

Review protocol for safety of restrictive practices

ID	Field	Content
0.	PROSPERO registration number	CRD420251139987
1.	Review title	Safety of restrictive practices
2.	Review question	What is the safety of restrictive practices for the short-term management of aggressive behaviour?
3.	Objective	To determine the safety of restrictive practices for the short-term management of aggressive behaviour
4.	Searches	<p>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</p> <ul style="list-style-type: none"> • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE ALL • Emcare • PsycInfo <p>Database functionality will be used, where available, to exclude:</p> <ul style="list-style-type: none"> • 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.

		<p>Date limits: Databases will be searched for papers published from 2005 onwards</p> <p>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</p> <p>Supplementary search techniques:</p> <ul style="list-style-type: none"> • Hand-searching of inclusion lists of systematic reviews <p>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</p> <p>The full search strategies for all databases will be published in the final review</p>
5.	Condition or domain being studied	Safety of restrictive practices
6.	Population	<ul style="list-style-type: none"> • People receiving restrictive practices in the management of aggressive behaviour
7.	Intervention	<p>Restrictive practices are defined as using different approaches to make someone do something they don't want to do or stopping someone doing something they want to do. The following restrictive practices will be included:</p> <ul style="list-style-type: none"> • Physical restraint (using your body), including: <ul style="list-style-type: none"> ○ prone, supine, or seated restraint positions ○ breakaway techniques with a restrictive component • Mechanical restraint (using equipment), including: <ul style="list-style-type: none"> ○ use of products to support restraint (for example, tasing, pods, or bean bags) • Surveillance • Blanket restrictions

		<ul style="list-style-type: none"> • Environmental restraint, including: <ul style="list-style-type: none"> ○ seclusion ○ segregation • Cultural restraint (using cultural norms) • Psychological restraint (using communication strategies) • Chemical restraint • Exclusion from care
8.	Comparator	<ul style="list-style-type: none"> • No restrictive practice • Head-to-head comparison of different categories of restrictive practices • Head-to-head comparison of alternative approaches within the same category of restrictive practice (for example, different physical restraint positions) • Before-and-after restrictive practice (only where sufficient controlled studies have not been identified, see types of study to be included section)
9.	Types of study to be included	<p>Include published full-text papers:</p> <ul style="list-style-type: none"> • Systematic reviews of RCTs • RCTs <p>If insufficient RCTs*, non-randomised studies will be considered in the following order:</p> <ul style="list-style-type: none"> ○ Systematic reviews of non-randomised studies ○ Quasi-randomised controlled trials ○ Non-randomised controlled trials/Prospective cohort studies ○ Retrospective cohort studies ○ Non-controlled before-and-after studies <p>*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</p> <p>Exclusion:</p> <p>Conference abstracts and dissertations will not be included. Papers that do not include methodological details will not be included as they do not provide sufficient information to evaluate risk of bias/study quality. Books and book chapters will also be excluded</p>

10.	Other exclusion criteria	<ul style="list-style-type: none"> • Papers published pre-2005 • 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)	<ul style="list-style-type: none"> • Number of participants with any (≥ 1) serious adverse events (as defined by study) • Mortality • 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) • Incidence of PTSD (defined as number of participants meeting DSM/ICD diagnosis or scoring above clinical threshold on a validated scale after the restrictive practice who did not have PTSD prior to the restrictive practice) • Self-harm incidents • Aggressive or agitated behaviour • Treatment refusal <p>Exclusion:</p> <ul style="list-style-type: none"> • Qualitative experience of restrictive practice • Subjective distress and traumatic impact measures, for example, the Coercion Experience Scale (CES) <p>If outcomes reported at more than one post-intervention timepoint, then data will be extracted at intervention endpoint and longest follow-up</p>
13.	Secondary outcomes (important outcomes)	None

