De-escalation techniques for managing aggression (Protocol)

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TABLE OF CONTENTS

[Intervention Protocol]

De-escalation techniques for managing aggression

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To evaluate the effectiveness of de-escalation techniques for staff and service users in the management of non-psychosis-induced aggression in adults.

BACKGROUND

Description of the condition

Aggression is any behaviour directed toward another individual that is carried out with the immediate intent to cause harm (Anderson 2002). This may be communicated verbally or may manifest in a range of behaviours causing physical or psychological harm towards the self or others, or damage to the environment (NICE 2015a). There is a substantial body of literature on the origins of aggressive behaviour and theories to account for the causes of aggression. For example, the general aggression model proposes that specific context and person-centred factors are mediated by variables such as cognition, affect and arousal in the manifestation of aggression (Anderson 2002). There is not scope within this review to fully explore all of the relevant literature on the aetiology of aggressive behaviour and therefore we will focus on the management of these behaviours within the broad context of health services.

Aggression can occur in many settings, including inpatient settings, emergency settings (NICE 2015a), and in communities served by emergency services such as police or paramedics (Hester 2009). Aggression that is left untreated may escalate into violence involving risks to the aggressor and those around them such as family and healthcare professionals (Bourget 2002; Maguire 2007). Workplace violence affects every country and healthcare setting, with reports estimating that 4% of the global employee population have experienced physical violence, and nurses are at three times greater risk of violence than any other profession (Di Martino 2003). A large international review of 424 studies reported an incidence rate of over 32% for violence in psychiatric hospitals, but a greater risk of violence in acute healthcare settings (Bowers 2011). In the UK, physical assaults against National Health Service (NHS) staff are estimated at 67,864 incidents per annum, with 67% of those occurring in mental health settings, 28% in acute hospitals and the remainder in ambulance and primary care settings (NHS Protect 2015). In England alone 14% of NHS staff reported having experienced physical violence from service users, relatives or the public (NHS 2014). Violence is also prevalent in

community settings where around half of care workers experience verbal abuse and over a third experience physical abuse (NICE 2015b). Aggressive and violent behaviour may have a significant impact on staff with an estimated 26%, 11% and 6% of incidents respectively relating to mild, moderate or severe injury (Bowers 2011). Verbal aggression toward staff is common and may lead to poor performance and functioning (Stone 2010; Uzun 2003); and low morale (Bowers 2009; Sprigg 2007). Increased exposure to violence from service users is correlated with increased stress and reduced job satisfaction in social care and social work staff (Harris 2012).

Aggression may be associated with intrinsic factors such as recognised mental health issues (Fazel 2006), including, for the purposes of this review, substance misuse, intellectual disability and other mental health issues (excluding psychosis), and extrinsic factors such as social and environmental conditions. Certain conditions also place individuals at increased risk of an episode of acute aggression such as head injury; Huntingdon's Disease (Johnson 2011); learning disability (Taylor 2005); and alcohol or substance misuse, or both (Roizen 1997; Snowden 2001). The multi-factorial origins of aggression mean that it can apply to a wide population.

Health care professionals are required to use strategies for managing incidents of aggression and violence that are proportionate to the potential or immediate risk posed to self and others, commensurate with the principles of least restrictive practice (DoH 2005). Interventional measures, such as physical restraint, rapid tranquillisation (for example, intramuscular injections) and seclusion, are used to manage aggression (NICE 2015a). The use of specialist nursing care, such as seclusion, is recommended only when the risk to self and others cannot be safely managed in communal or private environments, as containment is often aversive and unpleasant for both service users (Whittington 2009) and staff (Olofsson 1995). Seclusion suites used for physical containment are commonly found in Psychiatric Intensive Care Units (PICUs) to manage a range of circumstances, including disruptive behaviour (Oldham 1983), acute psychiatric symptoms (Morrison 1991), verbal and physical aggression (Mason 2001; Sullivan 2004), damage to property (Ahmed 2001), self harm (O'Brien 2004), and risk of absconding (Morrison 1997). Use of seclusion varies both within (Crenshaw 1995) and between countries (Bowers 2007), though rates are poorly reported in terms of specific context (Bowers 2000). However, as these invasive methods are associated with increased risk of injury to both service users (Hollins 2010) and staff (Farrell 2005), they are employed only when de-escalation is unsuccessful.

