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Title: THE PSYCHOLOGICAL AND PSYCHOSOCIAL INTERVENTIONS OFFERED TO FORENSIC MENTAL HEALTH IN-PATIENTS: A SYSTEMATIC REVIEW

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THE PSYCHOLOGICAL AND PSYCHOSOCIAL INTERVENTIONS OFFERED TO FORENSIC MENTAL HEALTH IN-PATIENTS: A SYSTEMATIC REVIEW

Abstract

Objective: To examine the evidence for the use of psychological and psychosocial interventions offered to forensic mental health in-patients.

Design: CINAHL, MedLine, PsycINFO, ScienceDirect, and Web of Science databases were searched for research published in English between 1 January 1990 and 31 May 2018.

Outcome measures: Disturbance, mental well-being, quality of life, recovery, violence/risk, satisfaction, seclusion, symptoms, therapeutic relationship and ward environment. There were no limits on the length of follow up.

Eligibility criteria: We included randomised controlled trial (RCT) studies of any psychological or psychosocial intervention in an in-patient forensic setting. Pilot or feasibility studies were included if a RCT design was used.

We restricted our search criteria to in-patients in low, medium, and high secure units aged over 18. We focused on interventions considered applicable to most patients residing in forensic mental health settings.

Data extraction and synthesis: Two independent reviewers extracted data and assessed risk of bias.

Results: 17,232 citations were identified with 195 full manuscripts examined in detail. Nine papers were included in the review. The heterogeneity of the identified studies meant that meta-analysis was inappropriate. The results were presented in table form together with a narrative synthesis. Only 7 out of 91 comparisons revealed statistically significant results with no consistent significant findings. The most frequently reported outcomes were violence/risk and symptoms. 61% of the violence/risk comparisons and 79% of the symptom comparisons reported improvements in the intervention groups compared to the control groups.

Conclusions: Current practice is based on limited evidence with no consistent significant findings. This review suggests psychoeducational and psychosocial interventions did not reduce violence/risk but there is tentative support they may improve symptoms. More RCTs are required with: larger sample sizes, representative populations, standardised outcomes and control group interventions similar in treatment intensity to the intervention.

Prospero Database Registration No: 42017067099

Strengths and limitations of this study

- This is the first published review examining psychological or psychosocial interventions that could be accessed by the majority of forensic mental health in-patients.
- Good quality RCTs are able to be undertaken in forensic settings to examine psychological and psychosocial interventions.
- Current practice is based on limited evidence with no consistent findings.
- Future large-scale trials are necessary to evaluate these interventions.

Introduction

Forensic mental health care is distinct from other psychiatric services¹. Patients in forensic mental health in-patient services are a complex group with a strong likelihood of presenting with multiple problems and a range of offending behaviours. These patients are generally subject to mental health or criminal justice legislation. Forensic mental health services tasked with the rehabilitation of this group of patients have additional roles to those of generic adult mental health services² with a dual rehabilitative role; providing interventions to restore mental well-being while reducing the risk posed by individuals in preparation for discharge to conditions of lower security³.

The therapies used with forensic mental health patients are generally based on research with non-offending patients in general mental health settings. The majority of these are not empirically tested in forensic populations. Reviewers have questioned the appropriateness of transposing these treatments⁴ with interventions viewed as effective in non-forensic settings having little or no effect in forensic settings⁵. This raises doubts about the efficacy of interventions used in a forensic mental health context.

Previous reviews of interventions in forensic units have focused on specific populations such as patients with personality disorder^{6,7} or sex offenders^{8,9}. However, there have been no published reviews examining psychological or psychosocial interventions that could be accessed by the majority of forensic mental health in-patients. Determining whether forensic interventions are effective is imperative to support the principle of evidence based practice in forensic services. Randomised controlled trials are the preferred option for generating this evidence and, though acknowledging a controlled trial design is hard to achieve in a secure in-patient setting, other specialities have overcome these challenges¹⁰. This review examines psychological and psychosocial interventions offered to forensic mental health in-patients. We focused on those interventions not specific to one offending type and so considered applicable to most patients residing in forensic mental health settings.

Methods

This systematic review followed a pre-specified protocol and is reported according to PRISMA guidelines.

Intervention and Outcomes – We included all studies reporting the results of a psychological or psychosocial intervention. These were defined broadly. Psychological interventions refer to treatments based on a theory of psychological functioning while psychosocial interventions represent less specific interventions designed to improve mental health through general support, advice, and encouragement¹¹. This includes psychoeducational strategies, cognitive behavioural therapy, interpersonal psychotherapy, non-directive counselling, supportive interactions and tangible assistance, through individual or group sessions¹². We were interested in ten outcomes: disturbance, mental well-being, quality of life, recovery, violence/risk, satisfaction, seclusion, symptoms, therapeutic relationship and ward environment. The outcomes were based on the rated importance of outcome domains for forensic mental health research¹³ and the suitability of assessing these outcomes in forensic in-patient settings. There were no limits on the length of follow up.

Study Design – We only included randomised controlled trial studies. Pilot or feasibility studies were included if a randomised controlled trial design was used.

Data Collection – The title and abstracts of studies identified through the search strategy were screened for eligibility by one reviewer using the inclusion criteria. The second reviewer independently screened a 20% random selection of the studies. Any disagreements were resolved through discussions between the two reviewers. Full text articles were obtained for all studies meeting the initial eligibility criteria. All full text articles were then examined independently by both reviewers to determine their eligibility for inclusion in the review. Reference lists of all relevant articles were also searched. A data extraction sheet was developed to enable assessment and synthesis of the included studies.

