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The research reported in this issue of the journal was commissioned by the HTA programme as project number 08/101/01. The contractual start date was in May 2009. The draft report began editorial review in April 2011 and was accepted for publication in June 2011. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

A systematic review of prevention and intervention strategies for populations at high risk of engaging in violent behaviour: update 2002–8

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Background: It has been estimated that violence accounts for more than 1.6 million deaths worldwide each year and these fatal assaults represent only a fraction of all assaults that actually occur. The problem has widespread consequences for the individual and for the wider society in physical, psychological, social and economic terms. A wide range of pharmacological, psychosocial and organisational interventions have been developed with the aim of addressing the problem. This review was designed to examine the effectiveness of these interventions when they are developed in mental health and criminal justice populations.

Objective: To update a previous review that examined the evidence base up to 2002 for a wide range of pharmacological, psychosocial and organisational interventions aimed at reducing violence, and to identify the key variables associated with a significant reduction in violence.

Data sources: Nineteen bibliographic databases were searched from January 2002 to April 2008, including PsycINFO (CSA) MEDLINE (Ovid), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Allied and Complementary Medicine Database (AMED), British Nursing Index/Royal College of Nursing, International Bibliography of the Social Sciences (IBSS), Education Resources Information Center (ERIC)/International ERIC, The Cochrane Library (Cochrane reviews, other reviews, clinical trials, methods studies, technology assessments, economic evaluations), Web of Science [Science Citation Index Expanded (SCIE), Social Sciences Citation Index (SSCI), Arts & Humanities Citation Index (A&HCI)].

Review methods: The assessment was carried out according to accepted procedures for conducting and reporting systematic reviews, including identification of studies, application of inclusion criteria, data extraction and appropriate analysis. Studies were included in meta-analyses (MAs) if they followed a randomised control trial (RCT) design and reported data that could be converted into odds ratios (ORs). For each MA, both a fixed-effects model and a random-effects model were fitted, and both Q statistic and I^2 estimates of heterogeneity were performed.

Results: A total of 198 studies were identified as meeting the inclusion criteria; of these, 51 (26%) were RCTs. Bivariate analyses exploring possible sources of variance in whether a study reported a statistically significant result or not, identified six variables with a significant association. An outcome was less likely to be positive if the primary intervention

was something other than a psychological or pharmacological intervention, the study was conducted in an penal institution, the comparator was another active treatment or treatment as usual and if a between-groups design had been used. An outcome was more likely to be positive if it was conducted with people with a mental disorder. The variation attributable to these variables when added to a binary logistic regression was not large (Cox and Snell $R^2 = 0.12$), but not insignificant given the small number of variables included. The pooled results of all included RCTs suggested a statistically significant advantage for interventions over the various comparators [OR 0.59, 95% confidence interval (CI) 0.53 to 0.65, fixed effects; OR 0.35, 95% CI 0.26 to 0.49 random effects, 40 studies]. However, there was high heterogeneity {$I^2 = 86$, $Q = 279$ [degrees of freedom (df) = 39], $p < 0.0001$}, indicating the need for caution in interpreting the observed effect. Analysis by subgroups showed that most results followed a similar pattern, with statistically significant advantages of treatments over comparators being suggested in fixed- and/or random-effects models but in the context of large heterogeneity. Three exceptions were atypical antipsychotic drugs [OR 0.21, 95% CI 0.16 to 0.27, fixed effects; OR 0.24, 95% CI 0.14 to 0.43, random effects; 10 studies, $I^2 = 72.2$, $Q = 32.4$ (df = 9), $p < 0.0001$], psychological interventions [OR 0.63, 95% CI 0.48 to 0.83, fixed effects; OR 0.53, 95% CI 0.31 to 0.93, random effects; nine studies, $I^2 = 62.1$, $Q = 21.1$ (df = 8), $p = 0.007$] and cognitive behavioural therapy (CBT) as a primary intervention [OR 0.61, 95% CI 0.42 to 0.88, fixed effects; OR 0.61, 95% CI 0.37 to 0.99, random effects; seven studies, $I^2 = 21.6$, $Q = 7.65$ (df = 6), $p = 0.26$].

Limitations: The heterogenity of the included studies inhibits both robust MA and the clear application of findings to establishing improvements in clinical practice.

Conclusions: Results from this review show small-to-moderate effects for CBT, for all psychological interventions combined, and larger effects for atypical antipsychotic drugs, with relatively low heterogeneity. There is also evidence that interventions targeted at mental health populations, and particularly male groups in community settings, are well supported, as they are more likely to achieve stronger effects than interventions with the other groups. Future work should focus on improving the quality of evidence available and should address the issue of heterogenity in the literature.

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Contents

List of abbreviations

A&E	accident and emergency
BCS	British Crime Survey
BIP	Batterer Intervention Programme
BPD	borderline personality disorder
CBT	cognitive behavioural therapy
CI	confidence interval
CTS	Conflict Tactics Scale
df	degrees of freedom
DV	domestic violence
ITT	intention to treat
LiVio	Liverpool Violence Research Group
MA	meta-analysis
M-OAS	Modified Overt Aggression Scale
NICE	National Institute for Health and Clinical Excellence
OAS	Overt Aggression Scale
OR	odds ratio
RCT	randomised controlled trial
RR	relative risk
SD	standard deviation
SE	standard error
SSRI	selective serotonin reuptake inhibitor
STAXI	State-Trait Anger Inventory
TAU	treatment as usual
WL	waiting list control

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.

Executive summary

Background

Interpersonal violence is a major public health issue. It has been estimated that violence accounts for more than 1.6 million deaths worldwide each year and these fatal assaults represent only a fraction of all assaults that actually occur. Public concern about the level of interpersonal violence in society keeps the issue at the top of the political agenda in many Western countries, including the UK. Thus, the problem has serious and widespread consequences for the individual and for the wider society in physical, psychological, social and economic terms. A wide range of pharmacological, psychosocial and organisational interventions have been developed with the aim of addressing the problem. This review was designed to examine the effectiveness of these interventions when they are deployed in mental health and criminal justice populations.

Objectives

The objectives of the review were to (1) update a previous review that examined the evidence base up to 2002 for a wide range of pharmacological, psychosocial and organisational interventions aimed at reducing violence and (2) identify the key variables associated with a significant reduction in violence. The scope of the review was designed to be very broad so that a comprehensive portrayal of the current global literature could be obtained in order to inform future research, practice and policy.

Methods

Data sources

Evidence for the effectiveness of interventions in reducing violence was identified using both a comprehensive search strategy to interrogate 19 bibliographic databases and the checking of reference lists of identified reviews. The database searches covered the period from January 2002 to April 2008.

Inclusion criteria

The inclusion criteria for papers were purposefully broad to capture as wide-ranging a selection of relevant studies as possible. Studies had to evaluate an intervention aimed at reducing violence against other people. Participants had to be aged ≥ 17 years and either have a mental disorder, be offenders or have committed indictable offences. A study also had to report an outcome measure of violence either directly (e.g. reconviction for a violent offence) or indirectly through a proxy measure (e.g. a validated anger measure).

Data extraction

Data extraction was carried out independently by nine reviewers, with regular meetings to co-ordinate activity and to explicitly cross-check extracted data. Data from each study relating to study design, sample, setting, type of intervention, type of outcome and whether or not a statistically significant outcome was reported were extracted into a predefined Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL, USA) database. Details of outcomes, effect sizes and statistical analyses were independently extracted into an Microsoft Excel (Microsoft

Corporation, Redmond, WA, USA) spreadsheet by one of four reviewers and were cross-checked by one reviewer.

Data synthesis

A series of bivariate analyses, using either a chi-squared test or Spearman's rho test, were conducted to explore possible sources of variance in whether or not a study reported a statistically significant result. Six variables identified as having a significant association in this way were entered into a binary logistic regression.

Studies were included in meta-analyses (MAs) if they followed a randomised control trial (RCT) design and reported data that could be converted into odds ratios (ORs). For each MA, both a fixed- and a random-effects model were fitted, and both Q and I^2 estimates of heterogeneity were performed.

Meta-analyses are presented for all included RCTs combined and also subgrouped by the type of comparison (e.g. compared with placebo or active treatment), broad intervention groups (e.g. pharmacological vs psychosocial) and specific intervention groupings [e.g. cognitive behavioural therapy (CBT), selective serotonin reuptake inhibitor (SSRI)]. Further MAs were conducted on models incorporating identified modifiers.

Publication bias was investigated using a funnel plot.

Results

A total of 198 studies were identified as meeting the inclusion criteria: of these, 51 (26%) were RCTs. The non-RCTs were primarily (49%) single-group designs. The literature was highly diverse and included 94 distinct types of intervention and 55 different types of outcomes.

The population, setting and type of interventions studied differed between RCTs and non-RCTs, with RCTs reporting primarily pharmacological studies of people with mental disorders in community settings and non-RCTs evaluating primarily psychological interventions with offenders in penal institutions. Most studies (62%) were conducted in North America and a large proportion targeted males only (48%).

Bivariate analyses exploring possible sources of variance in whether or not a study reported a statistically significant result identified six variables with a significant association. An outcome was less likely to be positive if (1) the primary intervention was something other than a psychological or pharmacological intervention; (2) the study was conducted in an offenders' institution; (3) the comparator was another active treatment; (4) the comparator was treatment as usual (TAU); and (5) a between-groups design had been used. An outcome was more likely to be positive if it was conducted with people with a mental disorder (6). The variation attributable to these variables when added to a binary logistic regression was not large (Cox and Snell $R^2 = 0.12$) but not insignificant given the small number of variables included.

The pooled results of all RCTs with data suitable for MA suggested a statistically significant advantage for interventions over the various comparators [OR 0.59, 95% confidence interval (CI) 0.53 to 0.65, fixed effects; OR 0.35, 95% CI 0.26 to 0.49 random effects; 40 studies). However, there was high heterogeneity [$I^2 = 86\%$, $Q = 279$ (degrees of freedom, df = 39), $p < 0.0001$], indicating the need for caution in interpreting the observed effect.

Analysis by subgroups showed that most results followed a similar pattern with statistically significant advantages of treatments over comparators being suggested in fixed- and/or random-effects models but in the context of large heterogeneity. This was not true for analyses of SSRIs, in which no effect was shown and the heterogeneity was low [OR 0.80, 95% CI 0.38 to 1.68, fixed effects; OR 0.76, 95% CI 0.30 to 1.93 random effects; four studies, $I^2 = 31.6\%$, $Q = 4.38$ (df = 3), $p = 0.22$]. Analysis of an active primary intervention compared with TAU indicated a significant advantage for the active treatment using a fixed-effects model but not for a random-effects model with only moderate heterogeneity [OR 0.76, 95% CI 0.60 to 0.97, fixed effects; OR 0.70, 95% CI 0.43 to 1.14, random effects; eight studies, $I^2 = 68.8\%$, $Q = 22.45$ (df = 7), $p = 0.002$]. The subgroup analysis of CBT as a primary intervention also showed a statistically significant advantage under a fixed- but not a random-effects model (OR 0.61, 95% CI 0.42 to 0.88, fixed effects; OR 0.61, 95% CI 0.37 to 0.99, random effects, seven studies); however, heterogeneity was low in this subgroup analysis [$I^2 = 21.6\%$, $Q = 7.65$ (df = 6), $p = 0.26$].

Two further subgroup analyses reported a statistically significant advantage for the primary intervention with moderate heterogeneity: atypical antipsychotic drugs (OR 0.21, CI 0.16 to 0.27, fixed effects; OR 0.24, CI 0.14 to 0.43, random effects; 10 studies, $I^2 = 72.2\%$, $Q = 32.4$ (df = 9), $p < 0.0001$) and psychological interventions [OR 0.63, CI 0.48 to 0.83, fixed effects; OR 0.53, CI 0.31 to 0.93, random effects; nine studies, $I^2 = 62.1\%$, $Q = 21.1$ (df = 8), $p = 0.007$].

The decision to set broad parameters to the review had the intended benefit of comprehensiveness in terms of capturing a very wide range of relevant studies, but inevitably resulted in a very heterogeneous group of studies, and this heterogeneity inhibits both robust MA and the clear application of findings to establishing improvements in clinical practice. Nevertheless, a number of noteworthy trends are emerging.

A funnel plot of the studies included in the overall MA produced an asymmetric distribution that was suggestive of publication bias. The pattern is consistent with, in particular, the rejection of smaller analyses with negative outcomes. This would be consistent with biases observed in other literatures and would not be an unexpected finding, notably in the context of a comprehensive search of the literature such as the one carried out here.

Conclusions

Results from this review show small-to-moderate effects for CBT for all psychological interventions combined and larger effects for atypical antipsychotic drugs, with relatively low heterogeneity. There is also evidence that interventions targeted at mental health populations, and particularly male groups in community settings, are well supported as they are more likely to achieve stronger effects than interventions with the other groups.

The research literature on interventions to reduce violence continues to grow rapidly in quantity, but the focus of research has shown no strong indication of a coalescence into the development of a common focus in design, treatment approach or outcome measurement. Design quality overall also remains relatively low and reflects the dominance of a pragmatic approach. Until the research effort becomes more homogeneous and well designed, any results from pooling studies will be limited in the robustness of results.

Recommendations for future research

1. Improvements are needed in the design quality of future research studies. Of particular note is the relative dearth of RCTs, especially in the evaluation of non-pharmacological interventions. Furthermore, RCTs themselves should be improved by extending the study follow-up period wherever possible. The quality and rigour of research in the field could be improved by more consistent attention to the protocols that have been published with respect to the reporting of both randomised and quasi-experimental designs. Researchers should identify a single primary outcome variable against which effectiveness is judged.
2. Any approach that could increase the homogeneity of research in this field will be welcomed. Greater homogeneity in study design, the interventions applied and outcome measures used, would all be beneficial, especially if actual aggression or violence rather than some proxy for these were to be adopted as the primary outcome measure. If the best-validated measures were to be more widely used it would strengthen internal validity and also facilitate comparability across studies for review purposes.
3. A programme of research funded and co-ordinated at a national or international level should be developed, as this would improve the capacity to conduct robust MAs and increase confidence in their results. The review has revealed the extensive literature that has been produced in just the past few years but this is coupled with relatively low design quality. Much of the research is conducted opportunistically by practitioners on the basis of what is possible within their clinical setting. Although this is laudable as a contribution to the principle of evidence-based practice, without adequate resources to improve study design the cumulative evidence base will never produce knowledge that is generalisable beyond specific local settings.
4. Some treatment approaches are particularly lacking in evidence-based interventions, such as psychosocial interventions other than CBT. A greater focus on improving the quantity and quality of research here is likely to prove very beneficial.
5. Psychosocial and other non-pharmacological interventions should be defined more clearly so that the theoretical elements they are testing is made explicit. In this way, the key components that make up a broad intervention, such as CBT, will be identified and examined for effectiveness.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research and the Research for Patient Benefit programme.

Chapter 1

Background

It has been suggested that worldwide incidents of violence account for more than 1.6 million deaths each year.[1] However, the proportion of personal violence resulting in death is only a fraction of personal violence or of violent assaults overall. In this introductory chapter we consider what we mean when we use the term 'violence' and examine the extent of violence in both the world and, specifically, the British context. Finally, the nature of the association between violence and mental disorder is explored.

The definition of violence

In a general sense, many would consider violence to consist of the use of physical force that is intended to hurt or injure another person.[2] However, arguably this rather simplistic and limited conceptualisation ignores the more insidious effects of non-physical violence, such as threats, intimidation and the self-directed violence of suicidal behaviour. It has been suggested that there may be several approaches to the definition of violence,[3] although at present there is no widely held agreement on which of these is most appropriate. In this document we have adopted the broad conception offered by the World Health Organization (WHO), which has defined violence as 'The intentional use of physical force or power, threatened or actual, against oneself, another person, or against a group or community, that either results in or has a high likelihood of resulting in injury, death, psychological harm, maldevelopment or deprivation'.[4]

This definition includes threats, intimidation, neglect and physical, sexual and psychological abuse, as well as acts of self-harm and suicidal behaviour. Furthermore, it conceives of violence in terms of its outcomes on health and well-being rather than, for example, its characteristics as a construct that is purely culturally determined.[5]

A number of attempts have been made to formulate a typology of violence. Krug *et al.*,[4] for example, suggested three broad categories: self-directed, interpersonal and collective violence. For our purposes here we propose to focus on only the second of these. This category, interpersonal violence, incorporates intimate partner violence, child abuse and stranger assaults, whether sexual or not. Excluded from this are acts of collective violence committed as a concomitant of war, terrorism or gang conflict.

The extent of violence

Determining the extent of serious violence at a global level is particularly problematic. Important among the range of obstacles to this is variation in the willingness and capacity of different governments and agencies to collect, and then make available, reliable data. The statistics that do exist indicate that global violence-related deaths in the year 2000 (the most recent year for which data exist) included 520,000 homicides, with rates being several times higher in low- to middle-income countries relative to high-income countries.[4] In absolute terms, death by homicide or suicide is considerably more likely among males, especially those aged 15–44 years, than among any other age/gender demographic grouping.[4] Comparable data for non-fatal violence are not

available, as the true extent of this can be determined only by self-report, which is necessarily unreliable because much violence is likely to go unreported to the authorities or untreated by medical personnel. However, it seems reasonable to conclude that the true degree of violence will far outstrip nationally recognised figures for homicide.[6]

In England and Wales, provisional data indicate that in the year 2008–9, 648 incidents of homicide were recorded in police figures, which represents the lowest level in 20 years. The most recent evidence from the British Crime Survey (BCS) and from police figures (crimes reported to the police) indicates that non-fatal violent crime remained essentially stable in the year 2008–9 compared with the previous year, with statistically non-significant reductions of between 4% and 6%.[7] In fact, BCS data suggest that the trend in all violence has gradually fallen year on year from a peak in 1995–6 to a current level that is 49% lower than this.[7] Nevertheless, the English Department of Health has identified the short-term management of violence as a key priority and supported development of clinical practice guidelines.[8]

Perhaps ongoing public concern about the level of person-to-person violence serves to retain violence at the top of the political agenda, no doubt partly because acts of violence against the person account for approximately 20% of total crime, as recorded in police figures and reported by the BCS, respectively.[7] Domestic violence (DV) in particular has come to be regarded as a key priority of the British government, which recently set out its National Domestic Violence Delivery Plan for 2008–9.[9] This document makes it clear that in England and Wales in the year 2008–9 DV accounted for 14% of all violent incidents and had more repeat victims than any other crime. Violence towards staff working in the NHS has also come to be seen as a significant element in the government agenda, with 12% of staff reporting physical violence from patients or their relatives in the previous 12 months.[10] The government response to concerns about violence in adult psychiatric inpatient settings and hospital emergency departments has been to develop guidelines and other initiatives to improve the short-term management of this behaviour.[11]

Although our focus in this document is principally on the perpetrators of violence, it is worth noting that, overall, 3% of adults in England and Wales have experienced a violent crime in the preceding year, with men being twice as likely as women to have been victims of some form of violence.[7] However, victim statistics are unlikely to present a true picture of the full extent of violence, as victim surveys tend to show lower rates of reporting for violence than for other types of crimes.[12,13]

The association of violence with mental disorder

As many as 10 years ago it was observed that the number of homicides in England and Wales committed by persons with serious mental disorders had steadily declined over a 38-year period.[14] Despite this, acts of violence committed by people with mental illness remain a matter of continuing major concern to the public, as well as to service providers and policy-makers.[15]

Recent large-scale reviews suggest that some diagnosed mental disorders, notably schizophrenia and other psychoses, are associated with an increased risk of violence. Fazel *et al.*[16] reviewed 20 studies with an aggregate sample of 18,423 individuals and, after discounting the influence of concurrent substance abuse, found an odds ratio (OR) of 2.1 for the relationship between active schizophrenia and violence. Douglas *et al.*[17] reviewed a total of 204 studies, subsuming 166 independent samples, and concluded that '… psychosis was reliably and significantly associated with an approximately 49–68% increase in the odds of violence relative to the odds of violence in the absence of psychosis' (p. 687). Although this is clearly a substantial increase, it should also be noted that 'the average effect size for psychosis … is comparable to numerous individual risk

factors' found in other research (p. 693). Furthermore, there was considerable heterogeneity in the findings surveyed. For example, approximately 25% of the effect sizes obtained were < 0 (with a mean OR of 0.73), whereas another 25% were large (above a mean OR of 3.30).

Violence reduction interventions

The mental health and criminal justice systems provide an important environment for the management and treatment of violence and for the prevention of future violence when the person is in the community. This review will examine the evidence base for a wide range of pharmacological, psychosocial and organisational interventions that have been used to deal with the problem of violence.

For the purpose of this report, an intervention is considered to be any explicitly defined action or set of actions taken by a practitioner with the aim of reducing the potential for violence by a specified individual. This definition incorporates a huge range of potential interventions[18,19] with varying degrees of evidence supporting them, and a number of distinctions can be introduced in order to organise the field. One distinction is whether an intervention is based on a view of violence as *secondary* and symptomatic of an underlying problem or whether it is an intervention explicitly and *primarily* targeting violence as the problem. Most interventions designed to reduce antisocial personality disorder 'globally', for instance, would expect reductions in violent behaviour as a result of success in improving the person's way of generally relating with the world. The review presented here includes both primary and secondary interventions, but includes only the former group when there is some assessment of violent behaviour as an outcome.

A further distinction must be drawn between *short-term* and *long-term* violence reduction interventions. Some interventions, such as rapid tranquillisation and verbal de-escalation, are designed for the prompt control and management of imminent violence involving highly aroused and disordered patients,[11] whereas many others are delivered over longer time periods, up to a period of years for some milieu therapies, and are designed as treatments dealing with underlying causes rather than temporary or short-term symptom management. These long-term structured therapeutic interventions tend to be delivered in relatively low-arousal settings aimed at preventing future violence in inpatient, prison or community settings.

The range of factors underlying violent behaviour is very wide, ranging from genetic and biochemical influences to cultural forces, and the interplay between these factors in any particular act of violence is extremely complex. Given the complex causal pathways for any violent act, interventions have been developed to operate at numerous different levels ranging across neurological, psychological and social processes. Most studies consider an intervention operating at only one of these levels, whereas most health practice involves multimodal interventions where, for instance, drug treatment is combined with psychological techniques within a particular social milieu. This disparity between research and real world practice should be borne in mind when examining the evidence base.

With regard to *pharmacological* interventions, there are no drugs designed specifically to reduce violence *per se*. Haloperidol and lorazepam have been recommended for rapid tranquillisation in emergency situations[11] and clozapine, among other second-generation antipsychotic drugs (e.g. olanzapine), has been reported to be effective in reducing violence associated with psychosis over longer time periods.[20] In the results of a systematic review,[21] there is support for the use of benzodiazepines, combined, if necessary, with antipsychotic drugs, as part of a longer-term maintenance regime for people with mental health problems who are acting aggressively as part of their disorder.

Psychosocial interventions can be targeted at the individual or may be delivered as part of a therapeutic milieu. At the individual level, most interventions, and certainly most evidence-based interventions, are based on cognitive behavioural principles designed to change the person's thinking style and interpretation of situations in which conflict may arise. The most well-articulated approaches within this family are Aggression Replacement Therapy[22] and the variants of anger management.[23] Individual-level psychological interventions may also be based on psychodynamic or humanistic principles (e.g. Doctor and Nettleton[24]), but these are less well evaluated.

Beyond these individually targeted interventions, therapeutic communities and milieus have been used to generate therapeutic change through immersion of the violent individual into a particular culture that reinforces non-violent behaviour and encourages confrontation with antisocial behaviour.[25] Similarly, some interventions in traditional mental health units (i.e. outwith therapeutic communities) are environmental and cultural, in that their delivery is mediated through a third party. For instance, the human environment of a ward may be changed by training all staff in proactive de-escalation strategies[26] or the physical environment may be adjusted.[27]

An important methodological issue is deciding whether an intervention is a cause or an effect. Certain short-term management approaches (e.g. seclusion of an agitated person in a locked room) are interventions (i.e. an *independent variable*) as defined above but may also be a proxy measure (i.e. a *dependent variable*), as they may indicate the failure of more long-term interventions. As a general rule in this review, reactive management strategies – such as seclusion and restraint – are considered as dependent variables, whereas proactive strategies such as de-escalation are considered as interventions, even although they are equally short term. Part of the justification for this is that reactive strategies are often the target themselves of interventions designed to reduce reliance on them.[28] It is acknowledged, however, that this distinction is difficult to maintain with complete consistency.

A distinction can be drawn between complex and non-complex interventions. Non-complex interventions, such as pharmacological and dietary approaches, are relatively simple in terms of the relationship between exposure to the intervention and changes in behaviour. The drug is targeted at one specific physical system and if, all other things being equal, it changes behaviour then the causal mechanism and its efficacy can be more easily established. Complex interventions are considered to be those that consist of several components, each of which may make a contribution to the success of the intervention.[29] They are also recognised to be operating within the complex social system of a ward, prison or organisation. There is a growing recognition that traditional methods used to evaluate non-complex interventions and which prioritise the randomised controlled trials (RCTs) are severely limited in evaluating complex interventions.

Rationale for the review

The scope of the review presented here is deliberately wide. We have noted above the complexity of the phenomenon of violence, but there are benefits from casting the net as widely as possible and looking for consistent patterns across populations. Two populations are covered by the review as a reflection of the need to integrate the insights that can be gained from clinical and criminological research. These populations (people with an Axis 1 or 2 diagnosis and people who have committed an indictable offence, regardless of whether they have been found guilty or not) often overlap and often move between the criminal justice and mental health systems.[30] For similar reasons, the review encompasses interventions delivered both in institutions (i.e. hospitals, prisons and their variants) and outside in the community as part of an outpatient or community offender management programme.

After 20 years of sustained activity in this area, the primary research literature is now very large, yet the evidence base for making clinical and policy decisions is often bemoaned as inadequate.[31] The quality of the evidence base is certainly poor considering the vast number of studies and reviews that have been published in the last decade,[32] largely because of a combination of methodological difficulties and lack of focus characteristic of the unusually rapid development of interest in the field. A number of systematic reviews have been conducted to summarise and integrate the findings from the literature and these provide evidence on a number of specific areas. However, inevitably these reviews tend to focus on a specific intervention, for example second-generation antipsychotic drugs[33] and/or a specific outcome (e.g. reoffending) in various special populations (e.g. sex offenders). This review will instead adopt a more comprehensive approach by aiming to capture research on all interventions relating to a broad range of violence-related outcomes among a wide mental health and criminal justice population. In this way it is anticipated that the fragmented clinical and criminological literatures can be reintegrated to the mutual benefit of practitioners and researchers in both settings.[34]

Other reviews

This review was conducted in the context of a number of other reviews of research on evaluations of violence reduction interventions by various teams around the world (for a survey of those pertaining to the field of criminal justice, see McGuire[35,36]). Given the breadth of the inclusion criteria adopted for the review here, 17 of these reviews are most relevant to the focus adopted here. However, these previous reviews cover specific populations and treat them distinctly, whereas the review reported below attempts to integrate the literature across these distinct groups. Four of the reviews focus exclusively on younger offenders in the age range of 12–21 years;[37–40] seven address the problem of sexual offending;[41–47] one deals with DV;[48] one includes both adolescent and adult samples;[49] and four are focused on studies of individuals diagnosed with personality disorders.[50–53]

The broadest review was a meta-analysis (MA) by Dowden and Andrews.[49] This subsumed a range of studies that included mixed samples of adult and adolescent offenders and target offence behaviours, including general violence, sexual and domestic assaults. These authors found 34 evaluations of interventions to reduce violence, yielding 52 effect-size tests. Approximately 70% of the included studies focused primarily on work with adults. Unfortunately, they do not report separate outcome data for the two age groups. The overall mean effect size (r) was relatively low at +0.07, although there was enormous heterogeneity in the findings: effect sizes ranged from a low of –0.22 to a high of +0.63. The effect size for interventions based on the risk–need–responsivity model[54] was better than the overall mean, at +0.12. This corresponds to recidivism rates of 44% for experimental and 56% for control groups. Possibly the most notable finding to emerge from this review was evidence of a close correspondence between the number of criminogenic needs targeted in interventions and the associated effect size: a correlation coefficient of 0.69 ($p < 0.001$).

Sexual offences

Regarding the specific phenomenon of sexual violence, to date a total of seven reviews have been reported; not surprisingly there is considerable overlap between these reviews, although they varied in their breadth of compass, their thoroughness and, in some cases, selected subdivisions of the field were the primary focus of interest.[41–47] The most comprehensive MA of this field[46] synthesised findings from 69 studies, covering a cumulative sample of 22,181 participants, and included both medical and psychosocial treatments. From these findings Lösel and Schmucker[46] were able to compute a total of 80 effect-size tests. A majority (60%) of the studies consisted of non-equivalent group designs, equivalence was assumed for a further 19, seven used statistical controls and six involved random allocation. Mean effect sizes across interventions, expressed as ORs, were +1.70 for reductions in sexual recidivism, equivalent to a 37% reduction relative to comparison samples; +1.90 for violent recidivism (44% reduction); and +1.67 for general

recidivism (31% reduction). The largest effects were for physical treatments (surgical castration, eight studies, OR = 15.34; hormonal medication, six studies, OR = 3.08). Some psychosocial interventions achieved significant effects (behavioural, seven studies, OR = 2.19; cognitive behavioural, 35 studies, OR = 1.45), whereas others (insight-oriented and therapeutic community approaches) had ORs that were not significantly different from 1. The mean effect size for cognitive behavioural methods is lower than the OR of 1.67 found in another review of sex offender treatment that focused solely on psychologically based interventions.[44]

Personality disorders

Personality disorder is a specific clinical phenomenon, which, in certain manifestations, can be relevant to violent behaviour. Two reviews have been reported of offenders with personality disorders, but neither is a systematic review nor has used statistical integration methods, because of the small number of studies that were located. Salekin[50] reviewed a series of 42 outcome studies; however, only eight involved group comparison designs, and many others were single case reports, so although the latter may be clinically instructive, any firmer conclusions must remain tentative at present. Of those studies that could be regarded as more robust, there were five studies of cognitive behavioural therapy (CBT) incorporating a cumulative sample of 246 individuals. There were high-effect sizes on intermediate outcome variables for several therapeutic approaches, including CBT, personal construct therapy, and other approaches which ' addressed patients' thoughts about themselves, others and society. Thus, they tended to directly treat some psychopathic traits' (p. 93).[50] Salekin[50] also observed that there was a strong association between effect size and duration and intensity of treatment: interventions lasting < 6 months were less likely to produce benefits than longer ones. Where attendance was maintained for > 1 year, or delivered at a rate of more than four sessions per week, a considerably higher fraction of the samples benefitted.

Addressing the controversial question of whether those individuals assessed as 'psychopaths' are untreatable, or (as reported by an earlier study) could potentially be made worse by treatment, Tanasichuk and Wormith[51] found only three studies that compared treated and untreated samples. They located an initial total of 21 studies yielding 50 effect-size estimates (cumulative sample $n = 5550$). In comparisons between those designated as psychopaths and samples of non-psychopaths, the former consistently showed higher general, violent and sexual recidivism, more antisocial behaviour, higher levels of substance abuse, and spent significantly less time in treatment. In the three studies where comparisons were possible between treated and untreated psychopaths, there were no significant differences in general or violent recidivism; other types of comparisons were not feasible given the available data. However, contrary to the findings of some earlier research there was no evidence that treatment made psychopaths worse.

Recent National Institute for Health and Clinical Excellence (NICE) guidance (NICE. *Antisocial personality disorder: treatment, management and prevention. NICE clinical guideline 77*. 2009. URL: www.nice.or.uk/CG77) with regard to the management of antisocial personality disorder warns against the routine use of pharmacological interventions for the disorder overall or for aggression associated with it, and notes that there is insufficient evidence to justify the use of any specific medication, although appropriate medications may be used for treatment of comorbid conditions. To address problems such as impulsivity, interpersonal difficulties and antisocial behaviour associated with antisocial personality disorder, psychological interventions such as group-based CBT (e.g. 'reasoning and rehabilitation' programme) are recommended instead.

Borderline personality disorder (BPD) is a second major diagnostic category that has been seen as linked to an increased risk of violent behaviour. A recent Cochrane review[52] of 27 pharmacotherapy trials indicated that pharmacotherapy had some beneficial but differential effects on all aspects of the disorder. The affective dysregulation element, for instance, which is

clearly relevant to aggressive propensities, was improved through treatment with haloperidol, aripiprazole, olanzapine and mood stabilisers. Other attempts to synthesise the evidence in this area (e.g. Herpertz *et al.*[53]) are inconclusive about the efficacy of pharmacotherapy on the specific aggressive aspects of BPD. As with antisocial personality disorder, recent NICE guidance (NICE. *Antisocial personality disorder: treatment, management and prevention. NICE clinical guideline 77*. 2009. URL: www.nice.or.uk/CG77) recommends avoiding pharmacological treatment for the core disorder or its associated behaviours (other than for short-term crisis management), while highlighting the potential benefits of psychological interventions. No specific theoretical approach is indicated as long as there is some explicit orientation to the therapy, which is shared with the service user.

Domestic violence/partner abuse

This review also included the specific phenomenon of DV in order to enable comparisons to be made between this and the related violence fields. There is one MA of methods or strategies designed to reduce DV, consisting (almost overwhelmingly) of assaults by males on female partners. Babcock *et al.*,[48] examined findings from 22 studies yielding (after elimination of outliers) 36 effect size tests; 17 of the studies were quasi-experiments and the remaining five were 'true' experimental designs. The overall conclusion of Babcock *et al.*[48] (p. 1044) was that '… there is great room for improvement in our batterers' treatment interventions' and it is widely recognised that this remains possibly the largest single area in which, to date, effective methods of intervention have not yet been firmly identified.

Young offenders

Although the focus below is on violence by adults (aged > 16 years) there is some overlap with previous reviews of young offenders as the definition of young offenders can include those up to the age of 21 years. The largest of the previous reviews focused on young offenders is that of Lipsey and Wilson,[37] who integrated findings from a total of 200 studies, 117 of interventions based in the community and 83 of interventions based in residential or custodial settings. All of these studies were with adjudicated offenders or with young people with adjustment problems, but not diagnosed with mental disorders. Intervention programmes in the 'most consistently effective' category were found to have an average impact in reducing recidivism by 40% in community settings and 30% in custodial settings.[37]

A later review by Garrido and Morales[38] is essentially an updated version of portions of the Lipsey and Wilson[37] review, combining studies carried out in the period up to 2006 but including only studies with 'chronic delinquents' detained in institutions. Covering a related but separate area of research, Wilson *et al.*[39] reviewed studies of methods designed to reduce aggression in schools. Addressing a more specific question, McCart *et al.*[40] compared the relative effectiveness of behavioural parent training and CBT in reducing aggression and other antisocial behaviour among young people < 18 years old; they found 41 studies of the former and 30 of the latter.

