Evidence Synthesis Program

Protocols to Reduce Seclusion in Inpatient Mental Health Units

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This report was prepared by the Evidence Synthesis Program Center located at the **VA Providence Health Care System,** directed by Eric Jutkowitz, PhD and James Rudolph, MD and funded by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development.

PREFACE

The VA Evidence Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted health care topics of importance to clinicians, managers, and policymakers as they work to improve the health and health care of Veterans. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The program comprises 4 ESP Centers across the US and a Coordinating Center located in Portland, Oregon. Center Directors are VA clinicians and recognized leaders in the field of evidence synthesis with close ties to the AHRQ Evidence-based Practice Center Program. The Coordinating Center was created to manage program operations, ensure methodological consistency and quality of products, interface with stakeholders, and address urgent evidence needs. To ensure responsiveness to the needs of decision-makers, the program is governed by a Steering Committee composed of health system leadership and researchers. The program solicits nominations for review topics several times a year via the program website.

The present report was developed in response to a request from the VA Office of Mental Health and Suicide Prevention (OMHSP). The scope was further developed with input from Operational Partners (below), the ESP Coordinating Center, the review team, and the technical expert panel (TEP). The ESP consulted several technical and content experts in designing the research questions and review methodology. In seeking broad expertise and perspectives, divergent and conflicting opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Ultimately, however, research questions, design, methodologic approaches, and/or conclusions of the review may not necessarily represent the views of individual technical and content experts.

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Operational Partners

Operational partners are system-level stakeholders who help ensure relevance of the review topic to the VA, contribute to the development of and approve final project scope and timeframe for completion, provide feedback on the draft report, and provide consultation on strategies for dissemination of the report to the field and relevant groups.

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To ensure robust, scientifically relevant work, the TEP guides topic refinement; provides input on key questions and eligibility criteria, advising on substantive issues or possibly overlooked areas of research; assures VA relevance; and provides feedback on work in progress. TEP members are listed below:

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The Coordinating Center sought input from external peer reviewers to review the draft report and provide feedback on the objectives, scope, methods used, perception of bias, and omitted evidence (see Appendix K for disposition of comments). Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The Coordinating Center works to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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ABBREVIATIONS TABLE

aOR	Adjusted odds ratio
BCW	Behavior change wheel
CI	Confidence interval
ESP	Evidence Synthesis Program
EssenCES	Essen Client Evaluation Schema
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HR	Hazard ratio
KQ	Key questions
HBIPS	Hospital-based inpatient psychiatric services
MeSH	Medical subject headings
N	Sample size
NR	Not reported
NS	Not significant
NRCS	Nonrandomized comparative study
OMHSP	Office of Mental Health and Suicide Prevention
PCC	Patient-staff conflict checklist
PCC-SR	Patient-staff conflict checklist shift reports
RCT	Randomized controlled trial
RoB	Risk of bias
RR	Relative risk
SD	Standard deviation
TEP	Technical expert panel
US	United States
VA	Veterans Affairs
VHA	Veterans Health Administration

EXECUTIVE SUMMARY

Key Findings

We identified 37 protocols to reduce the practice of seclusion in psychiatric inpatient settings that were evaluated in a comparative design and 6 protocols described without empirical data. Based on our coding of protocols using a scheme of 9 intervention functions (*education*, *persuasion*, *incentivization*, *coercion*, *training*, *restriction*, *environmental restructuring*, *modelling*, and *enablement*), we categorized protocols into 5 groups: hospital/unit restructuring ($N = 4$), staff education/training ($N = 3$), sensory modulation rooms ($N = 7$), risk assessment and management protocols ($N = 7$), and comprehensive/mixed interventions ($N = 22$). Within the risk assessment and management protocol group, we call out studies using the Brøset Violence Checklist (as it was the most commonly studied risk assessment tool evaluated in 4 studies). Likewise, within the comprehensive/mixed interventions we call out the Safewards intervention (as it is one of the most well-described protocols to reduce seclusion). We note the confidence we had in the conclusions (or because of insufficient evidence, where we had no conclusion).

- **Hospital/unit restructuring**
    - Hospital/unit restructuring protocols involved implementing architecturally positive elements and *restructuring the environment* (including, in some cases, implementing an open-door policy).
    - Hospital/unit restructuring may reduce seclusion events, seclusion duration, restraint duration, and forced medication use (all with low confidence). The impact on restraint events is mixed across studies and there is insufficient or no evidence regarding effects on composite measures of coercion events, patient outcomes (*eg*, aggressive incidents, injuries), or staff outcomes (*eg*, injuries, satisfaction) (all with no conclusion).
- **Staff education/training**
    - Education/training interventions provided staff with de-escalation techniques and alternative strategies to seclusion. Common intervention functions across the described protocols were *persuasion*, *education*, *training*, or *modelling*. *Staffing* was the primary resource associated with the interventions.
    - Staff education/training may reduce forced medication use and staff injuries (both low confidence). The impacts on seclusion events, restraint events, and coercion events are mixed across studies and there is insufficient or no evidence regarding effects on seclusion duration, restraint duration, and patient outcomes (all no conclusion).
- **Sensory modulation rooms**
    - Sensory modulation rooms involved creating a dedicated space in the unit to meet the multisensory needs of patients (*ie,* intervention function *environmental restructuring*). Protocols describing sensory rooms also included elements of e*ducation, persuasion, enablement,* and *restrictions*. Primary resource needs included *space* and *equipment*.

  - Sensory modulation rooms may reduce seclusion events and forced medication use (low confidence) but may not reduce seclusion duration (low confidence). The impacts on restraint events, coercion events, patient outcomes, and staff outcomes are mixed across studies, and there is insufficient or no evidence regarding effects on restraint events and restraint duration (all no conclusion).

- **Risk assessments and management protocols**
  - Risk assessment and management protocols involved using a structured tool to help staff identify potentially aggressive patients to direct clinical efforts (*eg,* de-escalation techniques). Risk assessment and management protocols included intervention functions of e*nvironmental restructuring, education,* and *training.* Resource requirements included *documentation* and *time staff spent to perform checks on patients*.
  - The **Brøset Violence Checklist** used as a risk assessment measure may reduce seclusion events and coercion events and may improve patient outcomes (low confidence). However, the checklist may not reduce restraint events and may increase restraint duration (both low confidence). The impact on seclusion duration is mixed across studies and there is no evidence regarding forced medication use and staff outcomes (all no conclusion).
  - **Investigator developed risk assessment measures** may reduce restraint events and restraint duration (low confidence) but may not reduce seclusion duration or staff outcomes (both low confidence). Their impact on seclusion events and patient outcomes is mixed across studies and there is no evidence regarding coercion events and forced medication use (all no conclusion).
- **Comprehensive/Mixed Models**
  - Comprehensive/mixed protocols were multi-component and included intervention functions of *education* and *training.* Protocols often included elements of *persuasion* to reinforce staff education and *environmental restructuring* to change the physical or social context of the wards. The most common resource needs explicitly stated in the protocols included *documentation* and *staffing* followed by *programming*.
  - The **Safewards protocol** may reduce a composite measure of coercion and patient conflicts (both low confidence). There is insufficient or no evidence for this model regarding seclusion events, seclusion duration, restraint events, restraint duration, forced medication use, and staff outcomes (all no conclusion).
  - **Other comprehensive models** may reduce seclusion events, seclusion duration, restraint events, restraint duration, and coercion events (all low confidence) but may not reduce forced medication use (low confidence). There is mixed evidence across studies regarding patient and staff outcomes (no conclusion).

INTRODUCTION

In psychiatric inpatient settings, conflict behaviors such as patient aggression, agitation, and self-harm require immediate intervention to prevent physical and emotional injury to the patient, other patients, and staff. Seclusion is commonly used to manage conflict behaviors that place patients and staff at risk of immediate harm. Seclusion generally consists of involuntarily confining a patient alone in a restricted area until the patient's conflict behaviors subside. There is large variation in the use of seclusion across the United States (US). For example, 1 large study of psychiatric facilities in the US found seclusion was used for 0.3 per 1,000 patient hours; however, the interquartile range was wide (0.02 to 0.22). When these data were stratified by hospital type in unadjusted analyses in 2014, for-profit psychiatric hospitals used seclusion the least and Veteran Affairs (VA) hospitals used it the most (mean 0.1 [standard deviation (SD) 0.7] vs 0.4 [SD 0.8] per 1,000 patient hours).