To minimise the potential for harm, an episode of escalating aggression needs to be promptly defused using de-escalation techniques as the first resort intervention measure (NICE 2015a).

Description of the intervention

The National Institute for Health and Care Excellence (NICE) guideline on management of violence in healthcare settings describes de-escalation as "talking with an angry or agitated service user in such a way that violence is averted and the person regains a sense of calm and self-control" (NICE 2015a, p 30). De-escalation, sometimes referred to as 'defusing' or 'talk-down', is a complex range of verbal and nonverbal communication skills used by staff in a range of settings to prevent escalation of aggressive behaviour (CRAG 1996). Recognised de-escalation techniques include verbal strategies, such as maintaining a calm tone of voice and not shouting or verbally threatening the person; and non-verbal techniques, including an awareness of self, body stance, eye contact, and personal safety (Cowin 2003; Johnson 2011). It has been suggested that verbal and non-verbal communication skills may help to redirect someone to a "calmer personal space" (Cowin 2003). Although de-escalation is recommended and widely used for the management of aggression, there is little literature on specific techniques and efficacy (Richmond 2012; Robertson 2012). The consensus statement from the American Association for Emergency Psychiatry Project BETA De-escalation Workgroup estimates that effective de-escalation of an aggressive episode, in order to return the agitated person to a calm state, should take approximately 5 to 10 minutes. De-escalation, therefore, is intended to ameliorate the immediate aggressive episode and is not associated with longer term benefits (Richmond 2012).

De-escalation is recommended as an early intervention in the management of aggression in order to prevent escalation to the crisis phase (NICE 2015a). Potential benefits to service users (such as improved health and well-being) from approaches that avoid physical intervention are relatively well established (Paterson 1997; Robertson 2012).

Staff training in de-escalation techniques is an important feature of aggression management programmes (Farrell 2005). Benefits for service users and staff are currently unclear, with reported improvements in staff morale and confidence (Gournay 2001; Nau 2009), but little impact on the frequency of aggressive incidents (Bowers 2006). In North America there are four widely used staff training programmes for the collective management of aggressive behaviour: The Mandt System (Mandt 1998); Nonviolent Crises Intervention (CPI 2005); Professional Assault Response Training (Smith 2004); and Therapeutic Options (Partie 2001), but these approaches are less commonly used elsewhere.

De-escalation may be deployed in a range of settings, including accident and emergency (A&E), psychiatric hospitals, learning disability services, and in restraint or containment settings used by the police force where it may be embedded in conflict resolution techniques (NHSBSA 2013). The application of de-escalation techniques may vary by specific context and population, for example when working with people with a cognitive impairment, such as dementia. In the UK, NICE guidelines for the management of people with dementia recommend that health and care staff receive specific training in the anticipation of challenging behaviour and

managing of violence using de-escalation techniques and restraint methods (NICE 2015b).

How the intervention might work

In clinical settings 'The Assault Cycle' is a theoretical model, which describes five phases in aggressive behaviour: the trigger phase, escalation phase, crisis phase, recovery phase, and depression phase (Kaplan 1983; Leadbetter 1995). De-escalation aims to arrest the progress of the assault cycle during the escalation phase. Some of the skills and techniques used to arrest the assault cycle, include the avoidance of confrontation, attitude and use of language, awareness of personal space, and posture. These components are described in the ACT (**A**ssessment, **C**ommunication and **T**actics) cyclical model by Dix 2008. There are a number of competing theoretical approaches to de-escalation but the key recommended components are: recognising the signs of escalating anger; and approaching the person in a calm manner (NICE 2015a). These techniques may help de-escalate potentially aggressive situations by establishing a positive relationship between staff and aggressor in the management of appropriate behavioural expectations (Levenson 2004). De-escalation techniques are recommended as a frontline response for defusing aggressive or agitated behaviour, but there is no universally accepted model and the core skill set is poorly documented (Robertson 2012).

