Review protocol for benefits and harms of post-incident debriefing for people who have received restrictive practices in the management of aggressive behaviour

ID	Field	Content
0.	PROSPERO registration number	
1.	Review title	Benefits and harms of post-incident debriefing for people who have received restrictive practices in the management of aggressive behaviour
2.	Review question	What are the benefits and harms of post-incident debriefing for people who have received restrictive practices in the management of aggressive behaviour?
3.	Objective	To determine the benefits and harms of post-incident debriefing after use of restrictive practices
4.	Searches	The principal search strategy will be developed in MEDLINE and then adapted, as appropriate, for use in the other sources listed, taking into account their size, search functionality and subject coverage • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE ALL • Emcare • PsycInfo • Social Policy and Practice Database functionality will be used, where available, to exclude: • Animal studies • Editorials, letters, news items and commentaries • Conference abstracts and posters • Trial registry entries without an associated journal publication • Theses and dissertations • Papers not published in the English language.

		Date limits: 2005 onwards Search filters and classifiers: As required the following standard NICE filters will be used to limit results by study type: systematic reviews / randomised controlled trials and cohort studies Supplementary search techniques: • Hand-searching of inclusion lists of systematic reviews The information services team at NICE will quality assure the principal search strategy based on the PRESS 2015 Guideline Evidence Based Checklist. Any revisions or additional steps will be agreed by the review team before being implemented The full search strategies for all databases will be published in the final review
5.	Condition or domain being studied	Acute management of aggressive behaviour
6.	Population	People who have received restrictive practices in the management of aggressive behaviour
7.	Intervention	Post-incident debriefing or review, defined as a structured or unstructured discussion about the use of restrictive practices to manage aggressive behaviour involving the person who received the restrictive practice (and sometimes their families and carers) and staff The review will examine the effectiveness of post-incident debriefing after the use of any restrictive practice, including: • Physical restraint • Mechanical restraint • Surveillance • Blanket restrictions • Environmental restraint

		• Cultural restraint • Psychological restraint • Chemical restraint • Exclusion from care
8.	Comparator	No post-incident debriefing after restrictive practice

9.	Types of study to be included	Include published full-text papers:
		• Systematic reviews of RCTs
		• RCTs
		
		• If insufficient RCTs*:
		  ○ Systematic reviews of non-randomised studies
		  ○ Quasi-randomised controlled trials
		  ○ Prospective cohort studies
		  ○ Retrospective cohort studies
		
		*Non-randomised studies will be considered for inclusion if insufficient RCT evidence is available for guideline decision making. Sufficiency will be judged taking into account factors including number/quality/sample size of RCTs, outcomes reported and availability of data from subgroups of interest
		
		If non-randomised studies are included in the review, key confounders will need to be adjusted for including age, primary condition, setting, and type of restrictive practice
		
		The review is not restricted by country, but for studies from countries with substantially different healthcare systems, we will check with the committee if the intervention would be feasible in a UK system
		
		Exclusion:
		• Papers published pre-2005
		• Conference abstracts
		• Dissertations and theses

		• Trial registry protocols • Books and book chapters
10.	Other exclusion criteria	• Non-English language papers
11.	Context	This guidance will fully update the following NICE guideline: Violence and aggression: short-term management in mental health, health and community settings (last updated 2015; NG10)
12.	Primary outcomes (critical outcomes)	• Symptoms of trauma, acute stress disorder or PTSD symptoms, as measured by a validated scale, for example, Clinician-Administered PTSD Scale for DSM–IV (CAPS) or DSM-V (CAPS-5), PTSD Symptom Scale – Interview Version (PSS-I), PTSD Checklist (PCL), including all versions (PCL-5, PCL-M, PCL-C and PCL-S), PTSD Symptom Scale – Self Report (PSS-SR), Trauma Screening Questionnaire (TSQ), Davidson Trauma Scale (DTS), and Impact of Event Scale (IES)/Impact of Event Scale Revised (IES-R) • Number of participants with PTSD (as defined by DSM/ICD diagnosis or scoring above clinical threshold on a validated scale) who did not have PTSD prior to the restrictive practice • Self-harm incidents or suicide attempts • Aggressive behaviour • Aggression or agitation scores • Exacerbation of primary disorder symptom severity • Further restrictive practice use to manage aggressive behaviour

		If outcomes reported at more than one timepoint, then data will be extracted at intervention endpoint and longest follow-up **Exclusion:** • Qualitative experience of post-incident debriefing • Satisfaction with care outcomes
13.	Secondary outcomes (important outcomes)	• Quality of life, as measured with a validated scale, for example, the World Health Organization Quality of Life (WHOQOL)
14.	Data extraction (selection and coding)	All references identified by the searches and from other sources will be uploaded into EPPI-Reviewer 5 and de-duplicated Titles and abstracts of the retrieved citations will be screened to identify studies that potentially meet the inclusion criteria outlined in the review protocol. Dual sifting will be performed on at least 10% of records; 90% agreement is required. Disagreements will be resolved via discussion between the two reviewers, and consultation with senior systematic reviewer if necessary Full versions of the selected studies will be obtained for assessment. Studies that fail to meet the inclusion criteria once the full version has been checked will be excluded at this stage. Each study excluded after checking the full version will be listed, along with the reason for its exclusion A standardised form will be used to extract data from studies. The following data will be extracted: study details (reference, country where study was carried out, type and dates), participant characteristics, inclusion and exclusion criteria, details of the interventions or practices, setting and follow-up, relevant outcome data and source of funding. One reviewer will extract relevant data into a standardised form, and this will be quality assessed by a senior reviewer
15.	Risk of bias (quality) assessment	Quality assessment of individual studies will be performed using the following checklists: • ROBIS tool for systematic reviews • Cochrane RoB tool v.2 for RCTs (including cluster-randomised trials) and quasi-RCTs