Seclusion is increasingly viewed as an intervention of last resort and there are multiple initiatives to reduce the practice. This includes the Veterans Health Administration (VHA) Handbook 1160.06, which directs clinicians in inpatient units to explore ways to prevent, reduce, and eliminate seclusion. Reducing a units' use of seclusion requires safe and effective alternative interventions. Multiple protocols have been devised to help reduce challenging patient behaviors that precede seclusion in an effort to reduce seclusion itself. The effect of protocols to reduce seclusion on patient and staff outcomes and the resource needs required to implement these protocols remain unclear.

The VA Evidence Synthesis Program (ESP) was asked by the VA Office of Mental Health and Suicide Prevention (OMHSP) for an evidence review on protocols to reduce seclusion practices for adults hospitalized in inpatient mental health units. In collaboration with VA stakeholders, we developed the following Key Questions (KQs):

KQ1: What protocols have been described to reduce seclusion practices for adult patients in inpatient mental health units?

KQ1.1: What are the described resource needs (such as personnel and space needs) of these protocols?

KQ2: What are the comparative effects of protocols to reduce seclusion practices on resource use, staff and unit practices, patient experiences, and staff experiences versus usual protocols?

METHODS

We searched for peer-reviewed articles in Medline (via PubMed), Embase, the Cochrane Register of Clinical Trials, PsycINFO, CINAHL, cairn.info, and ClinicalTrials.gov from date of inception to September 6, 2022. Eligible records for KQ1 (protocol descriptions) were organizational documents of protocols to reduce seclusion in inpatient psychiatric units for patients ≥18 years of age (produced by organizations in the US or Canada or implemented or intended to be implemented in the US or Canada). These records did not have to report outcomes. For KQ2 (effects of implementing protocols), eligible studies included adults ≥18 years of age with psychiatric conditions being treated in inpatient units or the frontline staff who worked in these units. Our focus was on the effects (or comparative effects) of protocols to reduce seclusion. Eligible articles compared unit-level protocols to reduce seclusion to a

comparison group (*eg,* usual care or the same unit pre-intervention). Studies could be randomized or observational. For KQ2, we included protocols intended to be implemented in the US or any other high-income country. For both KQs, studies were excluded if they included incarcerated or institutionalized populations. We defined protocols as including multiple components or a general overall policy to reduce seclusion (*ie,* not a single strategy only). We extracted protocol elements into 1 of 9 intervention functions defined by the Behavior Change Wheel, which characterizes behavior change interventions. We used this framework to describe the protocols since the protocols tried to change behavior (staff, patients, or both) to reduce seclusion events. The 9 intervention functions include *education*, *persuasion*, *incentivization*, *coercion*, *training*, *restriction*, *environmental restructuring*, *modelling*, and *enablement*. Prioritized outcomes included the use of seclusion, restraint, composite measures of seclusion and restraint, forced medication use, patient outcomes (aggression or injuries), and staff outcomes (injuries and satisfaction). We extracted data into standardized forms and assessed risk of bias of each study. We conducted a narrative synthesis of the evidence. The study results were not amenable to meta-analysis. Using GRADE (Grading of Recommendations Assessment, Development and Evaluation) methodology, we determined certainty of evidence for each major finding. A preregistered protocol for this review can be found on the PROSPERO international prospective register of systematic reviews (http://www.crd.york.ac.uk/PROSPERO/; registration number CRD42022363787).

RESULTS

We identified 6 protocols that were described without empirical data and an additional 37 protocols that were evaluated in a comparative design. Seventeen of the 37 comparative studies (with reported results) were from the US (4 of which were from the VA). Most of the evidence for protocols came from studies using a pre-post design ($N = 28$), followed by NRCSs with concurrent comparisons ($N = 5$) and RCTs ($N = 4$). All interventions were multicomponent and often targeted both patient and staff factors to reduce the likelihood of aggressive events or use of seclusion, respectively. Based on our coding of the interventions using the 9 intervention functions, we identified 5 intervention groups (from least to most intensive): hospital/unit restructuring ($N = 4$), staff education/training ($N = 3$), sensory modulation rooms ($N = 7$), risk assessment and management protocols (the Brøset Violence Checklist described separately $N = 4$, and investigator developed risk assessments $N = 3$), and comprehensive/mixed interventions (including Safewards, described separately $N = 2$, other mixed protocols $N = 14$, and mixed protocols without empirical data $N = 6$).

Hospital/Unit Restructuring

Four comparative studies described protocols that involved *environmental restructuring* of the unit. The 4 studies described the implementation of architecturally positive spaces and restructured patient programs (including 2 studies that implemented an open-door policy). For example, 1 study explicitly described changing from a locked unit into 3 programs that included an intensive care unit, an unlocked day program, and a transitional residential program. Another study described a contemporary building that replaced the existing 19th century building, outfitting it with open, naturally lit rooms.

Based on evidence from 4 pre-post studies, restructuring units to include architecturally positive elements (and in some cases implementing an open-door policy) may reduce episodes of seclusion, duration of seclusion, duration of restraint, and forced medication use. We have low

confidence in these findings because studies had serious methodological limitations (they relied on self-reported outcome data and conducted crude analyses) and there was some inconsistency in findings between studies for episodes of seclusion and episodes of restraint. Studies provide insufficient evidence (no conclusion) regarding episodes of restraint, other patient outcomes, and staff outcomes. The studies did not evaluate a composite measure of coercion.

Staff Education/Training

Three comparative studies evaluated the impact of staff education and/or training on seclusion practices. The common intervention function across the 3 interventions was *persuasion* (*ie,* using communication to stimulate action), with elements of *education*, *training*, or *modelling* also present. *Staffing* was the primary resource named across the 3 studies with the interventions employing multidisciplinary teams.

Based on the evidence from 3 pre-post studies, education and training of staff (*eg,* de-escalation, alternative strategies to seclusion, and preventing violence) may reduce staff injuries and use of forced medication. We have low confidence in these findings because of methodological limitations (mostly unadjusted analyses) and inconsistent findings within and between studies. Studies provide insufficient evidence (no conclusion) for episodes of seclusion, episodes of restraint, other patient outcomes (*eg*, aggression), and composite measures of coercion. Studies did not report on duration of seclusion or duration of restraint.

Sensory Modulation

Seven comparative studies evaluated the effect of sensory modulation rooms, which required changes to the physical ward (*ie, environmental restructuring* intervention function) to influence both staff and patients. Six of the protocols included elements of *education* and *persuasion* (to educate staff and patients about the rooms and how to use them), 3 protocols included elements of staff or patient *enablement*, and 2 protocols included elements of patient *restrictions*. The most common resource need for sensory modulation interventions was the *space* and *equipment* to facilitate the intervention.

Based on evidence from 2 concurrent comparison and 5 pre-post studies, episodes of seclusion, but not duration of seclusion, may be reduced by sensory modulation rooms on inpatient wards. Sensory modulation rooms may also reduce use of forced medication. We have low confidence in these findings due to serious methodological limitations, inconsistent findings across studies for some outcomes, and sparse reporting of data. Studies provide insufficient evidence (providing no conclusion) regarding episodes of restraint, composite measures of coercion, patient outcomes (*eg,* self-injury, patient-to-patient assault), and staff outcomes (patient-to-staff assault). Studies did not report on duration of restraint.

Risk Assessment and Management Protocols

Seven comparative studies evaluated risk assessment tools with management protocols. All 7 protocols involved the intervention function *environmental restructuring* affecting both staff and patients, as the implementation of the risk assessments changed the social context of how patients were managed in the unit. Protocols also involved elements of *education* and *training* (*eg,* training staff how to use the assessment tools). The 7 protocols included resource

requirements related to *documentation*, and 2 protocols explicitly reported resources related to *time staff spent to perform checks on patients.*

Brøset Violence Checklist

Based on evidence from 2 RCTs and 2 pre-post studies, episodes of seclusion, a composite measure (psychotropic medications, seclusion, and restraint), and patient aggressive incidents may be reduced by risk assessment protocols that include the Brøset Violence Checklist. We have low confidence in these findings due to serious methodological limitations, inconsistent findings for some outcomes, and sparse reporting of data. There is no evidence of differences in episodes of restraint and some evidence to suggest duration of restraint may increase (low confidence). The studies provide insufficient evidence regarding duration of seclusion (no conclusion). The studies did not evaluate forced medication use or staff outcomes.

Investigator Developed Assessments

Based on evidence from 3 pre-post studies, there is no difference in the duration of seclusion and staff satisfaction between interventions that include investigator-developed risk assessment tools compared to usual care, but episodes and duration of restraint may be reduced by these interventions. We have low confidence in these findings due to serious methodological limitations and sparse data. The studies provide insufficient evidence regarding episodes of seclusion and other patient outcomes (no conclusion). The studies did not evaluate a composite measure of coercion or use of forced medication.