Findings from all of these reviews showed on average positive outcome effects and the authors report analyses of the relative effectiveness of different interventions and the roles of moderator variables where possible. However, in all of these reviews a majority of the studies that were included consisted of quasi-experimental designs, with only a fairly small proportion using randomisation.

Previous review

The review reported here is an update of one part of an existing review. In 2002 the Department of Health commissioned the Liverpool Violence Research Group (LiVio) to complete a broad-ranging systematic review of interventions and risk assessment strategies for the management of violence in a widely defined population (offenders, people with mental health problems and

offenders with mental health problems). The aim was to provide a picture of the literature that was broad enough to inform future improvements in research, policy and clinical practice, while strictly adhering to the main criteria for high-quality reviews. The original review[55] covered publications released between 1955 and 2001 (with partial update to 2004) on a population that consisted of (1) adult offenders (> 17 years) with or without a mental disorder; (2) adults with a diagnosable mental disorder but no offences; and (3) adults in the general population exhibiting indictable acts of aggression without actual indictment (e.g. DV). Substance abuse alone was not deemed sufficient to constitute a diagnosis of mental disorder. Any pharmacological, psychological or other intervention targeted at the individual patient/offender and delivered individually or in small groups was included. Organisational interventions (e.g. ward-level changes) that did not report individualised outcomes were excluded. Changes on any outcome measure that was an actual or proxy assessment of aggression (e.g. observed aggression, self-reported hostility) were included. There were no exclusions based on design, language or publication format.

Search strategy and selection of studies

The primary method used to identify studies meeting the above criteria was to conduct (1) a detailed search of 31 electronic databases from their point of inception to December 2004; (2) a hand-search of 42 specialist research journals covering the period January 1990 to December 2000; and (3) a consultation exercise with a specified list of 50 active international violence researchers.

In total, 228,182 citations of relevance to human aggression were retrieved. Of these, 41,886 citations related, broadly speaking, to risk or intervention. Of the material meeting the broad review inclusion criteria, just over 1000 citations reported on empirical research, with aggression being the sole or main focus for nearly 90% of the reported studies. In line with the rapid expansion noted in the literature, the majority of empirical studies identified (85%) were written or published from 1980 onwards. An executive summary of the findings from the review can be found at www.liv.ac.uk/fmhweb/MRD%2012%2034%20Final%20Report.doc.

The final report[55] has had significant influence on national policy in England and was formerly flagged on the website of the Department of Health/Ministry of Justice (England) National Risk Management Programme.[56] It also formed the basis for a set of national best practice guidelines on risk management[57] and national policy guidance on selection of risk assessment tools.[58]

Update of the review

This update uses the same search strategy and the same databases were searched where possible. The four senior reviewers involved in the original review were also involved in this update and are referred to in this document as 'expert reviewers'.

Owing to the size of the original review it was decided that the update would be split into two distinct elements: this intervention review and, secondly, a review of risk assessment approaches with the same population (to be published at a later date). It is important to emphasise that the two processes are closely linked. Estimates of predictive validity from a risk assessment tool are of little use on their own if they are not used to design and target effective interventions. The structured clinical (or professional) judgement approach[59] is important in this context, as this approach is recognised as encouraging practitioners to focus on risk management and flexibility in choosing appropriate interventions.

Research question

Which interventions are the most effective in reducing violence and which key variables are associated with a significant outcome?

Chapter 2

Methods

This review was conducted by a large team of reviewers, with varying numbers working on the review at any particular stage. The searches were conducted by two reviewers, application of stage one inclusion criteria by 11 reviewers, stage two inclusion criteria by seven reviewers, data extraction and cross-checking by nine reviewers, extraction of statistical outcomes by five 'expert' reviewers (four of whom had been involved in the original review).

Search strategy

The search strategy (see example in *Table 54*) used in the original review was rerun on the 19 databases shown in *Table 1*. The first database to be searched was PsycINFO and the searches were run in April 2008. The last database to be searched was SIGLE (System for Information on Grey Literature In Europe) and the searches we carried out in November 2008. Where it was possible to limit searches, they were initially run without limits and then rerun limited to children *or* animals *or* editorials. These hits were then removed from the first run. This method was used so that papers that had not been indexed on a term, for example 'humans', were not missed when running the searches.

As the searches were run, citations were imported into EndNote XIV® (Thomson Reuters, CA, USA) sequentially. Owing to the limitations of EndNote, duplicate references were deleted first electronically and then manually.

The reference lists of relevant reviews identified at inclusion were searched for additional relevant references.

Inclusion and exclusion criteria

The identified citations were assessed for inclusion through two stages. The criteria used were those used in the previous review and are shown in *Table 2*.

Inclusion stage one

At stage one inclusion, six reviewers independently applied the inclusion criteria to 200 citations and a Cohen's kappa (Fleiss–Cuzick extension) was calculated [$\kappa = 0.63$ (SE = 0.019), z (for $k = 0$) = 34.24, $p < 0.0001$]. Each new reviewer who joined the team was required to look at 100 citations that had previously been looked at by a reviewer and a > 80% agreement had to be reached. At this stage an 'inclusive' attitude was taken, i.e. where there was doubt a citation was included. Given the high level of agreement and the inclusive approach, further citations were screened by only 1 of the 11 reviewers.

If a citation was excluded then it was possible to mark the citation as either a review that needed the reference list checked ('check') or a paper of particular interest that should be obtained ('obtain').

TABLE 1 Databases searched and limits used

Database	Limits used
PsycINFO (CSA)	Animals, editorials, childhood (birth to 12 years)
MEDLINE (Ovid)	(Animals or ("newborn infant (birth to 1 month)" or "infant (1 to 23 months)" or "preschool child (2 to 5 years)" or "child (6 to 12 years)") or editorial)
CINAHL (Cumulative Index to Nursing and Allied Health Literature)	Animals or ("newborn infant (birth to 1 month)" or "infant (1 to 23 months)" or "preschool child (2 to 5 years)" or "child (6 to 12 years)") or editorial)
AMED (Allied and Complementary Medicine Database)	None
British Nursing Index/Royal College of Nursing	None
IBSS (International Bibliography of the Social Sciences)	None
ERIC (Education Resources Information Center)/International ERIC	None
The Cochrane Library (Cochrane reviews, other reviews, clinical trials, methods studies, technology assessments, economic evaluations)	None
Web of Science [Science Citation Index Expanded (SCIE), Social Sciences Citation Index (SSCI), Art and Humanities Citation Index (A&HCI)]	Document type=(bibliography or editorial material or letter)
Sociological abstracts/SocioFile	None
Social Services Abstracts	None
EconLit (American Economic Association's electronic bibliography)	None
British Humanities Index Online	None
Elsevier Science Direct	None
ProQuest (dissertations and theses)	None
ASLIB (index to theses) (searched on screen)	None
C2-SPECTR	None
Emerald Fulltext	None
SIGLE (searched on screen)	None

TABLE 2 Inclusion and exclusion criteria

Inclusion	Exclusion
Active diagnosis of mental illness, learning disability or personality disorder *or*	Participants are members of the general public, with no identified mental illness and no recorded violent offence *and* no evidence of having committed an act of violence that would constitute an indictable offence
	Substance abuse (including alcohol abuse) in isolation from any other diagnosis of mental illness is not to be defined for the purposes of the review as an active diagnosis of mental illness
	Substance abuse (including and separately specified as alcohol abuse) *is* to be identified in relation to *participant characteristics* for the purposes of data extraction, as it is identified in primary studies
Offender (person subject to penal sanction) *or*	
Person(s) known to have committed one or more acts of aggression constituting an indictable offence (whether or not an indictment has been made)	
Aged ≥17 years	Aged ≤16 years
Any intervention specifically identified as being evaluated with the intention of preventing violent behaviour *or*	Interventions focused *solely* on reducing or preventing target behaviours *other* than aggression towards others
Implemented with the immediate intention of preventing violent behaviour (*e.g. 'naturalistic' evaluation in a clinical setting*)	

TABLE 2 Inclusion and exclusion criteria (*continued*)

Inclusion	Exclusion
Interventions must be targeted at the individual level	Studies that evaluate the impact of broad-based local or national population-level initiatives and which *also* fail to evaluate outcomes (compared with outcome criteria) at the individual level are to be excluded
	*Studies that have a focus on a main target behaviour which is **not** other-directed aggression (the target behaviour may be self-directed aggression), but which **do** include an evaluation of the association between exposure to an intervention and rates of other-directed aggression as a subsidiary focus are to be included*
	Studies that evaluate the impact of broad-based local or national population-level initiatives and which *also* fail to evaluate outcomes (compared with outcome criteria) at the individual level are to be excluded
	For example, a study evaluating the impact of a binge drinking campaign on aggression, which evaluated outcomes purely by noting changes in population rates of violence across time would be excluded; a study evaluating the same intervention but reporting outcomes based on the same set of individuals with behaviour evaluated before and after the initiative would be included. The key point is that the specific individuals being assessed need to be evaluated at outcome
Interventions may include, but are not restricted to, pharmacological, physical, psychological, environmental, or training initiatives	
Interventions include both 'single dose' and complex 'multiple dose' or 'multifactorial' interventions	
Studies that have a focus on a main target behaviour which is *not* other-directed aggression (the target behaviour may be self-directed aggression), but which *do* include an evaluation of the intervention on other-directed aggression as a subsidiary focus are to be included	Studies focused *solely* on self-directed aggression, including self-harm and suicidal behaviours are to be excluded
Any institutional setting/location	Setting/location of any study is not to be regarded as grounds for excluding that study
Any community setting/location	
Community-based 'institutional' settings, such as outpatient clinics, A&E, private practice clinics, etc., are also to be included	
Studies conducted at 'remote' locations, for example studies evaluating interventions conducted by telephone or in writing, are also to be included	
Any design explicitly measuring outcomes following an intervention meeting the above criteria	No attempt at any sort of empirical approach likely to elicit at least an association between dependent variables and outcomes should such exist
	No clear identification of an intervention taken as either the main *or* as a subsidiary focus of the study
Directly observed physical *or* verbal aggression by person(s) with an identified mental illness	No evaluation of outcomes
	Aggressive behaviour (as defined for the population groups considered), *not* either a main or subsidiary outcome of the evaluation
Directly observed physical aggression (meeting criteria for indictment) by members of the general public or current/previous offenders	
Proxy measures of the above (including but not restricted to: self or other report of the above categories of behaviour, including reports established via clinical records; official records of offence and conviction; psychometric and other scale-based outcomes of mentations or behaviours directly relevant to aggression, for example BPRS measures of 'hostility')	

continued

TABLE 2 Inclusion and exclusion criteria (*continued*)

Inclusion	Exclusion
Outcome evaluation must be based on individual-level data	Evaluations based on 'non-attributable' rates and other summary data are to be excluded: 'Collective' acts of aggression, such as terrorism, 'gang' violence, organised violent crime, football violence, drug feuds, etc., are excluded from consideration by the review where the focus of the study is on the phenomenon *as* a collective behaviour; studies focused specifically on individual behaviour *within* these contexts should be included
Evaluation of both imminent and non-imminent (future) violence is included within the review	Directly observed or proxy-evaluated aggressive behaviour (as defined for the population groups considered) is *not* either a main or subsidiary outcome of the evaluation

A&E, accident and emergency; BPRS, Brief Psychiatric Rating Scale.

Acquiring papers

Electronic copies of papers were then downloaded where possible by the University of Liverpool's interlibrary loans team. Where electronic copies were not available, paper copies were either obtained from the University of Liverpool's library or through interlibrary loans at the British Library.

Inclusion stage two

At stage two, the inclusion/exclusion criteria were applied to the full papers identified from stage one. To aid with this a Microsoft Access database (Microsoft Corporation, Redmond, WA, USA) was developed using a front page form with drop-down menus and tick boxes. It was at this stage that included papers were categorised into each of the two reviews: intervention or both risk and intervention. Furthermore, studies not reporting any statistical analysis, mainly due to qualitative designs, were excluded from the review though retained for future analysis.

As a quality control measure, all seven of the reviewers applied the inclusion criteria to 50 papers and a Kappa score was calculated [Cohen's kappa (Fleiss–Cuzick extension): $\kappa = 0.62$ (standard error, SE = 0.032) z (for $k = 0$) = 19.46, $p < 0.0001$]. Investigation of individual pairs of inter-rater agreement (*Table 3*) revealed that one reviewer (G) had poorer reliability scores owing to being more inclusive than other reviewers. Therefore, it was decided that there was high enough agreement to continue with single reviewer application of inclusion criteria.

Quality assessment

Owing to the diverse nature of the papers included in this review, no appropriate methodological quality assessment tool was identified. Therefore, variables pertinent to quality assessment were extracted as part of the full data extraction process (see *Data extraction*) and frequencies calculated where appropriate. Where there were available data, the effect of the quality of studies was explored in MAs.

TABLE 3 Inter-rater reliability at stage two inclusion

	A	B	C	D	E	F	G
A	1	0.618	0.86	0.753	0.66	0.711	0.55
B		1	0.537	0.702	0.685	0.57	0.421
C			1	0.683	0.684	0.684	0.68
D				1	0.571	0.628	0.477
E					1	0.523	0.59
F						1	0.355
G							1

Data extraction

Data extraction was carried out independently by nine reviewers, with regular meetings to co-ordinate activity and to explicitly cross-check extracted data. Data from each study relating to study design, type of intervention and whether or not a statistically significant outcome was reported were extracted into a predefined Statistical Package for the Social Sciences (SPSS) (SPSS Inc., Chicago, IL, USA) database.

The SPSS database was based on the one used in the original review and included both free-text variables, number variables and drop-down menus. The reviewers were then trained in its use and a pilot extraction conducted. Relevant changes were made and reviewers retrained. This process was repeated until the final version was agreed. Ongoing support was also given to reviewers in the form of a crib sheet covering each variable and an electronic forum was set up so that reviewers could post any queries that the expert reviewers could then answer.

Each paper was printed off and marked as data pertaining to the basic aspects of the study were extracted into the SPSS database. The data extracted were then cross-checked by another reviewer using the marked paper and any disagreements were noted in a Microsoft Excel (Microsoft Corporation, Redmond, WA, USA) spreadsheet. The two reviewers then discussed disagreements and where no consensus could be found a third reviewer adjudicated.

Papers included in the intervention review were then given to one of the expert reviewers to extract outcome data in an Excel spreadsheet. Intervention arm and resultant statistics were loaded, with multiple lines per study. In particular, specific data were extracted on dependent variable means and standard deviations (SDs) together with statistical test values, confidence intervals (CIs) and probability levels when study groups (treatment vs control and/or baseline vs end point) were compared. This level of analysis had not been attempted in the original review. Subgroup analyses were not extracted where an included full analysis was reported. The outcome extraction for any RCTs identified was then cross-checked and any discrepancies settled with a third party.

Descriptive data

Details of key variables pertaining to quality, trial characteristics, participant characteristics, and intervention characteristics are tabulated and are discussed in *Chapter 3*, along with comparisons of the characteristics of RCT and non-RCT studies. Where appropriate, differences between RCTs and non-RCTs were investigated with either a chi-squared test or Mann–Whitney *U*-test (kurtosis and skewness tests reported).

Statistical methods

In *Chapter 4*, the key variables, as discussed in the descriptive section above, are explored in terms of their role in explaining the variance in whether a study reported a statistical significant result or not. These subgroup analyses should be seen as hypothesis generating rather than providing conclusive answers.

Bivariate and multivariate analyses

Bivariate analyses

A series of bivariate analyses using either a chi-squared test (for dichotomous data) or Spearman's rho test (for continuous data) were conducted to explore possible sources of variance in whether or not a study reported a statistically significant result.

Multivariate analyses

A binary logistic regression was conducted, with categorical variables coded as 'dummy' (0/1, with 0 as the baseline category) and 'whether or not a statistically significant outcome in favour of the primary intervention arm was established' as the dependent variable (also coded 0/1). With no specific direction of effect or composite weighting in mind, the 'ENTER' method of adding variables to the model was used.

Selection of studies for analyses

Studies were selected for inclusion in these analyses if they provided statistical data suited to extraction and statistical analyses and reported data on statistical significance.

Where an individual study contributed more than one comparison to the data set, we selected for inclusion the main comparison focused on by the authors or, where comparisons appeared to be of equal weight, the comparison which provided the most substantive evaluation of effect (e.g. the comparison using the longest follow-up interval). This ensured, as far as possible, independence between the data points included in the MAs.

Meta-analysis

Selection of studies for meta-analysis

Studies were selected for inclusion into the MAs if they followed a RCT design and reported data that could be converted into ORs or risk ratios. Where an individual study contributed more than one comparison to the data set, we selected for inclusion the main comparison focused on by the authors or, where comparisons appeared to be of equal weight, the comparison that provided the most substantive evaluation of effect (e.g. the comparison using the longest follow-up interval). This ensured, as far as possible, independence between the data points included in the MA. Details of studies and outcomes selected for each MA are outlined in *Appendix 3*.

Effect sizes

Where possible, metrics were converted to ORs using equations provided by Lipsey and Wilson.[60] To provide a context in which to evaluate the relative impact implied by the mean effect sizes presented, effect sizes based on the standardised mean differences are also reported.

For each MA, both an fixed-effects model and a random-effects model were fitted, rather than assuming a priori that either was most appropriate.

Heterogeneity

To identify the indicative variance existing within various groupings of studies used in MA, we calculated both Q statistic and I^2 estimates of heterogeneity for each MA performed. The

rationale for providing two tests in this context was that the *Q*-statistic, although generally a reliable test of heterogeneity, fails to provide an estimate of the *extent* of heterogeneity. The I^2-statistic can be used to evaluate the extent of heterogeneity, which is useful in exploring the likely impact on outcomes.

Where heterogeneity was present, data were re-evaluated by modelling the impact of the potential modifiers on both observed heterogeneity and on effect size outcomes. The potential impact of each modifier was explored using metric-appropriate statistics (analysis of variance, logistic and linear regression). Further MAs focused on studies identified as similar in respect of these key characteristics were then carried out to explore the mean effect sizes generated for a range of interventions within relevantly similar groupings.

Subgroup analyses on the following were also conducted to investigate heterogeneity: (1) type of comparison, for example single group designs, active treatment versus treatment as usual (TAU); (2) broad intervention groups, i.e. pharmacological, psychological and 'other'; and (3) specific intervention groupings.

The exploration of potential modifiers that may account for the variation in outcome between studies was restricted to the variables that were reliably reported by the included studies. Taking into account the likely relevance of these to clinical practice and policy, sensitivity analyses were carried out for (1) clinically relevant factors; mental health status, age, sex and ethnicity and the setting in which the study was conducted; (2) type of outcome measure; and (3) study quality indicators, namely sample size, number lost to follow-up, blinding, length of follow-up baseline equivalence and whether an intention-to-treat (ITT) analysis was used.

Publication bias

Publication bias was explored using a funnel plot,[61] i.e. a scatterplot of effect size against sample size (or SE, which is expected to closely associate with sample size).

Advisory panel

As this review is part of a larger project Developing Evidence-based Guidelines for the Prevention of Violence in Mental Health Settings (EPOV) funded by the Department of Health, Research for Patient Benefit Programme (RfPB), the steering group for this larger project provided support and answered specific questions as the review progressed and commented on a draft of this report.

Chapter 3

Overview of the literature

Selection of included studies

As shown in *Figure 1*, the electronic searches identified 127,550 citations. After deduplication, both within and between the databases, 102,267 citations had the inclusion criteria applied at stage one. This resulted in 96,077 citations being excluded, 246 of which were reviews.

As a result of searching the reference lists of the 246 reviews, an additional 38 references were identified. Therefore, a total of 6240 papers had the inclusion criteria applied at stage two.

The process of applying stage two inclusion criteria resulted in 3760 references being excluded from both the intervention and risk reviews and a further 2053 being included in the risk review only. The remaining 326 papers met the inclusion criteria for the intervention review and data were extracted. At data extraction, 120 of the 326 papers were identified as not reporting any statistical analysis, mainly because of qualitative designs, and were therefore excluded from the review. A further 11 papers were identified as reporting data that were reported in other included papers. The primary paper for each study was retained, with any additional data reported in the linked paper combined, while the linked paper itself was excluded. A list of included papers is shown in *Appendix 1*, *Table 55*, and a list of excluded papers available on request.

Of the 195 included papers, three included more than one study, resulting in 198 studies being data extracted. All of the following analyses will be reported by study rather than by paper.

Different sections of the report require different selections of studies, as described throughout the report. However, *Table 4* summarises the number of studies for each level of analysis.

Quality assessment

Design of studies

Of 198 studies, 51 (25.8%) were RCTs, one-third (33.3%) were concurrent/cross-sectional group comparisons and 68 (34.3%) were before/after study comparisons. The remaining 13 studies were crossover comparisons, correlational studies and experimental case studies (*Table 5*).

TABLE 4 Number of studies included at each level of analysis

Chapter	Section	Description	No. of studies	No. of comparisons
3	Quality assessment; Study characteristics, Participant characteristics, Intervention characteristics	Descriptives	198	728
3	RCTs	RCTs	51	NA
3		Non-RCTs	147	NA
4		Bivariate/multivariate analyses	179	195
5		MAs	40	NA

NA, not applicable.

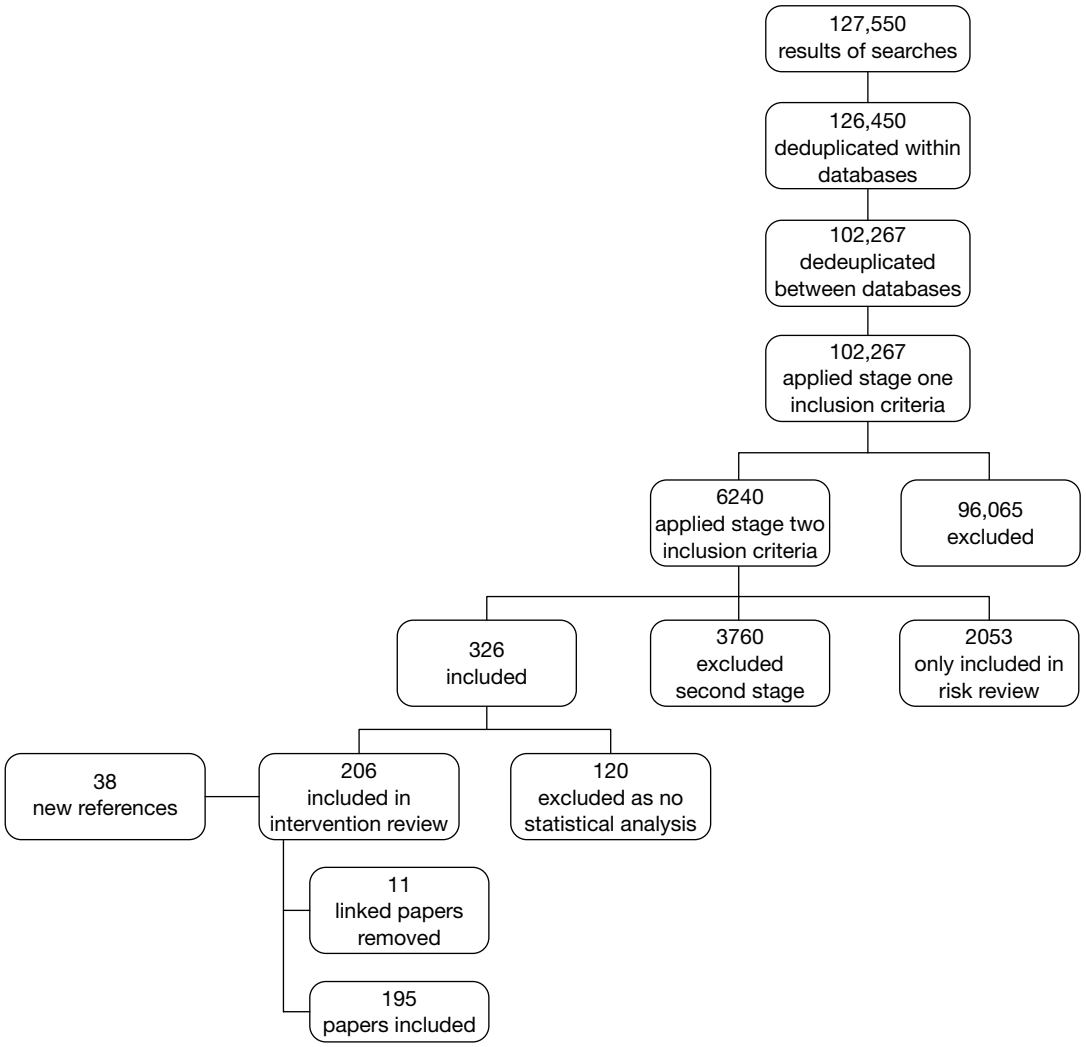

FIGURE 1 Flow diagram of inclusion of studies.

TABLE 5 Design of studies

Study design	*n*	%
RCT	51	25.8
Concurrent/cross-sectional group comparison	66	33.3
Crossover comparison ($n>1$)	2	1
Before-/after-study comparison ($n>1$)	68	34.3
Correlational/single group no comparator	8	4
Experimental case study ($n=1$ or set of Ns = 1)	3	1.5
Total	198	100

Ns, sets of case studies.

Length of follow-up

The maximum length of follow-up was reported by 179 studies and ranged from half an hour to 14 years, with the average length of follow-up being: mean = 524.26 days, median = 183.40 days and mode = 365 days (*Figure 2*).

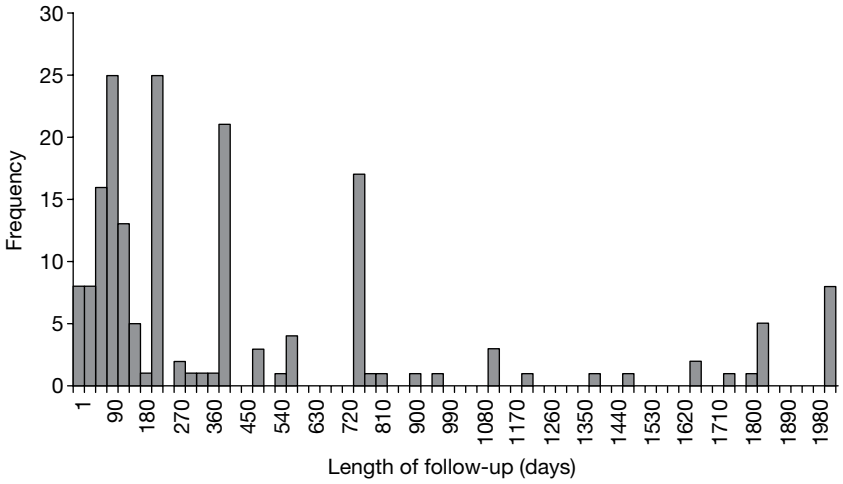

FIGURE 2 Total length of follow-up in days.

Attrition

Attrition was calculable for 189 of the studies: 67 (35.4%) reported no attrition and four (2.1%) more than 80% attrition (*Figure 3*). The mean attrition was 20.0% and the median was 9.9%.

Intention to treat

The 198 studies included in the review reported on 728 comparisons. Of these, 31.9% were analysed on an ITT basis, 59.1% were not analysed on an ITT basis and 9.1% did not state whether they were ITT analysis or not (*Table 6*).

Baseline equivalence

Of the 120 studies comparing different study groups, equivalent baseline measures of aggression were reported for 51 (42.5%) studies. A further 11 reported equivalence on some measures of aggression and 16 (13.3%) reported non-equivalence. Twenty studies reported the baseline levels of aggression for each group but did not compare them statistically and 22 (18.3%) did not report any baseline measure of aggression (*Table 7*).

Blinding

Given the nature of many of these studies it is not surprising that blinding was not stated in the majority of papers, as for practical reasons this is impossible to achieve when evaluating psychosocial interventions. Where it was stated, it was most frequently reported for patients and the interventionist, with 10.1% of patients not being blinded and 14.6% being blinded, and interventionists not being blinded in 12.1% of studies and blinded in 12.6% of studies (*Table 8*).

Study characteristics

Number of studies

The number of studies published was relatively steady across the years, with an average of 32 papers being published each full year (*Figure 4*).

Country in which studies were conducted

Studies were conducted in 21 different countries, with only three studies being multinational, i.e. participants from more than one country. The majority of studies were conducted in the USA (55.1%), with the UK being the second most common location (10.6%), followed by Canada (6.6%) (*Table 9*).

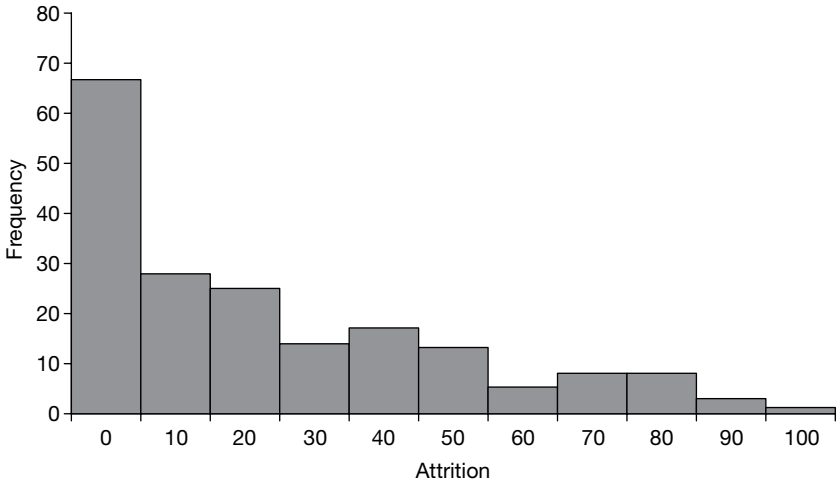

FIGURE 3 Attrition rates.

TABLE 6 Number and percentage of analyses reporting an ITT analysis

ITT analysis	*n*	%
No	430	59.1
Yes	232	31.9
Not stated	66	9.1
Total	728	100

TABLE 7 Equivalence of baseline measures of aggression

Equivalence of baseline measures of aggression	*n*	%
Yes, for all aggression outcome variables	51	42.5
Yes, for some aggression outcome variables	11	9.2
No	16	13.3
Unsure, no *p*-values stated	20	16.7
Not stated/unclear	22	18.3
Total	120	100.0

TABLE 8 Blinding reported in studies

	Patient		Interventionist		Assessor		Analyst	
Blinding	*n*	%	*n*	%	*n*	%	*n*	%
No	20	10.1	24	12.1	4	2	1	0.5
Yes, i.e. explicitly stated	29	14.6	25	12.6	16	8.1	3	1.5
Partial	0	0	0	0	4	2	176	88.9
Not stated/unclear	126	63.6	128	64.6	156	78.8	17	8.6
Not applicable	23	11.6	21	10.6	18	9.1	1	5
Total	198	100	198	100	198	100	198	100
	198	99.9	198	99.9	198	100	198	100

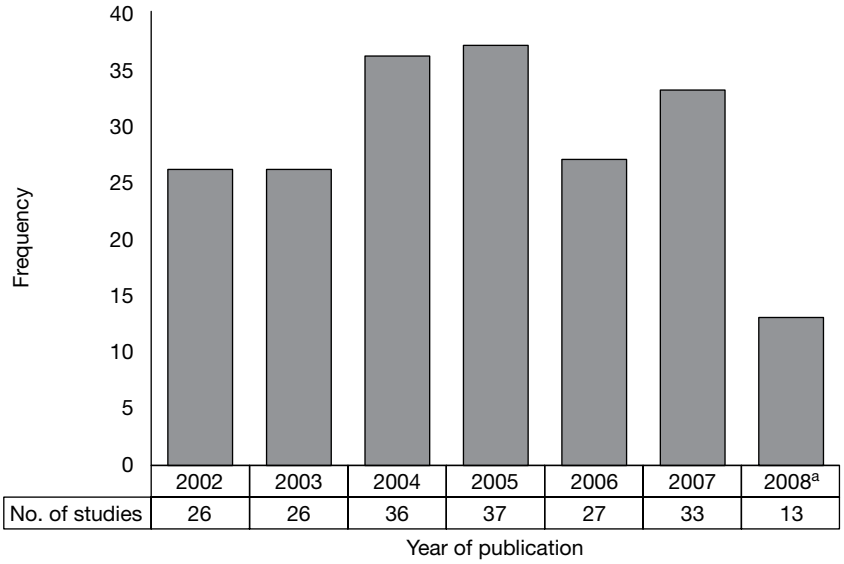

FIGURE 4 Number of studies by year of publication. a, The year 2008 was a partial year.

TABLE 9 Number of studies conducted in each country

Country	*n*	%
USA	109	55.1
UK	21	10.6
Canada	13	6.6
Australia	8	4.0
Netherlands	4	2.0
Italy	3	1.5
Spain	3	1.5
Brazil	2	1.0
Germany	2	1.0
India	2	1.0
Israel	2	1.0
New Zealand	2	1.0
South Korea	2	1.0
Sweden	2	1.0
Belgium	1	0.5
China	1	0.5
Finland	1	0.5
Japan	1	0.5
Norway	1	0.5
Switzerland	1	0.5
Taiwan	1	0.5
Multinational	3	1.5
Not stated/unclear	13	6.6
Total	198	100

Participant characteristics

Details of the characteristics of people included in the studies are shown below (see *Tables 10–14* and *Figures 5–7)*.

Number of participants

The number of people approached to take part in the studies was reported in 94 (47.4%) of studies and ranged from 1 to 8325. The number of participants enrolled was reported in 191 (96.5%) of studies and ranged from 1 to 10,753. The number of participants at the end point of the study was reported in 196 (99.0%) of studies meaning that two studies failed to report the final number of participants in their study.

The studies reporting the final number of participants described a total of 51,258 individuals, the smallest study having one participant and the largest 10,753 participants (*Figure 5*). The majority (60%) of studies included ≤ 100 people.

Demographics of participants

The sex of participants was reported in 183 (92.4%) studies, with 95 (52%) studies including only males and 15 (8%) including only females. The percentage of males in the remaining studies ranged from 8% to 95% (*Figure 6*).

The average age of participants was reported in 166 studies (158 reported the mean age, four reported the median age and four reported both the mean and median age). The mean age ranged from 19 to 80.9 years, with SDs (reported by 118 studies) ranging from 1 to 15.9 years. The range of ages was reported by 70 studies (an additional study reported minimum age only). The minimum age of participants ranged from 13 and 65 years and the maximum age ranged from 32 to 97 years. Therefore, the youngest participant was 13 years and the oldest was 97 years (*Table 10*).

The percentage of participants who were described as Caucasian was reported in 98 studies, with six (6%) studies not including any Caucasian participants, and one study (1%) including only Caucasian participants. The percentage of Caucasian participants in the remaining studies ranged from 6% to 99% (*Figure 7*).