Why it is important to do this review

In the UK, the Winterbourne Enquiry into the abuse of patients in learning disability services, including inappropriate use of physical interventions and restraints, resulted in increased pressure on all mental health and learning disability care settings to find safe alternatives to the use of physical intervention (CQC 2011). Evidence of effectiveness of alternative methods of managing aggressive behaviour, other than with physical intervention such as restraint and seclusion, is unclear. Muralidharan 2006 suggests that evidence is inconclusive due to lack of high quality studies and Gaskin 2007 argues for strong evidence in favour of alternative approaches on the basis of all available evidence. Although de-escalation techniques are recommended by a number of guidelines (for example, those of NICE or The American Psychological Association (APA)) for managing aggressive behaviour, there is no standard approach for the technique and little research has been published comparing the effectiveness of different methods, or the effectiveness of de-escalation training (Paterson 1997).

Improved staff morale and confidence have been reported as potential benefits of de-escalation training (Cowin 2003), but evidence of impact on staff outcomes is currently unclear. Alternatives to physical intervention are associated with reduced risk of injury for both staff and patients (Hill 1987; Johnson 2012), but the relative effectiveness of different approaches to de-escalation in terms of both staff and patient outcomes is also unclear. Therefore, there is a need to systematically review the evidence for the effectiveness of de-escalation in managing aggression. A Cochrane review that aims to evaluate de-escalation techniques for psychosis-induced aggression is currently in preparation (Rao 2012). We propose a companion and complementary review that will evaluate techniques for people without psychosis.

OBJECTIVES

To evaluate the effectiveness of de-escalation techniques for staff and service users in the management of non-psychosis-induced aggression in adults.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) and quasi-RCTs (defined as trials where participants are allocated to study groups using, for example, date of birth or alternate allocation).

Types of participants

Adults (≥ 18 years) in any care setting, who use threatening or aggressive behaviour.

Excluded

Service users with a diagnosis of schizophrenia spectrum disorder (APA 2013). This will exclude people with psychosis-induced aggression, which is covered by a separate Cochrane Review (Rao 2012).

Types of interventions

Experimental intervention

Any de-escalation technique, as defined above.

Control intervention

Standard practice (including rapid tranquillisation, physical intervention, seclusion) or an alternate de-escalation technique.

Types of outcome measures

Effects of de-escalation may range from a few minutes to several hours. The distinction between successful de-escalation of the primary aggressive event and subsequent events may be complex, and therefore we will collect outcome data at a range of follow-up points that will best reflect the available evidence from included studies.

Primary outcomes

1. Frequency of aggression-related serious untoward incidents (including mortality), leading to physical restraint or seclusion, or both: recorded in staff reports or routinely collected data.
2. Frequency of aggression-related injuries to staff: recorded in staff reports or routinely collected data such as untoward incident forms.

Secondary outcomes

1. Length of stay in seclusion: recorded in staff reports or routinely collected data such as untoward incident forms.
2. Validated (psychometric publication of scale properties; Streiner 2014; Zumbo 2007) generic or condition-specific quality of life scales (for example, Short Form 36 Health Survey (SF-36; Ware 1992) or De-escalating Aggressive Behaviour Scale (DABS; Nau 2009b)), or both.
3. Staff absenteeism: based on administrative data.
4. Costs of care; cost-benefit, cost-effectiveness: for example, monetary benefit or quality-adjusted life years (QALYs).

We will prioritise outcomes based on formally or routinely collected data such as untoward incident or adverse event forms.

Search methods for identification of studies

Electronic searches

We will search Ovid MEDLINE using the strategy in Appendix 1, and adapt it for use in other sources. We will not apply any language restrictions or time period limitations to the searches. We will search the following databases.