Comprehensive/Mixed Interventions

Safewards Model

Two comparative studies evaluated the effect of the Safewards model, which consists of 10 components to reduce conflict and use of coercive measures on inpatient wards. The components of the Safewards model include *education*, *persuasion*, *incentivization*, *training*, *environmental restructuring* (including restructuring of the social context), *modelling*, and *enablement*. Both studies reported resource needs for *equipment* (*eg*, sensory crates) and *staffing* since the intervention required nurses to engage in the care model.

Based on evidence from 1 RCT and 1 pre-post study, the comprehensive Safewards model may reduce a composite measure of coercion (restraint and seclusion and/or forced medication use) and patient conflicts. We have low confidence in these findings because studies had serious methodological concerns. The studies provide insufficient evidence (no conclusion) for staff outcomes. Studies did not report on seclusion, restraint (other than as a composite outcome), or forced medication use.

Other Comprehensive/Mixed Interventions

Six reports without empirical data and 14 comparative studies described comprehensive/mixed protocols using multiple intervention functions targeting both staff and patients. Most protocols included intervention functions of *education* and *training*, but the content varied between interventions. Protocols often described elements of *persuasion* to reinforce staff education and training and *environmental restructuring* to change the physical or social context of the wards for both patients and staff. A few protocols included elements of *modelling (eg,* expert staff

demonstrating behaviors to other staff) or *restriction*. The most common resource needs explicitly stated in the protocols included *documentation* and *staffing* followed by *programming*.

Based on evidence from 1 RCT, 2 concurrent comparison studies, and 11 pre-post studies, episodes of seclusion, duration of seclusion, duration of restraint, episodes of composite measures of coercion, and duration of composite measures of coercion may be reduced by comprehensive/mixed interventions. There is no evidence of differences for episodes of restraints and forced medication use. We have low confidence in all these findings due to serious methodological limitations (self-reported outcome data and crude analyses) and sparse data. Studies provide insufficient evidence (no conclusion) for other patient outcomes and staff outcomes.

DISCUSSION

Despite great interest from policymakers, staff, and patients for effective alternatives to seclusion, there are limited data on the benefits of protocols designed to reduce seclusion in adult inpatient mental health wards. We identified 48 reports that described 43 protocols to reduce seclusion, but, overall, the evidence base is limited, allowing at best low confidence conclusions. Protocols were diverse, highlighting that intervention designers are attempting to build complex solutions to address a complex practice problem. Two-thirds of protocols targeted both patients and staff to reduce the likelihood of a precipitating behavior requiring seclusion. Eight of 9 intervention functions were identified in efforts to reduce staff's use of seclusion (*education*, *incentivization*, *persuasion*, *training*, *restriction*, *environmental restructuring*, *modelling*, *enablement*), and 7 of the 9 intervention functions were identified in efforts to reduce patients' aggressive behavior (*education*, *persuasion*, *incentivization, training*, *restriction*, *environmental restructuring*, *enablement*).

The protocols we identified align with contemporary perspectives of patient-oriented recovery-focused mental health care. However, the evidence supporting the effectiveness of protocols to reduce seclusion (or their component intervention functions) needs to be interpreted with caution due to methodological limitations. First, all the studies relied on self-reported outcome data: staff were either the target or implementers of interventions and were also the outcome observers. Since most interventions were explicit in their aims to reduce seclusion, staff could have changed their behavior or measured their behavior differently to meet expectations (*ie,* performance bias). Second, there was inconsistent or sparse reporting of outcomes. Individual studies reported only select outcomes related to coercion (*eg,* a study would report use of seclusion but not use of restraints). Outcomes such as patient aggression, patient/staff injuries, and patient/staff satisfaction were infrequently reported. This made it challenging to compare outcomes between studies and to understand trade-offs (if any) between reducing seclusion and other forms of managing patients such as forced medication or restraint. Third, most studies were observational and they conducted crude (unadjusted) analyses that did not adequately account for confounding.

We restricted the review to studies conducted in countries that may be most applicable to inpatient mental health units in the US, but the unique elements of interventions may not generalize to all inpatient psychiatric hospitals. Most studies described protocols that were tailored to the local context and designed with stakeholder engagement. Safewards may be the most generalizable protocol, given the comprehensive nature of the intervention and that evidence comes from an RCT and observational study (it is well investigated but few studies of

Safewards met our review eligibility criteria). Importantly, resource needs associated with the interventions may be substantial, including increased personnel, equipment, and time for staff to complete training.

Implications for VA Policy

Several findings from this review may generalize to the VA. Four pre-post studies evaluated comprehensive/mixed interventions that involved creating a patient-centered ward culture in the VA. Consistent with VHA Handbook 1160.06 and the Design Guide for Inpatient Mental Health & Residential Rehabilitation Treatment Program Facilities, the studies we identified found that modifying the environment (*eg,* sensory rooms) may reduce the practice of seclusion. VA inpatient mental units should continue to view the environment as a component of treatment.

As the VA continues to implement protocols to reduce the practice of seclusion, there are opportunities for system-level approaches to evaluate efforts. VA-wide improvement efforts have already been implemented towards standardized documentation in the electronic health record, such as the Violence Risk Assessment; however, further opportunities exist for reporting on seclusion events and the use of least restrictive means prior to seclusion. Once data are uniformly reported, front-line staff and leadership can evaluate trends and identify units with above/below average process and outcome measures. With standardizing measures, it is also possible for the VA to conduct secondary database analyses to develop interventions to identify Veterans at high risk for seclusion or who exhibit conflict behaviors.

Research Gaps/Future Research

Most studies were observational and used data from the electronic medical records, but they did not account for potential confounding between groups. Future observational studies can account for confounders in their analyses by, at a minimum, conducting regression adjustment that includes patient characteristics that are also routinely captured in the electronic medical record. Studies should also make efforts to study effect modification based on demographics, diagnoses, or acuity. For hospitals that are part of large systems, there are opportunities to use electronic medical record data and quasi-experimental methods to compare units that do and do not implement interventions. Such larger studies should use more sophisticated methods to account for potential confounders (such as propensity score matching or inverse probability weighting). Reporting different forms of coercion as separate outcomes (*ie,* rather than reporting seclusion, restraint, and medication use as a combined outcome) would allow decision-makers to understand the trade-offs between reducing seclusion and other interventions. Finally, studies should use standardized reporting guidelines to clearly document intervention elements.

Limitations

We followed contemporary standards for conducting systematic reviews. The systematic review was broad enough to include all possible protocols to reduce seclusion but limited to restrict to protocols that could be feasibly delivered in US health care settings. A strength of this review was our detailed coding of the intervention functions of the protocols. This provided a structure to group the protocols into meaningful categories and can be used to inform future practice for units that aim to implement all or parts of these interventions. Although the coding and grouping of interventions into conceptually similar categories is a strength, it is possible the conclusions could change if groupings of interventions changed. Similarly, in operationalizing the review, the

review team had to make decisions about whether an intervention met our definition of a protocol of an alternative strategy to seclusion. It is possible we missed protocols in our operationalizing of our definition.

Conclusions

Reducing the use of seclusion has the potential to align care that respects patients' rights and autonomy (as long as it does not increase use of other coercive measures). Restructuring units to include architecturally positive designs, sensory/comfort rooms, structured risk assessments that include the Brøset Violence Checklist, and comprehensive/mixed interventions may reduce seclusion. Restructuring units may also reduce the use of restraints and forced medication. There is no difference in episodes of restraint for other comprehensive interventions or structured risk assessments that include the Brøset Violence Checklist. It is unknown if sensory rooms reduce episodes of restraint or whether staff training alone or investigator-developed risk assessment tools reduce seclusion. However, at best, we have low confidence in the conclusions due to methodological limitations of the studies and sparseness of studies addressing most interventions. Thus, it is likely that future research may change some conclusions and it remains unclear what specific interventions may be most effective. Nevertheless, these findings may generalize to the VA, which is already implementing several strategies demonstrating reductions in seclusion. Opportunities for future research and practice include standardizing reporting of process and outcome measures and conducting analyses that account for confounders. Users of this report may consider implementing evidence-informed elements of protocols that map to their local clinical contexts or complement existing protocols.