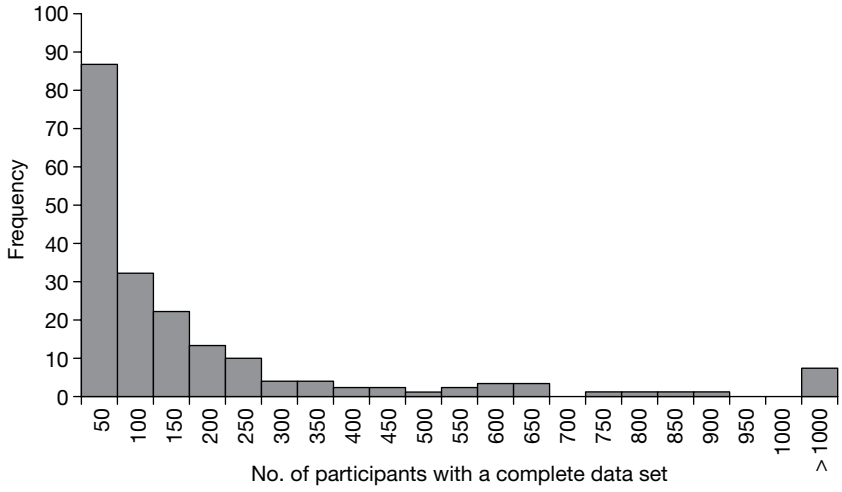

FIGURE 5 Number of participants in complete data set.

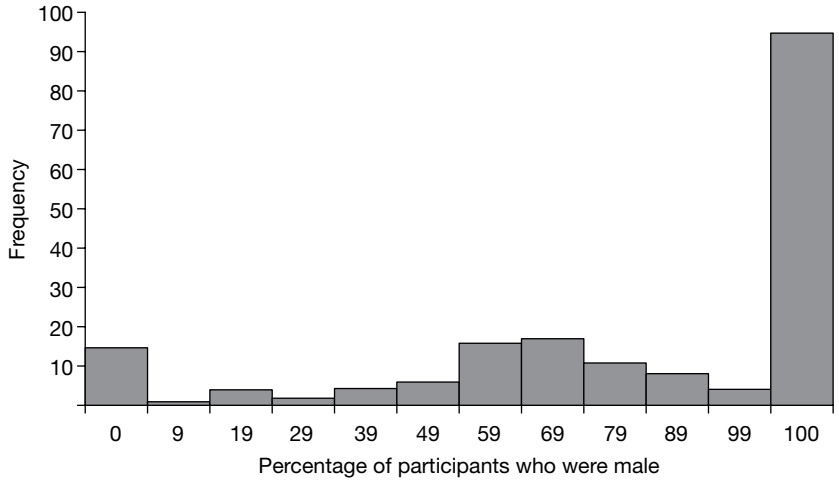

FIGURE 6 Percentage of participants who were male.

TABLE 10 Average ages and age ranges of participants

Variable	*n*	Lower value (years)	Upper value (years)
Mean age	158	19.0	80.9
SD	118	1	15.9
Median age	8	29	43
Minimum age	71	13	65
Maximum age	70	32	97

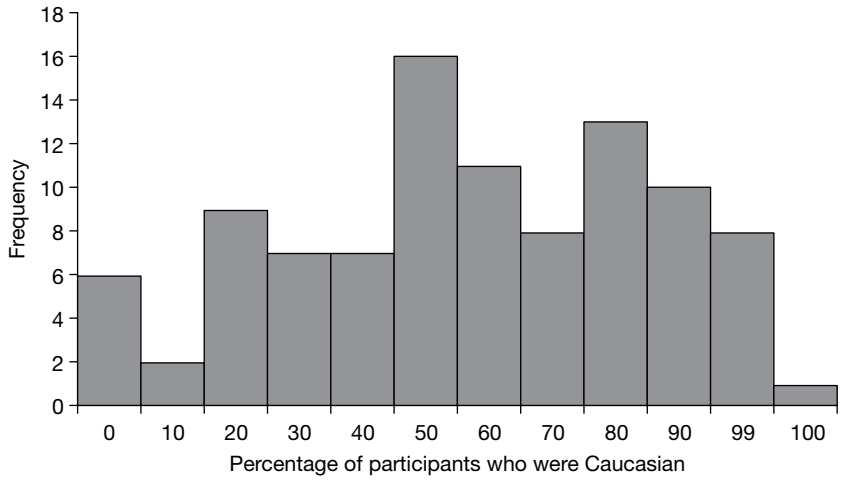

FIGURE 7 Percentage of participants who were Caucasian.

Population

Populations included in the review were either participants with a diagnosis of mental disorder, offenders, indictable offenders (i.e. those having committed indictable offences but not having been charged) or forensic participants (i.e. those with a diagnosis of mental disorder and offender/indictable offender status). The numbers of studies looking at each of these population types are shown in *Table 11*. Participants were mainly people with a mental disorder (38%) or

TABLE 11 Number and percentage of studies reporting each population group

Population	*n*	%
Mental disorder	75	38
Offender	70	35
Indictable offences	29	15
Forensic	24	12
Total	198	100

offenders (35%), with those reported to have committed an indictable offence being studied in 15% of studies and offenders with a mental disorder (forensic) being included in 12% of cases.

Studies reporting on individuals with a diagnosis of a mental disorder (including forensic groups) reported a range of diagnostic groups, with patients defined as having an 'other' single mental health grouping being the most frequently reported (34%), followed by participants with a 'mixed diagnosis' (28%). Participants with personality disorders only were studied in 20% of the studies and participants with a diagnosis of schizophrenia or schizoaffective disorder only were studied in 11% of the studies (*Table 12*).

There were differences between the diagnosis of participants in the mental disorder group and the forensic group. Almost half of the studies investigating forensic participants reported mixed diagnoses, and a further 37.5% reported participants with an 'other single mental health grouping'. Participants with a specific mental health diagnosis were reported in only 3 out of the 24 forensic studies (12.5%), whereas 32 out of the 75 studies (42.6%) examining participants with just a mental disorder reported investigating participants with specific mental disorder diagnoses.

The index offences that participants had committed differed greatly between the three groups. Offender participants had been charged with predominantly DV (44.3%), followed by mixed group of offences (28.6%) and sex offending (22.9%). For studies including forensic participants, mixed groups of offences were more frequently reported (41.7%), followed by sex offending (29.2%). A further 20.8% of studies did not report what offences participants had committed.

As expected, in the indictable group, DV was the most reported offence type (65.5%), with other indictable offences being reported in 24.1% of studies (*Table 13*).

Substance abuse

Substance abuse by participants was poorly reported in most studies, with only 43.4% (86) of papers reporting whether current substance abuse was or was not identified. Of the 86 studies reporting on substance abuse, 21 (24.4%) reported no substance abuse, five (5.8%) identified drug abuse, three identified (3.5%) alcohol abuse and 33 (38.4%) both alcohol and drug abuse. A further 24 (27.9%) studies identified some form of substance abuse, but did not report on the nature, i.e. whether it was drugs or alcohol (*Table 14*).

Intervention characteristics

Types of interventions

Of the 198 studies, 74 (37.37%) were single-group designs and 124 (62.6%) compared two or more groups. Of the 124 using a comparator group, 29.8% compared two different types of treatment (head-to-head comparisons), 24.2% TAU, 14.5% a placebo, 12.9% compared subgroups

TABLE 12 Number and percentage of participants within each diagnostic group

	Mental disorder		Forensic		Total	
Diagnostic group	***n***	**%**	***n***	**%**	***n***	**%**
Schizophrenia or schizoaffective disorder only	10	13.3	1	4.2	11	11.1
Dementia only	4	5.3	0	0.0	4	4.0
Personality disorder only	18	24.0	2	8.3	20	20.2
Other single mental health grouping	25	33.3	9	37.5	34	34.3
Mixed diagnostic groups	17	22.7	11	45.8	28	28.3
No specific diagnoses given	0	0.0	1	4.2	1	1.0
Not stated/unclear	1	1.3	0	0.0	1	1.0
Total	75	100	24	100	99	100

TABLE 13 Number of participants within each offence category by sample group

	Offender		Forensic		Indictable		Total	
Type of offence	***n***	**%**	***n***	**%**	***n***	**%**	***n***	**%**
General violence	3	4.3	1	4.2	3	10.3	7	5.7
Domestic violence	31	44.3	0	0.0	19	65.5	50	40.7
Sex offending	16	22.9	7	29.2	0	0.0	23	18.7
Mixed group of offences	20	28.6	10	41.7	0	0.0	30	24.4
Not stated/unclear	0	0.0	5	20.8	0	0.0	5	4.1
Other indictable offences	0	0.0	1	4.2	7	24.1	8	6.5
Total	70	100	24	100	29	100	123	100

TABLE 14 Number and percentage of studies reporting on substance abuse

Type of substance abuse	***n***	**%**	**% of studies reporting on substance abuse (*n*=86)**
No substance abuse identified	21	10.6	24.4
Illicit drug use identified	5	2.5	5.8
Alcohol abuse identified	3	1.5	3.5
Both illicit drug use and alcohol abuse identified	33	16.7	38.4
Substance not specified	24	12.1	27.9
Not stated or unclear	112	56.6	NA
Total	198	100	100

NA, not applicable.

of one treatment (e.g. completers vs non-completers) and 8.9% no treatment. The remaining seven studies used a historical control (3.2%) or self as a control (2.4%) (*Table 15*).

The types of intervention studied are shown in *Tables 16* and *17*. Half of included studies used a psychological intervention (50.5%) as the primary intervention, one-quarter used a pharmacological intervention (23.7%) and one-quarter another form of intervention (25.8%). The specific categories of intervention by comparison type are shown in *Table 16* and the comparators used in head-to-head studies in *Table 17*.

TABLE 15 Number and percentage of studies reporting different control groups

Type of comparison	*n*	%
Head to head	37	29.6
Historical control	5	4.0
Placebo	18	14.4
Self as control	3	2.4
Subgroup	16	12.8
TAU	30	24.0
No treatment	11	8.8
WL	5	4.0

WL, waiting list control.

Psychological studies were more likely to use single-group comparisons and pharmacological studies head-to-head or placebo comparators. Where head-to-head studies were used, the same categories of intervention were compared, i.e. psychological interventions compared with another psychological intervention, and pharmacological interventions compared with another pharmacological intervention.

Setting

The start and end settings are shown in *Table 18*. The term 'setting' here refers to the location where the intervention is conducted and in the case of 'community' under what conditions, i.e. a probation order, or under the supervision of a mental health practitioner or neither (e.g. a person concerned about their propensity for violence who is offered a self-help intervention). The most frequently reported setting was community with people on probation (18.7%), followed by penal institutions (16.2%), community (14.6%) and community mental health (12.1%). The majority of studies (87.9%) had the same start and end setting. Of the 24 studies reporting different start and end settings, 12 were studies that started in penal institutions but ended in either the community or in mixed settings.

When start settings for the interventions are examined by intervention type (*Table 19*), it can be seen that studies in a forensic mental health setting mainly studied behavioural and cognitive therapies (75.0%), as did penal institutions (56.3%), community (44.8%), mixed settings (33.3%) and other settings (40.0%), whereas community probation settings used DV programmes. Pharmacological interventions were the focus of the majority of studies in community mental health settings (58.0%), accident and emergency (A&E) settings (100%), mixed settings (33.3%) and studies where the setting was unclear or not stated (40.0%).

Level of intervention

The levels of interventions for each of the types of intervention are shown in *Table 20*. Pharmacological interventions were by design at an individual level, whereas the psychological interventions were generally at the small group level.

TABLE 16 Type of interventions by comparator group

	Comparator group: *n* (%)								
Primary intervention	**Single group**	**Historical control**	**Placebo**	**Self as control**	**Subgroup**	**TAU**	**No treatment**	**WL**	**Head to head**
Behavioural/cognitive	30 (40.5)			1 (33.3)	8 (50)	10 (33.3)	5 (45.5)	4 (80)	10 (27.0)
Other psychological therapy	4 (5.4)				1 (6.3)		1 (9.1)		2 (5.4)
Substance abuse therapy	2 (2.7)								
Domestic violence/batterer programmes	10 (13.5)				3 (18.8)	3 (10)		1 (20)	1 (2.7)
Case management model		1 (20)				2 (6.7)			
Legal	1 (1.4)	2 (40)				4 (13.3)	1 (9.1)		1 (2.7)
Clozapine									3 (8.1)
Divalproex	1 (1.4)		2 (11.1)		1 (6.3)				
Fluoxetine			2 (11.1)						
Fluvoxamine	1 (1.4)		1 (5.6)						
Haloperidol			1 (5.6)						1 (2.7)
Lamotrigine	1 (1.4)		1 (5.6)						
Lorazepam			1 (5.6)						1 (2.7)
Midazolam									1 (2.7)
Nefalzone	1 (1.4)								
Olanzapine			1 (5.6)						4 (10.8)
Quetiapine	2 (2.7)								
Risperidone			2 (11.1)						2 (5.4)
Topiramate			4 (22.2)						
Ziprasidone	1 (1.4)								1 (2.7)
Zuclopenthixol									1 (2.7)
Other pharmacological	4 (5.4)		3 (16.7)				1 (9.1)		2 (5.4)
Therapeutic communities						1 (3.3)			
Multimodal programme	7 (9.5)	2 (40)				5 (16.7)	3 (27.3)		3 (8.1)
Other form of intervention	9 (12.2)			2 (66.7)	3 (18.8)	5 (16.7)			4 (10.8)
Total studies	74 (100)	5 (100)	18 (100)	3 (100)	16 (100)	30 (100)	11 (100)	5 (100)	37 (100)

WL, waiting list control.

TABLE 17 Types of intervention in head-to-head studies

	Comparator group: *n* (%)													
Primary intervention	**Behavioural/cognitive**	**Other psychological therapy**	**Community therapy**	**Legal intervention**	**Multi-modal programme**	**Clozapine**	**Fluoxetine**	**Haloperidol**	**Olanzapine**	**Topiramine**	**Zuclopenthixol**	**Other pharmacological**	**Other form of intervention**	**Total**
Behavioural/ cognitive	3 (30.0)	2 (20.0)	1 (10.0)		1 (10.0)								3 (30.0)	10 (100)
Other psychological therapy	1 (50.0)												1 (50.0)	2 (100)
Domestic violence/batterer programmes		1 (100.0)												1 (100)
Legal				1 (100)										1 (100)
Clozapine									3 (100)					3 (100)
Haloperidol												1 (100)		1 (100)
Lorazepam												1 (100)		1 (100)
Midazolam												1 (100)		1 (100)
Olanzapine						1 (25)	1 (25)					2 (50)		4 (100)
Risperidone								1 (50)	1 (50)					2 (100)
Ziprasidone												1 (100)		1 (100)
Zuclopenthixol											1 (100)			1 (100)
Other pharmacological										1 (50)		1 (50)		2 (100)
Multimodal programme	1 (33.3)												1 (33.3)	3 (100)
Other form of intervention													4 (100)	4 (100)
Total	5 (13.5)	4 (10.8)	1 (2.7)	1 (2.7)	1 (2.7)	1 (2.7)	1 (2.7)	1 (2.7)	4 (10.8)	1 (2.7)	1 (2.7)	7 (18.9)	9 (24.3)	37 (100)

TABLE 18 Start and end settings of studies

	Setting follow-up ended in:												
Setting started in:	Forensic mental health	Penal institution, e.g. prison	Open inpatient hospital ward	Secure non-forensic inpatient ward	Nursing home	Community	Community: probation	Community mental health	A&E or psychiatric emergency service	Mixed settings	Other	Not stated or unclear	Total: *n* (%)
Forensic mental health	11	0	0	0	0	0	0	0	0	0	1	0	12 (6.1)
Penal institution, e.g. prison	0	20	0	0	0	6	1	0	0	5	0	0	32 (16.2)
Open inpatient hospital ward	0	0	14	0	0	1	0	1	0	0	0	0	16 (8.1)
Secure non-forensic inpatient ward	0	0	0	3	0	0	0	0	0	0	0	0	3 (1.5)
Nursing home	0	0	0	0	3	0	0	0	0	0	0	0	3 (1.5)
Community	0	0	0	0	0	28	0	0	0	1	0	0	29 (14.6)
Community: probation	0	0	0	0	0	0	33	0	0	3	0	1	37 (18.7)
Community mental health	0	0	0	0	0	0	0	24	0	0	0	0	24 (12.1)
A&E or psychiatric emergency service	0	0	0	0	0	0	0	0	7	0	0	0	7 (3.5)
Mixed settings	0	0	0	0	0	1	0	0	0	12	0	2	15 (7.6)
Other	0	0	0	0	0	0	0	0	0	0	10	0	10 (5.1)
Not stated or unclear	0	0	0	0	0	0	0	0	0	1	0	9	10 (5.1)
Total *n*	11 (5.6)	20 (10.1)	14 (7.1)	3 (1.5)	3 (1.5)	36 (18.2)	34 (17.2)	25 (12.6)	7 (3.5)	22 (11.1)	11 (5.6)	12 (6.1)	198 (100)

Studies with differing start and end settings are shown in shaded cells.

TABLE 19 Setting and types of intervention

	Intervention type										
Start setting	Pharmacological	Behavioural and cognitive therapies	Therapeutic community	DV programme	Other psychological intervention	Substance abuse	Case management	Legal	Multimodal	Other	Total
Forensic mental health	0	9	0	0	0	0	0	1	2	0	12
Penal institution, e.g. prison	1	18	1	0	1	0	0	3	3	5	32
Open inpatient hospital ward	6	2	0	0	0	0	0	0	2	6	16
Secure non-forensic inpatient ward	1	0	0	0	0	0	0	0	0	2	3
Nursing home	2	0	0	0	0	0	0	0	0	1	3
Community	4	13	0	4	1	1	0	1	4	1	29
Community: probation	1	10	0	11	3	0	1	3	5	3	37
Community mental health	14	5	0	0	1	0	0	1	1	2	24
A&E or psychiatric emergency service	7	0	0	0	0	0	0	0	0	0	7
Mixed settings	5	5	0	2	1	1	0	0	0	1	15
Other	2	4	0	1	1	0	1	0	0	1	10
Not stated or unclear	4	1	0	0	0	0	1	0	3	1	10
Total	47	67	1	18	8	2	3	9	20	23	198

Type of intervention is taken from primary intervention being tested.

TABLE 20 Level of intervention by intervention type

	Level of intervention								
Type of intervention	Individual	Small group	Ward or team	Hospital or institution	Population	Other	Mixed	Not stated/ unclear	Total
Behavioural and cognitive therapies	5	45	1	4	0	0	8	4	67
Therapeutic community	0	0	0	1	0	0	0	0	1
DV programme	1	13	0	0	0	0	2	2	18
Other psychological intervention	1	7	0	0	0	0	0	0	8
Substance abuse	1	1	0	0	0	0	0	0	2
Case management	1	1	0	0	0	0	0	1	3
Legal	6	0	0	2	0	1	0	0	9
Multimodal	4	9	0	3	0	0	3	1	20
Pharmacological	47	0	0	0	0	0	0	0	47
Other	12	2	5	2	1	0	1	0	23
Total	78	78	6	12	1	1	14	8	198

Type of intervention is taken from primary intervention being tested.

Randomised controlled trials

In total, 51 RCTs, reporting on 197 comparisons between active interventions and/or active interventions plus placebo or other inactive control, were identified in the literature. These studies represent 25.8% of all intervention studies identified as meeting our inclusion criteria.

Predictably, studies meeting the design criteria of prospective RCTs were also not entirely representative of the empirical literature as a whole. The differences between the RCTs and the other studies are outlined below.

Quality

On variables used to assess methodological quality of studies, the RCTs reflected what was found in the whole data set (see *Quality assessment*) for baseline equivalence [$\chi^2 = 2.347$, degrees of freedom (df) = 3, $p = 0.504$] (*Table 21*), and sample attrition (Mann–Whitney *U*-test, $p = 0.568$) (*Table 22*). However, the total length of follow-up reported in studies was significantly longer in the non-RCTs (mean 629 days, SD 932, median 364 days) than in the RCTs (mean 253 days, SD 731, median 84 days) (Mann–Whitney *U*-test, $p < 0.0001$) (see *Table 22*) and the number of studies using some form of blinding to the intervention was far higher in the RCT data set (58.8%) than in the non-RCTs (6.1%) ($\chi^2 = 66.486$, df = 1, $p < 0.0001$) (see *Table 21*). Of the 197 comparisons conducted in the RCT studies, 53.3% used an ITT analysis, whereas only 27.2% of the 464 comparisons reporting whether an ITT analysis was used in the non-RCT data set used an ITT analysis ($\chi^2 = 41.578$, df = 1, $p < 0.0001$) (see *Table 21*).

Trial and participant characteristics

The distribution of the number of papers being published in each year was the same for RCTs and non-RCTs ($\chi^2 = 3.629$, df = 6, $p = 0.774$) (*Table 23*), as was the distribution of the number of participants in the studies (Mann–Whitney *U*-test, $p = 0.422$), mean age (Mann–Whitney *U*-test, $p = 0.084$), proportion of sample who were Caucasian (Mann–Whitney *U*-test, $p = 0.436$) (*Table 24*), the reporting of substance abuse ($\chi^2 = 2.347$, df = 3, $p = 0.05$) and the types of offences offenders had committed (statistical analyses not appropriate) (see *Table 23*) (see *Study characteristics* and *Participants characteristics* for description of whole sample).

TABLE 21 Categorical quality variables in RCTs and non-RCTs

Categorical variable	Group	RCT		Non-RCT		*p*-value
		n	%	*n*	%	
Baseline equivalence	No	5	9.8	11	15.5	0.504
	Yes[a]	26	45.1	36	39.4	
	Unsure: no *p*-values stated	11	21.6	9	12.7	
	Not stated/unclear	9	17.6	15	21.1	
Blind	No	21	41.2	138	93.9	< 0.0001
	Yes	30	58.8	9	6.1	
ITT	No	92	46.7	338	72.8	< 0.0001
	Yes	105	53.3	127	27.2	
	Not stated	0	0.0	66	12.4	

Intention-to-treat results were conducted on all comparisons rather than studies.
a Three RCTs and eight non-RCTs reported baseline equivalence for only some variables.

TABLE 22 Continuous quality variables in RCTs and non-RCTs

Variable	Statistical test		RCT	Non-RCT	*p*-value
Attrition (%)	Mean		16.78	21.07	0.568
	SD		18.8	25.8	
	Kurtosis	Statistic	2.216	0.019	
		SE	0.668	0.407	
	Skewness	Statistic	1.575	1.079	
		SE	0.34	0.205	
Length of follow-up (days)	Mean		253	629	< 0.0001
	SD		731	932	
	Kurtosis	Statistic	41.754	41.754	
		SE	0.662	0.662	
	Skewness	Statistic	6.251	6.251	
		SE	0.337	0.337	

The country in which studies were conducted appeared to differ between RCTs and non-RCTs (see *Table 23*), most notably the proportion of RCTs that were conducted in the UK (3.9%) was lower than non-RCTs (13.0%) and RCTs were more likely to fail to report where the study was conducted than non-RCTs (13.7% vs 3.4%, respectively). RCTs also reported a lower percentage of males (mean 55.02%, SD 38.76) than non-RCTs (mean 83.0%, SD 26.06) (Mann–Whitney *U*-test, $p < 0.0001$) (see *Table 24*).

The populations in the studies also appeared different in the RCTS and non-RCTS (see *Table 23*). RCTs focused primarily on participants with mental disorder (66.7%) compared with non-RCTs (27.9%), whereas non-RCTs included offenders in 40.8% of studies compared with 17.6% of RCTs. Only one (2.0%) RCT included forensic patients, whereas 16.3% of non-RCTs included forensic patients.

The diagnoses of participants in studies investigating a population of people with a mental disorder seemed to differ between RCTs and non-RCTs (see *Table 23*), with RCTs focusing on participants with a personality disorder (38.2%) and non-RCT studies participants with other single mental health grouping (38.5%).

Intervention characteristics

As expected, the types of comparisons differed between RCTs and non-RCTs, with nearly half of the non-RCTs reporting single group comparisons (49.3%) (*Table 25*).

As shown in *Table 25*, the type of primary intervention being tested in the studies also differed between RCTs and non-RCTs ($\chi^2 = 43.611$, df = 2, $p < 0.0001$), with 56.9% ($n = 29$) of RCTs evaluating pharmacological intervention alone, and only 21.6% of studies ($n = 11$) evaluating a psychological intervention. This compares with 12.2% of non-RCTs testing a pharmacological intervention and 60.5% a psychological intervention. Within each of the four broad categories of primary interventions, the specific groupings of primary interventions had too few studies for statistical analyses.

The setting that interventions were started in appeared to differ between RCTs and non-RCTs. RCTs were more likely to fail to report the type of setting (11.8%) compared with non-RCTs (2.7%), and were more likely to be conducted in community mental health settings (RCTs 19.6%, non-RCTS 9.5%). In contrast, non-RCTs were more likely than RCTs to be conducted in a penal

TABLE 23 Categorical trial and participant characteristic variables in RCTs and non-RCTs

		RCT		Non-RCT		
Categorical variable	**Group**	***n***	**%**	***n***	**%**	***p*-value**
Year of publication	2002	8	15.7	18	12.2	0.774
	2003	6	11.8	20	13.6	
	2004	8	15.7	28	19.0	
	2005	8	15.7	29	19.7	
	2006	9	17.6	18	12.2	
	2007	7	13.7	26	17.7	
	2008	5	9.8	8	5.4	
Substance abuse	No substance abuse identified in sample	10	19.6	11	7.5	0.05
	Substance use identified in sample	16	31.4	49	33.3	
	■ Illicit drug use identified in sample	2	3.9	3	2.0	NA
	■ Alcohol abuse identified in sample	1	2.0	2	1.4	
	■ Both illicit drug use and alcohol abuse identified in sample	5	9.8	28	19.0	
	■ Substance not specified	8	15.7	16	10.9	
Not stated or unclear		25	49.0	87	59.2	
Types of offences	General violence	2	11.8	5	4.7	NA
	Domestic violence	6	35.3	44	41.5	
	Sex offending	1	5.9	22	20.8	
	Mixed group of offences	5	29.4	25	23.6	
	Not stated/unclear	0	0.0	5	4.7	
	Other single type of indictable offence	3	17.6	5	4.7	
Country study conducted	US	29	56.9	80	54.8	NA
	UK	2	3.9	19	13.0	
	Canada	0	0.0	13	8.9	
	Sweden	0	0.0	2	1.4	
	Finland	0	0.0	1	0.7	
	India	2	3.9	0	0.0	
	Brazil	2	3.9	0	0.0	
	Multinational	2	3.9	1	0.7	
	Norway	0	0.0	1	0.7	
	Netherlands	1	2.0	3	2.1	
	Belgium	0	0.0	1	0.7	
	Israel	0	0.0	2	1.4	
	Japan	0	0.0	1	0.7	
	Spain	1	2.0	2	1.4	
	Italy	1	2.0	2	1.4	
	Australia	0	0.0	8	5.5	
	New Zealand	0	0.0	2	1.4	
	Switzerland	0	0.0	1	0.7	
	Germany	2	3.9	0	0.0	
	China	0	0.0	1	0.7	
	South Korea	1	2.0	1	0.7	
	Not stated/unclear	8	15.7	5	3.4	

continued

TABLE 23 Categorical trial and participant characteristic variables in RCTs and non-RCTs (*continued*)

		RCT		Non-RCT		
Categorical variable	**Group**	***n***	**%**	***n***	**%**	***p*-value**
Population	Mental	34	66.7	41	27.9	NA
	Offender	9	17.6	60	40.8	
	Forensic	1	2.0	24	16.3	
	Indictable offender	7	13.7	22	15.0	
Diagnostic group	Schizophrenia or schizoaffective only	4	11.8	7	10.8	NA
	Dementia only	2	5.9	2	3.1	
	Personality disorder only	13	38.2	7	10.8	
	Other single mental health grouping	9	26.5	25	38.5	
	Mixed diagnostic groups	5	14.7	23	35.4	
	No specific diagnoses given	0	0.0	1	1.5	
	Not stated/unclear	1	2.9	0	0.0	

NA, not applicable.

TABLE 24 Continuous trial and participant characteristic variables in RCTs and non-RCTs

Variable	**Statistical test**		**RCT**	**Non-RCT**	***p*-value**
No. of participants	Mean		131.06	305.01	0.422
	SD		135.67	1,095.19	
	Kurtosis	Statistic	2.495	65.042	
		SE	0.668	0.397	
	Skewness	Statistic	1.562	7.627	
		SE	0.34	0.2	
% male	Mean		55.02	83	< 0.0001
	SD		38.76	26.06	
	Kurtosis	Statistic	–1.435	1.748	
		SE	0.681	0.413	
	Skewness	Statistic	–0.341	–1.535	
		SE	0.347	0.208	
Mean age (years)	Mean		35.98	36.67	0.084
	SD		12.84	7.31	
	Kurtosis	Statistic	5.42	6.554	
		SE	0.724	0.437	
	Skewness	Statistic	2.172	1.663	
		SE	0.369	0.22	
% Caucasian	Mean		56.7	51.33	0.436
	SD		28.61	28	
	Kurtosis	Statistic	–0.903	–0.846	
		SE	0.953	0.545	
	Skewness	Statistic	–0.514	–0.125	
		SE	0.491	0.276	

institution (non-RCTs 19.7%, RCT 5.9%) or on community probation (non-RCTs 22.4%, RCTs 7.8%) (see *Table 25*).

The level the intervention was conducted on also appeared to differ between RCTs and non-RCTs. RCTs were primarily conducted at the individual level (67%), probably reflecting the focus on pharmacological interventions, whereas non-RCTs were more frequently conducted in small groups (46%) (see *Table 25*).

TABLE 25 Categorical intervention characteristic variables in RCTs and non-RCTs

		RCT		Non-RCT		
Categorical variable	**Group**	***n***	**%**	***n***	**%**	***p*-value**
Type of comparison[a]	Head to head	18	36.0	18	12.8	NA
	Placebo	17	34.0	1	0.7	
	TAU	13	26.0	17	11.5	
	No treatment	1	2.0	10	6.8	
	WL	1	2.0	3	2.7	
	No comparator	1	2.0	73	49.3	
	Historical control	NA	NA	4	2.7	
	Self as control	NA	NA	4	2.7	
	Subgroup	NA	NA	16	10.8	
Broad category of primary intervention	Psychological	11	21.6	89	60.5	<0.0001
	Pharmacological	29	56.9	18	12.2	
	Other	11	21.6	40	27.2	
Specific category of primary intervention where broad category is psychological	Behavioural/cognitive	8	72.7	59	66.3	NA
	Therapeutic communities	0	0	1	1.1	
	DV/batterer programmes	2	18.2	16	18.0	
	Other psychological therapy	1	9.1	7	7.9	
	Substance abuse therapy	0	0	1	1.1	
	Multimodal programme	0	0	5	5.6	
Specific category of primary intervention where broad category is pharmacological	Clozapine	1	3.4	2	11.1	NA
	Divalproex	2	6.9	2	11.1	
	Fluoxetine	2	6.9	0	0	
	Fluvoxamine	1	3.4	1	5.6	
	Haloperidol	2	6.9	0	0	
	Lamotrigine	1	3.4	1	5.6	
	Lorazepam	1	3.4	1	5.6	
	Midazolam	1	3.4	0	0	
	Nefalzone	0	0	1	5.6	
	Olanzapine	4	13.8	1	5.6	
	Quetiapine	0	0	2	11.1	
	Risperidone	4	13.8	0	0	
	Topiramate	4	13.8	0	0	
	Ziprasidone	0	0	2	11.1	
	Zuclopenthixol	1	3.4	0	0	
	Other pharmacological	5	17.2	5	27.8	

continued

TABLE 25 Categorical intervention characteristic variables in RCTs and non-RCTs (*continued*)

		RCT		Non-RCT		
Categorical variable	**Group**	***n***	**%**	***n***	**%**	***p*-value**
Specific category of primary intervention where broad category is other somatic	Other form of intervention	0	0	1	100.0	NA
Specific category of primary intervention where broad category is other form of intervention	Substance abuse therapy	0	0	1	2.6	NA
	Case management model	2	18.2	1	2.6	
	Legal intervention	1	9.1	8	20.5	
	Multimodal programme	6	54.5	9	23.1	
	Other form of intervention	2	18.2	20	51.3	
Setting study started in	Forensic mental health	1	2.0	11	7.5	NA
	Penal institution, e.g. prison	3	5.9	29	19.7	
	Open inpatient hospital ward	3	5.9	13	8.8	
	Secure non-forensic inpatient ward	0	0	3	2.0	
	Nursing home	2	3.9	1	0.7	
	Community	10	19.6	19	12.9	
	Community: probation	4	7.8	33	22.4	
	Community mental health	10	19.6	14	9.5	
	A&E or psychiatric emergency service	5	9.8	2	1.4	
	Mixed settings	3	5.9	12	8.2	
	Other	4	7.8	6	4.1	
	Not stated or unclear	6	11.8	4	2.7	
Level of intervention	Individual	34	67	44	30	NA
	Small group	11	22	67	46	
	Ward or team	0	0	6	4	
	Hospital or institution	2	4	10	7.	
	Population	0	0	1	1.	
	Other	0	0	1	1.	
	Mixed	1	2	13	9.	
	Not stated/unclear	3	6	5	3	

NA, not applicable; WL, waiting list control.

a One RCT was a randomised crossover trial so no control group and one non-RCT reported on a head-to-head and WL.

Chapter 4

Results of bivariate and multivariate analyses

Overview

Of the 198 studies identified 188 (94.9%) provided statistical data suited to extraction and statistical analyses. The 10 analyses that did not report data suitable for statistical analyses included six non-RCT analyses[62–67] and four RCT analyses.[68–71] A further five analyses[72–76] were excluded from the analyses in this chapter as they did not report data on statistical significance (the dependent variable in all following analyses). Raveendran *et al.*,[75] Huf[72] and Huf *et al.*[73] presented only figures for relative risk (RR); Marques *et al.*[74] reported change in absolute proportions only and Villari *et al.*[76] presented mean/mean change data only. This resulted in 183 studies reporting on a total of 655 separate statistical analyses. Of the 655 separate analyses, 331 (50.5%) reported an outcome that was not statistically significant. A further 315 (48.1%) reported a statistically significant outcome in favour of the intervention that was the primary focus of the study, whereas only five (< 1%) analyses reported an outcome in favour of an active comparator and only four (< 1%) in favour of a placebo or other inactive comparator.

In order to maintain independence of samples, only studies reporting on different groups of participants are included in the remainder of the analyses. Whereas for the most part any overlap between populations occurred within studies, two studies[77,78] were excluded entirely, as the data they reported on overlapped with data included in other studies, which provided greater detail in respect of outcomes. A further two analyses[79,80] were subsequently excluded because of concerns over the correct interpretation of the analyses they presented (both studies presented summative figures only). Given the above, the final selection of outcomes to be included in the analyses outlined here comprised 195 analyses taken from 179 studies.