14.	Data extraction (selection and coding)	<p>All references identified by the searches and from other sources will be uploaded into EPPI-Reviewer 5 and de-duplicated</p> <p>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</p> <p>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</p> <p>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 restrictive 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</p>
15.	Risk of bias (quality) assessment	<p>Quality assessment of individual studies will be performed using the following checklists:</p> <ul style="list-style-type: none"> • 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 • Institute of Health Economics (IHE) Quality Appraisal of Case Series Studies Checklist for uncontrolled before-and-after studies <p>The quality assessment will be performed by one reviewer and this will be quality assessed by a senior reviewer</p>
16.	Strategy for data synthesis	<p>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, and data will be presented as risk ratios or odds ratios for dichotomous outcomes, and mean differences or standardised mean differences for continuous outcomes. 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</p>

		<p>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</p> <p>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</p> <p>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/</p> <p>Importance and imprecision of findings will be assessed against minimally important differences (MIDs):</p> <ul style="list-style-type: none"> • For dichotomous outcomes: Statistical significance will be used as the MID and imprecision will be assessed based on Optimal Information Size (OIS). The committee agreed that given the seriousness of the outcomes, e.g. mortality, PTSD incidence, statistical significance should be used as the MID • For continuous outcomes: SMD -0.5/0.5 as rule of thumb based on Cohen's moderate effect size
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17.	Analysis of sub-groups	<p>Evidence will be sub-grouped by the following only in the event that there is significant heterogeneity in outcomes:</p> <ul style="list-style-type: none"> • Age (based on the mean age reported in the study): <ul style="list-style-type: none"> ○ Older adults (aged 60 years and over) ○ Younger adults (aged 18-59 years) ○ Children and young people (aged under 18 years) • Neurodiversity: <ul style="list-style-type: none"> ○ Neurodevelopmental condition (for example, ADHD, autism, developmental coordination disorder (formerly known as dyspraxia), Tourette's Syndrome) ○ No neurodevelopmental condition • Ethnicity: <ul style="list-style-type: none"> ○ Black and minority ethnic background (BME) ○ White • Gender identity: <ul style="list-style-type: none"> ○ Trans or transgender, non-binary or gender diverse ○ Cisgender • Sensory impairment: <ul style="list-style-type: none"> ○ Blindness or deafness ○ Normal sight and hearing • Communication and language problems: <ul style="list-style-type: none"> ○ Communication and language problems ○ No communication or language problems <p>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</p>	
18.	Type and method of review	<input checked="" type="checkbox"/>	Intervention
		<input type="checkbox"/>	Diagnostic

		<input type="checkbox"/>	Prognostic	
		<input type="checkbox"/>	Qualitative	
		<input type="checkbox"/>	Epidemiologic	
		<input type="checkbox"/>	Service Delivery	
		<input type="checkbox"/>	Other (please specify)	
19.	Language	English		
20.	Country	England		
21.	Anticipated or actual start date	July 2025		
22.	Anticipated completion date	November 2026		
23.	Stage of review at time of this submission	Review stage	Started	Completed
		Preliminary searches	<input type="checkbox"/>	<input type="checkbox"/>
		Piloting of the study selection process	<input type="checkbox"/>	<input type="checkbox"/>
		Formal screening of search results against eligibility criteria	<input type="checkbox"/>	<input type="checkbox"/>

		Data extraction	<input type="checkbox"/>	<input type="checkbox"/>
		Risk of bias (quality) assessment	<input type="checkbox"/>	<input type="checkbox"/>
		Data analysis	<input type="checkbox"/>	<input type="checkbox"/>
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	<ul style="list-style-type: none"> • Senior Technical Analyst • Technical Analyst • Health Economist • Information Specialist 		
26.	Funding sources/sponsor	This systematic review is being completed by NICE which receives funding from the Department of Health and Social Care		
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	<p>NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as:</p> <ul style="list-style-type: none"> • 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	Restrictive; restraint; seclusion; aggression; violence; safety	
33.	Details of existing review of same topic by same authors	Not applicable	
34.	Current review status	<input checked="" type="checkbox"/>	Ongoing
		<input type="checkbox"/>	Completed but not published
		<input type="checkbox"/>	Completed and published
		<input type="checkbox"/>	Completed, published and being updated
		<input type="checkbox"/>	Discontinued
35..	Additional information	None	
36.	Details of final publication	www.nice.org.uk	