EVIDENCE REPORT

INTRODUCTION

PURPOSE

The Veterans Affairs (VA) Evidence Synthesis Program (ESP) was asked by the VA Office of Mental Health and Suicide Prevention (OMHSP) for an evidence review on protocols to reduce seclusion practices for adults ≥18 years of age hospitalized in inpatient mental health units. Previous systematic reviews have found limited benefits of seclusion, raising ethical concerns with the continued use of these practices. A 2017 report commissioned by the Joint Commission found that VA hospitals use more seclusion than non-VA hospitals. In response to the Joint Commission report, OMHSP developed a seclusion and restraint reduction toolkit, which was credited with a voluntary reduction in seclusion practices within the VA. OMHSP is in the process of updating the national Inpatient Mental Health Directive. This evidence review will inform the Inpatient Mental Health Directive and determine whether some level of seclusion practices provide benefit or if the harms merit a complete ban, relative to alternative practices.

BACKGROUND

In psychiatric inpatient settings, conflict behaviors such as patient aggression, agitation, self-harm, and other potentially dangerous behaviors require immediate intervention to prevent physical and emotional injury to the patient, other patients, and staff.[1] Conflict behaviors also contribute to staff stress and burnout.[2,3] There are limited data on the incidence of challenging or dangerous behaviors in inpatient settings, with estimates varying from 8% to 76%.[4] The large variation in estimates is, in part, due to ambiguous definitions of these behaviors and lack of processes for standardized reporting.[4,5] Managing aggression, agitation, and other potentially dangerous behaviors is challenging because it requires balancing the autonomy and safety needs of the patient with other individuals who may be impacted by the patient.[6]

Seclusion is 1 type of intervention that is used to manage conflict behaviors that place patients and staff at risk of immediate harm.[7] Although definitions in the literature vary, seclusion generally is recognized as involuntarily confining a patient alone in a locked room or restricted area until the patient's conflict behaviors subside.[8] How seclusion is implemented can vary significantly across settings. For example, the characteristics of the restricted area can vary (*eg,* furnished or unfurnished room), and seclusion may or may not be combined with other involuntary interventions such as physical restraints or pharmacological methods.[9]

There are few randomized controlled trials (RCTs) examining the benefits and harms of seclusion.[10-13] There is widespread ethical concern that seclusion is a coercive[a] practice that violates patients' rights and autonomy and some evidence that patients prefer forced medication over seclusion.[9,14-16] Staff also have negative perceptions of seclusion.[17] In addition,

[a] We use the term "coercion" in this report without judgment or intention of implying clinician stigma. Rather, we use this term to be consistent with our observations of how the literature describes a group of measures that may be applied "against the patient's will or in spite of his or her opposition" (such as seclusion, restraint, and forced medication) to manage patient care (Chieze 2021). If a study reported coercion as a composite outcome in their results (*ie,* a combined outcome of seclusion and other coercive measures), we report the study definition of coercion. If the study did not report the definition of coercion, we indicate it was not reported.

epidemiologic and quasi-experimental studies have found that seclusion may cause harms to patients including exacerbation of post-traumatic stress symptoms, emotional distress, negative attitudes toward psychiatric treatment,[18] and increased length of stay.[11,19-22] Furthermore, the practical act of placing patients in seclusion may expose staff to additional risk of injury and can cause staff to experience emotional distress.[23,24]

In 2008, the Joint Commission established the Hospital-Based Inpatient Psychiatric Services (HBIPS) measure set which includes hours of seclusion per 1,000 patient hours as a quality measure.[25] Data from hospitals reporting HBIPS show large variation in the use of seclusion across the United States (US).[26,27] For example, in 2014, psychiatric facilities in the US reported using seclusion for an average 0.3 (standard deviation [SD] 0.8) per 1,000 patient hours with a wide interquartile range (0.02 to 0.22).[26] When these data were stratified by hospital type, for-profit psychiatric hospitals used seclusion for the least amount of patient hours (mean 0.1 [SD 0.7], interquartile range: 0.002 to 0.1) and VA hospitals used it the most (mean 0.4 [SD 0.8], interquartile range: 0.0 to 0.3). It is important to note that these estimates do not account for patient case-mix, which may vary substantially across settings (leading to more or less aggressive or agitated behaviors potentially requiring seclusion). Less is known about the practical implementation of seclusion practices (*eg,* space and personnel resources associated with its use, or context-specific factors that may lead to greater or lesser use).

Over time, seclusion has increasingly been viewed as an intervention of last resort and there are multiple policy initiatives to reduce seclusion.[27-30] This includes the Veterans Health Administration (VHA) Handbook 1160.06, which states that "seclusion and restraint are interventions of last resort" and directs clinicians in inpatient units to explore ways to prevent, reduce, and eliminate seclusion.[30] However, reducing clinicians' use of seclusion requires safe and effective alternative intervention(s) to replace seclusion. Safewards is an example of a protocol to reduce seclusion and consists of a package of intervention strategies that target conflict-originating factors, flashpoints that indicate imminent conflict behaviors, and the link between flashpoints and conflict behaviors.[31] Examples of Safewards interventions include mutually agreed upon standards of behavior by and for staff, short advisory statements on handling flashpoints, distraction and sensory modulation tools to use with agitated patients, displays of positive messages around the ward for patients, and implementation of de-escalation plans.

Multiple inpatient unit-level policies, which we define in this review as protocols, have been devised to help reduce challenging patient behaviors that precede seclusion in an effort to reduce seclusion itself or help staff manage challenging patient behaviors when they occur; yet the effect of protocols on patient and staff outcomes and the resource needs required to implement these protocols remain unclear.[11-13,32] We therefore conducted a systematic review on protocols to reduce seclusion for adult patients in inpatient mental health units. In this report, we describe protocols and synthesize the evidence of the effects of the protocols in terms of high-priority clinical outcomes, resource utilization, and staff outcomes to help guide decision-making.

METHODS

TOPIC DEVELOPMENT

We worked with representatives from OMHSP and our technical expert panel (TEP), which included individuals from OMHSP, the VA Office of Nursing Services, and VA Inpatient Mental Health Program, to refine the review scope and develop the key questions (KQs). We focus on studies that report protocols to reduce seclusion practices for adult patients in inpatient mental health units. We define protocols as guidance documents or strategies recommended or already employed as alternatives to seclusion. Protocols needed to include multiple components or a general overall policy to reduce seclusion. We define seclusion as the use of involuntary time restricted to a space physically removed from other patients.

KEY QUESTIONS

KQ1: What protocols have been described to reduce seclusion practices for adult patients in inpatient mental health units?

KQ1.1: What are the described resource needs (such as personnel and space needs) of these protocols?

KQ2: What are the comparative effects of protocols to reduce seclusion practices on resource use, staff and unit practices, patient experiences, and staff experiences versus usual protocols?

PROTOCOL

A preregistered protocol for this review can be found on the PROSPERO international prospective register of systematic reviews (www.crd.york.ac.uk/PROSPERO/; registration number CRD42022363787).

DATA SOURCES AND SEARCHES

We conducted a preliminary search in PubMed which was focused on Medical Subject Headings (MeSH) terms for patient isolation and inpatient mental health, together with free text synonyms for both (identified from experts and a list of known relevant publications). Searches were expanded to capture additional terms identified in preliminary screening.

For our final searches, we searched PubMed, Embase, the Cochrane Register of Clinical Trials, PsycINFO, CINAHL, cairn.info, and ClinicalTrials.gov from date of inception to September 6, 2022 (see Appendix A for complete search strategies). Additional citations were identified from hand-searching reference lists of relevant systematic reviews and consultation with content experts. In addition to the above, for KQ1 we contacted VA experts to request relevant protocols (published or grey literature) on strategies to reduce seclusion practices.

STUDY SELECTION

Citations were uploaded into Endnote, where duplicates were removed. Remaining citations were uploaded into Abstrackr, abstract screening software (http://abstrackr.cebm.brown.edu).[33] Title and abstracts were reviewed for eligibility by a team of 8 researchers. To ensure

consistency and clarity of eligibility criteria, we held several pilot rounds of screening in which all team members screened the same set of titles and abstracts and any conflicts were resolved through discussion (Table 1). Subsequently, 2 independent reviewers screened titles and abstracts. Conflicts between screeners were resolved through group discussion or a third senior researcher.

Abstrackr uses machine learning algorithms to predict the likelihood that unscreened abstracts are relevant.[33] Based on empirical evidence, we stopped screening when all remaining unscreened abstracts had a prediction value of <0.40 (on a 0-1 scale), and subsequently 400 abstracts in a row were rejected. Full text of potentially relevant citations were obtained and rescreened for eligibility using an evidence mapping process by 1 researcher with confirmation of excluded articles by a second senior researcher. Although qualitative studies did not meet our eligibility criteria, they were noted of interest to the stakeholders, and thus isolated for bibliographic purposes during full-text review.