Registration Details - We registered the protocol of our systematic review on 21 May 2017 on the PROSPERO database. The registration number for this review is 42017067099 available at http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42017067099.

Search Strategy – The focus of the review was to examine psychological and psychological interventions in forensic mental health settings. CINAHL, MedLine, PsycINFO, ScienceDirect, and Web of Science databases were searched. We searched for peer-reviewed articles, working

papers and policy reports, published in English between 1 January 1990 and 31 May 2018. The following search terms were used:

psychiatr* OR mental*

AND

forensic OR secure OR disordered OR offender*

AND

psycholog* OR psychosocial* OR therap*

AND

quality OR wellbeing OR satisfaction OR recovery OR behavio* OR disturb* OR violen* OR seclusion OR abscond* OR symptom* OR environment OR atmosphere

AND

RCT OR random* OR control* OR placebo OR TAU

Inclusion and Exclusion Criteria – We included any psychological or psychosocial intervention given as an individual or group treatment in an in-patient forensic setting. We excluded interventions focusing specifically on a specific cohort (i.e sex offenders) as we were interested in examining approaches appropriate for the vast majority of in-patients in secure units.

We restricted our search criteria to forensic in-patients in low, medium, and high secure units aged over 18. Our exclusion criteria included community settings where patients received treatment outside of the forensic unit or resided outside of the forensic unit when they were not receiving treatment. However, as detailed in the results section, we decided to include one study where a minority of the participants were residing in the community. We also excluded prison settings which are not deemed places of treatment under the Mental Health Act.

Risk of bias summary - We used the Cochrane Risk of Bias tool¹⁴ to evaluate six domains of bias: selection bias (random sequence of generation and allocation concealment), performance bias (blinding of participants and personnel), detection bias (blinding of outcome assessment), attrition bias (incomplete outcome data), reporting bias (selective outcome reporting), and other bias. The risk of bias for each domain was rated as high (seriously weakens confidence in the results), low (unlikely to seriously alter the results) or unclear. The risk of bias assessment was conducted by the authors separately. There was an average of 1-2 domain ratings per study where there was an initial disagreement. In all cases, the reviewers discussed and agreed the ratings without involving a third party reviewer.

Data synthesis – Meta-analysis was initially planned but was considered inappropriate because of the heterogeneity of the identified studies due to: the different characteristics of the participant in-patient populations, the different types of approach used by the intervention and control groups, and the different outcome measures being used. We therefore present the results in table form together with a narrative synthesis.

Patient and public involvement

Patients and the public were not involved in the design or analysis of this review.

Results

Our search of the five databases yielded 33,321 hits with 17,232 hits recorded once duplicates were removed. A Flow Chart detailing the screening process is shown in Figure 1.

The number of hits recorded for each database was:

- Cinahl – 103
- Medline – 11,951
- PsychInfo – 850
- Science Direct – 2,189
- Web of Science – 18,228

From this number, a total of 195 papers were selected to be examined in more detail for eligibility for inclusion in the review. Of these, 13 full text papers were considered¹⁵⁻²⁷. The other 182 studies retrieved did not meet the inclusion criteria due to: the study not being a RCT, the study population not based in forensic in-patient settings, the intervention not psychological or psychosocially focused or a sex-offending intervention. From the 13 papers we considered in full, four were eventually excluded leaving nine papers chosen for inclusion in the review. Three papers were excluded because a quasi-experimental design was used^{17,20,24}. The fourth study was excluded as schema modes were the only outcomes reported²⁶.

Study setting and characteristics

The trials' characteristics are shown in Table One. The trials involved 523 participants with a median sample size of 63, ranging from 14 to 112. Five studies included women with a total of 37 participants accounting for 7.1% of the overall sample. All participants were individually randomised except for one study²³ where cluster randomisation was used. Eight studies were conducted in the UK, two in the Netherlands, one in Finland and one in Canada. Four studies were conducted in high secure settings and three studies in medium secure settings. The other two

studies were conducted in a combination of high, medium and low secure settings including one study where a minority of the participants were living in the community²¹. Four of the studies included participants diagnosed with schizophrenia or a psychotic disorder, three studies included participants with a diagnosis of personality disorder and two studies included participants from both diagnostic groups.

