did not provide any data.

Impulsivity

Two studies measured self-reported trait impulsivity using mean scores on the Barratt Impulsiveness Scale (BIS) (Huband 2007) and BIS-II (Tarrier 2010).

Anger

Four studies included a self-reported measure of anger: Davidson 2009 provided mean scores on the Novaco Anger Scale and Provocation Inventory (NAS-PI); Feigenbaum 2012 and Huband 2007 provided mean anger expression index scores using the State-Trait Anger Expression Inventory (STAXI) (STAXI for Feigenbaum 2012 and STAXI-2 for Huband 2007); and Tarrier 2010 reported scores on the NAS.

Mental state

Nine studies measured general mental state. Two studies reported depression scores using the Beck Depression Inventory (BDI) (Woody 1985) or BDI-II (Feigenbaum 2012). Eight studies measured both anxiety and depression symptoms using the 'Beck Anxiety Questionnaire' *(sic)* (Beck Anxiety and Depression Scale) (Asmand 2015) or the Hospital Anxiety and Depression Rating Scale (Davidson 2009; McMurran 2016); or generally using the Brief Symptom Inventory (Ball 2005; Priebe 2012), the Symptoms Checklist (Woody 1985; Bernstein 2012), or the Brief Psychiatric Rating Scale (Tarrier 2010; Priebe 2012). One study, Feigenbaum 2012, reported total scores on the Clinical Outcomes in Routine Evaluation-Outcome Measure and post-traumatic stress disorder symptoms.

Nine studies measured psychiatric symptoms. Four studies assessed early maladaptive schemas and schema modes using the Early Maladaptive Schema Questionnaire-Research (Ball 2005), Young Schema Questionnaire-Short version (Tarrier 2010; Bernstein 2012), Schema Mode Inventory (Bernstein 2012), or the Brief Core Schema Scales (Davidson 2009). Ball 2005 also reported on interpersonal problems via the Inventory of Interpersonal Problems and on the severity of personality disorder via the Personality Diagnostic Questionnaire. Bernstein 2012 additionally reported personality disorder symptoms on the Structured Interview for DSM-IV Personality Disorders, and patient and informant versions of Schedule for Nonadaptive and Adaptive Personality. Feigenbaum 2012 and Huband 2007 assessed dissociation using the Dissociative Experiences Scale. Huband 2007 also reported on shame using the Experience of Shame Scale, and both Huband 2007 and McMurran 2016 reported on social problem-solving ability via Social Problem Solving Inventory-Revised. Priebe 2012 reported borderline personality disorder symptoms using Zanarini Rating Scale for Borderline Personality Disorder and Tarrier 2010 reported antisocial personality traits using the Antisocial Personality Questionnaire.

Other relevant outcomes

Asmand 2015 reported illogical/irrational beliefs using the 'Jones Illogical Beliefs Questionnaire' *(sic)* (Jones Irrational Belief Questionnaire). Therapy retention was measured as total weeks in treatment (Ball 2005), as adherence to counselling sessions (Neufeld 2008) or as the proportion therapeutically transferred over to routine care due to poor/partial treatment response in response to ongoing drug use or poor attendance to scheduled services (Neufeld 2008). The mean number of continuing care sessions attended was additionally reported by McKay 2000 , and McMurran 2016 also examined the strength of the therapeutic alliance using the Working Alliance Inventory . Risk of violence was assessed by Bernstein 2012 and Tarrier 2010 using the Historical Clinical Risk Management - 20 and the Violence Risk Scale; Bernstein 2012 also used the Short-term Assessment of Risk and Treatability, and Tarrier 2010 also used the Institutional Behaviour Rating Scale.

WHAT'S NEW

Date	Event	Description
29 June 2020	New citation required but conclusions have not changed	We added eight new studies to the review. The conclusions of the review have not changed.
5 September 2019	New search has been performed	The review was updated following a new search on 29 September 2016, and top-up searches on 31 October 2017, 3 October 2018 and 5 September 2019.