1. Cochrane Central Register of Controlled Trials (CENTRAL; current issue; *The Cochrane Library*), which includes the specialised register of the Cochrane Developmental, Psychosocial and Learning Problems Group.
2. Ovid MEDLINE (1946 to current).
3. EMBASE (1974 to current; Ovid).
4. PsycINFO (1806 to current; Ovid).
5. CINAHL (1937 to current; EBSCOhost).
6. Science Citation Index Expanded (SCI-Expanded; 1970 to current; Web of Science).
7. Social Sciences Citation Index (SSCI; 1970 to current; Web of Science).
8. Conference Proceedings Citation Index - Science (CPCI-S; 1990 to current; Web of Science).
9. SciELO Citation Index (Web of Science; 1970 to current; Web of Science).
10. Academic Search Complete (1990 to current; EBSCOhost).
11. International Bibliography of the Social Sciences (1951 to current; Proquest).
12. British Education Index (1974 to current; EBSCOhost).
13. ERIC (1996 to current; EBSCOhost).
14. Criminal Justice Abstracts (all available years; EBSCOhost).
15. Cochrane Database of Systematic Reviews (CDSR; current issue; *The Cochrane Library*).
16. Database of Abstracts of Reviews of Effects (DARE; current issue; *The Cochrane Library*).
17. The Campbell Collaboration Library of Systematic Reviews (campbellcollaboration.org/lib/; current issue).
18. World Health Organisation International Clinical Trials Registry Platform (ICTRP; apps.who.int/trialsearch; all available years).
19. ClinicalTrials.gov (clinicaltrials.gov; all available years).
20. ISRCTN (ISRCTN.com; all available years).
21. OpenGrey (opengrey.eu; all available years).

Searching other resources

We will examine the reference lists of relevant studies and reviews to find any additional trials not identified by the electronic searches. We will contact authors of identified trials and authorities in the field in order to locate other published and unpublished studies

Data collection and analysis

Selection of studies

Two authors (PJ, SS) will independently assess the titles and abstracts of all retrieved trials. The same authors will then examine the full text of papers identified as relevant to determine inclusion in the review. We will resolve disagreements about eligibility and inclusion by discussion until consensus is reached.

Data extraction and management

SS and PJ will independently read and extract data from the included studies using a form based on the predefined outcome measures. We will contact study authors for information on missing data or further information about the trial. We will systematically record information on study design, participants, intervention, outcomes, methods, results, and study withdrawals in the 'Characteristics of included studies' tables. Disagreements will be resolved by discussion until consensus is reached.

Assessment of risk of bias in included studies

SS and PJ will independently assess the quality of each included study using the risk of bias criteria described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). Risk of bias will be rated as high, low or unclear across the domains below. We will resolve disagreements by discussion until a consensus is reached. The results will be tabulated in a 'Risk of bias' table.

Random sequence generation

1. Low risk of bias: adequate sequence generation using, for example, random number tables, coin toss, drawing lots, dice throw.
2. High risk of bias: inadequate sequence generation using a non-random method of allocation (for example, date of birth, hospital admission date or clinic number).
3. Unclear risk of bias: information on sequence generation not given or unclear.

Allocation concealment

1. Low risk of bias: adequate concealment (for example, central allocation method such as telephone or web-based randomisation, or sealed opaque envelopes).
2. High risk of bias: inadequate concealment of allocation (for example, open list of numbers, envelopes without concealed contents, or dates of birth).
3. Unclear risk of bias: information on allocation of randomisation not given or unclear.

Blinding of participants and personnel

1. Low risk of bias: adequate where study participants and personnel are blinded to allocated interventions or where authors judge that study outcomes will not be influenced by lack of blinding.
2. High risk of bias: inadequate where study outcomes are likely to be influenced by lack of blinding or incomplete blinding.
3. Unclear risk of bias: information on blinding not given or unclear.

Blinding of outcome assessment

1. Low risk of bias: adequate where study participants and personnel are blinded to outcome assessment or where authors judge that outcome measures will not be influenced by lack of blinding.
2. High risk of bias: inadequate where measurement of outcomes is not blinded and may be influenced by lack of blinding.
3. Unclear risk of bias: information on blinding of outcome assessment not given or unclear.

Incomplete outcome data

1. Low risk of bias: adequate (for example, no missing data, missing data unrelated to true outcome (for example, survival data) or balanced across study groups; reasons for missing data similar across groups; appropriate imputation (for example, uncertainty taken into account)).
2. High risk of bias: inadequate (for example, missing data may be related to true outcome (missing not at random); reasons for missing data or missing proportions differ between groups; inappropriate imputation (for example, high proportion of data imputed using last observation carried forward)).
3. Unclear risk of bias: information on incomplete outcome data not given or unclear.