Table One: Characteristics of Included Studies

Authors	Country	Setting	Inclusion criteria	Number	Withdraw /drop out	Intervention	Control	Other
Aho- Mustonen et al ¹⁵	FN	High Secure	Schizophrenia, schizo-affective	39 total 35 men 4 women	1 Int 2 TAU ITT - Unsure	Psycho-education programme 8 weekly sessions Therapists - 2 psychologists who completed 2 day training programme. Fidelity reported	TAU	
Bernstein et al ¹⁶	NL	High secure	Personality Disorder	35 All men	5 Not sure which arm. ITT - Yes	Three years of Schema Therapy usually delivered twice a week. Therapists completed 8 day training programme and 2 x monthly supervision groups. Fidelity reported.	TAU. clinics free to choose Typically a form of cognitive- behavioural, psychodynamic or humanistic psychotherapy	Part of a long term study of 102 patients.
Cullen et al ¹⁸ . Some outcomes reported in Cullen et al ²⁸	UK	Medium Secure	schizophrenia, schizoaffective disorder, bipolar disorder, or other psychotic disorder); a history of violence; no prior participation in R&R program previously	84 All men	31 Int 4 TAU 23 out of 44 (52.3%) did not complete treatment ITT –yes	Reasoning and Rehabilitation programme structured, manualised programme. Minimum of 36 two- hour sessions (2 or 3 per week). Therapists -experienced staff who received 3-5 days' training from programme authors. Fidelity reported	TAU	Small sample size and low base rates of violent behaviour reducing likelihood of effect sizes. randomisation occurred within sites, and may have led to contamination across treatment. Possibility of bias as it was not possible to blind researchers to allocation status. 23% of referred patients refused to participate in the study.
Doyle et al ¹⁹ Some outcomes reported in Tarrrier et al ²⁹	UK	High secure	Personality Disorder	63 total All men	At 36 mths 19 Int 14 TAU At 24 mths 14 Int ITT - Yes	Schema Focused Therapy. Weekly one hour sessions for at least 18 months. Therapists were 2 experienced cognitive therapists who received specialist SFT training with ongoing supervised practice and supervision. Fidelity reported – uncertain therapist competence	TAU. >14 reported. Group-based enhanced thinking skills and sex offender treatment the most frequently provided	Problems recruiting participants and refusing to be interviewed or filling in forms incorrectly (37 out of initial 136 pts considered – 29.4%). High attrition; poor statistical power; insufficient frequency of ST; and the provision of ST

								by only two therapists.
Haddock et al ²¹	UK	High, medium & low secure and community 48 (62.3%) in secure settings	Schizophrenia, schizo-affective, History of violent behaviour	77 total 66 men (85.7%) 11 women (14.3%)	9 in total Unclear regarding which groups. ITT – Yes.	CBT 25 sessions Therapists experienced in CBT for people with psychosis, received training in the protocol and supervision. Fidelity assessed.	Social activity therapy 25 sessions Fidelity assessed	108 of whom were identified as meeting initial inclusion criteria. Thirty-one refused to be assessed to determine eligibility (28.7%).
Hakvoort et al ²²	NL	High secure	Personality Disorder Addictions No previous TBS admission	14 Total All men	2 ITT - Unsure	Cognitive-behavioural music therapy and anger management 20 x 1 hr weekly sessions. 5 therapists experienced in CBT music therapy in forensic psychiatry. Trained on a standard protocol. Fidelity assessed	TAU Most also received anger management sessions 3hrs per week.	6 out of 21 identified refused to participate (28.6%)
MacInnes et al ²³	UK	Medium Secure	Schizophrenia, schizo-affective, bipolar, depression psychosis & personality disorder	112 total 91 men (85%) 16 women (15%) 5- Data missing	Int 7 (13%) 6 mhs 8 (15%) 12mths TAU 15 (26%) 6 mhs 15 (26%) 12mths ITT - Yes	Computer aided solution focused brief therapy 6 X 1 hr monthly session. Staff trained in SFBT techniques. Fidelity assessed.	TAU	Significantly more women withdrew from the study.
Tomlinson & Hoaken ²⁵	CAN	Medium Secure	Pts experiencing emotional dysregulation Schizophrenia, schizo-affective, bipolar, depression psychosis & personality disorder	18 total 14 men (78%) 4 women (22%)	Int 3 (33%) TAU 2 (22%) ITT - Unsure	DBT skills training sessions provided weekly for 1.5 hr for six months (24 total sessions). Followed training manual. 1 hour weekly staff consultation groups Fidelity not reported.	TAU	
Walker et al ²⁷	UK	High, medium & low secure	Schizophrenia, schizo-affective, bipolar, depression & psychosis	81 total 79 men 2 women	16 Int 0 TAU ITT - Unsure	Psycho -education programme 2 sessions per week for 11 weeks. Therapists - Consultant Psychiatrist and Clinical Nurse Specialist. Fidelity not reported	TAU No psychological interventions but able to attend social and occupational activities	Recruitment problems 26 out of 107 (24.3%) eligible participants not included. Recorded as not randomised.

Types of intervention

Five broad types of intervention were undertaken (Cognitive Behaviour Therapy, Dialectical Behaviour Therapy, Psychoeducation, Schema Focused Therapy and Solution Focused Brief Therapy):

Cognitive Behaviour Therapy (CBT)

Three studies used this approach. The aim of cognitive/behavioural treatment programmes in forensic mental health settings is to change the criminogenic thinking of offenders³⁰.

Cullen et al¹⁵ based their intervention on the “Reasoning and Rehabilitation” (R&R) programme developed in Canada and sought to teach offenders a range of cognitive and behavioural skills³¹.

Haddock et al²¹ used a manualised CBT programme including motivational strategies to aid engagement, strategies to reduce the severity and distress of psychotic symptoms and the severity of anger linked to aggression and violence.

Hakvoort et al²² focused on cognitive-behavioural music therapy and focused on minimizing risk and addressing the treatment needs of forensic psychiatric patients.

Dialectical Behaviour Therapy (DBT)

One study by Tomlinson and Hoaken used this approach. DBT³² blends validation and acceptance strategies with change-focused CBT²⁰. The study focused on DBT skills training to reduce aggression.

Psycho-education

This was the intervention in two studies. Education is offered to individuals with psychological disorders with interventions varying from the delivery of simple information through leaflets, emails or information websites to active multi-session group-intervention with therapist guidance and practice exercises³³.

Aho-Mustonen et al¹⁵ used a manualised psychoeducational programme.