Bivariate associations

Analyses by broad intervention groupings

Significant bivariate associations between broad category of intervention and the statistical significance of an analysis were not observed for either pharmacological or psychological interventions (60.8% of pharmacological and 57.3% of psychological intervention analyses found in favour of the primary intervention arm vs its comparator). Where an impact on outcomes was shown, was in the case of analyses focused on 'other' forms of intervention. Analyses focused on such interventions were less likely than analyses focused *either* on pharmacological or on psychological interventions to result in a statistically significant outcome in favour of the primary intervention arm of the analysis ($n = 195$, $\chi^2 = 6.006$, $p = 0.011$) (*Table 26*).

Population

Mental health status

The broad population group chosen for evaluation did have an impact on outcomes. Analyses focused on people with a mental disorder were overall more likely to find in favour of the primary intervention arm than those not focused on a general mental health population

TABLE 26 Number of analyses reporting a statistically significant outcome by intervention type

Intervention grouping		*n*	Favours treatment (%)	Does not favour treatment (%)	Chi-squared	*p*-value
Pharmacological	Yes	51	31 (60.8)	20 (39.2)	0.975	0.205
	No	144	76 (52.8)	68 (47.2)		
Psychological	Yes	110	63 (57.3)	47 (42.7)	0.587	0.267
	No	85	44 (51.8)	41 (48.2)		
Other	Yes	50	20 (40.0)	30 (60.0)	6.006	0.011
	No	145	87 (60.0)	58 (40.0)		

(64.5% vs 48.7%, $n = 195$, $\chi^2 = 4.377$, $p = 0.022$). In contrast, analyses that focused on offending populations were far less likely to report outcomes favouring the primary intervention arm (44.1% vs 60.6%, $n = 195$, $\chi^2 = 4.876$, $p = 0.02$). Analyses focused on interventions for people who have committed indictable acts of aggression but who have not yet been convicted of such were, overall, more likely to find in favour of the primary intervention arm (59.3% vs 54.2%), but this distinction failed to reach statistical significance ($n = 195$, $\chi^2 = 0.244$, $p = 0.390$) (*Table 27*).

Demographics

No statistically significant association was found between outcomes favouring the primary intervention arm and the demographic variables mean age, proportion of males and proportion of participants who were Caucasian (*Table 28*).

The mean age of participants in the analyses was 36.6 years and showed no significant association with statistically significant outcomes favouring the primary intervention ($n = 160$, $r = 0.027$, $p = 0.738$) (see *Table 28*).

The mean proportion of males within the analyses was 76.4% and again showed no association with statistically significant outcomes favouring the primary intervention ($n = 180$, $r = -0.141$, $p = 0.06$) (see *Table 28*).

Across the analyses, 53.9% of the sample were reported as being Caucasian although once again this showed no association with statistically significant outcomes favouring the primary intervention ($n = 93$, $r = 0.065$, $p = 0.534$) (see *Table 28*).

The only significant association between these demographic variables was a positive association between the percentage of participants in the sample who were Caucasian and increasing mean age of the participants ($n = 83$, Pearson's $r = 0.27$, $p = 0.014$) (see *Table 28*).

Setting

The 'setting' of a study can be categorised in a number of ways (e.g. start setting, end setting, change between start and end, settings based on usual transition through the health-care system, etc.). Based both on outcomes from a previous review[55] and the analysis numbers available within each context in this review, we chose to simplify the comparisons drawn here to reflect the initial choice of broad outcome setting identified in the analyses at their start point (categorised into mental health, offenders' institution, community and 'other'). Categorised in this way, there were no statistically significant differences with respect to the outcomes for the primary intervention based on setting (*Table 29*).

TABLE 27 Number of analyses reporting a statistically significant outcome by population

Population		*n*	Favours treatment (%)	Does not favour treatment (%)	Chi-squared	*p*-value
Mental disorder only	Yes	76	49 (64.5)	27 (35.5)	4.637	0.022
	No	119	58 (48.7)	61 (51.3)		
Offenders only	Yes	68	30 (44.1)	38 (55.9)	4.876	0.020
	No	127	77 (60.6)	50 (39.4)		
Forensic patients	Yes	28	14 (50.0)	14 (50.0)	0.313	0.360
	No	16	93 (55.7)	74 (44.3)		
Indictable offenders only	Yes	27	16 (59.3)	11 (40.7)	0.244	0.390
	No	168	91 (54.2)	77 (45.8)		

TABLE 28 Correlation between demographic variables and statistically significant finding in favour of primary intervention

Variable	Output	Statistical significance of finding in favour of primary intervention or not	Mean age (years)	% male	% Caucasian
Statistical significance finding in favour of primary intervention or not	Pearson's correlation	1	0.027	–0.141	0.065
	Significance (two tailed)		0.738	0.060	0.534
	n	195	160	180	93
Mean age of all participants in the study (years)	Pearson's correlation			0.066	0.270[a]
	Significance (two tailed)			0.419	0.014
	n (mean years)			154	83
% of sample who are male	Pearson's correlation				–0.168
	Significance (two tailed)				0.113
	n (mean)				90
% of sample who are Caucasian	Pearson's correlation				
	Significance (two tailed)				
	n				

a Correlation is significant at the 0.05 level (two tailed).

TABLE 29 Number of analyses reporting a statistically significant outcome by setting

Setting		*n*	Favours treatment *n* (%)	Does not favour treatment *n* (%)	Chi-squared	*p*-value
Mental health (including forensic)	Yes	34	18 (52.9)	16 (47.1)	0.062	0.475
	No	161	89 (55.3)	72 (44.7)		
Penal institution (excluding forensic)	Yes	33	17 (51.5)	16 (48.5)	0.181	0.406
	No	162	90 (55.6)	72 (44.4)		
Community	Yes	87	49 (56.3)	38 (43.7)	0.133	0.413
	No	108	58 (53.7)	50 (46.3)		
Other	Yes	28	14 (50.0)	14 (50.0)	0.313	0.360
	No	167	93 (55.7)	74 (44.3)		

Outcome measure

As the majority of studies in the literature use a scale-based outcome measure the impact of this choice on outcomes for the primary intervention was investigated. Although a trend was observed for scale-based outcomes to favour the primary intervention arm (58.1% of scale-based outcomes showed statistical significance in favour of the primary arm in contrast with 48.5% of non-scale-based outcomes), this trend did not reach statistical significance ($n = 195$, $\chi^2 = 1.644$, $p = 0.129$) (*Table 30*).

Study quality indicators

Perhaps unexpectedly, none of the 'design-quality' variables, including whether or not a RCT design was used in a study, showed a statistically significant association with whether or not the primary intervention arm was favoured in terms of outcome (*Table 31*).

Although direct measures of study quality did not show any association with outcomes, measures that can be seen as indicating the 'strength' of the evaluation being made did show such an association. Specifically, both the nature of the comparator (if any) against which the primary intervention was tested and whether the analysis focused on a within- (e.g. single group pre/post) or between-group evaluation showed a statistically significant association with outcomes (see *Table 31*).

TABLE 30 Number of analyses reporting a statistically significant outcome by outcome measure

Outcome measure	*n*	Favours treatment *n* (%)	Does not favour treatment *n* (%)	Chi-squared	*p*-value
Scale	129	75 (58.1)	54 (41.9)	1.644	0.129
Non-scale	66	32 (48.5)	34 (51.5)		

TABLE 31 Number of analyses reporting a statistically significant outcome by study quality indicator

Variable		*n*	Favours treatment *n* (%)	Does not favour treatment *n* (%)	Chi-squared	*p*-value
Blinding used	Yes	34	20 (58.8)	14 (41.2)	0.260	0.376
	No	161	87 (54.0)	74 46.0)		
Same baseline measure of aggression	Yes	48	27 (56.3)	21 (43.8)	0.049	0.480
	No	147	80 (54.4)	67 (45.6)		
ITT analysis	Yes	66	42 (63.6)	24 (36.4)	3.095	0.54
	No	129	65 (60.4)	64 (49.6)		
Within groups or between group analyses	Within	78	55 (70.5)	23 (29.5)	12.843	0.000
	Between	117	52 (44.4)	65 (55.5)		
RCT design	Yes	42	20 (47.6)	22 (52.4)	1.137	0.186
	No	153	87 (56.9)	66 (43.1)		
Head to head	Yes	50	20 (40.0)	30 (60.0)	6.006	0.011
	No	145	87 (60.0)	58 (40.0)		
Active vs TAU	Yes	31	11 (35.5)	20 (64.5)	5.595	0.015
	No	164	96 (58.5)	68 (41.5)		
Active vs placebo, WL or no intervention	Yes	36	21 (58.3)	15 (41.7)	0.214	0.393
	No	159	86 (54.1)	73 (45.9)		

WL, waiting list control.

Comparisons involving head-to-head contrasts between two active interventions were significantly less likely to favour the 'primary' intervention being evaluated ($n = 195$, $\chi^2 = 6.06$, $p = 0.01$). Similarly, comparisons against TAU were less likely to favour the intervention being evaluated ($n = 195$, $\chi^2 = 5.59$, $p = 0.01$). No significant difference was observed between analyses comparing the primary intervention with 'no treatment' [placebo, waiting list control (WL) or no intervention at all] and analyses drawing a comparison with an active comparator or TAU.

Analyses comparing two groups (one allocated to the primary intervention and one to a placebo, TAU or an active comparator) were substantially less likely to show favourable outcomes for the primary intervention than analyses relying on a single within-group comparison (e.g. pre/post evaluations) ($n = 195$, $\chi^2 = 12.84$, $p = 0.000$) (see *Table 31*).

Blinding

Studies that used some element of blinding were more likely to show outcomes in favour of the primary intervention arm (60.5% vs 54.1% of analyses), although this did not reach statistical significance ($n = 195$, $\chi^2 = 0.260$, $p = 0.376$) (*Table 32*).

Baseline evaluation

Least variance was shown by the variable indicating whether or not there was an equivalence in aggression between comparators at baseline ($n = 195$, $\chi^2 = 0.049$, $p = 0.48$) (see *Table 32*). This is particularly unexpected, as baseline equivalence is a variable noted to be of considerable theoretical importance within the violence literature as a whole. It may be accounted for by the hypothesis that where baselines have been recorded it is more likely that they show equivalence. This may be worth further exploration in future research.

Intention-to-treat analysis

Whether the analysis was an ITT or not had no statistically significant association with whether the results favoured the primary treatment or not ($n = 195$, $\chi^2 = 3.095$, $p = 0.54$) (see *Table 32*).

Design

Studies following a RCT design were *less* likely to report analyses in favour of the primary treatment (47.6% vs 52.4% of analyses) but this did not reach statistical significance ($n = 195$, $\chi^2 = 1.137$, $p = 0.186$) (see *Table 32*).

Sample size and loss to follow-up

The median sample size at recruitment was 87.5. This also showed no significant association with whether an analysis favoured the primary intervention or not ($n = 188$, $r = -0.07$, $p = 0.33$) (see *Table 32*).

The median dropout rate was 10.14% and was not associated with whether an analysis favoured the primary treatment or not ($n = 185$, $r = -0.43$, $p = 0.557$) (see *Table 32*).

Length of follow-up

The median length of follow-up in days was 182.4. This was not associated with whether an analysis favoured the primary intervention or not ($n = 178$, $r = -0.013$, $p = 0.865$) (see *Table 32*).

Summary of bivariate associations

Only six variables showed a significant bivariate association with outcomes based on the key dichotomised variable coding whether or not a study (based on its strongest measure) recorded a significant finding in favour of the primary intervention arm. These were:

TABLE 32 Correlation between continuous variables and statistically significant finding in favour of primary intervention

Variable	Output	Statistically significant finding in favour of primary intervention or not	No. in sample at initial recruitment	% dropout	Total length of follow-up (days)
Statistically significant finding in favour of primary intervention or not	Pearson's correlation	1	–0.071	–0.043	–0.013
	Significance (two tailed)		0.333	0.557	0.865
	n (median)	195	188	185	178
No. in sample at initial recruitment	Pearson's correlation			0.004	0.098
	Significance (two tailed)			0.953	0.199
	n (median)			185	172
% dropout	Pearson's correlation				–0.127
	Significance (two tailed)				0.101
	n (median)				169
Total length of follow-up (days)	Pearson's correlation				
	Significance (two tailed)				
	n (median)				

- whether the primary intervention was something other than a pharmacological or psychological intervention (outcome is less likely to be positive)
- whether or not the study was carried out in a general mental health population (outcome more likely to be positive)
- whether or not the intervention was carried out in an offenders' institution (outcome is less likely to be positive)
- whether or not the study design involved a head-to-head comparison between the primary intervention and another active intervention (outcome less likely to be positive if comparator is active intervention)
- whether or not the study design involved comparison against TAU (outcome less likely to be positive if comparator is TAU)
- whether the analysis was within or between groups (outcome less likely to be positive for between-groups analyses).

In addition to the above, one potential confounder in respect of analysis outcomes was identified in respect of associations between the demographic and study design variables. This was:

- proportion of participants who were Caucasian (increasing proportions associated with increasing age and decreasing likelihood of ethnic minority participants).

The very limited bivariate associations between key variables noted above fails to justify substantive multivariate analysis. To explore the extent of variation explained in respect of the central dependent variable (whether or not a significant outcome in favour of the primary intervention was established) we carried out a single regression analysis based around the above modifiers. The likely impact of the one potential confounding variable was not considered sufficiently strong to justify inclusion in the model.

Multivariate analyses

A binary logistic regression was conducted with 'whether or not a statistically significant outcome in favour of the primary intervention arm was established' as the dependent variable. The variation attributable to the model in attempting to account for outcomes was not large (Cox and Snell $R^2 = 0.12$), but also not insignificant given the small number of variables included.

The relative weight of each independent variable in accounting for variation within this model is given in *Table 33* below.

As indicated in *Table 33*, the impact of most of the modifiers on outcome is not strong. Their relative weight in contributing to the model suggests that, all else being equal, the use of a within-groups analysis and a focus on evaluating outcomes in the context of general mental health are the attributes of a study most likely to ensure positive outcomes for the primary intervention being evaluated.

Further exploration of variance

In an attempt to explore further potential modifying variables accounting for variation in outcome in the data set, we divided the broad intervention ('pharmacological/psychological/other') and outcome measure ('scale/not scale') categories into smaller component groups. In line with the 'scattergun' approach for this literature, the range of both interventions and outcome measures was entirely disproportionate to the number of analyses included. Within the 195 analyses included above, there were a total of 94 distinct types of intervention and 55 different types of outcome measure.

The only individual categories with numbers approaching sufficient for any further consideration were as follows.

Primary intervention

- Anger management (all programmes defined as such and not elsewhere categorised), $n = 13$.
- Batterer Intervention Programme (BIP) (broadly defined as any such programme), $n = 22$.
- Cognitive behavioural therapy (broadly defined as any such programme), $n = 29$.

Outcome measure

- Conflict Tactics Scale (CTS) (any subscale), $n = 14$.
- 'Hostility' (measured by observation or self-report), $n = 2$.

TABLE 33 Results of binary logistic regression

Variable	Beta	SE	df	Significance
Intervention is 'other'	–0.552	0.384	1	0.150
Mental disorder only	0.650	0.423	1	0.125
Offenders only	–0.143	0.404	1	0.723
Within- or between-group analyses	–0.797	0.457	1	0.081
Head to head	–0.583	0.458	1	0.203
Active vs TAU	–0.275	0.576	1	0.632
Constant	*0.827*	*0.337*	*1*	*0.014*

$n = 127$.

- Overt Aggression Scale (OAS) or Modified OAS (M-OAS), $n = 11$.
- Reassault (defined as any observed or otherwise objectively reported), $n = 67$.
- State-Trait Anger Inventory (STAXI) (any subscale), $n = 25$.

Of the above subcategories, all but one ('hostility') contained sufficient numbers for bivariate analysis with the dependent variable ('whether or not a statistically significant outcome in favour of the primary intervention arm was established'). However, none of the analyses carried out on these potential modifiers showed any significant associations with the dependent variable. Furthermore, the only observable trends within the data were a slight tendency for analyses using CBT as the primary intervention, to be more likely to report statistically significant outcomes in favour of this intervention and for analyses using reassault, but *not* using OAS/M-OAS (a scale-based observer measure of assault) as an outcome measure to identify significant findings in favour of the primary intervention. *Table 34* summarises the outcomes for this further exploratory analysis.

TABLE 34 Number of analyses reporting a statistically significant outcome by intervention type and primary outcome measure

Intervention type/outcome measure		*n*	Favours treatment *n* (%)	Does not favour treatment *n* (%)	Chi-squared	*p*-value
Anger management	Yes	13	6 (46.2)	7 (53.8)	0.428	0.355
	No	182	101 (55.5)	81 (44.5)		
BIP	Yes	22	11 (50.0)	11 (50.0)	0.238	0.396
	No	173	96 (55.5)	77 (44.5)		
CBT	Yes	29	107 (54.9)	88 (45.1)	0.713	0.262
	No	166	89 (53.6)	77 (46.4)		
CTS	Yes	14	8 (57.1)	6 (42.9)	0.031	0.543
	No	181	99 (54.7)	82 (45.3)		
Hostility	Yes	2	0 (0.0)	2 (100)	2.457	0.202
	No	193	107 (55.4)	86 (44.6)		
OAS/M-OAS	Yes	11	4 (36.4)	7 (63.6)	1.613	0.169
	No	184	103 (56.0)	81 (44.0)		
Reassault	Yes	67	40 (59.7)	27 (40.3)	0.961	0.204
	No	128	67 (52.3)	61 (47.7)		
STAXI	Yes	25	14 (56.0)	11 (44.0)	0.015	0.539
	No	170	93 (54.7)	77 (45.3)		

Chapter 5

Results of meta-analyses

All randomised controlled trials

In order to explore the general profile of the RCT data, we first carried out an exploratory MA. This analysis included all 40 analyses for which metrics suited to conversion to ORs were available (see *Chapter 2*, *Meta-analysis*). The number of 'risk ratio' analyses was too small to be meaningfully combined for this purpose.

Meta-analysis of all randomised controlled trials

Figure 8 summarises the outcomes for this initial exploratory analysis of the RCT data. Both on the assumption of a fixed- and random-effects model, the overall mean effect tends to slightly favour the intervention of interest rather than the placebo or active comparator. A diversity of interventions contribute to this profile, with studies evaluating psychological (e.g. Cavanaugh[81]), pharmacological (e.g. Krakowski *et al.*[82]) and 'other' (e.g. Lasley[83]) interventions all showing positive outcomes for the primary intervention of interest. For the majority of studies favouring the primary intervention, the CIs are also reasonably small, indicating that the sample outcomes are likely to be representative of the actual population profile. Pooled effect size estimates based on the standardised mean difference (see *Table 35*) suggest that, overall, interventions for violent behaviour can be expected to show a small to moderate impact.

Heterogeneity

Table 35 summarises the outcome of heterogeneity estimates and the effect sizes for this overall combination of RCTs. Although the likely general profile of outcomes for interventions evaluated in the literature can legitimately be drawn from an overview of this exploratory MA, it is important to recognise that we are combining across a very diverse range of studies. It is readily apparent from the estimates in *Table 35* that the RCT analyses in this literature are hugely variable. An I^2 of 86% is extremely large, indicating that from a statistical viewpoint the 'averaged' estimates contained in the MA are not robust. They should therefore be taken, at best, as an indicator of potential outcomes. Subsequent MAs, outlined below, demonstrate that this variance is not a simple function of either intervention or outcome type. Before moving on to explore this variability further, it is worth noting that three studies contributing to the MA have particularly large CIs,[84–86] suggesting that these studies' estimates of likely effect size are unlikely to be wholly representative of the potential outcomes in the population of interest. Studies reporting analyses with larger CIs are also not restricted to the smallest sample sizes, implying that levels of uncertainty are not purely the consequence of sampling error. The impact of study focus and study quality is explored further later on in the report. Removing the three studies reporting notably wide CIs from the analysis did not, however, serve to substantially reduce the observed heterogeneity ($Q = 260.88$, $I^2 = 89.6\%$) relative to that reported in *Table 35*. Neither did the removal of all analyses with CIs wider than the average for this group of analyses (the above three analyses plus Volavka *et al.*,[87] Nickel *et al.*[88] and Brown University[89]) ($Q = 232.19$, $I^2 = 89.66\%$).

Taking note of the likely unreliability of this exploratory analysis in respect of results, we calculated effect sizes based on standardised mean differences across all included analyses (see *Table 35*). The aim of this very broad estimate was to provide an initial indication of the potential efficacy of violence reduction interventions as such. Under a fixed-effects model, the mean effect

Model	Study name	Comparison	Outcome	Statistics for each study: OR	Lower limit	Upper limit	z-value	p-value
Fixed	Alexander 2004[112]	Lorazepam vs haloperidal + promethazine	Restraints 240 minutes	0.940	0.569	1.554	–0.241	0.810
	Arango 2006[113]	Oral zuclopenthixol vs depot zuclopenthixol	M-OAS any violence	0.353	0.120	1.038	–1.893	0.058
	Brown University 2006[89]	Aripiprazole vs placebo	STAXI trait anger	0.050	0.016	0.157	–5.135	0.000
	Cavanaugh 2007[81]	Dialectical psychoeducational workshop vs anger management workshop	STAXI state anger	0.109	0.038	0.309	–4.164	0.000
	Chan 2006[98]	Fluoxetine or nortryptiline vs placebo	PSE irritability	0.638	0.120	3.396	–0.527	0.598
	Citrome 2004[107]	Monotherapy vs combination therapy	PANSS hostility day 28	0.992	0.632	1.557	–0.034	0.973
	Cooper 2006[90]	Intervention programme vs TAU	Conviction violent crime	0.289	0.139	0.605	–3.299	0.001
	Duggan 2007[114]	Healthy Families Alaska program vs TAU	CTS severe assault	0.909	0.579	1.427	–0.413	0.680
	Easton 2005[110]	CBT substance abuse program vs twelve step facilitation	CTS physical	0.462	0.188	1.135	–1.684	0.092
	Easton 2007[111]	Substance Abuse Domestic Violence Group vs twelve step facilitation group	CTS physical 6 months	0.751	0.295	1.914	–0.599	0.549
	Frankenburg 2002[106]	Divalproex vs placebo	SCL-90 anger/hostility	0.199	0.047	0.838	–2.201	0.028
	Gottfredson 2002[92]	Baltimore Drug Treatment Court vs TAU	Violent/sex charge 1 year	0.535	0.333	0.861	–2.579	0.010
	Hollander 2003[91]	Divalproex vs placebo	M-OAS	0.998	0.624	1.594	–0.010	0.992
	Krakowski 2006[82]	Clozapine vs haloperidol	M-OAS physical	0.179	0.070	0.459	–3.585	0.000
	Labriola 2008[94]	Monthly monitoring vs graduated monitoring	DV 1-year post-sent	0.972	0.786	1.201	–0.267	0.789
	Lanza 2002[86]	CBT group vs psychodynamic group psychotherapy	STAXI monthly trait anger	8.367	0.703	99.557	1.681	0.093
	Lasley 2003[83]	Intensive bail supervision vs regular bail supervision	DV offending	0.583	0.422	0.804	–3.292	0.001
	Liau 2004[115]	EQUIP: psychoeducation vs without psychoeducation	Self-reported aggression	0.622	0.379	1.020	–1.883	0.060
	Linehan 2008[116]	DBT + olanzapine vs DBT + placebo	OAS physical	0.230	0.051	1.042	–1.906	0.057
	Loew 2006[117]	Topiramate vs placebo	SCL-90 hostility	0.002	0.001	0.010	–8.080	0.000
	Mackenzie 2007[95]	Boot camp vs TAU	STAXI	0.935	0.558	1.564	–0.257	0.797
	Mattes 2005[96]	Oxcarbazepine vs placebo	M-OAS assault	0.662	0.228	1.921	–0.760	0.447
	Meehan 2002[109]	Olanzapine (5 mg) vs placebo	PANSS hostility 2 hours	0.404	0.216	0.755	–2.839	0.005
	Monnelly 2003[85]	Risperidone vs placebo	M-OAS	0.784	0.124	4.949	–0.258	0.796
	New 2004[97]	Fluoxetine vs placebo	OAS	0.131	0.011	1.543	–1.615	0.106
	Nickel 2004[104]	Topiramate vs placebo	STAXI trait anger	0.001	0.000	0.009	–6.040	0.000
	Nickel 2005[88]	Topiramate vs placebo	STAXI trait anger	0.192	0.061	0.609	–2.803	0.005
	Nickel 2005[105]	Topiramate vs placebo	STAXI trait anger	0.147	0.057	0.379	–3.963	0.000
	Rinne 2002[99]	Fluvoxamine vs placebo	BPD severity/anger	0.638	0.200	2.035	–0.759	0.448
	Soler 2005[118]	DBT + olanzapine vs DBT + placebo	Impulsive/aggression	0.455	0.180	1.153	–1.660	0.097
	Suh 2004[101]	Risperidone vs haloperidol	CMAI aggression	0.079	0.047	0.133	–9.473	0.000
	Tritt 2005[103]	Lamotrigine vs placebo	STAXI trait anger	0.021	0.004	0.124	–4.254	0.000
	Tyrer 2008[108]	Risperidone vs placebo	M-OAS 4 weeks	0.415	0.161	1.070	–1.821	0.069
	Vannoy 2006[102]	Meditation vs TAU	STAXI anger (M) 10 weeks	0.718	0.083	6.205	–0.301	0.763
	Vannoy 2006[102]	Meditation vs TAU	STAXI anger (F) 10 weeks	0.443	0.084	2.342	–0.958	0.338
	Volavka 2004[87]	Clozapine vs haloperidol	OAS days 25–98	0.311	0.130	0.741	–2.638	0.008
	Walsh 2002[93]	Intensive care management vs standard care	Assaults	2.077	1.075	4.012	2.175	0.030
	Willner 2002[84]	CB anger management vs wL	Anger inventory/provocation/ carer/client	0.065	0.004	0.970	–1.982	0.048
	Zanarini 2003[119]	Ethyl-eicosapentaenoic acid vs placebo	M-OAS	0.884	0.207	3.774	–0.167	0.868
	Zanarini 2004[100]	Olanzapine vs fluoxetine	OAS	0.464	0.121	1.774	–1.123	0.261
				0.589	0.531	0.655	–9.864	0.000

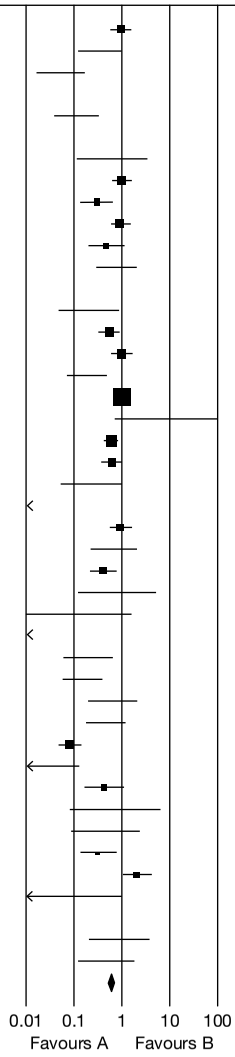

FIGURE 8 Meta-analysis of all RCTs. For a full explanation of the comparisons included see *Appendix 3*, *Table 56*. BPD, borderline personality disorder; CB, cognitive behavioural; CBT, dialectical behaviour therapy; CMAI, Cohen-Mansfield Agitation Inventory; F, female; M, male; PANSS, Positive and Negative Syndrome Scale; PSE, present state examination; SCL-90, Symptom-Checklist-90.

TABLE 35 Heterogeneity estimates and effect sizes of all included RCTs

Heterogeneity estimates and effect sizes		Model	
		Fixed	Random
n analyses		40	40
Effect size		0.59	0.35
95% CI	Lower	0.53	0.26
	Upper	0.65	0.49
Two-tailed test of null hypothesis (homogeneous data)	*z*	–9.86	–6.29
	p-score	0.0001	0.0001
Estimates of heterogeneity	*Q*	278.95	
	df *Q*	39	
	p-score	0.0001	
	I^2	86.02%	
Effect size estimates based on standardised mean difference		–0.29	–0.57
95% CI	Lower	–0.35	–0.75
	Upper	–0.23	–0.39
Two-tailed test of null hypothesis (homogeneous data)	*z*	–9.86	–6.29
	p-score	0.0001	0.0001

size was –0.29 and under a random-effects model the effect size increased to –0.57. Although these figures are subject to substantial caveats, as outlined above, they indicate the potential for small to moderate decreases in violent behaviour as a result of some intervention, with the potential for greater gain where modifying factors, such as population group, are taken into account (as the random-effects model identified a larger effect size than the fixed-effects model).

Analyses by comparison types

The first step in exploring the heterogeneity present in the overall MA was to analyse by the type of comparison conducted, i.e. comparison of two active treatments, comparison of an active treatment and TAU and comparison against a true control, for example placebo or no treatment (*Figures 9–11*).

Head-to-head comparisons

Although in the broader range of studies included in the bivariate analyses head-to-head comparisons were significantly less likely to favour the primary intervention, this is not the case for the RCT studies included in the MA (*Figure 9*). Here, again, both fixed-effects models and, to a lesser extent, random-effects models showed outcomes slightly in favour of the primary intervention. As for the general evaluation outlined above, favourable outcomes ranged across diverse intervention types. For all but one small study, CIs were acceptably small. The one exception to this was a small study[86] that also presented as something of an outlier in respect of the general trend, in favouring the comparative intervention ('psychodynamic psychotherapy') over the primary intervention being evaluated (CBT). As with the general model above, effect size estimates (*Table 36*) suggested a likely small-to-moderate impact on violence of the interventions taken as a whole, with some potential for further gains if population groups particularly responsive to the intervention could be identified (fixed-effects model effect size –0.26, random-effects model effect size –0.44).

Model	Study name	Comparison	Outcome	Statistics for each study: OR	Lower limit	Upper limit	*z*-value	*p*-value
Fixed	Alexander 2004[112]	Lorazepam vs haloperidal + promethazine	Restraints 240 minutes	0.940	0.569	1.554	–0.241	0.810
	Arango 2006[113]	Oral zuclopenthixol vs depot zuclopenthixol	M-OAS any violence	0.353	0.120	1.038	–1.893	0.058
	Cavanaugh 2007[81]	Dialectical psychoeducational workshop vs anger management workshop	STAXI state anger	0.109	0.038	0.309	–4.164	0.000
	Citrome 2004[107]	Monotherapy vs combination therapy	PANSS hostility day 28	0.992	0.632	1.557	–0.034	0.973
	Easton 2005[110]	CBT substance abuse programme vs twelve step facilitation	CTS physical	0.462	0.188	1.135	–1.684	0.092
	Easton 2007[111]	Substance Abuse Domestic Violence Group vs twelve step facilitation group	CTS physical 6 months	0.751	0.295	1.914	–0.599	0.549
	Krakowski 2006[82]	Clozapine vs haloperidol	M-OAS physical	0.179	0.070	0.459	–3.585	0.000
	Labriola 2008[94]	Monthly monitoring vs graduated monitoring	DV 1-year post-sent	0.972	0.786	1.201	–0.267	0.789
	Lanza 2002[86]	CBT group vs psychodynamic group psychotherapy	STAXI monthly trait anger	8.367	0.703	99.557	1.681	0.093
	Lasley 2003[83]	Intensive bail supervision vs regular bail supervision	DV offending	0.583	0.422	0.804	–3.292	0.001
	Liau 2004[115]	EQUIP: psychoeducation vs without psychoeducation	Self-reported aggression	0.622	0.379	1.020	–1.883	0.060
	Linehan 2008[116]	DBT + olanzapine vs DBT + placebo	OAS physical	0.230	0.051	1.042	–1.906	0.057
	Soler 2005[118]	DBT + olanzapine vs DBT + placebo	Impulsive/aggression	0.455	0.180	1.153	–1.660	0.097
	Suh 2004[101]	Risperidone vs haloperidol	CMAI aggression	0.079	0.047	0.133	–9.473	0.000
	Volavka 2004[87]	Clozapine vs haloperidol	OAS days 25–98	0.311	0.130	0.741	–2.638	0.008
	Zanarini 2004[100]	Olanzapine vs fluoxetine	OAS	0.464	0.121	1.774	–1.123	0.261
				0.629	0.551	0.718	–6.888	0.000

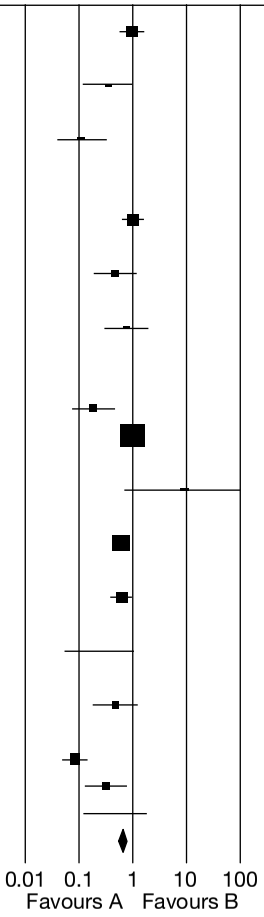

FIGURE 9 Meta-analysis of RCTs comparing two active treatments. For a full explanation of the comparisons included see *Appendix 3*, *Table 56*. CMAI, Cohen-Mansfield Agitation Inventory; DBT, dialectical behaviour therapy; PANSS, Positive and Negative Syndrome Scale.

TABLE 36 Heterogeneity estimates and effect sizes of RCTs comparing two active treatments

Heterogeneity estimates and effect sizes		Model	
		Fixed	Random
n analyses		16	16
Effect size		0.63	0.45
95% CI	Lower	0.55	0.29
	Upper	0.72	0.68
Two-tailed test of null hypothesis (homogeneous data)	*z*	–6.89	–3.71
	p-value	0.0001	0.0001
Estimates of heterogeneity	*Q*	111.21	
	df *Q*	15	
	p-value	0.0001	
	I^2	86.51%	
Effect size estimates based on standardised mean difference		–0.26	–0.44
95% CI	Lower	0.04	0.12
	Upper	–0.33	–0.68
Two-tailed test of null hypothesis (homogeneous data)	*z*	–0.18	–0.21
	p-value	0.0001	0.0001

Restricting the MA to 'head-to-head' comparisons had no impact on estimated heterogeneity between studies. With I^2 remaining at 86%, the outcomes for the analysis must be regarded with caution, as, despite their similar focus on drawing a direct comparison between interventions, the studies included clearly remain very diverse in other respects.

Active treatment versus treatment as usual

A smaller range of studies compared the primary intervention with 'treatment as usual' (*Figure 10*). Predictably, observed heterogeneity for this smaller group of studies, all but one of which (Willner *et al.*,[84] focusing on CBT anger management) focused on 'other' interventions, was less extreme than for the 'head-to-head' analyses. Nevertheless, with an I^2 of 68% (*Table 37*) overall outcomes for this MA still need to be regarded with caution. In addition, it should be noted that the studies included within this analysis vary quite considerably both in size (with larger studies carrying a greater weighting with respect to model outcomes) and in the length of their CIs. Taken as they stand, the fixed- and random-effects models show comparable outcomes, slightly favouring the primary intervention. Again, this is in contrast with the outcome observed for the broader range of studies included in the bivariate analysis. However, the suggested likely impact, based on the observed standardised mean difference, is very small and is also primarily driven by outcomes from one moderately sized study[90] that focused on an individually tailored intervention delivered in a hospital setting.