		• Cochrane ROBINS-I tool for non-randomised (clinical) controlled trials and cohort studies The quality assessment will be performed by one reviewer and this will be quality assessed by a senior reviewer
16.	Strategy for data synthesis	Depending on the availability of the evidence, the findings will be summarised narratively or quantitatively. Where possible, meta-analyses will be conducted using Cochrane Review Manager software. Data will be presented as risk ratios or odds ratios for dichotomous outcomes. It is anticipated that continuous outcomes will be synthesised using standardised mean differences (SMDs) due to variation between studies in the validated scales used. Frequency outcomes may also need to be meta-analysed as SMDs due to differences between studies in the scale of measures as a result of differences in the length of follow-up times, units, and populations. It is considered likely that a random-effects model will be used for meta-analyses (based on assumptions about methodological diversity of studies). Funnel plot asymmetry (relationship between the magnitude of the effect estimate and study size) will be considered (for meta-analyses that include at least 10 studies), and where asymmetry is indicated a fixed-effects model will be conducted (and both random-effects and fixed-effects analyses will be presented) or sensitivity analyses excluding small studies will be considered. Heterogeneity in the effect estimates of the individual studies will be assessed using the I^2 statistic. Alongside visual inspection of the point estimates and confidence intervals, the following criteria will be used to assess heterogeneity: no serious I^2 = <40%; serious I^2 = 40-60%; very serious I^2 = >60%. Where I^2 is 80% or above, the data will not normally be pooled. Heterogeneity will be explored as appropriate using sensitivity analyses and pre-specified subgroup analyses. The confidence in the findings across all available evidence will be evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group: http://www.gradeworkinggroup.org/

		Importance and imprecision of findings will be assessed against minimally important differences (MIDs): • SMD -0.5/0.5 as rule of thumb based on Cohen's moderate effect size • For dichotomous outcomes, statistical significance will be used as the MID and imprecision will be assessed based on Optimal Information Size (OIS)

17.	Analysis of sub-groups	Evidence will be sub-grouped by the following only in the event that there is significant heterogeneity in outcomes:
		• Age (based on the mean age reported in the study):
		  ○ Children and young people (aged under 18 years)
		  ○ Adults (aged 18 to 64 years)
		  ○ Older adults (aged 65 years and over)
		• Neurodiversity (including autism spectrum disorder, learning disabilities, and communication difficulties):
		  ○ Studies in a neurodiverse population
		  ○ Studies in a neurotypical population
		• Psychiatric or general setting:
		  ○ psychiatric
		  ○ general
		• Hospital or out-of-hospital settings:
		  ○ hospital
		  ○ out-of-hospital
		• Sex-specific settings:
		  ○ Male-only settings
		  ○ Female-only settings
		  ○ Mixed sex settings
		• Type of restrictive practice (see intervention section above)
		
		Where evidence is sub-grouped the committee will consider on a case by case basis if separate recommendations should be made for distinct groups. Separate recommendations may be made where there is evidence of a differential effect of interventions in distinct groups. If there is a lack of evidence in one group, the committee will consider, based on their experience, whether it is

		reasonable to extrapolate and assume the interventions will have similar effects in that group compared with others
18.	Type and method of review	☒ Intervention ☐ Diagnostic ☐ Prognostic ☐ Qualitative ☐ Epidemiologic ☐ Service Delivery ☐ Other (please specify)
19.	Language	English
20.	Country	England
21.	Anticipated or actual start date	July 2025
22.	Anticipated completion date	July 2026

23.	Stage of review at time of this submission	**Review stage**	**Started**	**Completed**
		Preliminary searches	☐	☐
		Piloting of the study selection process	☐	☐
		Formal screening of search results against eligibility criteria	☐	☐
		Data extraction	☐	☐
		Risk of bias (quality) assessment	☐	☐
		Data analysis	☐	☐
24.	Named contact	Named contact: National Institute for Health and Care Excellence (NICE) Named contact e-mail: violenceandaggression@nice.org.uk Organisational affiliation of the review: National Institute for Health and Care Excellence (NICE)		

25.	Review team members	• Senior Technical Analyst • Technical Analyst • Health Economist • Information Specialist
26.	Funding sources/sponsor	This systematic review is being completed by the Centre for Guidelines which receives funding from NICE.
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ng10432/documents
29.	Other registration details	None
30.	Reference/URL for published protocol	
31.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: • notifying registered stakeholders of publication • publicising the guideline through NICE's newsletter and alerts • issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.
32.	Keywords	Debriefing; post-incident review; restrictive; restraint; violence; aggression

33.	Details of existing review of same topic by same authors	Not applicable
34.	Current review status	☒ Ongoing ☐ Completed but not published ☐ Completed and published ☐ Completed, published and being updated ☐ Discontinued
35..	Additional information	None
36.	Details of final publication	www.nice.org.uk