Walker et al’s intervention²⁷ was based on a training manual developed by the State Hospital, Carstairs where the study was based³⁴.

Schema Focused Therapy (SFT)

Two studies employed schema focused therapy. This integrated therapy was specifically developed for people with personality disorder combining cognitive behaviour therapy with attachment, gestalt, object relations, constructivist and psychoanalytic approaches³⁵.

Bernstein et al¹³ focused on the emotional states (“schema modes”) most common in forensic patients with personality disorders that were hypothesized to play a role in violence and criminality. The goal of the intervention was to reduce the patient’s reliance on maladaptive coping modes.

Doyle et al's intervention¹⁶ was an adaptation of Young and colleagues treatment protocol for patients with personality disorder³⁵.

Solution Focused Brief Therapy (SFBT)

This was used by one study. MacInnes et al²³ used a computer assisted approach using SFBT. The therapy promotes movement toward positive change in individuals and is characterised by a focus on the future exploring what will be different when things are better³⁶.

Effect of Intervention

The outcomes of the interventions are reported in Table Two while an overview of whether the intervention reported improved or worse outcomes is shown in Table Three.

Table Two: Table of Outcomes

Outcome	Authors	Measure	Intervention Time point Mean scores (sd) OR Number of events*	Control	Estimated effect (and p value if recorded)
Disturbance	Cullen et al ¹⁸	Mean No of Leave Violations	Post Treat 0.33 (0.82) 12 months Post 0.52 (0.99)	Post Treat 0.83 (2.25) 12 months post 0.60 (1.19)	Mean diff: -0.5 p= 0.02 Mean diff: -0.08 p=0.74
	MacInnes et al ²³	No of absconsions No of physical restraints	6 months Post 2 22	6 months post 7 35	Diff: -5 Diff: -13
Quality of life	Aho-Mustonen et al ¹⁵	Sintonen's 15D Health Related Quality of Life	Post Treat 0.9 (0.08) 3 months Post 0.9 (0.06)	Post Treat 0.91 (0.06) 3 months Post 0.94 (0.08)	Mean diff: -0.1 p= 0.5 Mean diff: -0.2 p= 0.09
	MacInnes et al ²³	Manchester Short Assessment of Quality of Life	Post Treat 4.5 (0.4) 6 Months Post 4.7 (0.2)	Post Treat 4.3 (0.1) 6 Months Post 4.3 (0.3)	Mean diff: 0.2 Mean diff: 0.4
	Walker et al ²⁷	Schizophrenia Quality of Life Scale Revision 4	Post Treat 30.7 (19.1) 6 months post 29 (16.6)	Post Treat 30.6 (16.1) 6 months post Not reported	Mean diff: 0.1 p = 0.20
Recovery	Aho-Mustonen et al ¹⁵	Scale to Assess Unawareness of Mental Disorder	Post Treat 4.1 (0.9) 3 months Post 3.8 (1.1)	Post Treat 4.7 (1.0) 3 months Post 4.8 (0.8)	Mean diff: -0.6p = 0.67 Mean diff: 1.0 p = 0.09
	MacInnes et al ²³	Process of Recovery Questionnaire Interpersonal Intrapersonal	Post Treat 66.4 (2.0) 18.9 (0.4) 6 Months Post 65.6 (1.0) 18.9 (0.7)	Post Treat 64.1 (2.0) 19.0 (0.7) 6 Months Post 63.9 (1.1) 19.7 (0.9)	Mean diff: 2.3 Mean diff: -0.1 Mean diff: 1.7 Mean diff: -0.8
	Walker et al ²⁷	Schedule for Assessment of Insight	Post Treat 12.2 (5.4) 6 months Post 13.5 (4.5)	Post Treat 10.7 (5.1) 6 months Post Not reported	Mean diff: 1.5 p = 0.13
Satisfaction	MacInnes et al ²³	Forensic Satisfaction Scale	Post Treat 3.3 (0.2) 6 months Post 3.3. (0.1)	Post Treat 3.3 (0.3) 6 months Post 3.3. (0.1)	Mean diff: 0 Mean diff: 0
Seclusion	MacInnes et al ²³	No of Seclusions	6 months Post 9	6 Months Post 37	Diff: -28
Symptoms	Aho-Mustonen et al ¹⁵	Beck Depression Inventory-II	Post Treat 8.1 (5.7) 3 months Post 6.4 (6.2)	Post Treat 11.2 (4.5) 3 months Post 13.1 (7.9)	Mean diff: -3.1p = 0.46 Mean diff: -6.7 p = 0.30
	Aho-Mustonen et al ¹⁵	Brief Psychiatric Rating Scale	Post Treat 27.9 (7.5) 3 months Post 26.5 (8.0)	Post Treat 28.1 (5.4) 3 months Post 28.5 (4.6)	Mean diff: -0.2 p = 0.57 Mean diff: -2.0 p = 0.76