Active treatment versus true control

The number of studies included in our MA of 'active versus true control' evaluations was larger ($n = 16$) than that in the 'head-to-head' evaluation and again showed very high levels of heterogeneity ($I^2 = 87\%$, *Table 38*) despite the fact that all of the studies in this category focused on pharmacological intervention. The majority of RCTs in this category found in favour of the primary intervention (primarily antidepressant drugs and novel antipsychotic drugs). The main exception to this trend was one large study[91] which found no significant difference between divalproex (Depakote, Sanof-Aventis, UK) and placebo. The outcome of this study

Model	Study name	Comparison	Outcome	Statistics for each study: OR	Lower limit	Upper limit	*z*-value	*p*-value	OR and 95% CI
Fixed	Cooper 2006[90]	Intervention program vs TAU	Conviction violent crime	0.289	0.139	0.605	–3.299	0.001	
	Duggan 2007[114]	Healthy Families Alaska programme vs TAU	CTS severe assault	0.909	0.579	1.427	–0.413	0.680	
	Gottfredson 2002[92]	Baltimore Drug Treatment Court vs TAU	Violent/sex charge 1 year	0.535	0.333	0.861	–2.579	0.010	
	Mackenzie 2007[95]	Boot camp vs TAU	STAXI	0.935	0.558	1.564	–0.257	0.797	
	Vannoy 2006[102]	Meditation vs TAU	STAXI anger (M) 10 weeks	0.718	0.083	6.205	–0.301	0.763	
	Vannoy 2006[102]	Meditation vs TAU	STAXI anger (F) 10 weeks	0.443	0.084	2.342	–0.958	0.338	
	Walsh 2002[93]	Intensive care management vs standard care	Assaults	2.077	1.075	4.012	2.175	0.030	
	Willner 2002[84]	CB anger management vs wL	Anger inventory/provation/ carer/client	0.065	0.004	0.970	–1.982	0.048	
				0.764	0.604	0.968	–2.233	0.026	

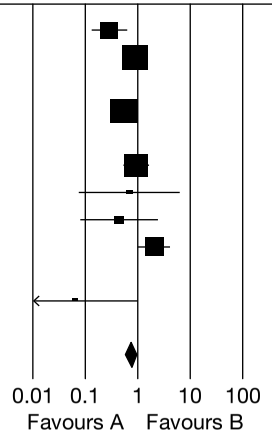

FIGURE 10 Meta-analysis of RCTs comparing an active treatment to TAU. For a full explanation of the comparisons included see *Appendix 3*, *Table 56*. CB, cognitive bahavioural; F, female; M, male.

TABLE 37 Heterogeneity estimates and effect sizes of comparing an active treatment to TAU

		Model	
Heterogeneity estimates and effect sizes		**Fixed**	**Random**
n analyses		8	8
Effect size		0.76	0.7
95% CI	Lower	0.6	0.43
	Upper	0.97	1.14
Two-tailed test of null hypothesis (homogeneous data)	*z*	–2.23	–1.43
	p-value	0.03	0.15
Estimates of heterogeneity	*Q*	22.45	
	df *Q*	7	
	p-value	0.002	
	I^2	68.82%	
Effect size estimates based on standardised mean difference		–0.15	–0.2
95% CI	Lower	–0.28	–0.5
	Upper	–0.02	0.07
Two-tailed test of null hypothesis (homogeneous data)	*z*	–2.23	–1.4
	p-value	0.03	0.15

notwithstanding, the overall effect size based on standardised mean difference (see *Table 38*) suggest a likely moderate-to-large impact on violence for the interventions combined in this MA (fixed effects –0.60, random effects –0.98), with potential additional gains to be made by tailoring the intervention to specific population groups.

Analyses by broad intervention groupings

In order to explore further potential sources of heterogeneity, we next compared results for each of the three main groups of interventions: pharmacological interventions, psychological therapies and the combined category of 'other' interventions. Note that none of the available RCTs sought to directly compare across these distinct modes of intervention (e.g. pharmacological vs psychotherapeutic). This is disappointing, and also further indicates the potential benefits of drawing on a broader range of analyses than purely RCTs in order to identify analyses that include such comparisons.

Pharmacological interventions

Figure 12 summarises the outcomes of a MA combining all RCTs with calculated ORs comparing a pharmacological product with either an active or placebo comparator.

Given that evaluations of pharmacological interventions formed the bulk of the RCT data, it is not surprising that outcomes for the data for pharmacological interventions alone broadly track those for the overall data set. For the same reason, they also track the outcomes reported above for studies comparing an intervention with a 'true control'. Specifically, the combined effect sizes tend to provide support for the likely efficacy of the main intervention rather than the active or placebo comparator. Estimates of overall outcome (pooled standardised mean difference using a fixed-effects model –0.54, using a random-effects model –0.81) suggest moderate-to-large impacts on aggressive behaviour with a likely significant benefit of fitting the intervention to appropriate populations, settings or other clinically relevant potential modifiers. Again, however,

Model	Study name	Comparison	Outcome	Statistics for each study: OR	Lower limit	Upper limit	z-value	p-value
Fixed	Brown University 2006[89]	Aripiprazole vs placebo	STAXI trait anger	0.050	0.016	0.157	–5.135	0.000
	Chan 2006[98]	Fluoxetine or nortryptiline vs placebo	PSE irritability	0.638	0.120	3.396	–0.527	0.598
	Frankenburg 2002[106]	Divalproex vs placebo	SCL-90 anger/hostility	0.199	0.047	0.838	–2.201	0.028
	Hollander 2003[91]	Divalproex vs placebo	M-OAS	0.998	0.624	1.594	–0.010	0.992
	Loew 2006[117]	Topiramate vs placebo	SCL-90 hostility	0.002	0.001	0.010	–8.080	0.000
	Mattes 2005[96]	Oxcarbazepine vs placebo	M-OAS assault	0.662	0.228	1.921	–0.760	0.447
	Meehan 2002[109]	Olanzapine (5 mg) vs placebo	PANSS hostility 2 hours	0.404	0.216	0.755	–2.839	0.005
	Monnelly 2003[85]	Risperidone vs placebo	M-OAS	0.784	0.124	4.949	–0.258	0.796
	New 2004[97]	Fluoxetine vs placebo	OAS	0.131	0.011	1.543	–1.615	0.106
	Nickel 2004[104]	Topiramate vs placebo	STAXI trait anger	0.001	0.000	0.009	–6.040	0.000
	Nickel 2005a[88]	Topiramate vs placebo	STAXI trait anger	0.192	0.061	0.609	–2.803	0.005
	Nickel 2005[105]	Topiramate vs placebo	STAXI trait anger	0.147	0.057	0.379	–3.963	0.000
	Rinne 2002[99]	Fluvoxamine vs placebo	BPD severity/anger	0.638	0.200	2.035	–0.759	0.448
	Tritt 2005[103]	Lamotrigine vs placebo	STAXI trait anger	0.021	0.004	0.124	–4.254	0.000
	Tyrer 2008[108]	Risperidone vs placebo	M-OAS 4 weeks	0.415	0.161	1.070	–1.821	0.069
	Zanarini 2003[119]	Ethyl-eicosapentaenoic acid vs placebo	M-OAS	0.884	0.207	3.774	–0.167	0.868
				0.339	0.263	0.438	–8.265	0.000

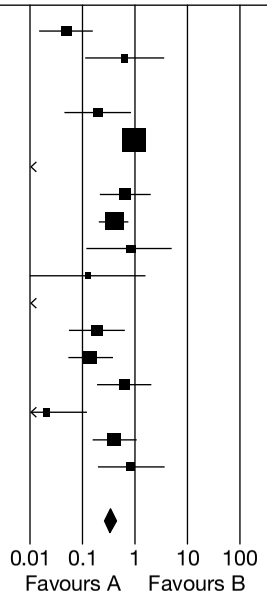

FIGURE 11 Meta-analysis of RCTs comparing an active treatment to a true control. For a full explanation of the comparisons included see *Appendix 3*, *Table 56*. BPD, borderline personality disorder; PSE, present state examination; SCL-90, Symptom-Checklist-90.

TABLE 38 Heterogeneity estimates and effect sizes of comparing an active treatment to a true control

		Model	
Heterogeneity estimates and effect sizes		**Fixed**	**Random**
n analyses		16	16
Effect size		0.34	0.17
95% CI	Lower	0.26	0.08
	Upper	0.44	0.37
Two-tailed test of null hypothesis (homogeneous data)	*z*	–8.26	–4.39
	p-value	0.0001	0.0001
Estimates of heterogeneity	*Q*	121.85	
	df *Q*	15	
	p-value	0.0001	
	I^2	87.69%	
Effect size estimates based on standardised mean difference		–0.60	–0.98
95% CI	Lower	–0.74	–1.42
	Upper	–0.45	–0.54
Two-tailed test of null hypothesis (homogeneous data)	*z*	–8.26	–4.39
	p-value	0.0001	0.0001

this implied profile needs to be considered cautiously, as estimates of heterogeneity (*Table 39*) for these studies, all focused on a single mode of intervention, remain very high ($I^2 = 87\%$).

Psychological interventions

Outcomes for the combined RCT data for psychological interventions taken as a whole (*Figure 13*) were slightly less optimistic overall than the combined outcomes for pharmacological intervention. Estimated potential reductions in aggression were towards the low end of the scale (pooled standardised mean differences based on a fixed-effects model –0.26, based on a random-effects model –0.35) with less promise of improvement to be gained by targeting relevant population groups or other modifiers.

Although the overall effect sizes observed were less than those observed for the model for pharmacological interventions, the outcomes of the MA for psychological interventions are more robust, as there is less observed heterogeneity among the psychological studies, so the observed outcomes are more likely to be 'real' than the result of artefact. Significant heterogeneity was still observed within this group of studies ($I^2 = 65\%$, *Table 40*), but to a moderate rather than an extreme degree. It is therefore reasonably, if not wholly, safe to conclude that psychological interventions do have the potential for making a small impact on violent behaviour. Given the range of approaches included within this category and the lack of a large and consistent body of work evaluating any single type of psychological intervention, further exploration is clearly needed to establish which form of psychological intervention may be most promising.

That the number of RCTs available in this context is so low is unfortunate, as the error margin entailed by this degree of variance cannot be adequately accounted for by dividing analyses into comparable smaller groupings. In the absence of any forthcoming additional RCT data in this area, any conclusions about the effect of psychological interventions will need to be informed by the existing non-RCT analyses to a greater degree than is the case for pharmacological intervention.

Model	Study name	Comparison	Outcome	Statistics for each study: OR	Lower limit	Upper limit	*z*-value	*p*-value
Fixed	Alexander 2004[112]	Lorazepam vs haloperidal + promethazine	Restraints 240 minutes	0.940	0.569	1.554	–0.241	0.810
	Arango 2006[113]	Oral zuclopenthixol vs depot zuclopenthixol	M-OAS any violence	0.353	0.120	1.038	–1.893	0.058
	Brown University 2006[89]	Aripiprazole vs placebo	STAXI trait anger	0.050	0.016	0.157	–5.135	0.000
	Chan 2006[98]	Fluoxetine or nortryptiline vs placebo	PSE irritability	0.638	0.120	3.396	–0.527	0.598
	Citrome 2004[107]	Monotherapy vs combination therapy	PANSS hostility day 28	0.992	0.632	1.557	–0.034	0.973
	Frankenburg 2002[106]	Divalproex vs placebo	SCL-90 anger/hostility	0.199	0.047	0.838	–2.201	0.028
	Hollander 2003[91]	Divalproex vs placebo	M-OAS	0.998	0.624	1.594	–0.010	0.992
	Krakowski 2006[82]	Clozapine vs haloperidol	M-OAS physical	0.179	0.070	0.459	–3.585	0.000
	Linehan 2008[116]	DBT + olanzapine vs DBT + placebo	OAS physical	0.230	0.051	1.042	–1.906	0.057
	Loew 2006[117]	Topiramate vs placebo	SCL-90 hostility	0.002	0.001	0.010	–8.080	0.000
	Mattes 2005[96]	Oxcarbazepine vs placebo	M-OAS assault	0.662	0.228	1.921	–0.760	0.447
	Meehan 2002[109]	Olanzapine (5 mg) vs placebo	PANSS hostility 2 hours	0.404	0.216	0.755	–2.839	0.005
	Monnelly 2003[85]	Risperidone vs placebo	M-OAS	0.784	0.124	4.949	–0.258	0.796
	New 2004[97]	Fluoxetine vs placebo	OAS	0.131	0.011	1.543	–1.615	0.106
	Nickel 2004[104]	Topiramate vs placebo	STAXI trait anger	0.001	0.000	0.009	–6.040	0.000
	Nickel 2005a[88]	Topiramate vs placebo	STAXI trait anger	0.192	0.061	0.609	–2.803	0.005
	Nickel 2005[102]	Topiramate vs placebo	STAXI trait anger	0.147	0.057	0.379	–3.963	0.000
	Rinne 2002[99]	Fluvoxamine vs placebo	BPD severity/anger	0.638	0.200	2.035	–0.759	0.448
	Soler 2005[118]	DBT + olanzapine vs DBT + placebo	Impulsive/aggression	0.455	0.180	1.153	–1.660	0.097
	Suh 2004[101]	Risperidone vs haloperidol	CMAI aggression	0.079	0.047	0.133	–9.473	0.000
	Tritt 2005[103]	Lamotrigine vs placebo	STAXI trait anger	0.021	0.004	0.124	–4.254	0.000
	Tyrer 2008[108]	Risperidone vs placebo	M-OAS 4 weeks	0.415	0.161	1.070	–1.821	0.069
	Volavka 2004[87]	Clozapine vs haloperidol	OAS days 25–98	0.311	0.130	0.741	–2.638	0.008
	Zanarini 2003[119]	Ethyl-eicosapentaenoic acid vs placebo	M-OAS	0.884	0.207	3.774	–0.167	0.868
	Zanarini 2004[100]	Olanzapine vs fluoxetine	OAS	0.464	0.121	1.774	–1.123	0.261
				0.378	0.318	0.449	–10.990	0.000

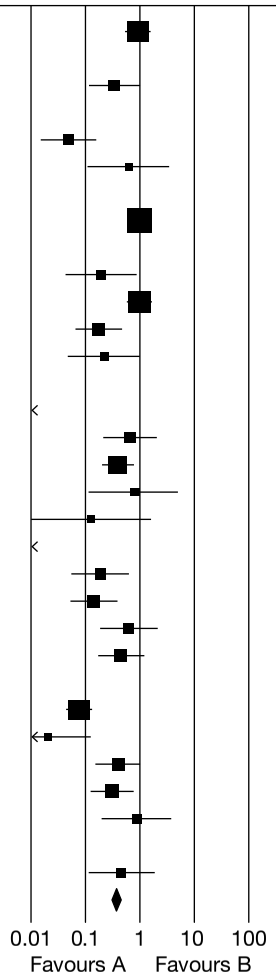

FIGURE 12 Meta-analysis of RCTs comparing pharmacological products with either an active or placebo comparator. For a full explanation of the comparisons included see *Appendix 3*, *Table 56*. BPD, borderline personality disorder; CMAI, Cohen-Mansfield Agitation Inventory; DBT, dialectical behaviour therapy; PANSS, Positive and Negative Syndrome Scale; PSE, present state examination; SCL-90, Symptom-Checklist-90.

TABLE 39 Heterogeneity estimates and effect sizes of RCTs comparing pharmacological products and either an active or placebo comparator

Heterogeneity estimates and effect sizes		Model	
		Fixed	Random
n analyses		25	25
Effect size		0.38	0.23
95% CI	Lower	0.32	0.14
	Upper	0.45	0.39
Two-tailed test of null hypothesis (homogeneous data)	*z*	–10.99	–5.46
	p-value	0.0001	0.0001
Estimates of heterogeneity	*Q*	190.22	
	df *Q*	24	
	p-value	0.0001	
	I^2	87.38%	
Effect size estimates based on standardised mean difference		–0.54	–0.81
95% CI	Lower	–0.63	–1.10
	Upper	–0.44	–0.52
Two-tailed test of null hypothesis (homogeneous data)	*z*	–10.99	–5.46
	p-value	0.0001	0.0001

Other interventions

The available prospective RCT data for evaluations of interventions other than either pharmacological or psychological intervention are extremely limited. Within this already limited field, only five of the available analyses contributed data suited to MAs based around ORs (*Figure 14*). These analyses addressed quite distinct forms of intervention, albeit all compared against TAU. Gottfredson and Exum[92] compared a drug treatment court approach with TAU, Walsh *et al.*[93] compared intensive case management with TAU, Labriola *et al.*[94] and Lasley[83] compared intensified bail supervision with other forms of bail supervision, and MacKenzie *et al.*[95]/Mitchell and MacKenzie[77] compared a multimodal 'boot camp' approach with TAU.

Given the diversity in focus, it is not surprising that the analyses showed substantial heterogeneity ($I^2 = 77\%$; *Table 41*). In contrast with both pharmacological intervention and psychological intervention, the averaged effect size of these 'alternative' forms of intervention is also very low, clustering around an outcome of no significant difference in aggression between treatment and TAU (pooled standardised mean differences based on fixed-effects model –0.09, based on random-effects model –0.08; see *Table 41*).

Although the overall MAs for the three primary modes of intervention suggest more promising outcomes for pharmacological intervention than for either psychological intervention or 'other' forms of intervention, it is important to note that, overall, the sets of data analysed here display either significant amounts of heterogeneity between analyses or, in the case of 'other' interventions, numbers too small to be suited to the further exploration of possible outcome modifiers. Additional appropriately large RCTs of psychological and 'other' interventions would be needed to allow any direct comparison between outcomes for pharmacological interventions and outcomes for other forms of intervention. Evaluation of pharmacological intervention is a well-established research field, while the evaluation of other modes of intervention for violent behaviour is, relatively speaking, in its infancy.

Model	Study name	Comparison	Outcome	Statistics for each study: OR	Lower limit	Upper limit	*z*-value	*p*-value	OR and 95% CI
Fixed	Cavanaugh 2007[81]	Dialectical psychoeducational workshop vs anger management workshop	STAXI state anger	0.109	0.038	0.309	–4.164	0.000	
	Duggan 2007[114]	Healthy Families Alaska programme vs TAU	CTS severe assault	0.909	0.579	1.427	–0.413	0.680	
	Easton 2005[110]	CBT substance abuse programme vs twelve step facilitation	CTS physical	0.462	0.188	1.135	–1.684	0.092	
	Easton 2007[111]	Substance Abuse Domestic Violence Group vs twelve step facilitation group	CTS physical 6 months	0.751	0.295	1.914	–0.599	0.549	
	Lanza 2002[86]	CBT group vs psychodynamic group psychotherapy	STAXI monthly trait anger	8.367	0.703	99.557	1.681	0.093	
	Liau 2004[115]	EQUIP: psychoeducation vs without psychoeducation	Self-reported aggression	0.622	0.379	1.020	–1.883	0.060	
	Vannoy 2006[102]	Meditation vs TAU	STAXI anger (M) 10 weeks	0.718	0.083	6.205	–0.301	0.763	
	Vannoy 2006[102]	Meditation vs TAU	STAXI anger (F) 10 weeks	0.443	0.084	2.342	–0.958	0.338	
	Willner 2002[84]	CB anger management vs WL	Anger inventory/provocation/carer/client	0.065	0.004	0.970	–1.982	0.048	
				0.629	0.477	0.828	–3.303	0.001	

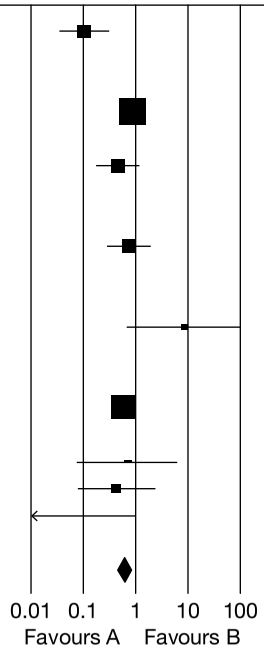

FIGURE 13 Meta-analysis of RCTs comparing psychological interventions. For a full explanation of the comparisons included see *Appendix 3*, *Table 56*. CB, cognitive behavioural; F, female; M, male.

TABLE 40 Heterogeneity estimates and effect sizes of RCTs for psychological interventions

Heterogeneity estimates and effect sizes		Model	
		Fixed	Random
n analyses		9	9
Effect size		0.63	0.53
95% CI	Lower	0.48	0.31
	Upper	0.83	0.93
Two-tailed test of null hypothesis (homogeneous data)	*z*	–3.30	–2.22
	p-value	0.001	0.03
Estimates of heterogeneity	*Q*	21.10	
	df *Q*	8	
	p-value	0.007	
	I^2	62.09%	
Effect size estimates based on standardised mean difference		–0.26	–0.35
95% CI	Lower	–0.41	–0.65
	Upper	–0.10	–0.04
Two-tailed test of null hypothesis (homogeneous data)	*z*	–3.30	–2.22
	p-value	0.001	0.03

Analyses for specific comparator groupings

Pharmacological analyses

Sufficient studies were available to analyse three pharmacological groupings in separate meta-analyses: anticonvulsant drugs against placebo, selective serotonin reuptake inhibitor (SSRI) antidepressants against placebo and atypical antipsychotic drugs against haloperidol or placebo.

Anticonvulsant drugs against placebo

As shown in *Figure 15* the majority of analyses evaluating anticonvulsant drugs against placebo reported statistically significant outcomes in favour of the active medication (Hollander *et al.*,[91] Mattes and Mattes[96] being the exceptions). Mean effect sizes suggested a substantive potential reduction in aggression, again notably if treatment can be appropriately applied within relevant populations or other modifier subgroups (pooled standardised mean differences based on fixed-effects model –0.62, based on random-effects model –1.47, *Table 42*).

Unfortunately, despite the evident similarities between the analyses in this category, very substantial heterogeneity remained apparent in this combined analysis (see *Table 42*). As previously, therefore, the promising mean effect sizes cannot be considered robust and should be regarded as indicative at best.

Selective serotonin reuptake inhibitor antidepressant against placebo

A second smaller grouping of analyses[97–100] compared three types of SSRI antidepressant (fluoxetine; fluoxetine or nortriptyline and fluvoxamine, respectively) primarily against placebo (against olanzapine in the case of Zanarini *et al.*[100]).

Figure 16 summarises the outcome of this MA. Both fixed- and random-effects models report an equivalently small mean effect size in favour of the primary intervention (pooled standardised mean differences based on fixed-effects model –0.12, based on random-effects model –0.15).

Model	Study name	Comparison	Outcome	Statistics for each study: OR	Lower limit	Upper limit	*z*-value	*p*-value
Fixed	Gottfredson 2002[92]	Baltimore Drug Treatment Court vs TAU	Violent/sex charge 1 year	0.535	0.333	0.861	–2.579	0.010
	Labriola 2008[94]	Monthly monitoring vs graduated monitoring	DV 1-year post-sent	0.972	0.786	1.201	–0.267	0.789
	Lasley 2003[83]	Intensive bail supervision vs regular bail supervision	DV offending	0.583	0.422	0.804	–3.292	0.001
	Mackenzie 2007[95]	Boot camp vs TAU	STAXI	0.935	0.558	1.564	–0.257	0.797
	Walsh 2002[93]	Intensive care management vs standard care	Assaults	2.077	1.075	4.012	2.175	0.030
				0.844	0.724	0.984	–2.169	0.030

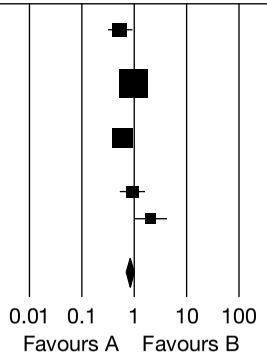

FIGURE 14 Meta-analysis of RCTs comparing other active or TAU interventions. For a full explanation of the comparisons included see *Appendix 3*, *Table 56*.

TABLE 41 Heterogeneity estimates and effect sizes of RCTs comparing other interventions

		Model	
Heterogeneity estimates and effect sizes		**Fixed**	**Random**
n analyses		5	5
Effect size		0.84	0.86
95% CI	Lower	0.72	0.59
	Upper	0.98	1.24
Two-tailed test of null hypothesis (homogeneous data)	*z*	–2.17	–0.82
	p-value	0.03	0.41
Estimates of heterogeneity	*Q*	17.65	
	df *Q*	4	
	p-value	0.001	
	I^2	77.34%	
Effect size estimates based on standardised mean difference		–0.09	–0.08
95% CI	Lower	–0.18	–0.29
	Upper	–0.009	0.119
Two-tailed test of null hypothesis (homogeneous data)	*z*	–2.17	–0.82
	p-value	0.03	0.41

The equivalence in outcomes for the two models implies that targeting specific populations or other modifiers is unlikely to result in additional gains.

Unlike the previous analyses, heterogeneity analyses failed to identify any important variances between these analyses (*Table 43*).

Atypical antipsychotic drugs against haloperidol or placebo

A final grouping of pharmacological analyses with sufficient commonality for evaluation via MA compared a number of atypical antipsychotic drugs (risperidone, aripiprazole, olanzapine, quetiapine and clozapine) with either haloperidol, fluoxetine or placebo. *Figure 17* summarises the outcome of this MA. The majority of comparisons drawn found in favour of the active atypical comparator. Mean effect size estimates were very high and roughly comparable between fixed- and random-effects models (pooled standardised mean differences based on fixed-effects model –0.86, based on random-effects model –0.78), suggesting a potentially large impact on aggressive behaviour for these drugs. One characteristic of note is the large effect reported by Suh *et al.*[101] This study differs from other studies included in the analysis in that it was conducted in a nursing home, with the mean age of patients being 81 years.

As indicated in *Table 44*, outcomes from this MA were again undermined by the presence of substantial heterogeneity, despite the small number of analyses included and their comparative similarity. No other combination of pharmacological analyses showed sufficient comparability in focus to justify MA.

Psychological analyses

The only set of psychological analyses with sufficient comparability to combine in a within-groupings MA was a broad set of analyses all comparing CBT (of diverse types) against a range of active and waiting list comparators (prison, anger management, psychotherapy and related interventions). One study[102] that focused on meditation is included in this MA, as the approach taken to meditation was relevantly similar to more usual forms of CBT (broadly defined as per

Model	Study name	Comparison	Outcome	Statistics for each study: OR	Lower limit	Upper limit	*z*-value	*p*-value	OR and 95% CI
Fixed	Frankenburg 2002[106]	Divalproex vs placebo	SCL-90 anger/hostility	0.199	0.047	0.838	–2.201	0.028	
	Hollander 2003[91]	Divalproex vs placebo	M-OAS	0.998	0.624	1.594	–0.010	0.992	
	Loew 2006[117]	Topiramate vs placebo	SCL-90 hostility	0.002	0.001	0.010	–8.080	0.000	
	Mattes 2005[96]	Oxcarbazepine vs placebo	M-OAS assault	0.662	0.228	1.921	–0.760	0.447	
	Nickel 2004[104]	Topiramate vs placebo	STAXI trait anger	0.001	0.000	0.009	–6.040	0.000	
	Nickel 2005a[88]	Topiramate vs placebo	STAXI trait anger	0.192	0.061	0.609	–2.803	0.005	
	Nickel 2005[105]	Topiramate vs placebo	STAXI trait anger	0.147	0.057	0.379	–3.963	0.000	
	Tritt 2005[103]	Lamotrigine vs placebo	STAXI trait anger	0.021	0.004	0.124	–4.254	0.000	
				0.322	0.230	0.452	–6.561	0.000	

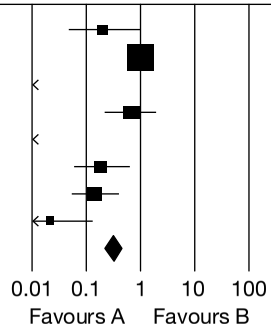

FIGURE 15 Meta-analysis of RCTs comparing anticonvulsant drugs to placebo. For a full explanation of the comparisons included *Appendix 3*, *Table 56*.
SCL-90, Symptom-Checklist-90.

TABLE 42 Heterogeneity estimates and effect sizes of RCTs comparing anticonvulsant drugs to placebo

		Model	
Heterogenity estimates and effect sizes of all included RCTs		**Fixed**	**Random**
n analyses		8	8
Effect size		0.32	0.07
95% CI	Lower	0.23	0.01
	Upper	0.45	0.32
Two-tailed test of null hypothesis (homogeneous data)	*z*	–6.56	–3.45
	p-value	0.0001	0.001
Estimates of heterogeneity	*Q*	105.82	
	df *Q*	7	
	p-value	0.0001	
	I^2	93.38%	
Effect size estimates based on standardised mean difference		–0.62	–1.47
95% CI	Lower	–0.81	–2.3
	Upper	–0.44	–0.63
Two-tailed test of null hypothesis (homogeneous data)	*z*	–6.56	–3.45
	p-value	0.0001	0.001

the range of approaches taken by this group of studies). *Figure 18* sets out the results of this MA and *Table 45* explores the degree of heterogeneity within this group of analyses.

Although the majority of individual analyses within this group were unable to report statistically significant findings in favour of CBT, the combined effect sizes, both fixed and random, indicated a small potential decrease in aggression by applying the CBT model (pooled standardised mean differences based on fixed-effects model –0.27, based on random-effects model –0.27). The size of effect being equivalent between fixed and random models again implied that increases in effectiveness are unlikely to be gained by targeting specific populations or other modifiers.

The outcomes of this MA, indicating a small effect of CBT, are likely to be robust. No significant degree of heterogeneity is indicated in the analysis set out in *Table 45* and the number of analyses although small is adequate for the exploration of heterogeneity. This type of intervention would therefore be a promising one to explore further in future RCTs. One caveat here is the need to define the intervention more tightly than has been done to date in the literature. The approaches to 'CBT' vary so widely that they could be considered very distinct interventions and it is of substantial importance to be able to identify which components of these diverse interventions actually contribute to the relative 'success' of CBT in impacting on aggressive behaviour.

Analyses of 'other' interventions

The number of analyses in this final grouping is small, as indicated previously, and the focus of the comparisons is diverse. No further benefit could be gained by attempting to partition these data further in additional MAs.

Exploring the impact of potential modifiers

The majority of the MAs outlined above exhibited substantial amounts of heterogeneity between analyses. Although random-effects models found a significant fit within these data, allowing the

Study name	Comparison	Outcome	Statistics for each study: OR	Lower limit	Upper limit	*z*-value	*p*-value	OR and 95% CI
Chan 2006[98]	Fluoxetine or nortryptiline vs placebo	PSE irritability	0.638	0.120	3.396	–0.527	0.598	
New 2004[97]	Fluoxetine vs placebo	OAS	0.131	0.011	1.543	–1.615	0.106	
Rinne 2002[99]	Fluvoxamine vs placebo	BPD severity/anger	0.638	0.200	2.035	–0.759	0.448	
Zanarini 2004[100]	Fluoxetine vs olanzapine	OAS	2.157	0.564	8.256	1.123	0.261	
			0.802	0.382	1.683	–0.584	0.559	

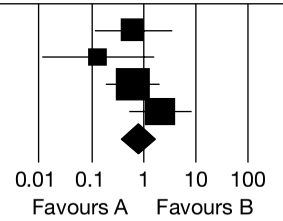

FIGURE 16 Meta-analysis of RCTs comparing SSRI antidepressant to placebo/olanzapine. For a full explanation of the comparisons included see *Appendix 3*, *Table 56*. BPD, borderline personality disorder; PSE, present state examination.

TABLE 43 Heterogeneity estimates and effect sizes of RCTs comparing SSRI antidepressant to placebo

		Model	
Heterogeneity estimates and effect sizes		**Fixed**	**Random**
n analyses		4	4
Effect size		0.80	0.76
95% CI	Lower	0.38	0.30
	Upper	1.68	1.93
Two-tailed test of null hypothesis (homogeneous data)	*z*	–0.58	–0.58
	p-value	0.57	0.56
Estimates of heterogeneity	*Q*	4.38	
	df *Q*	3	
	p-value	0.22	
	I^2	31.55%	
Effect size estimates based on standardised mean difference		–0.12	–0.15
95% CI	Lower	–0.63	–0.67
	Upper	0.29	0.36
Two-tailed test of null hypothesis (homogeneous data)	*z*	–0.58	–0.58
	p-value	0.56	0.56

assumption that heterogeneity may be distributed randomly rather than indicating systematic differences between analyses, ideally we should aim to identify the causes of variation between analyses. In the absence of such identified causes the pooled estimates of effect size drawn from these potentially quite distinct analyses are inevitably subject to question. In an attempt to account for variation, we explored the association between individual analysis effect size and a number of key factors of clinical and statistical significance with respect to study design.

The associations between effect size and categorical variables are set out in *Table 46*; the impact of these variables on heterogeneity is outlined in *Table 47*. The associations between continuous variables and effect size are set out in *Table 48*, with the potential impact on heterogeneity discussed later in this chapter.

Table 58 in *Appendix 4* outlines the values for each of these potential modifier variables. Where data are missing for an analysis, the analysis itself will have been excluded from the analysis focused on that particular variable.

Although in the context of the broader range of studies included in our bivariate analyses, design characteristics of the included studies appeared to have little impact on outcomes, in the context of this more tightly defined set of RCTs design features did show a significant impact, both on effect sizes and associated levels of heterogeneity between studies.

Clinically relevant factors

Focus

The potential 'modifier' of choice of intervention (pharmacological vs psychological vs other) has been discussed previously in this chapter. As discussed, the more numerous pharmacological analyses produced relatively large effect sizes, but with concomitantly high levels of heterogeneity. Psychological analyses showed a more equivocal profile, with low-to-moderate effect sizes and slightly less heterogeneity. 'Other' forms of intervention provided the most equivocal outcomes but also the lowest level of heterogeneity, despite their very diverse range of interventions.