Selective reporting

1. Low risk of bias: adequate (for example, it is clear that all pre-specified or expected study outcomes have been reported consistently).
2. High risk of bias: inadequate (for example, not all pre-specified outcomes reported, primary outcomes reported that were not pre-specified, or outcome reported using methods not pre-specified).
3. Unclear risk of bias: information on outcome reporting not given or unclear.

Other bias

1. Low risk of bias: adequate where no other sources of bias are identified.
2. High risk of bias: inadequate where other important sources of bias are identified such as an inappropriate study design.
3. Unclear risk of bias: insufficient information on which to evaluate risk of other bias.

Measures of treatment effect

Continuous data

We will estimate the intervention effect using the mean difference (MD) and its 95% confidence interval (CI). If standard deviations (SD) are not reported but other measures of variance around mean differences, such as standard error, CIs, or P value are reported, we will calculate these according to Section 7.3 in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). In this review it is likely that different scales may be used to measure the same outcome (for example, level of aggression). In this case, we will use the standardised mean difference (SMD) and its 95% CI, ensuring a consistent direction of effect by reversing scaling where necessary, supported by a statement in the text on direction of interpretation. Where studies use the same outcome measure, we will use the mean difference (MD).

Binary data

For dichotomous data, we will use risk ratios (RR) with 95% CIs.

Unit of analysis issues

Cross-over trials

We will only use data from the first pre-cross-over phase to minimise potential bias from carry-over effects.

Cluster-randomised trials

These will be analysed in accordance with methods described in Section 16.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a), using the average cluster size and an estimate of the intraclass correlation coefficient (ICC) to adjust sample sizes to the 'effective sample size'. Where an estimate of the ICC is not available from the trial we will use an estimate from a similar trial or a trial with a similar population. We will combine single RCTs with cluster-RCTs if the designs and interventions are considered sufficiently similar and the effect of the intervention is unlikely to be influenced by the method of randomisation.

Multiple arm trials

For trials with more than two arms, we will describe all study groups in the 'Characteristics of included studies' table, but we will only include in the analysis the intervention groups that meet our review criteria. Where the variance of the difference between the intervention and the comparator is not reported, we will calculate this from the variances of all trial arms.

Where a study compares multiple relevant interventions groups to one eligible control group, we will divide the sample size for the shared comparator group evenly, in order to prevent the same participants from being included twice. Where a study compares one eligible intervention group to two or more distinct but eligible control groups, we will combine the groups to create a single pairwise control comparison (Higgins 2011b). For dichotomous outcomes, both the sample sizes and the numbers of people with events will be summed across groups; and for continuous or time-to-event outcomes, means and SDs will be combined using methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). If this prevents identification of potential heterogeneity, we will compare each group separately as part of subgroup analyses. Decisions made concerning unit of analysis issues will be reported in the review.

Dealing with missing data

We will contact all authors of included studies to provide any unreported data such as missing outcomes, missing data, means or SDs. We will note differential dropout between study groups and note reasons for withdrawal. Where a particular outcome includes substantial loss to follow-up (50%), we will report this in the text and mark the data with an asterisk. We will also note differential missing data and reasons for missing data, where reported. We will use available cases for data analysis and we will not impute missing data. Where trials include analyses based on the imputation of missing values, we will include data at low risk of bias and report data separately for those at higher risk of bias in the text of the review. Multiple imputation methods that include sensitivity analyses, pre-specified in published protocols, are considered at low risk of bias (Gewandter 2014; Little 2012).

Where missing data are related to the outcome it is not considered appropriate to impute data using carry-forward methods such as last observation carried forward or baseline observation carried forward; for example, if a participant dies due to an intervention-related adverse event shortly after randomisation, it would not be appropriate to carry over the baseline data in order to complete missing data (Gewandter 2014). Where studies report per protocol data (that is, only those who completed the study), we will contact the authors for unreported data on all study participants, including those lost to follow-up. Missing data will be described in the 'Risk of Bias' table and its influence on study outcomes discussed in the text. If there are sufficient trials, we will use sensitivity analyses to determine the resistance of our results to the effects of missing data (see Sensitivity analysis).