Aho-Mustonen et al ¹⁵	Rosenberg Self-Esteem Scale	Post Treat 29.7 (3.6) 3 months Post 29.4 (2.8)	Post Treat 29.3 (2.9) 3 months Post 29.5 (4.3)	Mean diff: 0.4 p = 0.03 Mean diff: -0.1p = 0.06	
Aho-Mustonen et al ¹⁵	Nurses' Observation Scale for Inpatient Evaluation-30	Post Treat 100.6 (3.7) 3 months post 99.2 (3.8)	Post Treat 101 (4.3) 3 months Post 100.8 (3.9)	Mean diff: -0.4 p = 0.77 Mean diff: 1.6 p = 0.31	
Doyle et al ¹⁹	Brief Psychiatric Rating Scale	No raw scores reported		24 months Post ^a 0.29 p = 0.74	
Haddock et al ²¹	Global Assessment of Functioning	Post Treat 41.86 (15.63) 6 months Post 42.94(19.30)	Post Treat 33.34 (14.64) 6 months post 40.93 (22.06)	Mean diff: 8.52 Mean diff:-2.01	
Haddock et al ²¹	Positive And Negative Syndrome Scale +ve -ve General +ve -ve General	Post Treat 14.79 (5.95) 15.75 (5.70) 55.24 (12.47) 6 months post 15.03 (6.97) 15.88 (5.66) 53.97 (20.27)	Post Treat 11.66 (3.67) 13.50 (5.59) 58.68(16.14) 6 months post 12.06 (4.91) 14.31 (6.08) 57.73 (16.31)	Mean diff: 3.13 Mean diff: 2.25 Mean diff: -3.44 Mean diff: 2.97 Mean diff: 1.57 Mean diff: -3.76	
Haddock et al ²¹	Psychotic Symptom Rating Scales Auditory Delusions Auditory Delusions	Post Treat 9.74 (13.92) 4.90 (6.55) 6 months post 9.36 (12.72) 7.60 (8.25)	Post Treat 11.38(15.13) 11.04 (6.70) 6 months post 10.83(16.63) 8.38 (8.03)	Mean diff: -1.64 Mean diff: -6.14 Mean diff: -1.47 Mean diff: -0.78	
Walker et al ²⁷	Positive And Negative Syndrome Scale +ve -ve General +ve -ve General	Post Treat 12.8 (3.9) 15.2 (6.2) 27.2 (7.2) 6 months post 12.5 (7.2) 14.1 (6.3) 27.8 (10.8)	Post Treat 14.3 (6.2) 17.9 (6.9) 30.4 (9.8) 6 months post Not reported Not reported Not reported	Mean diff: -1.5 Mean diff: -2.7 Mean diff: -3.2 	
Walker et al ²⁷	Calgary Depression Scale for Schizophrenia	Post Treat 1.8 (4.4) 6 months post 1.8 (3.6)	Post Treat 2 (3.46) 6 months post Not reported	Mean diff: -0.2 p = 0.32	
Therapeutic Relationship	MacInnes et al ²³	Helping Alliance Scale	Post Treat 6.6 (0.6) 6 months Post 7.0 (0.8)	Post Treat 6.3 (0.5) 6 months Post 6.7 (0.2)	Mean diff: 0.3 Mean diff: 0.3
Violence/Risk	Bernstein et al ¹⁶	Historical, Clinical, Risk Management-20	No raw scores recorded		Higher scores in control group. No statistically significant p values reported.
	Cullen et al ¹⁸	Mean acts of aggression per patient Verbal Physical Verbal Physical	Post Treat 3.95 (8.42) 0.55 (1.38) 1 year post 7.33 (10.83) 0.90 (1.96)	Post Treat 3.53 (6.44) 0.68 (1.33) 1 year post 8.23 (15.71) 0.88 (2.00)	Mean diff: 0.42 p = 0.01 Mean diff: -0.13 p = 0.11 Mean diff: -0.9 p = 0.02 Mean diff: 0.02 p = 0.65
	Cullen et al ¹⁸	Novaco Anger Scale Cognitive Arousal Behavioural Cognitive Arousal Behavioural	Post Treat 28.5 (5.0) 24.9 (5.2) 23.8 (5.3) 1 year post 28.6 (5.4) 27.5 (6.3) 25.1 (5.4)	Post Treat 27.3 (4.9) 25.5 (5.4) 25.6 (5.7) 1 year post 27.7 (4.9) 24.7 (5.3) 24.2 (4.8)	Mean diff: 1.2 Mean diff: -0.6 Mean diff: -1.8 Mean diff: 0.9 Mean diff: 0.8 Mean diff: 0.9
	Doyle et al ¹⁹	Mean acts of Physical, verbal or property aggression	Post Treat 2.32	Post Treat 1.32	Mean diff: 1.0
	Doyle et al ¹⁹	Novaco Anger Scale Cognitive Arousal Behavioural	No raw scores reported		24 months Post ^a -0.57 p = 0.47 -0.92 p = 0.35 0.44 p = 0.65