For KQ1, our focus was on reporting the characteristics/features of protocols to reduce seclusion in general inpatient psychiatric units for patients ≥18 years of age. Eligible records were either organizational documents of protocols to reduce seclusion or primary studies that described a protocol to reduce seclusion. These records did not have to report outcomes. To ensure relevance to the VA setting, we only included protocols produced by organizations in the US or Canada or protocols intended to be implemented in these countries for KQ1. Records had to describe protocols with a callout of how these may differ from usual seclusion protocols.

For KQ2, eligible populations were patients ≥18 years of age with psychiatric conditions being treated in hospital inpatient units or the frontline staff who worked in these units. Our focus was on the effects (or comparative effects) of protocols to reduce seclusion. To be included, studies had to compare protocols to reduce seclusion to some form of comparison (*eg,* another protocol to reduce seclusion or "usual care"). Recognizing the challenges of conducting RCTs and non-randomized controlled studies (NRCS) with concurrent control groups, we allowed for the inclusion of pre-post studies (*ie,* same unit assessed before and after the implementation of the protocol) to satisfy these criteria. We only included protocols intended to be implemented in the US or other high-income countries.[34]

For both KQ1 and KQ2, studies were excluded if they included incarcerated or institutionalized populations, as these settings and populations were outside the scope of interest to our stakeholders.

Table 1. Inclusion and Exclusion Criteria

	Inclusion Criteria	Exclusion Criteria
Population	• KQs 1 & 2: Adults with psychiatric conditions admitted (voluntary/involuntary) and being treated in hospital inpatient units • KQ2 (additional): Frontline staff and other psychiatric unit and hospital personnel	• Incarcerated • Institutionalized
Intervention	• Psychiatric unit-level protocols to reduce seclusion practices • Protocols to be defined by research study or organization guidance as strategies recommended (or already employed) as an alternative to seclusion. Protocols needed to include multiple components or a general overall policy to reduce seclusion (*ie,* not a single strategy only).	• KQs 1 and 2: Laws or regulations related to use/disuse of seclusion
Comparator	• KQ1: Not required explicitly (as KQ1 did not include an evaluation of protocols) but implicitly the protocols should be in contrast to seclusion practices. • KQ2: Usual seclusion protocols (*ie,* no protocol directly aimed at reducing or minimizing seclusion) ○ Example comparisons include: same unit pre-intervention (*ie,* pre-post protocols to reduce seclusion) or concurrent controls from other units that do not use protocols to reduce seclusion.	.

Outcomes	• KQ1: Descriptions of protocols, with explicit callout of how these may differ from usual seclusion protocols
	• KQ1.1: Center/unit/hospital resource use:
	  ○ Staffing needs and mix
	  ○ Environment (home-like vs clinical)
	  ○ Programming (*eg,* meaningful activities)
	  ○ Security personnel needs
	  ○ Space (*eg,* rooms) requirements
	  ○ Equipment needs
	  ○ Documentation needs (*eg,* patient engaged in treatment planning and update of treatment plan)
	  ○ Staff debriefings
	  ○ Other direct medical use
		• KQs 1.1 and 2: Dollar (or other currency) costs, hospital charges or payer costs, patient costs (direct or indirect), or other indirect costs/resources

Outcomes (continued)	• KQ2: Patient outcomes
	  ○ Injuries
	  ○ Aggressive incidents or behaviors
	  ○ Patient satisfaction with treatment (assessed post-hospitalization)	

	Inclusion Criteria	Exclusion Criteria
	○ Psychiatric medication use, either as needed, urgent/emergency, scheduled, or forced • KQ2: Staff outcomes ○ Staff/personnel injuries (including physical, emotional, or other harms to staff) ○ Staff/personnel satisfaction with policy ○ Debriefings (whether occurred and qualitative description) • KQ2: Process measures ○ Characteristics of seclusion events ▪ Episodes of seclusion ▪ Episodes of restraint ▪ Time in seclusion (per inpatient stay, and per episode) ▪ Time in restraint (per inpatient stay, and per episode) ○ Staffing ▪ Time to perform checks on patient ▪ Time to perform documentation ▪ Changes in other service provisions ○ Center/unit/hospital resource use ▪ Staffing needs and mix ▪ Security personnel needs ▪ Space (*eg,* rooms) requirements ▪ Equipment needs ▪ Documentation needs ▪ Other direct medical costs	
Timing	KQ1: Published since 2012 KQ2: No restrictions	
Setting	• In hospital inpatient units • KQ1: Produced by North American organizations or implemented or intended to be implemented in North America only • KQ2: High-income countries defined by the World Bank	• Emergency department, prisons, and outpatient settings • KQ1: Not produced by organizations in the US or Canada or implemented or not intended to be implemented in US or Canada • KQ2: Not intended to be implemented in US or other high-income countries

	Inclusion Criteria	Exclusion Criteria
Study Design	• KQ1: Organizational documents of protocols to reduce seclusion or intervention and observational studies (only for protocol descriptions) • KQ2: Comparative studies (pre-post same unit or comparison of units), interventional or observational, prospective or retrospective, surveys with explicit comparison of intervention and comparator	• Case studies, opinion pieces, letters, editorials • KQ1: Published before 2012

DATA EXTRACTION AND ASSESSMENT

For both KQs 1 and 2, we extracted details about the organization/research group that produced the protocol (*eg,* country, organization, rationale, process) and specific protocol elements. As protocol elements may have varied depending on the target of the element (staff vs patient), we extracted elements for staff and patients separately. We categorized extracted protocol elements into 1 of 9 Intervention Functions defined by the behavior change wheel (BCW), which characterizes behavior change interventions.[35] The framework is relevant to describing the protocols included in this review, as the protocols often tried to change behavior (staff, patients, or both) to reduce seclusion events. The 9 intervention functions include *education*, *persuasion*, *incentivization*, *coercion*, *training*, *restriction*, *environmental restructuring*, *modelling*, and *enablement* (Appendix B lists the intervention functions and their definitions). We also extracted resource use/needs associated with the protocols.

For KQ2, in addition to protocol characteristics, we extracted details on study design (RCT, concurrent non-randomized comparison, pre-post comparison), the setting and population it was implemented in (*eg,* hospital and patient characteristics), and patient, staff, and process outcomes (including seclusion and restraint events). Data extraction was conducted by 1 reviewer and confirmed by a second reviewer. Disagreements were resolved by consensus or discussion with a third reviewer.

Study risk of bias was independently assessed by 1 senior reviewer using questions derived from the Cochrane Risk of Bias and the ROBINS-I (Risk Of Bias In Non-randomized Studies - of Interventions) tools (Appendix C).[36,37] For all study designs, we additionally evaluated whether the article was free of discrepancies and reporting of patient eligibility criteria, protocols, setting, and outcome assessments were sufficiently clear. For RCTs, we also evaluated methods of randomization, allocation concealment, and whether staff were blinded. For NRCSs (with concurrent or pre-intervention controls), we evaluated selection of patients, characteristics of comparison ward, and strategies to deal with confounders.

SYNTHESIS AND CERTAINTY OF EVIDENCE

Due to extensive variability in settings, interventions, and measured outcomes, we synthesized results qualitatively. For KQ1, we described the characteristics of protocols, as well as factors associated with their design (*eg,* organization, intended setting) and potential implementation (*eg,* resource and staffing needs, where reported).