Model	Study name	Comparison	Outcome	Statistics for each study: OR	Lower limit	Upper limit	*z*-value	*p*-value	OR and 95% CI
Fixed	Brown University 2006[89]	Aripiprazole vs placebo	STAXI trait anger	0.050	0.016	0.157	–5.135	0.000	
	Krakowski 2006[82]	Clozapine vs haloperidol	M-OAS physical	0.179	0.070	0.459	–3.585	0.000	
	Linehan 2008[116]	DBT + olanzapine vs DBT + placebo	OAS physical	0.230	0.051	1.042	–1.906	0.057	
	Meehan 2002[109]	Olanzapine (5 mg) vs placebo	PANSS hostility 2 hours	0.404	0.216	0.755	–2.839	0.005	
	Monnelly 2003[85]	Risperidone vs placebo	M-OAS	0.784	0.124	4.949	–0.258	0.796	
	Soler 2005[118]	DBT + olanzapine vs DBT + placebo	Impulsive/aggression	0.455	0.180	1.153	–1.660	0.097	
	Suh 2004[101]	Risperidone vs haloperidol	CMAI aggression	0.079	0.047	0.133	–9.473	0.000	
	Tyrer 2008[108]	Risperidone vs placebo	M-OAS 4 weeks	0.415	0.161	1.070	–1.821	0.069	
	Volavka 2004[87]	Clozapine vs haloperidol	OAS days 25–98	0.311	0.130	0.741	–2.638	0.008	
	Zanarini 2004[100]	Olanzapine vs fluoxetine	OAS	0.464	0.121	1.774	–1.123	0.261	
				0.208	0.158	0.275	–11.073	0.000	

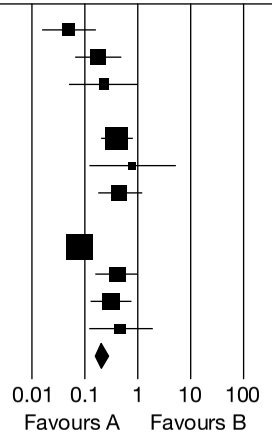

FIGURE 17 Meta-analysis of RCTs comparing atypical antipsychotic drugs to haloperidol or placebo. For a full explanation of the comparisons included see *Appendix 3*, *Table 56*. CMAI, Cohen-Mansfield Agitation Inventory; DBT, dialectical behaviour therapy; PANSS, Positive and Negative Syndrome Scale.

TABLE 44 Heterogeneity estimates and effect sizes of RCTs comparing atypical antipsychotic drugs to haloperidol or placebo

Heterogeneity estimates and effect sizes		Model	
		Fixed	Random
n analyses		10	10
Effect size		0.21	0.24
95% CI	Lower	0.16	0.14
	Upper	0.27	0.43
Two-tailed test of null hypothesis (homogeneous data)	*z*	–11.07	–4.87
	p-value	0.0001	0.0001
Estimates of heterogeneity	*Q*	32.4	
	df *Q*	9	
	p-value	0.0001	
	I^2	72.23%	
Effect size estimates based on standardised mean difference		–0.86	–0.78
95% CI	Lower	–1.02	–1.09
	Upper	–0.71	–0.46
Two-tailed test of null hypothesis (homogeneous data)	*z*	–11.07	–4.87
	p-value	0.0001	0.0001

Population

Mental health status

As indicated in *Table 47*, the mental health status of the population group included within an analysis showed a statistically significant association with the effect size, under both fixed and random models. Overall, interventions targeted at people with a mental health problem were more likely to succeed than interventions targeted at non-mental health offender groups (convicted offenders and those known to have offended but not as yet indicted). However, analyses for studies focused on the general mental health population also showed the greatest degree of heterogeneity, indicating less robust outcomes (see *Table 48*). RCTs focused on forensic populations were too few in number ($n = 1$) to provide useable data in this context.

Demographics

Three demographic factors were coded for data extraction, namely age, sex and ethnicity. To take account of the diverse range of ways in which these characteristics were recorded in the analysis papers, we coded each as a continuous variable indicating, respectively, the proportion of groupings included within a study (% male, % Caucasian) and the mean age of the sample (a small number of studies recorded only median age and these have been excluded from analysis here). As indicated in *Table 48*, the only demographic characteristic showing a statistically significant association with the effect size for an analysis was sex, with analyses including a higher proportion of males tending to report more positive outcomes for the target intervention. Although statistically significant, it should be noted that the association is not a particularly strong one.

Setting

Four settings provided sufficient data for analysis, namely community settings (pooled between distinct types of community setting), open wards, prisons and the eclectic combined group of 'other or mixed' settings. As noted previously, the number of identified RCTs carried out in forensic settings is disappointingly small ($n = 1$). Overall, analyses focused on community settings that were most likely to produce comparatively large effect sizes (see *Table 46*), under

Model	Study name	Comparison	Outcome	Statistics for each study: OR	Lower limit	Upper limit	*z*-value	*p*-value	OR and 95% CI
Fixed	Easton 2005[110]	CBT substance abuse programme vs twelve step facilitation	CTS physical	0.462	0.188	1.135	–1.684	0.092	
	Easton 2007a[111]	Substance Abuse Domestic Violence Group vs twelve step facilitation group	CTS physical 6 months	0.751	0.295	1.914	–0.599	0.549	
	Lanza 2002[86]	CBT group vs psychodynamic group psychotherapy	STAXI monthly trait anger	8.367	0.703	99.557	1.681	0.093	
	Liau 2004[115]	EQUIP: psychoeducation vs without psychoeducation	Self-reported aggression	0.622	0.379	1.020	–1.883	0.060	
	Vannoy 2006[102]	Meditation vs TAU	STAXI anger (M) 10 weeks	0.718	0.083	6.205	–0.301	0.763	
	Vannoy 2006[102]	Meditation vs TAU	STAXI anger (F) 10 weeks	0.443	0.084	2.342	–0.958	0.338	
	Willner 2002[84]	CB anger management vs WL	Anger inventory/provocation/ carer/client	0.065	0.004	0.970	–1.982	0.048	
				0.611	0.423	0.884	–2.617	0.009	

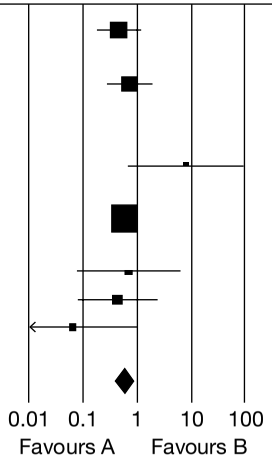

FIGURE 18 Meta-analysis of RCTs comparing CBT to a range of active and waiting list comparators. For a full explanation of the comparisons included see *Appendix 3*, *Table 56*. CB, cognitive behavioural; F, female; M, male.

TABLE 45 Heterogeneity estimates and effect sizes of RCTs comparing CBT to a range of active and waiting list comparators

Heterogeneity estimates and effect sizes		Model	
		Fixed	Random
n analyses		7	7
Effect size		0.61	0.61
95% CI	Lower	0.42	0.37
	Upper	0.88	0.99
Two-tailed test of null hypothesis (homogeneous data)	*z*	–2.62	–1.97
	p-value	0.009	0.05
Estimates of heterogeneity	*Q*	7.65	
	df *Q*	6	
	p-value	0.26	
	I^2	21.62%	
Effect size estimates based on standardised mean difference		–0.27	–0.27
95% CI	Lower	–0.47	–0.54
	Upper	–0.07	–0.001
Two-tailed test of null hypothesis (homogeneous data)	*z*	–2.62	–1.97
	p-value	0.009	0.05

both fixed- and random-effects models. The relatively greater pooled effect size for fixed than for random effect sizes relating to community settings suggests that there is unlikely to be a benefit to further targeting within this broad category.

Outcome measures

In the context of the RCT analyses, there was considerable consistency in the choice of outcome measure, with the vast majority of included analyses favouring scale-based measures. Contrasting scale versus non-scale (generally behavioural) measures (*Tables 46* and *47*), scale-based measures tended to be associated with better outcomes under both fixed- and random-effects models, with non-scale-based analyses showing non-significant pooled effect sizes. Both types of grouping showed large heterogeneity between analyses, although the diversity (in all likelihood because of analysis numbers) was smaller between analyses not using scale-based outcomes.

Study quality indicators

Clearly, the studies used for these analyses had been selected on the basis of perceived 'study quality', following the accepted gold standard of the prospective RCT. This notwithstanding, they of course differed in other aspects of study design and a number of these have implications for the likely reliability and validity of analysis outcomes. The 'quality modifiers', for which we have sufficient data for analysis, are explored below.

Sample size and loss to follow-up

An agreed 'cut-off' mark for partitioning sample size is not readily available, since virtually no studies reported power calculations. However, a natural split within the data appeared between studies recording up to 100 participants (generally substantially less) and studies recording rather more than this figure. Larger sample sizes (see *Table 48*) were, predictably, associated with larger individual effect sizes and hence with a greater likelihood of positive outcome.

The proportion of a given sample lost to follow-up, in contrast, did not quite reach statistical significance with regard to the potential association with analysis effect size. This is possibly

TABLE 46 Associations between effect size and potential modifier variables (categorical data)

Variable	Group	*n* analyses	Pooled standardised mean: fixed effects	*z*	*p*-value	Pooled standardised mean: random effects	*z*	*p*-value
Population	Indictable	3	–0.22	–2.10	0.04	–0.44	–1.32	0.19
	Mental health status	28	–0.47	–10.04	0.0001	–0.73	–5.00	0.0001
	Offend	9	–0.17	–0.49	0.0001	–0.25	–3.20	0.001
Start setting	Community	20	0.64	–6.15	0.000	0.23	–5.50	0.0001
	Open ward	3	0.36	–3.20	0.001	0.36	–3.20	0.001
	Prison	9	0.45	–7.48	0.0001	0.52	–1.91	0.06
	Other or mixed	3	0.34	–0.58	0.56	0.34	–0.58	0.56
Scale-based outcome measures	Not scale	7	–0.13	–3.21	0.001	–0.17	–1.77	0.08
	Scale	33	–0.48	–11.02	0.0001	–0.71	–5.72	0.0001
Blinding	Not blinded/unstated	16	–0.15	–4.03	0.0001	–0.23	–2.65	0.008
	Blinded (any type)	26	–0.52	–10.91	0.0001	–0.81	–5.49	0.0001
Baseline aggression	Different baseline or not stated	19	0.57	–6.35	0.0001	0.43	–3.80	0.0001
	Same baseline	21	0.60	–7.56	0.0001	0.30	–4.89	0.0001
ITT	Not ITT	22	0.36	–6.55	0.0001	0.48	–3.70	0.0001
	ITT	16	0.33	–8.97	0.0001	0.21	–5.07	0.0001

TABLE 47 Impact of effect size of potential modifier variables on heterogeneity

Variable	Group	*n* analyses	*Q*	df *Q*	*p*-value	I^2 (%)
Population	Indictable	3	13.47	2	0.001	85.15
	Mental health status	28	221.69	27	0.0001	87.82
	Offender	9	19.16	8	0.01	58.25
Start setting	Community	20	126.38	19	0.0001	84.85
	Open ward	3	0.56	2	0.76	0.0001
	Prison	9	69.57	8	0.0001	86.57
	Other or mixed	3	0.73	2	0.69	0.0001
Scale-based outcome measures	Not scale	7	26.45	6	0.0001	77.31
	Scale	33	217.97	32	0.0001	85.32
Blinding	Not blinded/unstated	16	49.03	14	0.0001	71.45
	Blinded (any type)	26	192.12	24	0.0001	87.50
Baseline aggression	Different baseline or not stated	19	66.78	18	0.0001	79.02
	Same baseline	21	192.96	20	0.0001	89.63
ITT	Not ITT	22	132.46	21	0.0001	84.15
	ITT	16	112.81	15	0.0001	86.70

TABLE 48 Associations between effect size and modifier variables and impact on heterogeneity (continuous data)

Mixed-Effects regression model (maximum likelihood)									
Variable	*Q* model	df *Q*	*Q* Residual	df *Q*	*Q* Total	df *Q*	*p*-value (model)	*p*-value (residual)	*p*-value (total)
Mean age	0.19	1	38.28	32	38.46	33	0.66	0.20	0.23
Sex (% male)	8.63	1	43.95	36	52.60	37	0.003	0.17	0.05
Ethnicity (% Caucasian)	0.11	1	7.54	16	7.88	17	0.73	0.35	0.41
Initial sample size	6.40	1	48.53	38	54.92	39	0.01	0.12	0.05
Dropout (% lost to follow-up)	3.24	1	42.85	36	46.09	37	0.07	0.20	0.15
Follow-up (total in days)	2.99	1	45.09	36	48.06	37	0.08	0.14	0.10

because of the quite constrained nature of the RCTs identified. Unlike the more 'real-world' studies contained within the non-RCT data, loss to follow-up in the RCT setting was, overall, quite small, ranging, in the main, from 0% to around 15%.

Blinding

A number of distinct aspects of blinding were considered in our analysis (blinding of the participants, persons carrying out the intervention and persons collating and analysing the data). Aside from the blinding of participants, however, papers for the studies showed poor attention to detail in recording these various options. In the current analysis, therefore, of necessity, we combined across the various measures to define a combined 'blinded or not' variable. Although both design options (see *Table 46*) showed a positive association with analysis effect size, analyses that reported one or more methods of blinding showed a substantially stronger association with positive outcomes. Studies without blinding showed less heterogeneity than studies with blinding (see *Table 47*).

Length of follow-up

Surprisingly, length of follow-up (recorded in days) showed no statistically significant association with effect size (see *Table 48*). The range in timescale for the RCTs was substantially more varied than that recorded for the data overall. The consequent lack of any smooth distribution may have impacted on outcomes here.

Baseline evaluation

Baseline similarities/differences in the core aggression variables were poorly reported overall in the identified violence literature. Poor reporting of this highly significant moderating variable in the RCT data was particularly disappointing. To explore potential associations with effect size, we therefore contrasted analyses reporting equivalent aggression baselines for comparator groups at study outset, with analyses either recording differing baselines or analyses failing to record any attempt to measure relevant baselines. In the event, there was little difference in the level of association with outcomes shown by either grouping (see *Table 46*). Levels of heterogeneity between analyses in either grouping remained substantive (see *Table 47*).

Intention-to-treat analysis

There was comparatively little difference in effect size for studies evaluating interventions with an ITT or with a non-ITT approach (notably under the fixed-effects model). The extent of heterogeneity within analyses in the two groupings remained very high despite taking this characteristic into account (see *Table 47*).

Meta-analytic models incorporating identified modifiers

In an attempt to explore potentially more robust estimates of outcomes for subgroups of analyses selected with regard to both their intervention focus and with regard to potential modifiers highlighted as being associated with effect size, we outline below a final set of MAs.

Taking into account those modifiers now known to be associated with effect size (e.g. design characteristics such as sample size and demographic characteristics such as sex or population group) we identified subgroups of analyses with comparable characteristics on key features. Subdividing the data in this way led to four meta-analytic models with the potential to provide non-heterogeneous data for a more robust evaluation of outcomes. All but one of these comparisons focused on pharmacological interventions. In the event, only two of the models resulted in MAs with non-heterogeneous outcomes. This is a further indication of the substantial degree of variance that exists within this literature.

The models set out below each combine data from the studies within a given category (e.g. pharmacological interventions), which show the greatest degree of overall similarity of the range of key potential modifiers outlined above. Specifically, we looked for studies that focused on the same (or at least broadly similar) comparisons between interventions, which were also similar in profile on all, or most, of the following:

- population
- outcome measure (whether scale based or not)
- sex (all male, all female, mixed group of participants)
- setting study started in (prison, community, general mental health, forensic mental health, 'other/mixed')
- number of participants at start of trial
- whether or not any form of blinding was used in the study.

The number of studies available for each analysis is inevitably small and the 'equivalence' of the studies on the range of modifiers identified will vary between models. The main aim here is to see whether or not heterogeneity can be reduced by excluding studies that vary considerably on key features such as population, proportion of males included and so forth. None of the studies will show perfect equivalence on these features, as design diversity is a characteristic of this literature, but it was hoped that the models might provide an indication of how heterogeneity could be reduced and more robust outcomes identified via MA.

Model 1: anticonvulsant drugs versus placebo

Four studies were included in this model.[103–106] All four studies focused on an exclusively female, general mental health population. All studies took place in a community setting and used some form of blinding. Sample sizes at the outset ranged from 30 to 64 participants and outcomes for all four studies were scale based. Frankenburg and Zanarini[106] evaluated the efficacy of divalproex sodium, Nickel *et al.*[104,105] evaluated the efficacy of topiramate and Tritt *et al.*[103] evaluated the efficacy of lamotrigine (*Figure 19*).

Despite the similarities between these studies both in respect of their main focus and in respect of relevant modifiers, substantive heterogeneity was observed ($Q = 20.21$, $p = 0.0001$, $I^2 = 85.16\%$) (*Table 49*). Although the model could be viewed as suggesting a potential impact of anticonvulsant medication on violent behaviour, it is consequently not advisable to draw this conclusion because of the substantial heterogeneity observed.

Model 2: atypical antipsychotic drugs versus any active comparator

Three studies were included in this model.[82,101,107] All three focused again on a general mental health population. Participants in all three studies included both males and females, with the proportion of male participants ranging from 25% to 83.8%. Settings were not specified for two of the studies[82,107] and the setting for Suh *et al.*[101] fell into the 'other/mixed' category. Some form of blinding was used in all three studies and outcomes for all three were scale based. Citrome *et al.*[107] compared monotherapy with either risperidone or olanzapine to combination therapy with either of these drugs plus divalproex sodium. Krakowski *et al.*[82] compared clozapine with haloperidol and Suh *et al.*[101] compared risperidone with haloperidol (*Figure 20*).

Again, despite selecting studies for apparent similarities in respect of focus and potential modifiers, a significant degree of heterogeneity was observed in this model ($Q = 52.96$, $p = 0.0001$, $I^2 = 96.22\%$) (*Table 50*). The promising outcomes suggested for atypical antipsychotic drugs therefore fall prey to the unreliability generated within the model by characteristics of the studies that we have yet to identify.

Model 3: atypical antipsychotic drugs versus placebo

Three studies were included in this model.[89,108,109] Again, all three focused on a general mental health population. Participants in all three studies included both males and females, with the proportion of male participants ranging from 19.23% to 59%. Two of the studies took place in community settings,[89,108] and the setting for Meehan *et al.*[109] fell into the 'other/mixed' category. Some form of blinding was used in all three studies and outcomes for all three were scale based. Sample sizes ranged from 52 to 272. Brown University[89] evaluated the efficacy of aripiprazole, Tyrer *et al.*[108] evaluated the efficacy of risperidone, and Meehan *et al.*[109] evaluated the efficacy of olanzapine (*Figure 21*).

This model follows a very similar pattern to the model 2, with promising outcomes undermined by significant heterogeneity in the data ($Q = 10.67$, $p = 0.0001$, $I^2 = 81.26\%$) (*Table 51*) despite apparent similarities between the studies with respect to focus and key modifiers.

Study name	Comparison	Outcome	Statistics for each study					OR and 95% CI
			OR	Lower limit	Upper limit	*z*-value	*p*-value	
Frankenburg 2002[106]	Divalproex vs placebo	SCL-90 anger/hostility	0.199	0.047	0.838	–2.201	0.028	
Nickel 2004[104]	Topiramate vs placebo	STAXI trait anger	0.001	0.000	0.009	–6.040	0.000	
Nickel 2005[105]	Topiramate vs placebo	STAXI trait anger	0.147	0.057	0.379	–3.963	0.000	
Tritt 2005[103]	Lamotrigine vs placebo	STAXI trait anger	0.021	0.004	0.124	–4.254	0.000	
			0.074	0.037	0.147	–7.411	0.000	

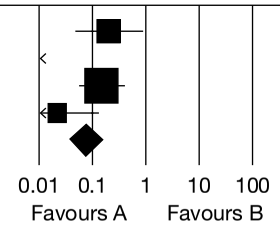

FIGURE 19 Meta-analysis model 1. For a full explanation of the comparisons included see *Appendix 3*, *Table 56*. SCL-90, Symptom-Checklist-90.

TABLE 49 Heterogeneity estimates and effect sizes of model 1

Heterogeneity estimates and effect sizes		Model	
		Fixed	Random
n analyses		4	4
Effect size		0.07	0.03
95% CI	Lower	0.04	0.005
	Upper	0.15	0.24
Two-tailed test of null hypothesis (homogeneous data)	z	–7.41	–3.39
	p-value	0.0001	0.001
Estimates of heterogeneity	*Q*	20.21	
	df *Q*	3	
	p-value	0.0001	
	I^2	85.16%	
Effect size estimates based on standardised mean difference		–1.44	–1.88
95% CI	Lower	–0.47	–0.54
	Upper	–1.82	–2.97
Two-tailed test of null hypothesis (homogeneous data)	*z*	–1.06	–0.79
	p-value	–7.41	–3.39

Model 4: cognitive behavioural therapy versus any active comparator

Three studies were included in this model.[86,110,111] All three studies focused exclusively on male participants, none of the studies used any form of blinding, outcomes for all three studies were scale based and sample sizes ranged from 42 to 78. All studies took place in either community[111] or 'other/mixed' settings. This group of studies were more varied in respect of their target participant group than studies included in the above three models. Lanza *et al.*[86] focused on a general mental health population, Easton[110] on an offender population, and Easton *et al.*[111] on a group of participants who had committed acts of violence but as yet had not been indicted for these acts (*Figure 22*).

Despite the clear differences in population focus, this model generated the least heterogeneity ($Q = 4.70$, $p = 0.09$, $I^2 = 57.4\%$) (*Table 52*).

Publication bias

Figure 23 presents a funnel plot of the analyses included in the overall MA. The asymmetric distribution apparent in *Figure 23* is suggestive of publication bias. The pattern is consistent with, in particular, the rejection of smaller analyses with negative outcomes. This would be consistent with biases observed in other literatures and would not be an unexpected finding, notably in the context of a comprehensive search of the literature such as the one carried out here. Although the possibility of publication bias is therefore worth bearing in mind, it is important to note that a similar distribution could result from systematic associations between sample size and other analysis characteristics that impact on outcome.

Study name	Comparison	Outcome	Statistics for each study: Standard difference in means	SE	Variance	Lower limit	Upper limit	*z*-value	*p*-value	Standard difference in means and 95% CI
Citrome 2004[107]	Monotherapy vs combination therapy	PANSS hostility day 28	–0.004	0.127	0.016	–0.253	0.244	–0.034	0.973	
Krakowski 2006[82]	Clozapine vs haloperidol	M-OAS physical	–0.948	0.265	0.070	–1.467	–0.430	–3.585	0.000	
Suh 2004[101]	Risperidone vs haloperidol	CMAI aggression	–1.400	0.148	0.022	–1.690	–1.110	–9.473	0.000	
			–0.637	0.090	0.008	–0.814	–0.460	–7.045	0.000	

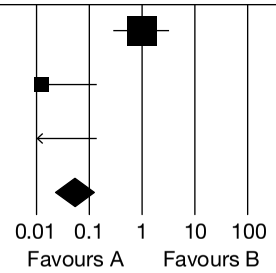

FIGURE 20 Meta-analysis model 2. For a full explanation of the comparisons included see *Appendix 3*, *Table 56*. PANSS, Positive and Negative Syndrome Scale.

Summary

It is evident from the summary data presented in *Table 53* that the 'scattergun' approach to empirical evaluation of interventions to prevent or reduce aggressive behaviour has produced a literature in the main that is unsuited to MA. This having been said, the MAs as set out serve both to provide a profile of the available 'high-quality' (RCT) data available and to provide some indicators of likely effect modifiers that are informative for the design of future studies. On the assumption that the observed variation can be accounted for by non-systematic differences between the analyses included in any given analysis (an assumption in part supported by the effect size models), the pooled outcome data can be taken as likely indicators of outcome for the intervention groupings evaluated.

Combining together this relatively large group of 'gold standard' analyses is particularly useful for gaining insight, as above, into the nature of the literature openly available. However, it is of rather less value in establishing a robust estimate of the likely impact of intervening to reduce violent behaviour using the combined range of interventions evaluated to this standard to date.

TABLE 50 Heterogeneity estimates and effect sizes of model 2

		Model	
Heterogeneity estimates and effect sizes		**Fixed**	**Random**
n analyses		3	3
Effect size		0.31	0.24
95% CI	Lower	0.23	0.04
	Upper	0.43	1.43
Two-tailed test of null hypothesis (homogeneous data)	*z*	–7.04	–1.56
	p-value	0.0001	0.12
Estimates of heterogeneity	*Q*	52.96	
	df *Q*	2	
	p-value	0.0001	
	I^2	96.22%	
Effect size estimates based on standardised mean difference		–0.64	–0.78
95% CI	Lower	–0.81	–1.75
	Upper	–0.46	0.2
Two-tailed test of null hypothesis (homogeneous data)	*z*	–7.04	–1.56
	p-value	0.0001	0.12

Study name	Comparison	Outcome	Statistics for each study: OR	Lower limit	Upper limit	*z*-value	*p*-value	OR and 95% CI
Brown University 2006[89]	Aripiprazole vs placebo	STAXI trait anger	0.050	0.016	0.157	–5.135	0.000	
Meehan 2002[109]	Olanzapine (5 mg) vs placebo	PANSS hostility 2 hours	0.404	0.216	0.755	–2.839	0.005	
Tyrer 2008[108]	Risperidone vs placebo	M-OAS 4 weeks	0.415	0.161	1.070	–1.821	0.069	
			0.283	0.176	0.456	–5.204	0.000	

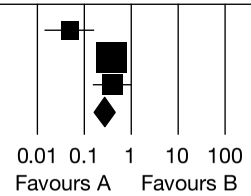

FIGURE 21 Meta-analysis model 3. For a full explanation of the comparisons included see *Appendix 3*, *Table 56*. PANSS, Positive and Negative Syndrome Scale.

TABLE 51 Heterogeneity estimates and effect sizes of model 3

		Model	
Heterogeneity estimates and effect sizes		**Fixed**	**Random**
n analyses		3	3
Effect size		0.28	0.22
95% CI	Lower	0.18	0.07
	Upper	0.46	0.71
Two-tailed test of null hypothesis (homogeneous data)	*z*	–5.2	–2.51
	p-value	0.0001	0.01
Estimates of heterogeneity	*Q*	10.67	
	df *Q*	2	
	p-value	0.005	
	I^2	81.26%	
Effect size estimates based on standardised mean difference		–0.69	–0.84
95% CI	Lower	–0.96	–1.49
	Upper	–0.43	–0.18
Two-tailed test of null hypothesis (homogeneous data)	*z*	–5.2	–2.51
	p-value	0.0001	0.01

Study name	Comparison	Outcome	Statistics for each study: Standard difference in means	SE	Variance	Lower limit	Upper limit	*z*-value	*p*-value	Standard difference in means and 95% CI
Easton 2005[110]	CBT substance abuse programme vs twelve step facilitation	CTS physical	–0.426	0.253	0.064	–0.921	0.070	–1.684	0.092	
Easton 2007[111]	Substance Abuse Domestic Violence Group vs twelve step facilitation group	CTS physical 6 months	–0.158	0.263	0.069	–0.673	0.358	–0.599	0.549	
Lanza 2002[86]	CBT group vs psychodynamic group psychotherapy	STAXI monthly trait anger	1.171	0.697	0.485	–0.194	2.537	1.681	0.093	
			–0.203	0.176	0.031	–0.548	0.143	–1.151	0.250	

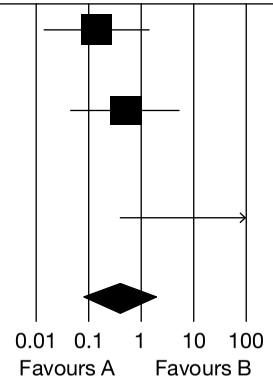

FIGURE 22 Meta-analysis model 4. For a full explanation of the comparisons included see *Appendix 3*, *Table 56*.

TABLE 52 Heterogeneity estimates and effect sizes of model 4

Heterogeneity estimates and effect sizes		Model	
		Fixed	Random
n analyses		3	3
Effect size		0.69	0.86
95% CI	Lower	0.37	0.29
	Upper	1.29	2.55
Two-tailed test of null hypothesis (homogeneous data)	*z*	–1.15	–0.26
	p-value	0.25	0.79
Estimates of heterogeneity	*Q*	4.7	
	df *Q*	2	
	p-value	0.09	
	I^2	57.43%	
Effect size estimates based on standardised mean difference		–0.2	–0.08
95% CI	Lower	–0.55	–0.68
	Upper	0.14	0.52
Two-tailed test of null hypothesis (homogeneous data)	*z*	–1.15	–0.26
	p-value	0.25	0.79

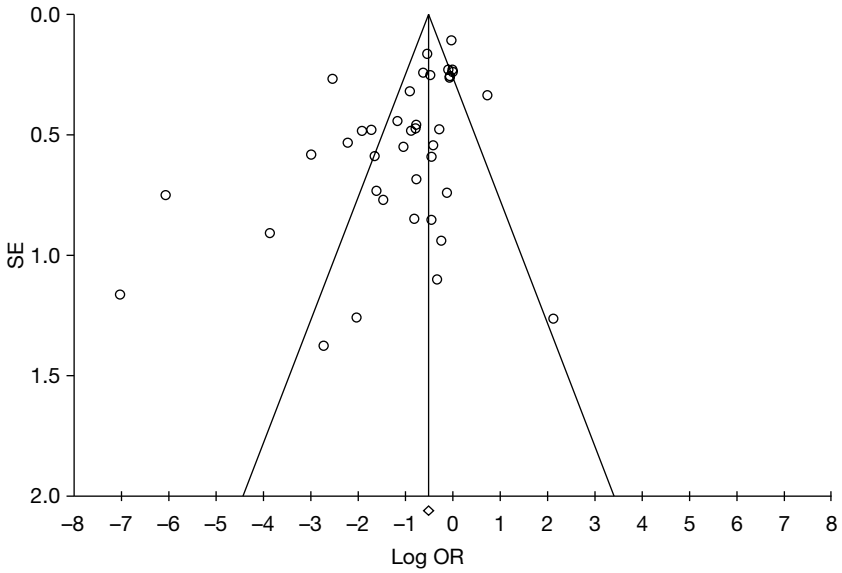

FIGURE 23 Funnel plot of SE by logs, OR and all included RCTs.

TABLE 53 Summary of effects sizes from all MAs

		Fixed-effects model		Random-effects model		Heterogeneity			
Variable	*n*	Effect size (95% CI)	*p*-value	Effect size (95% CI)	*p*-value	*Q*	df *Q*	*p*-value	I^2 (%)
All RCTs	40	0.59 (0.53 to 0.65)	0.00001	0.35 (0.26 to 0.49)	0.00001	279	39	0.0001	86
Two active treatments	16	0.63 (0.55 to 0.72)	0.0001	0.45 (0.29 to 0.68)	0.0001	111.2	15	0.0001	86.5
Active treatment vs TAU	8	0.76 (0.60 to 0.97)	0.03	0.70 (0.43 to 1.14)	0.15	22.4	7	0.002	68.8
Active treatment vs true control	16	0.34 (0.26 to 0.44)	0.0001	0.17 (0.08 to 0.37)	0.0001	121.9	15	0.0001	87.7
Pharmacological intervention	25	0.38 (0.32 to 0.45)	0.0001	0.23 (0.14 to 0.39)	0.0001	190.2	24	0.0001	87.4
Anticonvulsant drugs	8	0.32 (0.23 to 0.45)	0.0001	0.07 (0.01 to 0.32)	0.001	105.8	7	0.0001	93.4
SSRIs	4	0.80 (0.38 to 1.68)	0.57	0.76 (0.30 to 1.93)	0.56	4.38	3	0.22	31.6
Atypical antipsychotic drugs	10	0.21 (0.16 to 0.27)	0.0001	0.24 (0.14 to 0.43)	0.0001	32.4	9	0.0001	72.2
Psychological intervention	9	0.63 (0.48 to 0.83)	0.001	0.53 (0.31 to 0.93)	0.03	21.1	8	0.007	62.1
CBT	7	0.61 (0.42 to 0.88)	0.009	0.61 (0.37 to 0.99)	0.05	7.65	6	0.26	21.6
Other intervention	5	0.84 (0.72 to 0.98)	0.03	0.86 (0.59 to 1.24)	0.41	17.7	4	0.001	77.3
Model 1: anticonvulsant drugs vs placebo	4	0.07 (0.04 to 0.15)	0.0001	0.03 (0.01 to 0.24)	0.001	20.2	3	0.0001	85.2
Model 2: atypical antipsychotic drugs vs any active comparator	3	0.31 (0.23 to 0.43)	0.0001	0.24 (0.04 to 1.43)	0.12	53.0	2	0.0001	96.2
Model 3: atypical antipsychotic drugs vs placebo	3	0.28 (0.18 to 0.46)	0.0001	0.22 (0.07 to 0.71)	0.01	10.7	2	0.005	81.3
Model 4: CBT vs any comparator	3	0.69 (0.37 to 1.29)	0.25	0.86 (0.29 to 2.55)	0.79	4.7	2	0.09	57.4

Chapter 6

Discussion and conclusions

Strengths and limitations of the review

This review offers a number of advantages over previous work in this area. The key strength is an attempt to combine breadth of scope in terms of widely defining aggression and relevant populations with rigour in terms of the depth to which each study was analysed. The review set out to encompass not only the *highest-quality* empirical studies, but also *all* relevant quantitative studies. RCTs are regarded, of course, as the gold standard for empirical evaluation. However, such trials emphasise internal validity over external validity and so are frequently constrained in a way that departs substantively from the reality of intervention in the clinical context. Having collated data from all available empirical studies, we have been able to contextualise the findings of RCTs by exploring the outcomes suggested by more pragmatic studies. Another benefit of this broad approach has been the identification of studies focusing on the head-to-head comparison of pharmacological and psychotherapeutic interventions. The approach also reflects the varied clinical reality faced by practitioners in mental health and criminal justice settings working with violent people. We are confident, therefore, that the review offers the most comprehensive account of the recent research literature to date with regard to the effectiveness of interventions to prevent or manage violence in mental health settings.

It is clear that the research literature on both violence risk assessment and treatment has grown enormously during the period of study, but at the same time the focus of research has shown no strong indication of a coalescence into the development of a common focus in design, treatment approach or outcome measurement. There is no obvious co-ordinated programmatic approach to the problem across different countries or even within specific countries. In consequence the heterogeneity noted above in many areas inhibits both robust MA and the clear application of findings to establishing improvements in clinical practice. Nevertheless a number of noteworthy trends are emerging, which are discussed below.

Summary of key findings

We deal first with aspects of the literature itself, then with the findings on effectiveness obtainable from the regression and MA of data extracted from it.

Characteristics of the overall literature

The descriptive analysis in the review provides a summary of the overall literature. Approximately 25–30 new studies are published each year and 70% of these are conducted in three countries (USA, UK and Canada). Inevitably, this restricts the generalisability of findings to less developed and/or non-English-speaking countries. The median length of follow-up is 6 months, with an average attrition rate of 10%. Given the intractability of the propensity to violence compared with more acute problems such as active psychosis and its lifelong nature for many people, this follow-up is not much more than a snapshot of the potential for change or otherwise. A third of the literature focuses on three diagnostic groups exclusively (schizophrenia, dementia and personality disorder). Half of the studies are conducted on males only, with < 10% conducted on female-only populations, and there is a disproportionate emphasis on non-Caucasian populations

(i.e. half of the studies have samples in which the majority of participants are non-Caucasian). As, for instance, rates of violence by women with some types of mental health problem are not very different from those for similar men,[120] this could be taken to suggest that there is an emphasis on certain groups in society that does not reflect the actual scale of the problem.