		Total			0.27 p = 0.91
Doyle et al ¹⁹		Historical, Clinical, Risk Management-20			24 months Post ^a
		Risk Clinical	No raw scores reported		0.12 p = 0.73 -0.19 p =0.69
Doyle et al ¹⁹		Violence Risk Scale Total	No raw scores reported		24 months Post ^a -3.43 p =0.04
Haddock et al ¹¹		No. of Incidents of Aggression	Post Treat	Post Treat	
		Verbal	31	103	Diff: -72 p = 0.15
		Physical	2	46	Diff: -44 p = 0.039
			6 months post	6 months post	
		Verbal	34	80	Diff: -46 p =0.765
		Physical	5	22	Diff: -17 p = 0.594
Haddock et al ²¹		Ward Anger Rating Scale B	Post Treat 4.03 (4.19) 6 months post 4.2 (4.65)	Post Treat 6.36 (6.79) 6 months post 6.3 (8.00)	Mean diff: -2.33 Mean diff: -2.1
Haddock et al ²¹		Novaco Anger Scale	Post Treat 88.13 (16.88) 6 months post 85.51 (17.33)	Post Treat 82.36 (20.12) 6 months post 84.41 (22.62)	Mean diff: 5.77 Mean diff: 1.1
Haddock et al ²¹		Novaco Provocation Inventory	Post Treat 59.75 (18.51) 6 months post 61.65(13.15)	Post Treat 55.63 (17.51) 6 months post 58.32(18.01)	Mean diff: 4.12 Mean diff: 3.33
Haddock et al ²¹		Historical, Clinical, Risk Management 20	Post Treat	Post Treat	
		Risk Clinical	Not reported Not reported 6 months post	Not reported Not reported 6 months post	
		Risk Clinical	4.00 (3.96) 3.57 (2.54)	4.23 (2.83) 4.03 (2.64)	Mean diff: -0.23 Mean diff: -0.46
Hakvoort et al ²²		Social Dysfunction and Aggression Scale	6 months post 2.56	6 months post 2.4	Mean diff: 0.16 p = 0.34
Hakvoort et al ²²		Atascadero Skills Profiles Scale 4	6 months post 2.51	6 months post 2.01	Mean diff: 0.5 p = 0.86
MacInnes et al ²³		No of Violent Incidents	6 months post 50	6 months post 96	Mean diff: -46
Tomlinson & Hoaken ²⁵		Buss-Perry Aggression Questionnaire -SF	Post Treat	Post Treat	
		Overall	2.05 (0.47)	2.14 (0.88)	Mean diff: -0.09
		Physical	2.13 (0.90)	2.87 (1.87)	Mean diff: -0.74
		Verbal	2.07 (0.43)	1.67 (0.47)	Mean diff: 0.4
		Hostility	2.20 (0.96)	2.26 (0.95)	Mean diff: -0.06
		Anger	1.80 (0.56)	2.26 (0.89)	Mean diff: -0.46
Tomlinson & Hoaken ²⁵		Impulsive/Premeditated Aggression Scale	Post Treat	Post Treat	
		Overall	2.23 (0.21)	2.94 (0.59)	Mean diff: -0.71
		Premeditated aggression	2.00 (0.27)	2.75 (0.91)	Mean diff: -0.75
		Impulsive aggression	2.40 (0.20)	3.09 (0.57)	Mean diff: -0.89
Walker et al ²⁷		Behaviour Status Index	Post Treat 572 (99.1) 6 months post 559 (86.3)	Post Treat 535.7 (96.2) 6 months post Not reported	Mean diff: 34.3 p = 0.41
Ward environment	MacInnes et al ²³	Essen Climate Evaluation Schema	Post Treat	Post Treat	
		Pt Cohesion	8.8 (1.0)	9.3 (0.7)	Mean diff: -0.5
		Experienced safety	15.4 (1.2)	16.3 (2.4)	Mean diff: -0.9
		Therapeutic hold	10.7 (1.5)	11.6 (1.2)	Mean diff: -0.9
			6 Months Post	6 Months Post	
		Pt Cohesion	10.6 (0.2)	9.3 (0.7)	Mean diff: 1.3
		Experienced safety	16.3 (2.3)	15.4 (2.7)	Mean diff: 0.9
		Therapeutic hold	11.7 (1.0)	12.2 (0.5)	Mean diff: -0.5

Notes

^a A positive estimate indicates that the mean effect size for that variable is higher in the control group. A negative estimate (-) means that it is lower.

Aho-Mustonen et al¹⁵. The p values relate to the differences in mean change scores from baseline at post-treatment and 3-month follow-up on outcome measures between the groups.

Table Three: Type of intervention content and number of interventions effective for each outcome (n=9 studies)

	Psychoeducation		CBT		SFT		SFBT		DBT	
	Better	Worse	Better	Worse	Better	Worse	Better	Worse	Better	Worse
Disturbance	n/a	n/a	2 (1)	0	n/a	n/a	2	0	n/a	n/a
Quality of life	0	3	n/a	n/a	n/a	n/a	2	0	n/a	n/a
Recovery	2	1	n/a	n/a	n/a	n/a	2	2	n/a	n/a
Therapeutic Relationship	n/a	n/a	n/a	n/a	n/a	n/a	2	0	n/a	n/a
Satisfaction	n/a	n/a	n/a	n/a	n/a	n/a	0	0	n/a	n/a
Seclusion	n/a	n/a	n/a	n/a	n/a	n/a	1	0	n/a	n/a
Symptoms	11 (1)	1	8	4	1	0	n/a	n/a	n/a	n/a
Ward Environment	n/a	n/a	n/a	n/a	n/a	n/a	2	4 (1)	n/a	n/a
Violence /Risk	1	0	13 (2)	11 (1)	3	5 (1)	1	0	7	1

n/a – not applicable as no comparison undertaken

Time Points

All studies detailed the baseline assessments with the scores for the intervention and control group comparable at baseline. The studies also reported assessment scores immediately post treatment (except²²), at 3 months post treatment¹⁵, six month post treatment^{21,22,23,27}, and one year post treatment¹⁸. Doyle¹⁹ recorded scores at 6, 12 and 24 months and Bernstein¹⁶ at 3, 6, 12, 18, 24, 30 and 36 months

Outcomes

Nine of the ten outcomes of interest were reported in the studies. Eight studies reported violence/risk outcomes, four reported symptoms outcomes, three reported quality of life outcomes, three studies reported recovery outcome two studies reported disturbance with one study reporting on therapeutic relationship/engagement, satisfaction, ward environment/atmosphere, and seclusion. There were no reported outcomes for wellbeing.