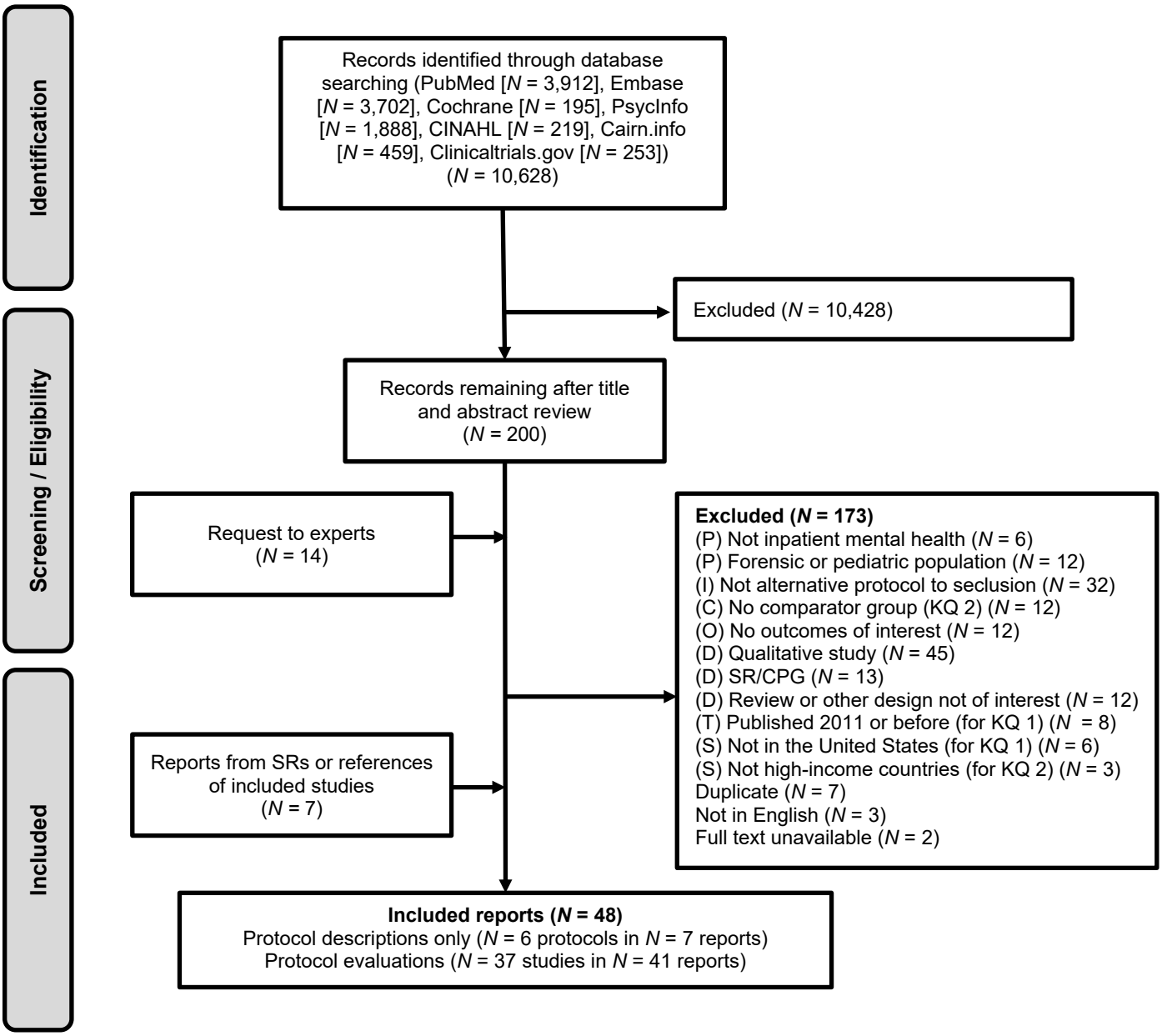
For KQ2, in addition to the information described for KQ1 about the protocols, we describe their design and their implementation. Additionally, we assessed the strength of evidence following the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach

for determining conclusions and certainty of evidence.[38] We compiled key study findings in evidence profiles, which provide the basis for determination of certainty of evidence and summarize conclusions for prioritized outcomes. Within each priority outcome, we considered the study design, the number of studies (and participants), methodological limitations (*ie,* risk of bias), directness of the evidence, precision of the findings, consistency across studies, and other issues. Based on these, we determined certainty of evidence, which could be high, moderate, or low. Where we found extremely limited evidence, we report that there is insufficient evidence to draw conclusions. We report our summary of findings for each outcome, within comparable protocol groups.

RESULTS

LITERATURE FLOW

Figure 1. Literature Flowchart



Abbreviations. C=comparator; CPG=clinical practice guideline; D=design; I=intervention; KQ=key question; O=outcome; P=population; S=setting; SR=systematic review; T=timing.

LITERATURE OVERVIEW

Of 10,628 citations obtained via database searching, 200 were retrieved for full-text review and evidence mapping. An additional 14 records were obtained through expert solicitation, and 7 records were obtained from references of included studies or previous systematic reviews. Upon reviewing the full-text articles, 48 reports were deemed eligible and were included for final review (Figure 1).[31,39-85] We found descriptions of 24 protocols implemented or developed in the US or Canada, of which 6 were described without reporting comparative results of implementing the protocols.[39-45] Overall, 37 studies described an empirical evaluation of protocols to reduce seclusion (in 41 reports), conducted in 9 high-income countries.[31,46-85] A list of studies excluded at full-text review is available in Appendix D. The most common reasons for exclusion included qualitative design (*N* = 45), lack of comparison to alternative protocols to seclusion (*N* = 32), and not being primary studies (13 systematic review for guideline and 12 other non-systematic reviews/editorials).

Table 2 shows the characteristics of the eligible records. Overall, 23 of the 43 protocols were from the US.[39-41,43-45,47,51,52,54,57,59,61,64,67,70,73-75,77,78,80,85] One protocol was from Canada.[62] Seven protocols were from the VA[41,43,44,70,77,78,85] and 4 of these were reported in comparative analyses.[70,77,78,85]

Table 2. Summary Characteristics of Eligible Studies

Characteristics	# Protocols Without Results	# Protocols With Results by Design		
	Protocols (n = 6[a])	RCT (n = 4[b])	NRCS (Concurrent) (n = 5)	NRCS (Pre-post) (n = 28[c])
Countries				
Australia/New Zealand (*N* = 7)	--	--	1	6
Canada (*N* = 1)	--	--	--	1
Finland (*N* = 1)	--	1	--	--
Germany (*N* = 1)	--	--	--	1
Netherlands (*N* = 3)	--	1	2	
Switzerland (*N* = 3)	--	1	--	2
United Kingdom (*N* = 4)	--	1	1	2
United States (*N* = 23)	6	--	1	16
VA Protocol				
Yes (*N* = 7)	3	0	0	4
No (*N* = 36)	3	4	5	24
Protocol Type				
Hospital/unit restructuring (*N* = 4)	--	--	--	4
Staff education/training (*N* = 3)	--	--	1	2
Sensory modulation (*N* = 7)	--	--	2	5
Risk assessment (*N* = 7)	--	2	--	5
Comprehensive/mixed (*N* = 22)	6	2	2	12

Characteristics	# Protocols Without Results	# Protocols With Results by Design		
	Protocols (n = 6[a])	RCT (n = 4[b])	NRCS (Concurrent) (n = 5)	NRCS (Pre-post) (n = 28[c])
Process Outcomes				
Seclusion (*N* = 25)	NA	2	2	21
Restraint (*N* = 15)	NA	1	1	13
Composite (*N* = 14)	NA	2	1	11
Patient Outcomes				
Patient injuries (*N* = 7)	NA	2	--	5
Aggressive incidents/behaviors (*N* = 14)	NA	3	1	10
Patient satisfaction (*N* = 3)	NA	1	--	2
Medication use (*N* = 5)	NA	--	1	4
Staff Outcomes				
Staff injuries (*N* = 5)	NA	--	--	5
Satisfaction with policy (*N* = 8)	NA	2	--	6
Staff debriefing (*N* = 1)	NA	--	--	1

Notes. [a] Reported in 7 reports; [b] Reported in 7 reports; [c] Reported in 25 reports.
Abbreviations. KQ=key questions; NRCS=nonrandomized comparative study; RCT=randomized controlled trial.