Methodologically speaking, it is clear that there are comparatively few RCTs in this research area (51/198, 26%: see *Table 53*). Compared with the number of trials in many other areas of health care, the proportion is very small.[121] The proportion is smaller still within the psychosocial intervention literature. Possible reasons for this are familiar from other research reviews and include the impracticality of achieving formal randomisation in service delivery settings, within interventions that entail individual contact or of using appropriate placebos, and the absence of means of checking against multiple treatment interference. On the other hand, it is worth noting that, across both literatures, non-RCTs had much longer follow-up periods than RCTs so that gains in causal inference from improved design quality in RCTs have to be weighed against losses in terms of tracking the persistence of an effect. Taken together, these issues reflect the complexity of the violence phenomenon and make it difficult to address the issue of effectiveness with any simplicity.

Within the located studies there are relatively few that focus on measured or recorded aggressive or violent behaviour as outcomes. The majority define outcome in non-behavioural terms, such as hostility or anger (e.g. the STAXI instrument), which can be detected only through self-report. Although these types of outcome measure obviously have value in some respects, they are only ever a proxy or risk factor for the main problem of actual aggressiveness as recorded, for example, on the basis of inpatient ward incident reports or of criminal reconvictions. Much of the literature can therefore provide evidence of effectiveness in terms of only a relatively subjective aspect of the problem.

Finally, a funnel plot of the data set, as a whole, is indicative of the possibility of there being some publication bias within the studies analysed. This is despite significant efforts having been undertaken to secure unpublished studies via extensive search for dissertations. Although this requires the exercise of caution when interpreting the findings, the number of studies conducted and the extent of the review team's contact with other researchers active in the field, thus ensuring inclusion of a substantial number of unpublished studies, suggests that this bias does not distort the findings as much as in other reviews. It is important to note that the distribution observed here could result from systematic association between sample size and other study characteristics that impact on outcome and that the absence of funnel plot asymmetry does not rule out the possibility of publication bias anyway so the impact of funnel plots should not be exaggerated. Nevertheless, it must be acknowledged that the presence of such funnel asymmetry indicates that the MA results could well be overestimates of the effectiveness of interventions and that the literature is more suited to informing future research strategies than answering clinical questions at this stage.

Regression analysis of the overall literature: correlates of effectiveness

The regression analysis of all 198 studies (RCTs and non-RCTs) was aimed at establishing the design and population factors associated with a statistically significant effect ($p < 0.05$) in favour of the active intervention, and highlighted a number of issues of interest.

In terms of intervention types, 'other' interventions were less likely than psychological or pharmacological interventions to be associated with an effective outcome.

Two population variables showed a significant association with effectiveness. Offender-focused studies were significantly less likely to be effective, whereas mental health-focused studies were

more likely to be effective. However, it is worth noting that analysis based on settings rather than populations showed that application in either mental health or offender settings was not relevant to outcome. This gives grounds for optimism with mentally ill samples whether they are located in general mental health or offender settings, but conversely highlights difficulties in implementing therapeutic interventions with offender populations wherever they are located. Furthermore, three design variables were associated with a reduced likelihood of demonstrated effectiveness: head-to-head comparisons, comparison against TAU, and between-groups comparisons.

Further (multivariate) analysis was then conducted to explore the extent of variation explained by outcomes in favour of the primary intervention arm. None of the selected factors had a significant relationship to effectiveness but, in population terms, the relative advantage noted above of studies focused on a mental illness sample over those focused on an offender sample was maintained. The relative disadvantage of 'other'-type interventions was also maintained. Methodologically, only the use of a within-groups design approached significance in this analysis. Further analysis may help to identify if the lack of effect for evaluations of 'other' interventions and those conducted in penal institutions are due to design issues (e.g. insufficient power), implementation issues (e.g. lack of protocols) or the actual inapplicability of these approaches.

Meta-analysis

Heterogeneity became a particular problem when conducting the MA. This underpinned our decision to conduct the above preliminary regression analysis of variables associated with a significant outcome and, when considering the more stringent formal MA, indicates that great caution should be used when interpreting the results. *Q*-statistics for a series of comparisons in the MA, for instance, were as follows: for all pharmacological interventions comparing two active treatments $Q = 111.21$ ($p < 0.0001$), and for all psychological interventions, $Q = 21.1$ ($p < 0.007$). I^2 estimates are similarly large and statistically significant. The exception to this is the comparison between SSRI antidepressants and placebo, for which across four studies *Q* was exceptionally low, at 4.38 ($p = 0.22$), suggesting relatively low heterogeneity in this particular set of comparisons. The relatively high heterogeneity overall is a function of the comprehensive scope of the review but does again indicate the absence of a programmatic approach to violence research in which there is consistency in outcome measurement. Also, with regard to non-pharmacological interventions, it indicates a failure to specify the treatment approaches adopted. Even 'CBT interventions', supposedly drawing on a consistent theoretical model, adopt a range of different techniques. Although this high degree of heterogeneity limits the conclusiveness of the overall review, the estimation of the size of heterogeneity is an important step in itself in bringing some order to the violence research field.

Notwithstanding the heterogeneity issue, across the data set as a whole there is evidence from the MA of a positive outcome of intervention, and this emerges from both fixed-effect and random-effects analyses of the results. Discussion of mean effects across this entire data set is not, however, likely to be especially informative, given (1) the variability of intervention methods (both with respect to different principal categories, e.g. pharmacological vs psychosocial) and the combinations within those categories and (2) the mixed range of outcome measures used. Comparisons between the same method applied to different populations, in different settings, or using different outcome measures is simply not possible. The exception to this is the set of seven studies of CBT[84,86,102,110,111,198] (which are based on a common theoretical model and possess similar operational characteristics). Using Lipsey's[60] 'rule of thumb', which, in turn, drew on conventions proposed by Cohen,[122] small-to-moderate effects (combined with relatively low heterogeneity) are found for CBT, for all psychological interventions combined and larger effects for atypical antipsychotic drugs. Caution must be exercised when interpreting all results, however, as 95% CIs are relatively wide and sometimes include zero, particularly in the random-effects models.

Analysis of the modifier variables provides some evidence that interventions targeted at mental health populations, and particularly male groups in community settings, are more likely to achieve stronger effects. In terms of future research design, high-quality features such as blinding and ITT analysis are likely to be associated with larger effects, which indicates the detection of a 'true' effect. However, the low-quality marker of baseline non-equivalence of comparison groups was also associated with such effects. It is nonetheless encouraging to note that in a review of cognitive behavioural programmes for offenders, examining criminal recidivism as the principal outcome variable, the mean OR effect size for studies with 'best practice' design features was considerably higher than that for the collection of studies overall.[123]

Scale-based measurement was also associated with stronger effects but we have noted above that these provide only a proxy for actual aggression and thus interventions aimed at such behaviour should include observational measures as well, which may reduce the effect size estimate. It is of course legitimate to study such proxies as anger in their own right using validated scales, as they are likely to be predictive of subsequent violence.

There was evidence, although again not emerging in a clear or entirely consistent pattern, for larger effects to be found in community than in institutional settings, a finding obtained in a number of previous MAs in criminal justice.[123,124] Similarly, larger effects sizes were not from smaller samples, reinforcing the impression that emerges from large-scale dissemination exercises that effects are attenuated possibly because of compromises in integrity of treatment or service delivery.[125]

The findings obtained from the present review tailor reasonably well with the trends noted in previous reviews summarised earlier (see *Chapter 1*, *Other reviews*), given that, being mainly sited in criminal justice settings, they also focused on aggression and violent behaviour (including sexual assault) rather than adopting a diagnostic approach. Thus, there is further support for the use of cognitive and behavioural interventions. The principal residual difficulty arises from the heterogeneity of specific methods used; thus, although theoretically grounded in the cognitive social learning model there is still insufficient evidence regarding any single treatment programme to identify a 'treatment of choice' or make firm selective recommendations. The evidence of effectiveness found here for some forms of pharmacotherapy does not fit well with the recommendations made by NICE against routine use of such treatments for aggression associated with antisocial or BPD, and could be an opportunity to reopen some aspects of this question. The effect observed in this review, for instance, could reflect the general tranquillising or suppressing effect on acting-out behaviour. It does support the conclusions to the Cochrane review[52] with regard to the role of antipsychotic drugs with BPD symptoms associated with aggression (e.g. affective dysregulation) and some of the individual studies of neuroleptics cited by Herpertz *et al.*[53] Nevertheless, the latter review overall was, like NICE, inconclusive with regard to pharmacotherapy and aggression in antisocial personality disorder. On the other hand, the effectiveness of psychological interventions, including CBT, observed here for reducing aggression reinforces the recommendations made by NICE for the role of such interventions in the overall treatment of borderline and antisocial personality disorder.

Conclusions and implications for research

1. There is evidence that interventions targeted at mental health populations, and particularly male groups in community settings, are well supported, as they are more likely to achieve stronger effects than interventions with the other groups.
2. Improvements are needed in the design quality of future research studies. Of particular note is the paucity of RCTs in all areas, but especially in the evaluation of non-pharmacological

interventions. Furthermore, RCTs themselves should be improved by extending the study follow-up period wherever possible so that it more closely matches that for non-RCTs. The quality and rigour of research in the field could be improved by more consistent attention to the protocols that have been published with respect to the reporting of both randomised and quasi-experimental designs [e.g. for RCTs, the Consolidated Standards of Reporting Trials (CONSORT) statement;[126,127] for non-randomised designs, the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) statement[128]]. Researchers should identify a single primary outcome variable against which effectiveness is judged to avoid the impression of trawling for significant results across multiple outcome variables.

3. Any approach that could increase the homogeneity of research in this field will be welcomed. Greater homogeneity in study design, the interventions applied and outcome measures used would all be beneficial, especially if actual aggression or violence were to be adopted as an outcome rather than some proxy for these. With reference to outcome evaluation methods for example, a recent review has identified those measures that have the firmest evidence for these purposes in forensic mental health.[129] Were the best-validated measures to be more widely used, it would strengthen internal validity and also facilitate comparability across studies for review purposes.
4. Small-to-moderate effects are found for CBT and for all psychological interventions combined and larger effects for atypical antipsychotic drugs and this occurs in the context of relatively low heterogeneity.
5. A programme of research funded and co-ordinated at a national or international level should be developed as this would improve the capacity to conduct robust MAs and increase our confidence in their results. The review has revealed the extensive literature that exists, especially in the past few years, but coupled with relatively low design quality. Much of the research is conducted opportunistically by practitioners on the basis of what is possible within their clinical setting. Although this is laudable as a contribution to the principle of evidence-based practice, without adequate resources to improve study design, the cumulative evidence base will never produce knowledge that is generalisable beyond specific local settings.
6. Some treatment approaches are particularly lacking in evidence-based interventions, such as psychosocial treatments other than CBT. A greater focus on improving the quantity and quality of research here is likely to prove very beneficial.
7. Psychosocial and other non-pharmacological interventions should be defined more clearly so that the theoretical elements they are testing is made explicit. In this way, the key components that make up a broad intervention such as CBT will be identified and examined for effectiveness.

Acknowledgements

About the Assessment Group

The Assessment Group was based on a partnership between two research groups within the University of Liverpool.

The Liverpool Reviews and Implementation Group (LRiG) was established at The University of Liverpool in April 2001. It is a multidisciplinary research group whose purpose, in the first instance, is to conduct Health Technology Assessments (HTAs) commissioned by the HTA programme.

The LiVio is a multidisciplinary partnership of academics and clinicians with a commitment to both qualitative and quantitative research approaches and their application to problems of violence and self-harm linked to mental health issues in real-world settings. It has received funding from the Department of Health since 2002 to run both primary research studies in secondary mental health service settings and to conduct the preceding stage of this systematic review.

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Ms Janet Atkinson, University of Liverpool's Inter-Library Loan team and all members of the review team.

Advisory Panel members (provided feedback to the team during the review process)

- Dr Joy Duxbury, Reader in Mental Health Nursing, Faculty of Health and Social Care, University of Central Lancashire.
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- Ms Sue Imlack, patient representative.
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Appendix 1

Search strategies

TABLE 54 PsycINFO search strategy (April 2008)

#	Searches	Results
1	((Homicid* or murder* or manslaughter* or infanticid* or parricid* or assault* or ((bodily and (harm or assault)) or assail* or bugger* or sodom* or molest* or pedophil* or paedophil* or sadis* or sadomasochis* or sado-masochis* or anger* or cruel* or rapist* or (rape* and offend*) or physical abus* or spouse abus* or partner abus* or sexual abus*) or (((dangerous* and (behavior* or behaviour* or histor* or conduct*)) or violen*) and (risk* or predict* or anteced* or assess* or cause* or reason* or interven* or prevention* or preventing* or controlling* or manage* or treatment* or treating* or reduction* or reducing* or stop* or mental* or forensic* or psychiatric* or offend* or Axis 1 or Axis 2 or criminal* or detain* or insan* or NGRI or retard* or (learning disab* or learning-disab*) or acquit* or (child abus* or elder abus* or hostil* or killing* or attack* or aggress*)) and (mental* or forensic* or psychiatric* or offend* or axis 1 or axis 2 or criminal* or detain* or insan* or NGRI or retard* or (learning disab* or learning-disab*) or acquit* or disorder*))) not (cancer* or cancer or tumo* or tumour or heart* or heart)).mp.	22,934
2	limit 1 to ((100 childhood <birth to age 12 yrs> or 120 neonatal <birth to age 1 mo> or 140 infancy <age 2 to 23 mo> or 160 preschool age <age 2 to 5 yrs> or 180 school age <age 6 to 12 yrs> or 200 adolescence <age 13 to 17 yrs>) and yr="2002 - 2008")	5631
3	Limit 1 to (animals and yr="2002 - 2008")	235
4	Limit 1 to (editorial and yr="2002 - 2008")	332
5	2 or 3 or 4	6198
6	1 not 5	16,736

Appendix 2

Included studies

TABLE 55 Included studies

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Appendix 3

Selection of data for meta-analyses

TABLE 56 All reported RCT comparators and outcomes and those selected for MAs

Study ID	Line	Comparators	Outcome	Metric
Alexander 2004[112]	I	Lorazepam vs haloperidol + promethazine	In physical restraints at 60 minutes	OR
	II	Lorazepam vs haloperidol + promethazine	In physical restraints at 15 minutes	OR
	III	Lorazepam vs haloperidol + promethazine	In physical restraints at 30 minutes	OR
	IV	Lorazepam vs haloperidol + promethazine	In physical restraints at 120 minutes	OR
	Va	Lorazepam vs haloperidol + promethazine	In physical restraints at 240 minutes	OR
Arango 2006[113]	I	Oral zuclopenthixol vs depot zuclopenthixol	No. of months from baseline to first violent episode (M-OAS)	OR
	II	Oral zuclopenthixol vs depot zuclopenthixol	Severity of violence (using M-OAS)	OR
	III	Oral zuclopenthixol vs depot zuclopenthixol	Violence during follow-up: yes/no (using M-OAS)	OR
	IV	Oral zuclopenthixol vs depot zuclopenthixol	Violence frequency (M-OAS)	OR
Brodaty 2003[139]		Risperidone vs placebo	Cohen-Mansfield Agitation Inventory – aggressive behaviour subscale	NSD
Brown University 2006[89]	I	Aripiprazole vs placebo	STAXI – anger in	OR
	II	Aripiprazole vs placebo	STAXI – anger control	OR
	III	Aripiprazole vs placebo	SCL-90-R aggressiveness/hostility subscale	OR
	IV	Aripiprazole vs placebo	STAXI – state anger	OR
	V	Aripiprazole vs placebo	STAXI – anger out	OR
	VI	Aripiprazole vs placebo	STAXI – trait anger	OR
Cavanaugh 2007[81]	I	Dialectical psychoeducational workshop vs anger management workshop	STAXI – state anger feelings	OR
	II	Dialectical psychoeducational workshop vs anger management workshop	STAXI – state anger verbal	OR
	III	Dialectical psychoeducational workshop vs anger management workshop	STAXI – state anger physical	OR
	IV	Dialectical psychoeducational workshop vs anger management workshop	STAXI – trait anger temperament	OR
	V	Dialectical psychoeducational workshop vs anger management workshop	STAXI – trait anger reactions	OR
	VI	Dialectical psychoeducational workshop vs anger management workshop	STAXI – anger expressions out	OR
	VII	Dialectical psychoeducational workshop vs anger management workshop	STAXI – anger expressions in	OR
	VIII	Dialectical psychoeducational workshop vs anger management workshop	STAXI – anger control out	OR
	IX	Dialectical psychoeducational workshop vs anger management workshop	STAXI – anger control in	OR
	X	Dialectical psychoeducational workshop vs anger management workshop	Risk of Eruptive Violence Scale	OR
Chan 2006[98]		Fluoxetine *or* nortriptyline vs placebo	Present State Examination irritability	OR

continued

TABLE 56 All reported RCT comparators and outcomes and those selected for MAs *(continued)*

Study ID	Line	Comparators	Outcome	Metric
Citrome 2004[107]	I	Combination therapy: (olanzapine or risperidone + divalproex sodium) vs monotherapy: (olanzapine or risperidone) + placebo	PANSS hostility: change to day 7	OR
	II	Combination therapy: (olanzapine or risperidone + divalproex sodium vs monotherapy: (olanzapine or risperidone + placebo	PANSS hostility: change to day 3:	OR
	III	Combination therapy: (olanzapine or risperidone) + divalproex sodium vs monotherapy: (olanzapine or risperidone + placebo	PANSS hostility: change to day 5:	OR
	IV	Combination therapy: (olanzapine or risperidone) + divalproex sodium vs monotherapy: (olanzapine or risperidone) + placebo	PANSS hostility: change to day 14	OR
	V	Combination therapy: (olanzapine or risperidone) + divalproex sodium vs monotherapy: (olanzapine or risperidone) + placebo	PANSS hostility: change to day 10	OR
	VI	Combination therapy: (olanzapine or risperidone) + divalproex sodium vs monotherapy: (olanzapine or risperidone) + placebo	PANSS Hostility: change to day 21	OR
	VII	Monotherapy: (olanzapine or risperidone) + placebo vs combination therapy: (olanzapine or risperidone) + divalproex sodium	PANSS Hostility: change to day 28	OR
Clarkin 2007[68]		DBT vs transference focused psychotherapy		NSD
Cooper 2006[90]	Ia	Violence Intervention Program vs standard medical treatment	Convicted for violent crime	OR
	II	Violence Intervention Program vs standard medical treatment	Ever arrested violent crime	OR
Duggan 2007[114]	I	Healthy Families Alaska Program – positive parenting, etc. vs TAU	CTS – extreme physical punishment	OR
	II	Healthy Families Alaska Program – positive parenting, etc. vs TAU	CTS – corporal/verbal punishment	OR
	III	Healthy Families Alaska Program – positive parenting, etc. vs TAU	CTS – hit with object	OR
	IV	Healthy Families Alaska Program – positive parenting, etc. vs TAU	CTS – severe assault	OR
	V	Healthy Families Alaska Program – positive parenting, etc. vs TAU	CTS – common corporal punishment	OR
	VI	Healthy Families Alaska Program – positive parenting, etc. vs TAU	CTS – mild physical assault	OR
	VII	Healthy Families Alaska Program – positive parenting, etc. vs TAU	CT – psychological aggression	OR
Easton 2005[110]		CBT substance abuse program vs twelve-step facilitation	CTS – physical	OR
Easton 2007[111]	I	Substance Abuse Domestic Violence Group vs twelve-step facilitation	CTS – physical violence frequency at 12 weeks	OR
	II	Substance Abuse Domestic Violence Group vs twelve-step facilitation	CTS – physical violence % at 12 weeks	OR
	III	Substance Abuse Domestic Violence Group vs twelve-step facilitation group	CTS – physical violence frequency at 6 months	OR

TABLE 56 All reported RCT comparators and outcomes and those selected for MAs *(continued)*

Study ID	Line	Comparators	Outcome	Metric
Frankenburg 2002[106]	I	Divalproex vs placebo	SCL-90 anger/hostility subscale	OR
	II	Divalproex vs placebo	M-OAS	OR
Galovski 2002[69]		Cognitive behavioural psychological intervention vs self-monitoring of symptoms only		NSD
Gottfredson 2002[92]		Baltimore Drug Treatment Court vs TAU	% with violent or sex charge at 1 year	OR
Hollander 2003[91]		Divalproex vs placebo	M-OAS (median)	OR
Houston 2006[70]				NSD
Huf 2003[72]		Midazolam vs haloperidol + promethazine	% not needing restraints at 120 minutes	RR
		Midazolam vs haloperidol + promethazine	% no further aggression at 24 hours	RR
Huf 2007[73]		Haloperidol vs haloperidol plus promethazine	No other episodes of aggression at 24 hours	RR
		Haloperidol vs haloperidol plus promethazine	Restraints not needed at 120 minutes	RR
Krakowski 2006[82]	I	Clozapine vs haloperidol	M-OAS physical aggression	OR
	II	Clozapine vs olanzapine	M-OAS physical aggression	OR
	III	Olanzapine vs haloperidol	M-OAS physical aggression	OR
	IV	Clozapine vs haloperidol	M-OAS verbal aggression	OR
	V	Clozapine vs olanzapine	M-OAS verbal aggression	OR
	VI	Olanzapine vs haloperidol	M-OAS verbal aggression	OR
Labriola 2008[94]	I	Batterer programme vs no TAU	Any rearrest for domestic violence at 1-year post-sentence	OR
	II	Batterer programme vs no TAU	Any rearrest for domestic violence at 18-months post-sentence	OR
	III	Batterer programme vs no TAU	Any rearrest for domestic violence at 1-year post-monitoring	OR
	IV	Batterer programme vs no TAU	Victim report of any type of new abuse	OR
	V	Batterer programme vs no TAU	Victim report new physical abuse	OR
	VI	Batterer programme vs no TAU	Victim report new threats	OR
	VII	Batterer programme vs no TAU	Victim report other abuse	OR
	VIII	Monthly monitoring vs graduated monitoring	Any rearrest for domestic violence at 1-year post-sentence	OR
	IX	Monthly monitoring vs graduated monitoring	Any rearrest for domestic violence at 18-months post-sentence	OR
	X	Monthly monitoring vs graduated monitoring	Any rearrest for domestic violence at 1-year post-monitoring	OR
	XI	Monthly monitoring vs graduated monitoring	Victim report of any type of new abuse	OR
	XII	Monthly monitoring vs graduated monitoring	Victim report new physical abuse	OR
	XIII	Monthly monitoring vs graduated monitoring	Victim report new threats	OR
	XIV	Monthly monitoring vs graduated monitoring	Victim report other abuse	OR
Lanza 2002[86]	I	CBT group vs psychodynamic group psychotherapy	Monthly STAXI trait anger change	OR
	II	CBT group vs psychodynamic group psychotherapy	OAS	OR
	III	CBT group vs psychodynamic group psychotherapy	Weekly STAXI anger control change	OR
	IV	CBT group vs psychodynamic group psychotherapy	Weekly STAXI state anger change	OR
Lasley 2003[83]		Intensive bail supervision vs regular bail supervision	Repeat DV offending	OR

continued

TABLE 56 All reported RCT comparators and outcomes and those selected for MAs *(continued)*

Study ID	Line	Comparators	Outcome	Metric
Levesque 2005[200]	I	Computerised stage-matched intervention for DV offenders adjunctive to traditional batterer programme vs traditional batterer programme	Beat up partner	NSD
	II	Computerised stage-matched intervention for DV offenders adjunctive to traditional batterer programme vs traditional batterer programme	Slapped	NSD
	III	Computerised stage-matched intervention for DV offenders adjunctive to traditional batterer programme vs traditional batterer programme	Physical aggression	NSD
	IV	Computerised stage-matched intervention for DV offenders adjunctive to traditional batterer programme vs traditional batterer programme	Psychological aggression	NSD
Liau 2004[115]		Psychoeducational component of the EQUIP program vs EQUIP without psychoeducational component	Self-reported aggression	OR
Linehan 2008[116]	I	DBT plus olanzapine vs DBT plus placebo	OAS – irritability	OR
	II	DBT plus olanzapine vs DBT plus placebo	OAS – physical aggression	OR
	III	DBT plus olanzapine vs DBT plus placebo	OAS – verbal aggression	OR
Loew 2006[117]		Topiramate vs placebo	SCL-90 hostility subscale	OR
MacKenzie 2007[95]		Boot camp vs prison	STAXI	OR
Marques 2005[74]	I	Relapse prevention vs volunteer control	Sexual reoffence	NSD
	II	Relapse prevention vs non-volunteer control	Sexual reoffence	NSD
	III	Relapse prevention vs volunteer control	Violent reoffence	NSD
	IV	Relapse prevention vs non-volunteer control	Violent reoffence	NSD
Mattes 2005[96]	I	Oxcarbazepine vs placebo	Change in BPRS hostility rating	OR
	II	Oxcarbazepine vs placebo	M-OAS – global (change in score)	OR
	IV	Oxcarbazepine vs placebo	M-OAS verbal aggression (change in score)	OR
	VI	Oxcarbazepine vs placebo	M-OAS – assault against others (change in score)	OR
Meehan 2002[109]	I	Olanzapine (5 mg) vs placebo	Change PANSS hostility item: 2 hours	OR
	II	Lorazepam vs placebo	Change PANSS hostility item: 2 hours	OR
	III	Olanzapine (2.5 mg) vs placebo	Change PANSS hostility item: 2 hours	OR
Mitchell 2006[77]		Boot camp vs traditional correctional facility	Self-control scale – temper	Linked with MacKenzie[95]
Monnelly 2003[85]		Risperidone vs placebo	M-OAS – aggression subscale	OR
New 2004[97]		Fluoxetine vs placebo	OAS – aggression	OR
Nickel 2004[104]	I	Topiramate vs placebo	STAXI – anger control	OR
	II	Topiramate vs placebo	STAXI – anger out	OR
	III	Topiramate vs placebo	STAXI – state anger	OR
	IV	Topiramate vs placebo	STAXI – trait anger	OR
	V	Topiramate vs placebo	STAXI – anger in	OR
Nickel 2005[88]	I	Topiramate vs placebo	Anger symptoms – anger in	OR
	II	Topiramate vs placebo	Anger symptoms – anger control	OR
	III	Topiramate vs placebo	Anger symptoms – anger out	OR
	IV	Topiramate vs placebo	Anger symptoms – state anger	OR
	V	Topiramate vs placebo	Anger symptoms – trait anger	OR
Nickel 2005[105]	I	Topiramate vs placebo	Anger symptoms – anger control	OR
	II	Topiramate vs placebo	Anger symptoms – anger in	OR
	III	Topiramate vs placebo	Anger symptoms – anger out	OR
	IV	Topiramate vs placebo	Anger symptoms – state anger	OR
	V	Topiramate vs placebo	Anger symptoms – trait anger	OR

TABLE 56 All reported RCT comparators and outcomes and those selected for MAs *(continued)*

Study ID	Line	Comparators	Outcome	Metric
Raveendran 2007[75]	I	Olanzapine vs haloperidol plus promethazine	In restraints at 120 minutes	RR
	II	Olanzapine vs haloperidol plus promethazine	In restraints at 15 minutes	RR
	III	Olanzapine vs haloperidol plus promethazine	In restraints at 240 minutes	RR
	IV	Olanzapine vs haloperidol plus promethazine	In restraints at 30 minutes	RR
	V	Olanzapine vs haloperidol plus promethazine	In restraints at 60 minutes	RR
Rinne 2002[99]		Fluvoxamine vs placebo	Borderline Personality Disorder Severity Index – anger subscale	OR
Soler 2005[118]		DBT plus olanzapine vs DBT plus placebo	Impulsivity/aggressive behaviour (bi-weekly reports)	OR
Suh 2004[101]	I	Risperidone vs haloperidol	Cohen-Mansfield Agitation Inventory – aggressive behaviour subscale	OR
	II	Risperidone vs haloperidol	Behavioural Pathology in Alzheimer's Disease Rating Scale – aggressiveness subscale	OR
Theall 2007[71]		Four-session motivated focused condition vs four-session negotiation-focused condition (TAU) National Institute on Drug Abuse (NIDA)		NSD
Tritt 2005[103]	I	Lamotrigine vs placebo	STAXI – anger control	OR
	II	Lamotrigine vs placebo	STAXI – anger out	OR
	III	Lamotrigine vs placebo	STAXI – state anger	OR
	IV	Lamotrigine vs placebo	STAXI – trait anger	OR
	V	Lamotrigine vs placebo	STAXI – anger in	OR
Tyrer 2008[108]	I	Risperidone vs placebo	M-OAS 4 weeks	OR
	II	Haloperidol vs placebo	M-OAS 4 weeks	OR
	III	Risperidone *or* haloperidol vs placebo	M-OAS 4 weeks	OR

continued

TABLE 56 All reported RCT comparators and outcomes and those selected for MAs *(continued)*

Study ID	Line	Comparators	Outcome	Metric
Vannoy 2006[102]	RCTI	Anger control based on Buddhist meditation vs TAU	STAXI anger (males) 1-week post-treatment	OR
	RCTII	Anger control based on Buddhist meditation vs TAU	AQ anger (males) 1-week post-treatment	OR
	RCTIII	Anger control based on Buddhist meditation vs TAU	AQ hostility (males) 1-week post-treatment	OR
	RCTIV	Anger control based on Buddhist meditation vs TAU	CM hostility (males) 1-week post-treatment	OR
	RCTV	Anger control based on Buddhist meditation vs TAU	STAXI anger (females) 1-week post-treatment	OR
	RCTVI	Anger control based on Buddhist meditation vs TAU	AQ anger (females) 1-week post-treatment	OR
	RCTVII	Anger control based on Buddhist meditation vs TAU	AQ hostility (females) 1-week post-treatment	OR
	RCTVIII	Anger control based on Buddhist meditation vs TAU	CM hostility (females) 1-week post-treatment	OR
	RCTIX	Anger control based on Buddhist meditation vs TAU	STAXI anger (males) 10-weeks post-treatment	OR
	RCTX	Anger control based on Buddhist meditation vs TAU	AQ anger (males) 10-weeks post-treatment	OR
	RCTXI	Anger control based on Buddhist meditation vs TAU	AQ hostility (males) 10-weeks post-treatment	OR
	RCTXII	Anger control based on Buddhist meditation vs TAU	CM hostility (Males) 10-weeks post-treatment	OR
	RCTXIII	Anger control based on Buddhist meditation vs TAU	STAXI anger (females) 10-weeks post-treatment	OR
	RCTIX	Anger control based on Buddhist meditation vs TAU	AQ anger (females) 10-weeks post-treatment	OR
	RCTXV	Anger control based on Buddhist meditation vs TAU	AQ hostility (Females) 10-weeks post-treatment	OR
	RCTXVI	Anger control based on Buddhist meditation vs TAU	CM hostility (Females) 10-weeks post-treatment	OR
Villari 2008[76]	I	Risperidone vs olanzapine	BPRS hostility	NSD
	II	Risperidone vs quetiapine	BPRS hostility	NSD
	III	Risperidone vs haloperidol	BPRS hostility	NSD
	IV	Olanzapine vs quetiapine	BPRS hostility	NSD
	V	Olanzapine vs haloperidol	BPRS hostility	NSD
	VI	Quetiapine vs haloperidol	BPRS hostility	NSD
	VII	Risperidone vs olanzapine	M-OAS verbal aggression	NSD
	VIII	Risperidone vs quetiapine	M-OAS verbal aggression	NSD
	IX	Risperidone vs haloperidol	M-OAS verbal aggression	NSD
	X	Olanzapine vs quetiapine	M-OAS verbal aggression	NSD
	XI	Olanzapine vs haloperidol	M-OAS verbal aggression	NSD
	XII	Quetiapine vs haloperidol	M-OAS verbal aggression	NSD
	XIII	Risperidone vs olanzapine	M-OAS physical aggression	NSD
	XIV	Risperidone vs quetiapine	M-OAS physical aggression	NSD
	XV	Risperidone vs haloperidol	M-OAS physical aggression	NSD
	XVI	Olanzapine vs quetiapine	M-OAS physical aggression	NSD
	XVII	Olanzapine vs haloperidol	M-OAS physical aggression	NSD
	XVIII	Quetiapine vs haloperidol	M-OAS physical aggression	NSD
	XIX	Risperidone or olanzapine or quetiapine vs haloperidol	BPRS hostility	NSD

TABLE 56 All reported RCT comparators and outcomes and those selected for MAs *(continued)*

Study ID	Line	Comparators	Outcome	Metric
	XX	Risperidone or olanzapine or quetiapine vs haloperidol	M-OAS verbal aggression	NSD
	XXI	Risperidone or olanzapine or quetiapine vs haloperidol	M-OAS physical aggression	NSD
Volavka 2004[87]	I	Clozapine vs olanzapine	Incident of aggression during 14-week study (OAS)	OR
	II	Clozapine vs risperidone	Incident of aggression during 14-week study (OAS)	OR
	III	Clozapine vs haloperidol	Incident of aggression during 14-week study (OAS)	OR
	IV	Olanzapine vs risperidone	Incident of aggression during 14-week study (OAS)	OR
	V	Olanzapine vs haloperidol	Incident of aggression during 14-week study (OAS)	OR
	VI	Risperidone vs haloperidol	Incident of aggression during 14-week study (OAS)	OR
	VII	Clozapine vs olanzapine	Incident of aggression during 14-week study (OAS)	OR
	VIII	Clozapine vs risperidone	Incident of aggression during 14-week study (OAS)	OR
	IX	Clozapine vs haloperidol	Incident of aggression during 14-week study (OAS)	OR
	X	Olanzapine vs risperidone	Incident of aggression during days 25–98 of study (OAS)	OR
	XI	Olanzapine vs haloperidol	Incident of aggression during days 25–98 of study (OAS)	OR
	XII	Risperidone vs haloperidol	Incident of aggression during days 25–98 of study (OAS)	OR
Walsh 2002[93]		Intensive care management vs standard care	More assaults	OR
Willner 2002[84]	I	CB anger management vs WL	Anger Inventory – client ratings	OR
	II	CB anger management vs WL	Composite score of anger inventory and provocation index both clients and carers	OR
	III	CB anger management vs WL	Composite score of anger inventory and provocation index clients ratings	OR
	IV	CB anger management vs WL	Provocation Index – client ratings	OR
	V	CB anger management vs WL	Composite score of anger inventory and provocation index carer ratings	OR
	VI	CB anger management vs WL	Provocation Index – carer ratings	OR
	VII	CB anger management vs WL	Anger Inventory – carer ratings	OR
Zanarini 2003[119]		Ethyl-eicosapentaenoic acid vs placebo	M-OAS	OR
Zanarini 2004[100]	I	Olanzapine vs fluoxetine	OAS (change)	OR
	II	Olanzapine vs olanzapine + fluoxetine combined	OAS (change)	OR
	III	Fluoxetine vs olanzapine + fluoxetine combined	OAS (change)	OR

AQ, Aggression Questionnaire; BPRS, Brief Psychiatric Rating Scale; CB, cognitive behavioural; CM, Cook–Medley Hostility Scale; DBT, dialectical behaviour therapy; DV, domestic violence; E-EPA, ethyl-eicosapentaenoic acid; NSD, no suitable data; PANSS; Positive and Negative Syndrome Scale; RR, relative risk; SCL-90, Symptom-Checklist-90; SCL-90-R, Symptom-Checklist-90-Revised.
Shaded rows are those that were selected for use in MAs.