Two of studies did not report any raw scores. Doyle¹⁹ reported the outcomes at the three different follow-up times (6, 12 and 24 months) with these analysed simultaneously in a repeated measures analysis using all available data and recording the estimated treatment effects (group differences) and p values. Bernstein¹⁶ used repeated measures ANOVA to analyse the effect of SFT versus TAU on HCR-20 scores over the course of treatment. They did not analyse other outcome variables because of the low statistical power in the sample.

Overall, there were few significant findings with only 7 reported out of 91 statistical comparisons.

Violence/Risk

Seventeen violence/risk outcomes were recorded by eight studies^{16,18,19,21,22,23,25,27}. Four significant findings were reported which was more than for any other outcome. Two significant outcomes reported an improvement for the intervention group and two for the control group with significant findings only recorded at one time point. Rates of verbal aggression reported by Cullen¹⁸ were higher in the intervention group during the treatment period with an incident rate ratio (IRR) of 0.48 (95% CI 0.28, 0.85) though higher in the control group in the 12 months post treatment with an IRR of 0.56 (95% CI 0.34, 0.91). Haddock²¹ recorded the CBT group had a significantly lower number of incidents of violence or aggression during the treatment period while Doyle¹⁹ reported that the intervention scores were significantly lower in the control group with an effect size of -3.43. No other statistically significant findings were found by these two studies using the seven other violence/risk measures. The majority of the studies examining violence/risk outcomes used a CBT or SFT intervention. The information in Table Three suggests an approximately 61% (25 out of 41) improvements were recorded in the intervention groups using these approaches. Tomlinson and Hoaken²⁵ reported reduced levels of violence self-reported aggressive behaviour using DBT as an intervention but was undertaken with a small sample with several potential risks of bias present. Overall, there does not appear to be any consistency between the significant scores recorded and little difference in the number of improvements reported.

Symptoms

Ten outcomes were recorded by four studies^{15,19,21,27} with a wide variety of different symptoms measured. Only one significant finding was reported; higher levels of self-esteem in the intervention group post treatment¹⁵. This difference was not maintained at the 3 months post treatment assessment. The main interventions reporting symptoms as outcomes used a psychoeducational or CBT approach. In Table Three, 79% of the outcomes (19 out of 24) show an improvement for those patients in receipt of an intervention. It gives some support to the view that interventions are able to improve symptoms though how much improvement is achieved or whether certain symptoms are more amenable to certain interventions is unclear.

Quality of Life

There was little difference in scores between the intervention and control groups recorded in the five outcomes reported by three studies^{15,23,27}. The psychoeducational approach was used as an intervention in two studies. All three outcomes reported a slightly lower non-significant quality of

life in the intervention. The SFBT study reported improved quality of life scores post treatment and 6 months post giving cautious support to the view this approach may be effective.

Recovery

Three studies recorded three recovery outcomes^{15,23,27}. This outcome was reported for psychoeducational and SFBT interventions with no significant differences noted. The psychoeducational outcomes reported better scores for those in the intervention group tentatively suggesting the psychoeducational approach may help recovery. The SFBT results were more equivocal.

Disturbance

Two studies recorded three different types of disturbance outcome^{18,23}. A CBT intervention¹⁸ reported less leave violations during the treatment period and remained lower (though non-significant) in the year following the end of treatment. The SFBT study²³ reported lower levels of absconsions and less physical restraints for the intervention group. These findings give initial indications these approaches may reduce levels of disturbance

Other Outcomes

Four further outcomes (satisfaction, seclusion, therapeutic relationship, ward environment/ atmosphere) were assessed by one study²³. Better therapeutic relationships were reported for the intervention group at both time points suggesting a potential improvement using this approach. There were also reduced numbers of seclusions for the intervention group during the 6 month follow up period. No differences were reported in the satisfaction scores between the intervention and control groups while the ward environment scores suggest a better atmosphere in the control group including one statistically significant result (patient cohesion) post treatment.

Risk of Bias of Evidence

The majority of domains had a low risk of bias (Figure 2). In relation to the potential of performance bias, we determined that participants and staff would be aware of which arm of the trial they have been allocated but any performance bias would be minimal. We, therefore rated these studies as having a low risk. There were difficulties with recruitment and attrition adding to the limitations of the small sample sizes of the studies. Five of the studies reported problems with recruitment with between 23%-29.4% of patients deemed as eligible refusing to participate. Three

studies were rated as high risk of attrition bias due to incomplete outcome data^{18,19,27} with two studies reporting over 50% of their intervention group not completing the sessions^{18,19}.

Six studies were able to limit detection bias through ensuring the blinding of the raters of the outcome assessments. One study where blinding was not performed acknowledged the participants may have shown social desirability bias²⁵ while another used raters who were blind to patients' treatment condition status double-scored a subset of these assessments with good levels of inter-rater agreement recorded¹³.