Appendix E shows the quality appraisal for all studies in the review, Appendix F shows the study design details (including the setting and study-level eligibility criteria) and Appendix G shows the baseline details for studies. Study eligibility criteria were at the inpatient unit level and consistent across studies, except for 1 study which also reported patient-specific exclusion criteria.[64] All studies included inpatient units with the capacity for seclusion, and units were often described as providing intensive or acute psychiatric care. The 37 studies reporting comparative data included 4 RCTs[31,60,66,69,81-83] and 33 NRCSs.[46-59,61-65,67,68,70-80,84,85] The 4 RCTs included 81 wards ($N > 11{,}341$[b]) and were conducted in Europe; they all relied on record linkage (based on staff self-report) to obtain primary outcome data, resulting in methodological concern. The 33 NRCSs included 99 wards ($N > 36{,}488$[c]) and were mostly conducted in the US ($N = 17$),[47,51,52,54,57,59,61,64,67,70,73-75,77,78,80,85] with the remaining conducted in Europe ($N = 12$),[46,48-50,58,60,66,68,69,76,79,82] Australia/New Zealand ($N = 7$),[53,55,56,63,65,72,84] and Canada ($N = 1$).[62] Most NRCSs were described as quality improvement projects and 4 were conducted in VA settings. Five of the NRCSs were prospective and involved identifying a contemporary comparison ward in the same hospital, health system, or region.[50,54,55,68,76] The remaining 28 NRCSs were pre-post studies evaluating data before and after a hospital/ward/unit change in seclusion protocol. All studies had methodological concerns of bias due to the self-report nature. In addition, most had concerns of bias due to lack of adjustment for confounding as only 5 of these studies analyzed some outcomes using multivariate regression to control for confounders.[46,50,72,76,77]

[b] One study (Bowers 2015) did not report patient sample size.
[c] One study (Blair 2017) did not report ward sample size and 17 studies (Rohe 2017, Bowers 2008, Forster 1999, Lloyd 2013, Azuela 2018, Sivak 2012, Clark 2010, Blair 2015, Dickens 2020, Hellerstein 2007, Khadivi 2004, Lewis 2009, McDonagh 2019, Pollard 2007, Richmond 1996, Stoll 2022 and Taxis 2002) did not report patient sample size.

Outcomes evaluated across studies varied and included episodes or time in seclusion ($N = 25$), episodes or time in restraint ($N = 15$), composite measures of coercion including some combination of seclusion, restraint, or forced medication use ($N = 14$), patient injuries ($N = 7$), aggressive incidences ($N = 14$), patient satisfaction ($N = 3$), medication use ($N = 5$), staff injuries ($N = 5$), staff satisfaction with policy ($N = 8$), and staff debriefing ($N = 1$).

In the following sections, we describe the identified protocols, report results by outcome (*eg,* episodes of seclusion and time in seclusion) for each grouping of protocols (*eg*, staff education), and present overall certainty of evidence for summary findings for each group of protocols regarding these outcomes.

DESCRIPTION OF PROTOCOLS TO REDUCE SECLUSION

Studies described diverse protocols of various elements targeted to staff and patients to reduce seclusion practices. Table 3 shows coded intervention functions of protocols. Protocols often contained elements designed to either reduce patients' aggressive and agitated behavior (*eg,* calming environments, patient-specific strategies to self-soothe) or elements to reduce use of seclusion by staff (*eg,* education on alternative strategies, modeling by peers). The most common elements across interventions included *education*, *persuasion*, *training*, and *environmental restructuring* (including efforts to shift the ward culture). Less common, but still present were elements relating to *incentives*, *restrictions*, *enablement*, or *modelling* (for example, by more experienced peers). Based on our intervention function coding and the stated aims and hypotheses of these protocols (Appendix H), we grouped protocols into 5 categories. From least to most intensive, these included:

1) **Hospital unit/restructuring** ($N = 4$)[46-49]
2) **Staff education/training** ($N = 3$)[50-52]
3) **Sensory modulation** ($N = 7$)[53-57,59]
4) **Risk assessment and management protocols** ($N = 7$)[60-66]
5) **Comprehensive/mixed** ($N = 22$)[31,39-45,67-85]

Below we first describe the features of the protocols within each group, and then we describe the results for comparative studies within each group.

Table 3. Coding of Intervention Functions Across KQ1 and KQ2 Reports

	Staff Behavior Targets										Patient Behavior Targets									
Author, Year	Education	Persuasion	Incentivization	Coercion	Training	Restriction	Environment	Modelling	Enablement	Other	Education	Persuasion	Incentivization	Coercion	Training	Restriction	Environment	Modelling	Enablement	Other
Hospital/Unit Restructuring (N = 4 Studies)																				
Hochstrasser, 2018, pre-post							x										x			
Hunter,1993, pre-post							x				x		x			x	x			
Jenkins, 2014, pre-post							x										x			
Rohe, 2017, pre-post																	x			
Staff Education/Training (N = 3 Studies)																				
Bowers, 2008, concurrent		x						x												
Forster, 1999, pre-post	x	x			x															
Haefner, 2021, pre-post	x	x			x												x			
Sensory Modulation (N = 7 Studies)																				
Lloyd, 2013, concurrent	x	x			x		x		x		x	x					x		x	
Cummings, 2010, concurrent		x					x		x		x	x				x	x			
Azuela, 2018, pre-post		x			x		x										x			
Sivak, 2012, pre-post	x						x				x	x	x			x	x		x	
Novak, 2012, pre-post	x	x					x				x	x					x			
Smith, 2013, pre-post							x										x			
Zimmermann, 2020, pre-post	x						x				x						x			
Risk Assessment (N = 7 Studies)																				
Abderhalden, 2008, RCT	x	x					x													
van de Sande, 2011, RCT					x		x		x											
Blair, 2017, pre-post					x	x	x										x			
Clarke, 2010, pre-post	x						x													
Harrington, 2019, pre-post	x	x			x		x				x	x					x		x	
Manning, 2022, pre-post	x	x			x	x	x					x				x	x		x	
Trauer, 2010, pre-post	x	x			x		x				x	x					x		x	
Comprehensive/Mixed (N = 16 Studies and N = 6 Protocols Without Evaluation Results)																				
Protocols with evaluation results																				

Author, Year	Staff Behavior Targets										Patient Behavior Targets									
	Education	Persuasion	Incentivization	Coercion	Training	Restriction	Environment	Modelling	Enablement	Other	Education	Persuasion	Incentivization	Coercion	Training	Restriction	Environment	Modelling	Enablement	Other
Bowers, 2015, RCT	x	x			x		x	x	x			x					x		x	
Valimaki, 2022, RCT	x	x			x				x											
Boumans, 2014, concurrent	x	x			x		x		x										x	
Noorthoorn, 2014, concurrent					x		x		x						x	x			x	
Blair, 2015, pre-post		x			x		x				x	x					x		x	
Dickens, 2020, pre-post	x				x															
Hellerstein, 2007, pre-post	x	x				x	x					x					x		x	
Khadivi, 2004, pre-post	x				x		x												x	
Lewis, 2009, pre-post		x			x		x		x			x					x		x	
McDonagh, 2019, pre-post	x	x			x		x	x			x				x		x			
Pollard, 2007, pre-post	x	x					x													
Richmond, 1996, pre-post	x	x			x															
Stoll, 2022, pre-post		x																		
Taxis, 2002, pre-post	x	x			x		x				x				x		x		x	
Whitecross, 2020, pre-post	x						x	x												
Zuehlke, 2016, pre-post					x		x		x			x					x		x	
Protocols Without Evaluation Results																				
APNA statement, 2018	x	x			x	x	x										x			
Ashcraft, 2012	x	x			x	x	x				x	x								
Clement, 2021	x	x			x	x	x				x	x					x			
Iwamasa, 2017	x	x			x		x		x	x	x	x					x			
VA Northern California HCS					x	x	x		x			x								
Wale, 2011	x	x	x		x	x				x					x					

Abbreviations. APNA=American Psychiatric Nurses Association; HCS=Health Care System; KQ=key question; RCT=randomized controlled trial.

Hospital/Unit Restructuring

Four pre-post studies (conducted between 1989 and 2015) evaluated physically redesigning an inpatient unit/ward and seclusion outcomes.[46-49] Two studies were conducted in Europe,[46,49] 1 study was conducted in the United Kingdom,[48] and 1 in the US.[47] The studies were conducted in single hospitals with 1,[48] 2,[47] 10,[49] and 15[46] psychiatric units; none of the studies were conducted in a VA setting. The protocols were all locally produced by the hospital in which they were implemented. In 3 cases, restructuring was in response to identified site-specific limitations that were impacting care and possible use of seclusion (*eg,* dated building, staff shortages, change in patient caseload).[47-49] In the fourth study, the authors noted the hospital's motivation to restructure was based on findings reported in the literature.[46] While all implied that the restructuring would lead to reduced use of seclusion, only 1 study stated this hypothesis explicitly.[46] One study hypothesized the new ward environment would be associated with a reduction in arousal and aggression levels.[48] Patient sample size ranged from 18 to 2,924. Patients tended to be in their 40s and often had diagnoses of schizophrenia or mood (affective) disorders.

Environmental restructuring (*ie,* changing the physical or social context) was the common intervention function across the 4 studies. Hochstrasser et al described the implementation of an open-door policy in a Swiss hospital in which 6 previously closed wards were permanently opened in conjunction with a culture shift towards patient-centered and recovery-oriented care.[46] Hunter et al described restructuring an existing locked-door program in the US into 3 complimentary programs that included an intensive care unit, an unlocked day program, and a transitional residential program.[47] Rohe et al described a contemporary building in Germany that replaced the existing 19th century building, outfitting it with open, warm, and bright rooms.[49] Finally, Jenkins described the development of a new ward with better layout, visibility, and therapeutic activity space, in response to an independent assessment that identified environmental difficulties with the old ward.

