Review protocol for effectiveness of organisational level interventions targeted at reducing aggressive behaviour and restrictive practices

ID	Field	Content
0.	PROSPERO registration number	CRD420251127301
1.	Review title	Effectiveness of organisational level interventions targeted at reducing aggressive behaviour and restrictive practices
2.	Review question	What is the effectiveness of organisational level interventions targeted at reducing aggressive behaviour and the use of restrictive practices?
3.	Objective	To determine the effectiveness of organisational level interventions targeted at reducing aggressive behaviour and the 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	Aggressive behaviour in people who are receiving health, mental health or social care
6.	Population	**Inclusion:** • Staff providing health, mental health or social care • People using health, mental health and social care services

7.	Intervention	**Inclusion:**
		Organisational level interventions or policies targeted at reducing aggressive behaviour and the use of restrictive practices. This includes complex multicomponent interventions, for example, Safewards, Six Core Strategies, and REsTRAIN YOURSELF, and standalone interventions. Organisational level interventions or policies may include, but are not restricted to, the following components:
		• Staff training in:
		  ○ verbal de-escalation techniques
		  ○ non-verbal de-escalation techniques
		  ○ communication practices

		○ non-restrictive breakaway techniques ○ goal setting ○ human rights • Psychologically informed environments • Person-centred care • Trauma-informed care • Methods of observation • Organisational protocols based on structured risk assessments to inform clinical decision-making • Co-produced interventions **Exclusion:** • Patient-level interventions, such as rapid tranquillisation, or oral antipsychotic medication (sometimes referred to as p.r.n medication) to prevent the onset of aggressive behaviour • Post-incident debriefing or formal review as stand-alone interventions (not in the context of a multicomponent programme)
8.	Comparator	• Standard care, no new intervention to reduce aggressive behaviour and the use of restrictive practices • Head-to-head comparison of different organisational level interventions (between category comparison) targeted at reducing aggressive behaviour and the use of restrictive practices • Attention-placebo control (a new intervention added to standard care, but one that is not targeted at reducing aggressive behaviour and the use of restrictive practices) • Before-and-after intervention
9.	Types of study to be included	**Inclusion:** • Systematic reviews of RCTs • RCTs • If insufficient RCTs*: ○ Systematic reviews of non-randomised studies ○ Quasi-randomised controlled trials ○ Non-randomised controlled trial/Prospective cohort studies ○ Retrospective cohort studies ○ Historically controlled study

		○ Controlled before-and-after study ○ Non-controlled before-and-after 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 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:** Conference abstracts, dissertations, and protocols 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 be excluded
10.	Other exclusion criteria	• Non-English language papers • Papers published pre-2005
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)	• Use of restrictive practices • Duration of restrictive practice • Aggressive behaviour • Aggression or agitation scores
13.	Secondary outcomes (important outcomes)	• Staff absence

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), patient characteristics where reported (including number of patients, age [study mean and standard deviation], sex [% female], primary diagnosis), organisation characteristics (including specific setting, psychiatric or general, number of wards, number of beds, number of staff), inclusion and exclusion criteria, details of the interventions (including components in multicomponent interventions), and follow-up, and relevant outcome data. 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 • Institute of Health Economics (IHE) Quality Appraisal of Case Series Studies Checklist for uncontrolled before-and-after 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. It is anticipated that data for continuous outcomes will be synthesised using standardised mean differences (SMDs) due to variation between studies in the validated scales used to measure aggression or agitation scores, and in the scale of frequency measures as a result of differences in the length of follow-up times, units, and populations (baseline

		frequency). Where dichotomous outcomes are available and can be meta-analysed, they will be synthesised as risk ratios (RRs). 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. If studies are sufficiently similar (in terms of setting, intervention and participant characteristics) and a true intervention effect is judged to be plausible then a fixed effect analysis will be considered from the outset, although this is not expected 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): • For continuous outcomes: SMD -0.5/0.5 as rule of thumb based on Cohen's moderate effect size • For dichotomous outcomes: RR <0.75 or >1.25
17.	Analysis of sub-groups	Evidence will be sub-grouped by the following only in the event that there is significant heterogeneity in outcomes: • Setting:

		○ inpatient hospital psychiatric ○ inpatient hospital non-psychiatric ○ residential settings ○ forensic settings ○ emergency care ○ outpatient care ○ primary care ○ community settings • Setting by age: ○ adult settings ○ child and adolescent settings Where possible, subgroup analysis and/or meta-regression will explore differences in effectiveness associated with components of multicomponent organisational interventions or policies (see intervention section above), for example, comparing the effectiveness of all interventions that include methods of observation and those that don't including both stand-alone observation interventions and complex interventions that include an observation component Where evidence is sub-grouped the committee will consider on a case-by-case basis if separate recommendations should be made for distinct settings. Separate recommendations may be made where there is evidence of a differential effect of interventions in distinct settings. If there is a lack of evidence in one setting, the committee will consider, based on their experience, whether it is reasonable to extrapolate and assume the interventions will have similar effects in that setting 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	November 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 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	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	Restrictive; restraint; seclusion; aggression; violence; organisational interventions
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