Discussion

Main Findings

This systematic review found a total of nine published RCTs examining psychological and psychosocial interventions in forensic mental health in-patient settings deliverable to any patient residing in a forensic mental health inpatient setting. The studies were heterogeneous resulting in a narrative review of the main findings. There were few statistically significant findings reported; only 7 out of the 91 comparisons analysed and none of these significant findings revealed a consistent result. This indicates the current evidence base for supporting any psychological or psychosocial intervention is limited. Table Three gives some indication of areas where particular interventions may have a positive benefit though, with the lack of significant differences recorded, these findings need to be treated with caution. In general, psychoeducational approaches reported improvements in recovery and symptom outcomes and poorer findings for quality of life outcomes. The CBT interventions noted improved findings for absconding and symptoms outcomes though the impact on violence/risk was more equivocal. A similar finding is noted in relation to the SFT intervention with an equal amount of better and worse outcomes recorded for measures of violence/risk. The DBT intervention show promising results for reducing violence/risk while the SFBT approach reported improved quality of life, therapeutic relationships and reduced disturbed behaviour. However, the results of both interventions are based on single small scale studies indicating more extensive studies are required to produce clearer evidence. This review suggests that psychological and psychosocial interventions do not reduce violence/risk in this group of patients though there is some tentative support that the interventions may improve mental health symptoms.

A number of other factors may have contributed to these findings: individual study designs were quite different, a variety of different secure settings were included with two studies recruiting from different levels of security^{21,27} and most studies recruited from multiple sites. The

interventions may have had different impacts due to differences in the therapeutic uses of security and related legal governance systems². The study sample sizes were small ranging from 14-112 participants. This lack of statistical power limited the ability of the study to detect treatment differences²¹. The representativeness of the findings was reduced through most studies only including participants with either a diagnosis of psychosis or personality disorder and by the small number of women participating. The paucity of women participants in forensic research has been viewed as indicative of the realities of research undertaken in this area where basic services to women were often poor or lacking³⁷. One study noted the significant number of women withdrawing from the study when compared to men and suggested examining reasons for higher dropout rates and whether specific support was required during the intervention²³. The time line of the intervention varied considerably from 8 weekly sessions of psychoeducation¹⁵ to twice weekly sessions of schema therapy for three years¹⁶. The recording of the control group intervention varied greatly and consisted of widely differing approaches. There were also differences between the number of treatment sessions with only one study offering the intervention and control groups the same number of sessions of an alternative therapy²¹. It is possible that the different treatment intensity may have influenced the outcomes¹⁶. The lack of standardised outcomes was also problematic. Thirty one outcomes measures were used with only five measures used more than once with making it difficult to draw conclusions across studies¹³.

Other reviews of research in forensic mental health settings have reported similar difficulties preventing a homogenous dataset³⁸⁻⁴¹ with few studies with enough similarities to each other to draw firm conclusions regarding the impact of interventions³⁸. Continuing with small scale research with MDOs is questionable due to these studies being underpowered and unlikely to detect differences³⁹. Future studies would benefit from larger sample sizes which include representative groups of the forensic inpatient population. It is likely multisite studies will need to be undertaken with the impact of different environments reviewed as part of the study. To increase the homogeneity of studies, future studies also need similar participants, interventions and outcome measures³⁸. Using measures that are familiar in practice might be a productive way of developing standardised outcomes¹³.

Strengths

The majority of studies included in the review had a low risk of bias indicating it is possible to conduct well designed RCTs in forensic mental health in-patient settings¹⁰. RCTs remain the gold standard for investigating the effectiveness of treatments and are needed to determine beneficial interventions for this group of patients¹⁶. The randomisation procedures worked well in the

majority of the studies. Seven studies reported on the fidelity of the intervention approach with staff trained in the specific procedures. The intervention approaches were competently performed with only one study¹⁹ noting that therapists providing the intervention may not have met relevant standards. Most studies were also able to blind researchers to allocation status when assessing outcomes.

Limitations

The review excluded non-English language publications which may have led to some relevant research not being included in the review. Some limitations were noted with recruitment and attrition. Five studies reported that approximately 25% or more of the patients approached declined to participate. It was likely the patients who declined to participate were more unwell and/or antisocial and these factors might have influenced treatment outcomes²⁸. Attrition was also a problem which is not surprising considering the high levels of anti-social behaviour and non-compliance prevalent in this cohort²⁹. Overall, 25% of participants withdrew or dropped out of the studies. In the main, those interventions that took longer to complete or that required a high level of weekly commitment recorded a greater number of drop outs and withdrawals.

Conclusions

This is the first review to specifically examine psychological or psychosocial interventions a) accessible to the majority of patients in forensic mental health in-patient settings and b) focusing only on RCTs to evaluate the effectiveness of the interventions. Nine RCTs were found. The current evidence from these studies suggests current practice is based on limited evidence with no consistent significant findings. These interventions may have the potential to improve some outcomes, particularly symptoms, using CBT or psychoeducational approaches. The individual DBT and SFBT studies also report promising results. However, the limitations in the conduct of the studies means specific psychological or psychosocial interventions cannot be supported at present. The studies' low risk of bias assessments supports the view that good quality RCTs are able to be undertaken to evaluate the effectiveness of these interventions. If more RCTs are undertaken, the evidence base will become clearer. As highlighted in our analysis, the existing evidence base is too diverse for it to be reliable. A key priority for the future is that efforts are placed in devising a standardised framework of reference for study protocols. More specifically, future trials would benefit from: a larger sample size, ensuring participants are representative of the overall forensic in-patient population, using standardised outcomes and clearly detailing

control group interventions that are similar in treatment intensity to the intervention. Further work would also be helpful to look at ways of addressing problems concerning rates of recruitment and attrition.

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Figure 1: Flow Diagram

Figure 2: Risk of Bias table