Appendix 4

Selection of data for meta-analyses

TABLE 57 Selection of RCTs for MAs

Study ID	MA overall	MA head to head	MA active vs TAU	MA active vs true	MA all pharma	MA all psych	MA all other	MA anticonvulsant drugs	MA SSRI	MA atypical	MA CBT	MA model 1	MA model 2	MA model 3	MA model 4	MA model 5
Alexander 2004[112]	Yes	Yes			Yes											
Arango 2006[113]	Yes	Yes			Yes											Yes
Brown University 2006[89]	Yes			Yes	Yes					Yes				Yes		
Cavanaugh 2007[81]	Yes	Yes				Yes										
Chan 2006[150]	Yes			Yes	Yes				Yes							Yes
Citrome 2004[107]	Yes	Yes			Yes							Yes				
Cooper 2006[90]	Yes		Yes			Yes										
Duggan 2007[114]	Yes		Yes			Yes										
Easton 2005[110]	Yes	Yes				Yes					Yes					
Easton 2007[111]	Yes	Yes				Yes					Yes					
Frankenburg 2002[106]	Yes			Yes	Yes			Yes					Yes			
Gottfredson 2002[92]	Yes		Yes				Yes									
Hollander 2003[91]	Yes			Yes	Yes			Yes				Yes				
Krakowski 2006[82]	Yes	Yes			Yes					Yes		Yes				
Labriola 2008[94]	Yes	Yes					Yes									
Lanza 2002[86]	Yes	Yes				Yes					Yes				Yes	
Lasley 2003[83]	Yes	Yes					Yes									
Liau 2004[115]	Yes	Yes				Yes					Yes					
Linehan 2008[116]	Yes	Yes			Yes					Yes						
Loew 2006[117]	Yes			Yes	Yes			Yes					Yes			
MacKenzie 2007[95]	Yes		Yes				Yes									
Mattes 2005[96]	Yes			Yes	Yes			Yes								Yes
Meehan 2002[109]	Yes			Yes	Yes					Yes				Yes		
Monnelly 2003[85]	Yes			Yes	Yes					Yes						Yes
New 2004[97]	Yes			Yes	Yes				Yes							Yes
Nickel 2004[104]	Yes			Yes	Yes			Yes					Yes			

continued

TABLE 57 Selection of RCTs for MAs *(continued)*

Study ID	MA overall	MA head to head	MA active vs TAU	MA active vs true	MA all pharma	MA all psych	MA all other	MA anticonvulsant drugs	MA SSRI	MA atypical	MA CBT	MA model 1	MA model 2	MA model 3	MA model 4	MA model 5
Nickel 2005[88]	Yes			Yes	Yes			Yes								Yes
Nickel 2005[105]	Yes			Yes	Yes			Yes					Yes			
Rinne 2002[99]	Yes			Yes	Yes				Yes				Yes			
Soler 2005[118]	Yes	Yes			Yes					Yes						
Suh 2004[101]	Yes	Yes			Yes					Yes				Yes		
Tritt 2005[103]	Yes			Yes	Yes			Yes					Yes			
Tyrer 2008[108]	Yes			Yes	Yes					Yes						Yes
Vannoy 2006[102]	Yes		Yes			Yes					Yes					
Vannoy 2006[102]	Yes		Yes			Yes					Yes					
Volavka 2004[87]	Yes	Yes			Yes					Yes		Yes				
Walsh 2002[93]	Yes		Yes				Yes									
Willner 2002[274]	Yes		Yes			Yes					Yes				Yes	
Zanarini 2003[119]	Yes			Yes	Yes								Yes			
Zanarini 2004[100]	Yes	Yes			Yes				Yes	Yes			Yes			

pharma, pharmacological; psych, psychological.

Appendix 5

Modifier data for meta-analyses

TABLE 58 Modifier data

Study ID	Primary focus	Specific focus		Population	Scale	Sex	Start setting	Start *n*	Blinding
		Arm A	Arm B						
MacKenzie 2007[95]	Other	Boot camp	TAU	Offend	Yes	Male	Prison	234	No/ns
Gottfredson 2002[92]	Other	Drug court	TAU	Offend	No	Mix	Commun	235	No/ns
Lasley 2003[83]	Other	Intensive monitoring	Active	Offend	No	Female	Othmix	552	No/ns
Walsh 2002[93]	Other	Intensive	TAU	Mental	No			122	No/ns
Labriola 2008[94]	Other	Monthly monitoring	Active	Offend	No	Male	Commun	420	No/ns
Cooper 2006[90]	Other	Intervention programme	TAU	Offend	No	Mix	Commun	100	No/ns
Vannoy 2006[102]	Other	Meditation	TAU	Offend	Yes	Male	Prison	11	No/ns
Vannoy 2006[102]	Other	Meditation	TAU	Offend	Yes	Female	Prison	21	No/ns
Loew 2006[117]	Pharma	Anticonvulsant	Placebo	Mental	Yes	Female		56	Yes
Frankenburg 2002[106]	Pharma	Anticonvulsant	Placebo	Mental	Yes	Female	Commun	30	Yes
Hollander 2003[91]	Pharma	Anticonvulsant	Placebo	Mental	Yes	Mix	Commun	246	Yes
Nickel 2004[109]	Pharma	Anticonvulsant	Placebo	Mental	Yes	Female	Commun	31	Yes
Nickel 2005[68]	Pharma	Anticonvulsant	Placebo	Mental	Yes	Female	Commun	64	Yes
Nickel 2005[105]	Pharma	Anticonvulsant	Placebo	Mental	Yes	Male	Commun	44	Yes
Tritt 2005[103]	Pharma	Anticonvulsant	Placebo	Mental	Yes	Female	Commun	27	Yes
Mattes 2005[96]	Pharma	Anticonvulsant	Placebo	Mental	Yes	Mix	Othmix	48	Yes
New 2004[97]	Pharma	Antidepressant	Placebo	Mental	Yes	Mix	Commun	20	Yes
Chan 2006[150]	Pharma	Antidepressant	Placebo	Mental	Yes	Mix	Open	92	Yes
Rinne 2002[99]	Pharma	Antidepressant	Placebo	Mental	Yes	Female	Othmix	38	Yes
Citrome 2004[107]	Pharma	Atypical antipsychotic	Active	Mental	Yes	Mix		249	Yes
Krakowski 2006[82]	Pharma	Atypical antipsychotic	Active	Mental	Yes	Mix		110	Yes

Study ID	Primary focus	Specific focus		Population	Scale	Sex	Start setting	Start *n*	Blinding
		Arm A	Arm B						
Suh 2004[101]	Pharma	Atypical antipsychotic	Active	Mental	Yes	Mix	Othmix	120	Yes
Brown University 2006[89]	Pharma	Atypical antipsychotic	Placebo	Mental	Yes	Mix	Commun	52	Yes
Tyrer 2008[108]	Pharma	Atypical antipsychotic	Placebo	Mental	Yes	Mix	Commun	86	Yes
Zanarini 2004[100]	Pharma	Atypical antipsychotic	Placebo	Mental	Yes	Female	Commun	45	Yes
Volavka 2004[87]	Pharma	Atypical antipsychotic	Placebo	Mental	Yes	Mix	Open	167	Yes
Meehan 2002[109]	Pharma	Atypical antipsychotic	Placebo	Mental	Yes	Mix	Othmix	272	Yes
Monnelly 2003[85]	Pharma	Atypical antipsychotic	Placebo	Mental	Yes	Male	Othmix	16	Yes
Soler 2005[118]	Psych	Atypical antipsychotic	Placebo	Mental	Yes	Mix		60	Yes
Linehan 2008[116]	Psych	Atypical antipsychotic	Placebo	Mental	Yes	Female	Commun	44	Yes
Alexander 2004[112]	Pharma	Benzodiazepine	Active	Mental	No	Mix	Othmix	200	No/ns
Zanarini 2003[119]	Pharma	E-EPA	Placebo	Mental	Yes	Female	Commun	30	Yes
Arango 2006[113]	Pharma	Typical antipsychotic	Active	Mental	Yes	Mix	Open	46	Yes
Lanza 2002[86]	Psych	CBT	Active	Mental	Yes	Male	Othmix	42	No/ns
Easton 2005[110]	Psych	CBT	Active	Offend	Yes	Male	Othmix	64	No/ns
Easton 2007[111]	Psych	CBT	Active	Indict	Yes	Male	Commun	78	No/ns
Willner 2002[274]	Psych	CBT	Wait list	Mental	Yes	Mix	Commun	16	No/ns
Duggan 2007[114]	Other	CBT	TAU	Indict	Yes	Female	Commun	325	Yes
Cavanaugh 2007[81]	Psych	DiaPsyEd	Active	Indict	Yes	Male	Commun	55	No/ns
Liau 2004[115]	Psych	PsyEd EQUIP	Active	Offend	No	Mix	Commun	316	No/ns

Commun, community; DiaPsyEd, dialectical psychology education; E-EPA, ethyl-eicosapentaenoic acid; No/ns, no or not state; Othmix, other or mixed settings; Pharma, pharmacological, Psych, psychological; PsyEd EQUIP, Psychoeducational component of the EQUIP program.

Appendix 6

Protocol

Campbell Collaboration Review Protocol

Intervention Protocol

1. Cover Sheet

Title: Systematic Review of Intervention Strategies for the Prevention, Treatment and Management of Violent Behaviour by Adults in Contact with Forensic Mental Health Services or the Criminal Justice System.

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Sources of Support: Department of Health (England): National Forensic Mental Health R&D Programme (original review) and National Institute for Health Research / Research for Patient Benefit Programme (review update)

2. Background for the review

Violent behaviour is a significant source of public and political concern, and most perpetrators will eventually come into contact with either the forensic mental health (FMH) services or the criminal justice system (CJS) (or both). This contact provides an opportunity for assessment of the individual's risks and needs and for interventions aimed at managing violence within the institutional setting and preventing future violence within the community. Numerous risk assessment and risk management technologies have been developed over the past thirty years which are available for practitioners to deploy when working with individual perpetrators, and many of these technologies have at least a moderate evidence base. The systematic review proposed here sets out to address the global evidence base underpinning interventions for preventing, treating and managing violence in both FMH and CJS settings. It will be conducted in parallel with another review (submitted to the Campbell Collaboration under separate cover) addressing issues of violence risk assessment.

A very diverse range of interventions have been developed with the aim of preventing and managing violent behaviour by people in contact with these two agencies (Hodgins 2000; Hollin 2003). These interventions range from pharmacological treatment, through a wide range of psychological approaches to, at the social end of the spectrum, environmental manipulations. They may include the use of physical force (Sailas and Fenton 2002). Psychosocial interventions tend to be based on cognitive-behavioural principles but may include psychodynamic, humanistic and/or systems theory elements and may be delivered on an individual one-to-one, group or 'therapeutic community' basis. Intensive interventions may combine many of these components simultaneously. Intervention may take place in forensic in-patient or correctional settings to prevent violence within those settings or in preparation for discharge / release into the community, or they may take place in community settings as part of an outpatient or community offender management programme. Distinctions can be drawn between short-term interventions aimed at preventing imminent violence or managing actual violence by highly aroused and disordered patients on the one hand (NICE 2005), and long-term structured therapeutic interventions delivered in relatively low-arousal settings aimed at preventing future violence in in-patient, prison or community settings on the other. Pharmacological and psychosocial interventions may be 'single dose' or 'multiple dose'. Most interventions will be delivered directly face-to-face with the patient but some relevant interventions (e.g. staff training, environmental changes) are delivered indirectly via a human or physical mediator. It should be noted that the precipitants and mediators of violence by people with a personality disorder can be very different from those related to violence by people with an active mental disorder, particularly psychosis and thus interventions will be tailored appropriately.

After twenty years of sustained activity in this area, the primary research literature is now very large yet the evidence base for making clinical and policy decisions is often bemoaned as inadequate (Department of Health 2000). The evidence base is certainly poor considering the vast number of studies which have been published in the last decade (Cure, Chua et al. 2005), largely because of a combination of methodological difficulties and lack of focus characteristic of the unusually rapid development of interest in the field. A number of systematic reviews have been conducted to summarise and integrate the findings from the literature and these provide evidence on a number of specific areas. However, inevitably these reviews tend to focus on a specific intervention e.g. second generation antipsychotics (Bhana, Foster et al. 2001) and/or a specific outcome (e.g. reoffending) in various special populations (e.g. sex offenders). This review will instead adopt a more comprehensive

approach by aiming to capture research on all interventions relating to a broad range of violence-related outcomes amongst a wide FMH and CJS population. In this way it is anticipated that the fragmented clinical and criminological literatures can be reintegrated to the mutual benefit of practitioners and researchers in both settings (Hollin 2008).

This Interventions review is being conducted in tandem with a review of Risk Assessment approaches with the same population and it is important to emphasise that the two processes should be closely linked. Estimates of predictive validity from a risk assessment tool are of little use on their own if they are not used to design and target effective interventions. The structured clinical judgement approach (Maden 2007) discussed in the introduction to the other review is important in this context as this approach is recognised as encouraging practitioners to focus on risk management and flexibility in choosing appropriate interventions.

The two protocols (Interventions and Risk Assessment) build on the work of a previously completed systematic review in this area. The final report of this review has had significant influence on national policy in England and is currently flagged on the website of the Department of Health / Ministry of Justice (England) National Risk Management Programme (CSIP/NIMHE). It also formed the basis for a set of national best practice guidelines on risk management (Department of Health 2007) and national policy guidance on selection of risk assessment tools (Leitner 2006).

3. Objectives of the review

3.1 To provide a systematic review of primary research evaluating interventions to prevent violent behaviour specifically targeted at people in contact with forensic mental health or criminal justice systems.

3.2 To produce a general statement about the effects of treatment for violent behaviour specifically targeted at people in this group through the synthesis of individual study results.

3.3 To examine reasons for conflicting evidence on effectiveness in this area.

4. Methods

This protocol relates to a systematic review which, in its entirety will cover the publication period from the inception of the research literature to mid-2008. The original review(covering studies published up to the end of 2002) has been completed and resulted in the inclusion of approximately 1200 studies in the Liverpool Violence (LiVio) Research Archive and the construction of an associated SPSS database of extracted information on 200+ variables per study. About half of these studies relate to interventions and half to risk assessment. A technical report on the original review is available (Leitner, Barr et al. 2006). The review update, covering studies between 2002 and 2008 will, in the main, match the original review methods strategy . Any divergence between the methods is noted below.

4.1 Criteria for inclusion and exclusion of studies in the review

For a study to be included in this systematic review it must have the following characteristics:

I. Participant/Population characteristics

1. The study participants must (a) have an active diagnosis of mental illness, learning disability or personality disorder, OR (b) be an offender (person subject to penal sanction), OR (c) be a person known to have committed one or more acts of aggression constituting an indictable offence (whether or not an indictment has been made). Studies will be excluded if (a) the sample participants are members of the general public, with no identified mental illness and no evidence of having committed an act of violence which would constitute and indictable offence, (b) Substance abuse (including alcohol abuse) in isolation from any other diagnosis of mental illness is not to be defined for the purposes of the review as an active diagnosis of mental illness. Substance abuse (including and separately specified as alcohol abuse) *is* to be identified in relation to *participant characteristics* for the purposes of data extraction, as it is identified in primary studies.
2. The study participants must be aged 17 years and older.

II. Intervention Characteristics

1. The intervention must (a) be specifically identified as being evaluated with the intention of preventing violent behaviour OR (b) implemented with the immediate intention of preventing violent behaviour *(e.g. 'naturalistic' evaluation in a clinical setting)*. Studies will be excluded if interventions are focussed *solely* on reducing or preventing target behaviours *other* than aggression towards others.
2. Interventions must be targeted at the individual level. Studies will be excluded if (a) studies evaluate the impact of broad-based local or national population-level initiatives and which also fail to evaluate outcomes (cf. outcome criteria) at the individual level are to be excluded. Studies which have a focus on a main target behaviour which is <u>not</u> other-directed aggression (the target behaviour may be self-directed aggression), but which <u>do</u> include an evaluation of the association between exposure to an intervention and rates of other-directed aggression as a subsidiary focus are to be included. (b)Studies evaluate the impact of broad-based local or national population-level initiatives and which *also* fail to evaluate outcomes *(cf. outcome criteria)* at the individual level are to be excluded. For example, a study evaluating the impact of a binge drinking campaign on aggression which evaluated outcomes purely by noting changes in population rates of violence across time would be exclude a study evaluating the same intervention but reporting outcomes based on the same set of individuals with behaviour evaluated before and after the initiative would be included. The key point is that the specific individuals being assessed need to be evaluated at outcome.
3. Interventions may include, but are not restricted to, pharmacological, physical, psychological, environmental, or training initiatives
4. Interventions include both 'single dose' and complex 'multiple dose' or 'multifactorial' interventions
5. Studies which have a focus on a main target behaviour which is <u>not</u> other-directed aggression (the target behaviour may be self-directed aggression), but which <u>do</u> include an evaluation of the intervention on other-directed aggression as a subsidiary focus are to be included. Studies will be excluded if they focus <u>solely</u> on self-directed aggression, including self-harm and suicidal behaviours.

III. Setting/location

1. Setting/location of any study is not to be regarded as grounds for excluding that study. Therefore any setting such as (a) any institutional setting/location, (b) any community setting/location, (c) community-based 'institutional' settings such as out-patient clinics, A&E, private practice clinics etc, (d) studies conducted at 'remote' locations, for example studies evaluating interventions conducted by telephone or in writing, are to be included.

IV. **Study Design Characteristics**

1. The study design must be explicitly measuring outcomes following an intervention meeting the above criteria. Studies will be excluded if (a) there is no attempt at any sort of empirical approach likely to elicit at least an association between dependent variables and outcomes, OR (b) there is no clear identification of an intervention taken as either the main *or* as a subsidiary focus of the study.
2. For inclusion in empirical analyses studies must be (a) randomized controlled trials with a no treatment or treatment as usual control group will be included, (b) quasi-experimental (non-randomized) comparison group designs with an treatment group and no treatment or treatment as usual control group.
3. All other designs will be included and used as supporting evidence.

V. Outcome measure characteristics

1. Studies must report (a) directly observed physical *or* verbal aggression by person(s) with an identified mental illness OR (b) directly observed physical aggression (meeting criteria for indictment) by members of the general public or current/previous offenders. Studies will be excluded if (a) There is no evaluation of outcomes, (b) aggressive behaviour (as defined for the population groups considered) is *not* either a main or subsidiary outcome of the evaluation
2. Proxy measures of the above (including but not restricted to: self or other report of the above categories of behaviour, including reports established *via* clinical records; official records of offence and conviction; psychometric and other scale based outcomes of mentations or behaviours directly relevant to aggression, for example BPRS measures of 'hostility') Studies will be excluded if directly observed or proxy-evaluated aggressive behaviour (as defined for the population groups considered) is *not* either a main or subsidiary outcome of the evaluation.
3. Outcome evaluation must be based on individual-level data. Studies will be excluded if (a) evaluations are based on 'non-attributable' rates and (b) other summary data. 'Collective' acts of aggression, such as terrorism, 'gang' violence, organised violent crime, football violence, drug feuds etc. are excluded from consideration by the review where the focus of the study is on the phenomenon *as* a collective behaviour; studies focussed specifically on individual behaviour *within* these contexts should be included.
4. Evaluation of both imminent and non-imminent (future) violence is included within the review

4.2 Search strategy for identification of relevant studies

A search strategy for electronic databases (outlined in generic form below) was developed for in collaboration with information technology staff from the British Library, taking into account lessons drawn from previous work in similar areas, kindly supplied to us by colleagues in the Cochrane and Campbell Collaborations. The search strategy is intentionally broad and designed to serve both the needs of the current review and those of the Risk Assessment Review referred to earlier. The approach adopted for search development was the *Successive Fractions* approach described by Hartley, Keen et al. (1993). Initial trials of the search strategy were carried out on the DIALOG system by British Library information staff and subsequently refined by the Review Team using MEDLINE as a search model. The search strategy is designed to be sufficiently inclusive to provide a comprehensive overview of relevant material in this area. It will be used to identify both completed and ongoing research and will encompass both primary research and review material.

4.2.1 Search term (structure modified to suit individual data sources)

(((Homicid* OR murder* OR manslaughter* OR infanticid* OR parricid* OR assault* OR (bodily AND (harm OR assault)) OR assail* OR bugger* OR sodom* OR molest* OR pedophil* OR paedophil* OR sadis* OR sadomasochis* OR sado-masochis* OR anger* OR cruel* OR rapist* OR (rape* AND offend*) OR physical abus* OR spouse abus* OR partner abus* OR sexual abus*) OR (((dangerous* AND (behavior* OR behaviour* OR histor* OR conduct*)) or violen*) AND (risk* OR predict* OR anteced* OR assess* OR cause* OR reason* OR interven* OR prevention* OR preventing* OR controlling* OR manage* OR treatment* OR treating* OR reduction* OR reducing* OR stop* OR mental* OR forensic* OR psychiatric* OR offend* OR Axis 1 OR Axis 2 OR criminal* OR detain* OR insan* OR NGRI OR retard* OR (learning disab* OR learning-disab*) OR acquit*)) OR ((child abus* OR elder abus* OR hostil* OR killing* OR attack* OR aggress*) AND (mental* OR forensic* OR psychiatric* OR offend* OR axis 1 OR axis 2 OR criminal* OR detain* OR insan* OR NGRI OR retard* OR (learning disab* OR learning-disab*) OR acquit* OR disorder*))) NOT (cancer* OR cancer [mh] OR tumo* OR tumour [mh] OR heart* OR heart [mh]))

4.2.2 Electronic searches

Electronic searches are not restricted by either geographic or site location of the research or the type of publication. In the review update, studies will be restricted to those with an English language abstract and dissertations will be restricted to those available electronically. Electronic searches will be restricted to the publication period 2002-2008. The following sources will be searched

AMED (Allied & Complementary Medicine)
Arts & Humanities Citation Index
ASLIB (Index to theses) [searched as a full text print-out]
British Humanities Index Online
British Nursing Index/RCN
C2-SPECTR, a trials register of the Campbell Collaboration, covering sociology, psychology, education and criminology [searched on-screen]
CINAHL

Cochrane Library
CRIB (Current Research in Britain) [searched as a full text print-out]
DARE [searched as a full text print-out]
Econlit
Elsevier Science Direct
ERIC/International ERIC
HTA [searched as a full text print-out]
IBSS (The International Bibliography of the Social Sciences)
Medline
NHS EED [searched as a full text print-out]
PsycINFO
Science Citation Index/Web of Science (including proceedings index to conference material)
SIGLE (a grey literature database) [searched on-screen]
Social Sciences Citation Index
Social Services Abstracts
Sociological Abstracts/Sociofile
PROQUEST

Following a reliability exercise within the team inclusion criteria will be applied to the search results in two stages. Firstly, each reviewer will be allocated a subset of the retrieved citations (title, publication details and abstract) to which they will independently apply the inclusion criteria. Full-text versions of all studies deemed to meet all five sets of inclusion criteria will be obtained for full review. Stage two will involve the application of the inclusion criteria to full-text versions that were identified. Each paper will be looked at by one reviewer. A conservative, inclusive approach will be adopted toward doubtful studies so that reviewers will err in favour of inclusion where any uncertainty exists and decisions regarding inclusion will be made through consultation with a second reviewer.

4.2.3 Handsearching, reference lists and consultation with experts

The original review demonstrated that the benefits of handsearching 34 journals did not justify the effort involved in running it. Therefore, in the review update the five most relevant journals will be identified empirically and handsearched for the period 2002-2008 in order to ensure the comprehensiveness of the review and assess the reliability of the electronic search.

The Review Team will also handsearch the reference lists of all systematic reviews obtained in the course of the review process.

Discussions with, and formal requests to, experts in the field - notably those who have authored reviews and/or are actively engaged in primary research - will also be used to supplement the formal searches. Finally, the Advisory Panel will be asked to review the complete list of selected material for missing studies of relevance to the review.

4.2.4 Data Management

Citations and abstracts downloaded from the electronic searches will be entered into Endnote (a data management package for bibliographic material). Material from separate databases will be combined in a composite database, prior to pre-screening for inclusion, to exclude

duplicates. Citations from each data source will be catalogued separately and tagged to allow the Review Team to keep track of the relative value of each source in contributing to the final review material. As the search strategy has also been developed to inform the Risk Assessment review mentioned earlier, a tagging system will be used in the initial screening stages to track material of relevance to each review, as there will be some overlap. Separate databases will then be established for the two reviews.

4.3 Description of methods used in the component studies

The review report will include descriptions of the principal recurring features of the research design and methodology employed in the specified field. Definitions will be provided of the main methods of investigation used. Using summary data obtained from systematic searches, the proportions of studies falling into each of these categories will be tabulated. Illustrative studies will be presented to clarify these points and to facilitate communication of the findings of the review. Methodological variables have been shown to have important and ineluctable effects on review findings (Wilson 2001) and careful account will be taken of trends arising from methodological artefacts. All analyses that are carried out will incorporate checks for the influence of methodological variables on the findings obtained e.g. moderator analyses.

It should be noted that the review is designed to be as comprehensive as possible and thus to capture non-experimental (including qualitative) designs. Apart from pharmacological interventions, the field is dominated by non-RCT designs due to the complexity of the population and other factors so evidence must be based, with appropriate caveats, on lower-quality designs. An exclusive focus on RCTs would boost internal validity but at the cost of restricting the analysis to a very small number of studies in some areas. Lower quality designs such as single-group pre-post designs can still yield estimates of effect size based on changes from baseline to study endpoint in a single group. The statistical analysis will however follow C2 guidelines and report meta-analysis of RCT, comparative groups and pre-post designs separately (see below for further details).

4.4 Criteria for the determination of independent findings

The reviewers will attempt to identify samples reported in more than one study. Where this is detected, the most stringent test (i.e. the study with the longest period between baseline and endpoint will be selected for inclusion in the meta-analysis). Where individual studies report multiple outcomes (k) each of them will be coded separately for analysis. The method of computing outcomes will be coded as a method variable. Discrete analyses will be conducted across effect size measures integrating findings obtained with different measures as separate outcome variables. For all effect size measures so obtained, conversion formulae will be used to present overall findings in several ways, for example as mean effect sizes (Cohen's d), correlation coefficients (r or φ), and odds ratios where appropriate.

Findings utilising identical outcome variables within studies (e.g. from separate sub-samples) will be coded as independent outcome indicators and regarded as equivalent to outcome variables comparably defined from other studies. Where individual studies report a number of

variables, types of outcomes will be coded and in each case mean effect sizes will only be computed for individual variables of comparable types from independent studies. Where studies report multiple outcome measures, the reviewers will identify the main effect size for one primary and one subsidiary outcome measure on the basis of the authors' stated goals. Any additional effect sizes (either for these outcome measures or any subsidiary outcome measures) will be coded in a separate annex to the main coding form.

4.5 Data extraction

Data extraction will be performed by two coders and extracted data will be loaded onto the LiVio SPSS database holding information from the original review. For conceptual clarity the extracted variables will be grouped into the following clusters, which will assist in defining separate analyses and inferential tests to be conducted.

- Data management cluster
- Publication cluster
- Design cluster
- Sample cluster
- Interventions cluster
- Outcomes cluster
- Results cluster

The following variables will be used to check the influence of methodological variables on the findings obtained.

- Aggression is main focus
- Drop out is less than 10%
- Final N is 100+
- Study follow-up is prospective
- Fidelity of implementation evaluated and confirmed
- Baseline aggression evaluated and stated
- Random assignment of participants
- Blinding of at least those evaluating outcomes
- Baseline equivalent for aggression (group comparisons only)
- Other key factors similar for groups at baseline (group comparisons only)
- Equal group sizes at start (group comparisons only)

4.5.1 Data synthesis

A narrative synthesis of the available material will be used to explore and outline the extent, nature and quality of the available evidence in this area. This qualitative assessment of the available data will also be used to explore any observed heterogeneity (in study or sample characteristics, study designs and outcomes) and to inform the structure for quantitative synthesis of the data, including the choice of comparisons to be made and the outcome measures amenable to quantitative treatments. It will also be used to address the issue of generalisability. The extent of heterogeneity will then be established quantitatively *(e.g. Q or*

I2) and, where appropriate, data will be combined in meta-analysis as outlined below, to obtain combined effect sizes for individual interventions and their associated confidence intervals. It is unlikely that individual patient data will be made available to the Review Team given the timescale of the Review. Sensitivity analyses will be used to explore the robustness of the review outcomes to changes in the underlying assumptions regarding the data and regarding the methods applied. Publication bias will be explored using funnel plots.

4.6 Statistical procedures and conventions

Descriptive information and statistics

Descriptive information from the studies located will be extensively tabulated reporting distribution statistics in relation to all criteria coded for independent studies. Explanatory and discursive text will accompany main summary tables with detailed and comprehensive supplementary data sets being included in appendices or in a parallel quantitative data report.

Inferential statistics, outcome effects and supplementary analyses

The most appropriate method of meta-analysis depends on the nature of the data identified. A final decision regarding whether meta-analysis is appropriate at all and, if so, which method(s) should be adopted will therefore be made once the data have been collected. Analysis of studies in the original review identified an unusually high degree of heterogeneity between studies. This was sufficient in fact to rule out meta-analysis as an appropriate approach in all but a minority of sub-groups of the studies included. Judging again from the original review, binary data in meta-analysis can be validly presented either as odds ratios or as relative risk ratios, since the base rates for violence are generally low and both measures give comparable estimates under this condition. Absolute risk differences are less likely to be appropriate, since in the original review variation in baseline event rates was commonly found when comparing across studies, even where these used very similar measures and populations. In comparing odds ratios and relative risk, the eventual choice of effect measure for the meta-analysis of binary data is likely to depend on the eventual audience for the outcomes of a particular analysis. For example, physicians are more familiar with the concept of relative risk and may find results presented using this effect measure more readily interpretable. In contrast statisticians and psychologists are more familiar with odds ratios.

In meta-analyses of continuous data a weighted mean difference effect measure is the most likely choice, with the weight given to the mean difference in each study equal to the inverse of the variance. However, the original review revealed that a number of otherwise comparable studies had measured outcomes using different scales. In such cases, it would be more appropriate to adopt a standardised mean difference approach (dividing the mean difference by an estimate of the within-group standard deviation to produce a unit-free standardised measure of effect). This will produce 'equated effect sizes'. It should also be noted that a number of studies in the original review used survival curve data to summarise outcomes. In combining such studies in a meta-analysis, it would be most appropriate to use hazard ratios as the effect measure.

The statistical analysis will follow C2 guidelines and report meta-analysis of RCT, comparative groups and pre-post designs separately. It is anticipated that the research literature since 2001 has become more coherent given the development of protocols etc and

thus that more recent studies captured in the review update will show a greater degree of homogeneity. Nevertheless it seems likely that a random effects model will be the most appropriate approach to combining data in meta-analysis. The studies identified to date that may be suitable for integration using meta-analysis show considerable heterogeneity, and following the recommendations of experts such as Hunter and Schmidt (2000) a random-effects model is less likely to result in Type I errors, and misleadingly narrow confidence intervals. This will be remain pertinent if it is found that publication bias, poor design and implementation quality remain an issue in more recent studies. We will report tests of heterogeneity for all effect sizes and employ graphical displays such as forest plots.

It was previously identified that moderator variables in this context are confounded. Associations within and between moderators will initially be identified via tests of individual association appropriate to the variables in question (e.g. correlation coefficients for continuous variables, $\chi 2$ statistic for discrete variables). The combined impact of multiple moderator variables identified as confounded will then be modelled using suitable multivariate regression analyses. Additionally where possible, we will examine effects of moderator variables by sub-grouping studies according to hypothesized moderator effects, and conduct parallel analyses within groups.

The original review also identified study design (broadly described here as 'method') as a moderator variable. Given also a priori concerns regarding the quality of distinct designs, the reviewers intend, if sufficient resources are available, to run a set of meta-analyses weighting effect sizes by study design /'quality' rather than simply by sample size in order to evaluate the impact on outcomes. This is referred to as a 'methods adjusted effect size'. Following the outcome of the moderator regression analyses described above, this analysis may be redundant, in which case the plan of analysis will be adjusted accordingly

As stated above, it should be noted that studies identified in the original review were judged to not meet homogeneity requirements and so meta-analysis was not conducted. It is anticipated that the research literature since 2001 has become more coherent given the development of protocols etc. and thus that a proportion of studies in the review update will meet these requirements and be a suitable basis for such analysis. Where methodological criteria and sample sizes permit, inter-relationships of independent, moderator and outcome variables will be explored using logistic regression or structural equation models.

Effect sizes will be computed in a number of patterns as follows:

- Using observed effect sizes from individual studies
- Using method-adjusted effect sizes
- Using equated effect sizes defined in terms of separate variables rendered statistically equivalent for purposes of analysis

For report and communication purposes, meta-analytic findings will be presented in two ways:

- Using original effect size data
- Tabulating conversions of reported effect size data to common-language effect sizes

4.7 Treatment of qualitative research

There are two aspects to this, which will be considered separately in the final reports: Firstly, qualitative aspects of quantitatively-based studies included in systematic reviews will be reviewed and this material will be used to exemplify the nature of the studies described, for example to characterise the nature of key types of intervention, to illustrate the range of interventions, or to typify the kinds of intervention found to be associated with the larger or more consistent outcome effects. Secondly, qualitative research studies per se will be approached using a pre-selected method of research integration for qualitative research (Popay, Rogers et al. 1998; Thomas and Harden 2007).

5. Timeframe

We intend to produce the updated review report by July 2009. The project has been funded and is currently underway, with a project timetable and milestones agreed with the funders as follows:

October 2008: identification of relevant studies completed.
December 2008: data extraction and loading completed.
March 2009: data analysis completed.
July 2009: preliminary report available.

The Review Report to be provided to the funding body will serve as a focus for dissemination. Rather than breaking this large report into separate journal articles, a contract has been obtained with Cambridge University Press for production of a research monograph incorporating both this and the parallel Risk Assessment review. Executive summaries of the report will be made available to relevant stakeholders.

6. Plans for updating the review

All search material will be maintained on Endnote. Updating and subsequent transparency will be supported by clear documentation of the search process. If the Campbell Collaboration accept the review, the expectation would be for biennial updates of the review to be carried out, providing sufficient funding or institutional support could be obtained to secure the necessary staff time.

7. Acknowledgements

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8. Statement Concerning Conflict of interest

None.

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We look forward to hearing from you.

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