HISTORY

Protocol first published: Issue 1, 2009
Review first published: Issue 6, 2010

Date	Event	Description
25 August 2020	Amended	Minor changes in response to copy editing
2 November 2017	Amended	Searches updated and full revision of data and analyses

CONTRIBUTIONS OF AUTHORS

Simon Gibbon selected studies for inclusion, extracted data, assessed risk of bias, rated the certainty of the evidence, provided a clinical perspective, and helped to write and revise the final review. Simon Gibbon is the guarantor for the review.

Lucy McCarthy coordinated the review, selected studies for inclusion, obtained papers, extracted data, corresponded with study authors for additional information, entered data into Review Manager (Review Manager 2014), assessed risk of bias, rated the certainty of the evidence, interpreted the data, and wrote and revised the final review.

Natalie Cheung selected studies for inclusion, extracted data, assessed risk of bias, rated the certainty of the evidence, and contacted authors of papers for additional information.

Najat Khalifa selected studies for inclusion, extracted data, assessed risk of bias and rated the certainty of the evidence.

Birgit Vollm obtained and reviewed reports of studies published in the German language and provided resources for the review.

DECLARATIONS OF INTEREST

Simon Gibbon - none known.

Lucy McCarthy is a former colleague of the authors of Huband 2007 and is acknowledged in that study. She was not involved in the assessment of eligibility, extraction of data, or assessment of 'Risk of bias' for that study. However, she was involved in the GRADE assessment, but this was independently reviewed by Simon Gibbon.

Natalie H-Y Cheung - none known.

Najat Khalifa - none known.

Birgit A Völlm - none known.

Disclaimer: The results of a Cochrane Review can be interpreted differently depending on people's perspectives and circumstances. Please consider the conclusions presented carefully. They are the opinions of review authors, and are not necessarily those of the NHS or the Department of Health.

SOURCES OF SUPPORT

Internal sources

- Nottinghamshire Healthcare NHS Foundation Trust, UK

  Provided financial support for the time of LM, SG, NC and NK to facilitate review.

External sources

- None, Other

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

This review differs from the original protocol (Gibbon 2009) and previous review (Gibbon 2010) in the following ways.

Authorship

- For this update, the following review authors stepped down: Conor Duggan, Jutta Stoffers, Nick Huband, Michael Ferriter, and Klaus Lieb. They were replaced by Najat R Khalifa, Natalie H-Y Cheung, and Lucy McCarthy.

Types of participants

- For this update, we added an additional restriction to this section to apply to studies where participants with antisocial or dissocial personality disorder formed a small subgroup. This required that studies included in the review should have randomised at least five people with antisocial or dissocial personality disorder. The rationale was that variance and standard deviation cannot be calculated in samples of two or less, and so a two-condition study randomising fewer than five (relevant) participants would have at least one arm for which the standard deviation could not be calculated (Newman 1939).
- We included in this update, studies where the AsPD group or subgroup data were not available, but where at least 75% of participants had a diagnosis of AsPD. We chose a threshold of 75% as this appeared pragmatic and reflects that the overwhelming majority of participants have AsPD; these data were analysed separately.

Types of outcome measures

- For this update, we:
  - modified the social functioning criteria to include also proxy measures of social functioning to reflect clinically relevant changes (e.g. decreased level of support required/time taken to achieve leave from hospital);
  - modified the outcome of 'substance misuse', so that a reader would find it easier to differentiate drug misuse outcomes from alcohol misuse outcomes (specifically, we replaced it with two separate categories: 'substance misuse - drugs' and 'substance misuse - alcohol');
  - added two additional secondary outcomes 'mental state' and 'prison and service outcomes' to collect data on outcomes relevant to participants' general mental health symptoms (i.e. specific symptoms such as dissociative experiences, mood/anxiety, or global mental health) and use of prison/probation services (e.g. treatment of people in the community, duration of treatment programme, changes in services provided by or through care/probation teams), respectively;
  - reported other outcomes measured in the included studies that did not fall into one of the above categories (continuous or dichotomous outcomes dependent upon how the outcomes were reported); and
  - took the decision to exclude any study that did not report any of our primary or secondary outcomes, as any additional outcomes would be considered to be clinically irrelevant, trivial or potentially confusing, and the review is already looking at a large number of clinically-relevant outcomes (five primary outcomes and 12 secondary outcomes).
- We acknowledge that there was an oversight in the original protocol regarding the possible use of dichotomous or time-to-event data for certain outcomes (e.g. reconviction, leaving the study early and adverse events); these outcomes are more likely to be dichotomous (or time-to-event), rather than continuous, data.