Assessment of heterogeneity

In this review, it is likely that there will be considerable variability between studies in terms of the specification of the intervention, the study design and the outcomes. The variability may be a consequence of clinical variation in the population or the intervention, differences in study quality, or random differences. We will assess potential sources of variability between studies in the following ways.

1. Clinical variability: we will compare the distribution of participants, interventions, and outcomes across the included studies. In particular, we will look at the distribution of trials that only include people with cognitive impairment (such as dementia), as potential sources of variability. We will discuss and agree potential clinical heterogeneity by consensus.
2. Methodological variability: we will compare study designs and study quality using risk of bias criteria.
3. Statistical heterogeneity (where variability in the effects of interventions is greater than expected by chance alone): we will evaluate the statistical significance of heterogeneity using the Chi^2 test ($P \leq 0.10$ significant). However, this test may be unreliable, lacking power to detect important heterogeneity with few or small studies and the potential to detect clinically insignificant heterogeneity with large numbers of studies. It is also possible for trials to show large consistent effects in the face

of significant heterogeneity. Therefore, in addition to assessing the strength of evidence for heterogeneity using the Chi² test as above, we will also quantify the magnitude of heterogeneity

using the ² (random-effects model only), and I² statistics with the following interpretation thresholds, based on recommendations in Section 9.5 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a):

i) 0% to 40%: might not be important;
ii) 30% to 60%: may represent moderate heterogeneity;
iii) 50% to 90%: may represent substantial heterogeneity; and
iv) 75% to 100%: considerable heterogeneity.

Assessment of reporting biases

We will compare the results of data from published and unpublished studies as a direct test of publication bias. If there are a sufficient number of studies (approximately 10 or more), we will explore potential bias arising from small study effects using Egger's method, to test for asymmetry in funnel plots (Egger 1997). If smaller studies show larger intervention effects compared to larger studies, we will evaluate potential causes (for example, poor methodological quality; differences in populations or interventions) and report studies at high risk of bias in the text of the review. If small study effects are detected, we will explore if this is a genuine finding due to heterogeneity (small studies give larger effects because they differ from large ones in some aspect that modifies the effect of the intervention) or if this is because of poor quality, publication bias etc.

Data synthesis

We will undertake separate meta-analyses for the comparisons of interest in this review (de-escalation versus physical intervention; de-escalation method X versus de-escalation method Y).
Studies will be included in meta-analyses where the study designs, interventions and outcomes are similar. Where substantial heterogeneity (> 50%; Higgins 2011a) is identified we will report outcomes in the text, giving direction and size of the effect along with strength of the evidence (risk of bias). It is likely that included studies will vary in their population, design and outcomes, and therefore data synthesis using meta-analysis with a random-effects model would be most appropriate. However, where there are few studies or the effects of interventions across studies are not randomly distributed (for example, with publication bias), the random-effects model estimates may be unreliable or biased. It is likely that this review will only include a small number of low-powered studies, where meta-analysis with a fixed-effect model would give more reliable estimates. To resolve the uncertainty over model choice we will (a) only pool data using meta-analysis where studies appear sufficiently similar (for example, all dementia populations or all learning disability), and (b) compare pooled data estimates from both a random-effects model and a fixed-effect model, reporting both in the text. We will report the mean effect estimate and the CI around the estimate for both models. We will synthesise and report dichotomous and continuous data separately for a given outcome, should the need arise. Where end-of-study point estimates and change from baseline scores are reported we will analyse these separately. We will perform the analyses using Review Manager (RevMan) Version 5 (Review Manager 2014)
The results of analyses of head-to-head comparisons of de-escalation techniques will be interpreted tentatively in the absence of data from trials comparing de-escalation techniques versus physical intervention.