Search methods for identification of studies

- In the previous version of the review (Gibbon 2010), we added the National Criminal Justice Reference Service Abstracts Database, to capture relevant studies in the justice and drug-related literature.
- For this update, we revised:
  - the list of electronic databases because we either no longer had access (ASSIA, BIOSIS, Dissertation Abstracts which we replaced with WorldCat, National Criminal Justice Reference Service Abstracts which we replaced with Criminal Justice Abstracts), or because previous searches were unproductive (OpenSIGLE, now OpenGrey, COPAC, which has since been replaced by Library Hub Discover.and Zetoc);
  - added two daily updated segments of MEDLINE (MEDLINE Epub Ahead of Print and MEDLINE In-Process & Other Non-Indexed Citations), which were unavailable last time;

- used the *Cochrane Database of Systematic Reviews* and DARE, to identify other relevant systematic reviews, in order to search their reference lists;
- did not search the specialised register of the Cochrane Schizophenia group because people with comorbid major functional mental illnesses (including schizophrenia) were excluded from this review; and
- searched trials registers using WHO ICTRP as metaRegister of Controlled Trials was no longer available.

Data collection and analysis

- This update omits six analyses specified in the original protocol because of insufficient data (see Table 5).
- In this update, we added the following new methods, which we may use in future updates of this review (see Table 5).
  - We may consider widening the range of interventions examined in future reviews to include concepts such as 'motivation to change', in order to assess the impact, if any, this would have on producing a behaviour change.
  - Contrary to the protocol (Gibbon 2009), we have specified that we will summarise change-from-baseline ('change score') data alongside endpoint data where these are available in future updates of this review, and combine both data types in a meta-analysis using the methods described by Da Costa 2013 since both types may be included together in meta-analysis when using the MD (Higgins 2011a, p 270). However, we have specified that we would prefer change-from-baseline data to endpoint data if their distribution is less skewed, and that where the data are insufficient for meta-analysis, we will report the results of the trial investigators' own statistical analyses comparing treatment and control conditions using change scores. We prefer change scores because they are more efficient and powerful than end scores.
  - To reduce ambiguity, we clarified that we would only draw funnel plots when there are more than 10 studies included in a meta-analysis.
  - Where a meta-analysis is undertaken, we will assess the impact of including studies with attrition rates greater than 50% through a sensitivity analysis. If inclusion of data from this group results in a substantive change in the estimate of effect of the primary outcomes, we will not add the data from these studies to trials with less attrition and will present them separately. Any imputation of data will be informed, where possible, by the reasons for attrition where these are available. We will interpret the results of any analysis based in part on imputed data with recognition that the effects of that imputation (and the assumptions on which it is based) can have considerable influence when samples are small. In studies with less than a 50% dropout rate, we will consider people leaving early to have had the negative outcome, except for adverse effects such as death.
  - We will consider pooling outcomes reported at different time points where this does not obscure the clinical significance of the outcome being assessed.
  - We explained how we would manage issues of multiplicity should they arise in future updates of the review, as this was missing from the protocol.
  - We have specified that we will conduct a sensitivity analysis of studies with data where at least 75% of participants have a diagnosis of antisocial personality disorder in order to test its impact on the results.

Summary of findings and assessment of the certainty of the evidence

In keeping with current recommendations, we included a new section on 'Summary of findings and assessment of the certainty of the evidence' in this update, in which we explain how we assessed the certainty of the evidence for clinically relevant outcomes and summarised these in a 'Summary of findings' table.

INDEX TERMS

Medical Subject Headings (MeSH)

Aggression [psychology]; Antisocial Personality Disorder [mortality] [*therapy]; Cocaine-Related Disorders [therapy]; Cognitive Behavioral Therapy [methods]; Driving Under the Influence; Prisoners [statistics & numerical data]; Psychotherapy [*methods]; Randomized Controlled Trials as Topic; Recidivism [statistics & numerical data]; Reward; Treatment Outcome

MeSH check words

Adult; Female; Humans; Male