Summary of Findings

We will report the primary outcomes, and the following secondary outcomes, in a 'Summary of findings' table for each intervention comparison: frequency of aggression-related serious untoward incidents, frequency of aggression-related injuries to staff, and validated quality of life scales. The table will also report the quality of evidence for each outcome using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, which considers within-study risk of bias, directness of evidence, heterogeneity, precision of effect estimates, and risks of publication bias (GRADE 2004). We will tabulate the summary of findings using GRADEpro software (GRADEPro GDT 2015). The GRADE Working Group grades of evidence are as follows:

1. High quality: further research is very unlikely to change confidence in the estimate of effect;
2. Moderate quality: further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate;
3. Low quality: further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate; and
4. Very low quality: we are very uncertain about the estimate.

Subgroup analysis and investigation of heterogeneity

Subgroup analyses

Where there are a sufficient number of trials (≥ 10; Section 9.6.5.1, Higgins 2011a), we will conduct subgroup analyses by:

1. Staff training (trained versus untrained staff).

Investigation of heterogeneity

We will manage potential sources of heterogeneity as follows:

1. Check data integrity, including measures of effect and units of analysis;

2. Explore the impact of subgroups (for example, small versus large studies); and

3. Exclude outliers where there is a clear reason for exclusion such as markedly different intervention effect estimates or clear population differences (for example, dementia or learning disability). We will visually inspect forest plots and iteratively remove outlying studies to determine whether homogeneity is restored.

We will fully discuss and report our decisions in the review.

Sensitivity analysis

We will perform sensitivity analyses for missing data, and for risk of bias based on random sequence generation, blinding of participants and incomplete outcome data by including and excluding studies at high risk of bias and comparing the results.

Although little data are available on the measurement of outcomes following de-escalation of aggressive episodes, it is plausible that outcomes may vary by duration of follow-up. Therefore, we will explore potential heterogeneity between studies according to length of follow-up (that is, all studies versus excluding the longest studies).

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Ovid MEDLINE

Lines 29 to 39 form the Cochrane highly sensitive search strategy for identifying randomised trials in Medline (Lefebvre 2011).

1 Aggression/
2 Psychomotor agitation/
3 Agonistic Behavior/
4 Violence/
5 Workplace Violence/
6 exp Anger/
7 Hostility/
8 (aggress$ or agitat$ or agonistic or anger or angry or assault$ or hostil$ or rage or threat$ or violen$).tw.
9 ((abusive or challenging or disturbed or disruptive) adj1 behav$).tw.
10 or/1-9
11 Risk management/

12 Behavior control/
13 Safety management/
14 Security measures/
15 (de-escalat$ or deescalat$ or non-escalat$ or nonescalat$ or defus$ or de-fus$).tw.
16 (non$ adj (authorit$ or coerc$ or co-erc$ or combativ$ or confrontation$ or physical or provocative or violen$)).tw.
17 (non$ adj (drug$ or pharma$)).tw.
18 ((alternative$ or avoid$ or reduc$ or without$) adj3 (seclusion or restrain$)).tw.
19 (talkdown or talk-down or one to one).tw.
20 (limit$ adj1 setting).tw.
21 Negotiating/
22 negotiat$.tw.
23 ((verbal$ or nonverbal$ or non-verbal$) adj3 (communicat$ or intervention$ or strateg$ or method$ or technique$)).tw.
24 Crisis intervention/
25 (cris#s adj3 (intervention$ or manag$ or resol$ or respon$ or team$)).tw.
26 (conflict adj3 (avoid$ or manage$ or prevent$ or resol$)).tw.
27 (calm or calming).tw.
28 or/11-27
29 randomized controlled trial.pt.
30 controlled clinical trial.pt.
31 randomi#ed.ab.
32 placebo$.ab.
33 drug therapy.fs.
34 randomly.ab.
35 trial.ab.
36 groups.ab.
37 or/29-36
38 exp animals/ not humans.sh.
39 37 not 38
40 10 and 28 and 39

CONTRIBUTIONS OF AUTHORS

SS and PJ drafted the protocol.

For the review, SS and PJ will select trials for inclusion, extract data from trials, assess risk of bias, enter data into RevMan, perform the analyses, and draft the final review.

SS has overall responsibility for the review.

DECLARATIONS OF INTEREST

Sally Spencer - none known.

Paula Johnson - none known.

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