Hunter et al also included elements of *education* (*ie,* increasingly knowledge or understanding), *incentivization* (*ie,* creating expectation of reward), and *restrictions* (*ie,* using rules to reduce the opportunity to engage in the target behavior or opportunities to engage in the competing behavior), depending on which program patients were triaged.

Only 2 studies reported on the resource needs required for unit restructuring (Appendix I shows intervention resource needs).[47,48] Hunter et al described different *staffing* levels per unit with mental health workers monitoring the residential day program and nurses operating the intensive care unit for high-risk patients. Importantly, when patients were admitted to the hospital, they were assigned a multidisciplinary care team who followed them across units. The study also described changes in *documentation* associated with the restructuring and the introduction of recreation *programming*.[47] Jenkins described *space* requirements needed for the new ward.[48] This included single bedrooms with ensuite facilities to enhance privacy, gender-specific areas, a designated activities room and visiting area, and a seclusion area conforming to the Department of Health guidelines.[48]

All 4 pre-post studies evaluating the impact of hospital/unit restructuring on seclusion practices relied on self-reported outcome data. Three studies conducted only crude analyses and were at

high risk of bias for confounding.[47-49] One study conducted multivariate regression to control for confounders for some key outcomes and had medium risk of bias for confounding.[46]

Staff Education/Training

Two pre-post studies[51,52] and 1 study with a concurrent comparison group[50] (all conducted between 1995 and 2019) evaluated the impact of staff education and/or training on seclusion practices. The concurrent comparison study (which also evaluated outcomes pre-post in the ward implementing the protocol) was conducted in the United Kingdom.[50] The study compared patients in 3 wards where staff received training in conflict and containment strategies (City Nurse intervention; *eg*, positive appreciation of patients and skills to manage response to patient behaviors including low-conflict, low-containment, high-therapy nursing) to 5 wards in the same hospital where staff did not receive the training.[50] The study did not report a sample size, but noted a 58% response rate (N = 5,316) on the patient-staff conflict checklist shift reports (PCC-SR), which was a tool completed by a ward nurse at the end of each shift to document patient behavior and ward containment measures.[50] One pre-post study (N = 5,570) was conducted in an 83-bed acute urban psychiatric hospital in the US and compared the 12 months after the implementation of mandatory staff training on management of behaviors and hospital wide charting to 12 months before the intervention.[51] Another pre-post study (N = 730) was conducted in a 37-bed psychiatric unit located in the US and compared the 2 months after nurses underwent training in verbal de-escalation (TeamSTEPPS intervention) to 2 months before the training.[52] Neither of these studies were conducted in the VA. There was inconsistent reporting of patient sample size and patient characteristics. One study did not report patient sample size[50] and only 1 study reported details about diagnoses of the sampled patient population.[52]

Two studies[50,52] implemented previously tested and named protocols (City Nurse and TeamSTEPPS intervention), while 1 study tested a hospital-specific protocol developed by a multidisciplinary workgroup that sought to support a local policy to reduce seclusion and restraint.[51] The common intervention element across these interventions was *persuasion* (*ie,* using communication to stimulate action), with elements of *education*, *training* (*ie,* imparting skills), or *modelling* (*ie,* providing an example for people to aspire to or imitate) also present. Persuasion related to how the protocol was implemented (whether top-down[51,52] or negotiated with staff[50]) but also to how staff were encouraged to view and respond to patients (*eg,* City Nurses encouraged staff to "appreciate" patients;[50] TeamSTEPPS encouraged staff to have a more "authentic engagement" with patients and to use verbal de-escalation techniques to manage aggressive behavior).[52] Staff training generally consisted of online modules and in-person demonstrations of de-escalation techniques and alternative strategies to seclusion.[51,52] Additionally, the City Nurses intervention used modelling (of 2 nurses recognized as clinical experts in acute inpatient care) to work with ward staff 3 days per week to demonstrate how to reduce conflict and containment and increase positive ward culture.[50]

The primary resource named across the 3 studies was *staffing*. Two interventions[51,52] employed multidisciplinary teams in their design, including the involvement of registered nurses, psychiatric pharmacy technicians, psychiatric nurse practitioners, social workers, occupational therapists, and activity therapists. These interdisciplinary teams met regularly to inform intervention development and implementation. The City Nurses program[50] required the appointment of 2 lead nurses, who were identified as clinical experts in inpatient psychiatric care with experience in practice development.

The concurrent design study did not report the characteristics of patients in the comparison ward and relied on self-reported outcome data, but did conduct multivariate regression to control for confounders for some outcomes.[50] Both pre-post studies relied on self-reported outcome data and used crude (unadjusted) analyses to evaluate all outcomes, and thus were at high risk of bias for confounding.

Sensory Modulation

Seven NRCSs (2 concurrent comparisons[54,55] and 5 pre-post[53,56-59]) conducted between 2011 and 2020 (where reported; Cummings et al did not report date of study conduct[54]) compared units with a sensory modulation room to a comparison unit or a period before the unit installed the sensory modulation room. Three studies were conducted in the US,[54,57,59] 3 were conducted in Australia or New Zealand,[55,53,56] and 1 was conducted in the United Kingdom.[58]

One concurrent comparison study was conducted in a single Australian hospital with 2 20-bed acute inpatient psychiatric units (patients or number of admissions was not reported).[55] Another concurrent comparison study (which also involved a pre-post comparison) was conducted in the US in 2 acute inpatient units in a large psychiatric hospital.[54] One dissertation using a pre-post design was conducted in New Zealand in 2 inpatient units (sample sizes were unclear).[53] Unit A had 29 beds focused on assessment, treatment planning, and group activities, and unit B had 26 beds focused on people with acute episodes of mental illness. Another pre-post study was conducted in Australia in a single hospital 40-bed acute inpatient psychiatric unit.[56] One pre-post study was conducted in the United Kingdom in an inner city male-only 15-bed inpatient psychiatric unit.[58] Two pre-post studies were conducted in the US in rural mental health hospitals.[57,59] None were conducted in a VA setting. Only 2 studies reported sample size data at the patient level ($N = 321$ admissions[59] and $N = 75$ seclusion events [56]).

With the exception of 1 study,[54] all sensory modulation rooms were informed by previous literature,[86-91] although the studies typically described the sensory modulation rooms as being iteratively designed with staff and patient input. Studies hypothesized that sensory modulation rooms would help patients reduce or manage experiences of distress through various sensory stimuli, which would in turn reduce rates of aggression and seclusion on the unit.

Given that the sensory modulation room involved a change of the physical ward space, all studies involved the *environmental restructuring* intervention function. Rooms were designed to meet the multisensory needs of patients, with light colored walls, soothing artwork, or patient-selected murals, and included various features and materials to engage and calm patients such as comfortable seating (*eg*, recliners, rocking or beanbag chairs), TV and videos, CD player and calming music, scented sprays, drawing materials, games and puzzles, and other sensory tools (*eg*, weighted blankets, stress balls, fidget spinners).[53,54,56-59] Five studies provided *education* to staff and/or patients to make them aware of the sensory modulation room and how to use it,[54-57,59] and 1 study provided in-depth staff *training* on competencies and skills for using the sensory modulation therapeutically (*eg*, sensory assessments, selection of sensory modulation therapeutic activities, therapeutic demeanor and attitude while using the sensory modulation room, *etc*).[53] Most studies also included the element of *persuasion,* whereby staff and patients were encouraged to use the rooms for early intervention when patients were feeling distress.[53-57] Some studies encouraged patients to bring their own sensory modulation material, like music,[54] and to keep the room in good condition so others could use it later.[57] Two studies tried to ensure

stakeholder buy-in by involving staff[54] and patients[57] in the planning and implementation of sensory modulation rooms. Two studies implemented *restrictions* associated with the sensory modulation rooms such as continuous video monitoring and staff entry privileges should patient behavior become unsafe[54] or requirement that patients sign an agreement prior to their use of sensory modulation rooms (patients who were unable or unwilling to sign the agreement form were not allowed to use the sensory modulation room).[57] Several studies included elements of *enablement* (*ie,* increase means/decrease barriers to increase capability or opportunity) by tailoring sensory modulation rooms to the specific needs and requests of patients,[55,57] and supporting patients to voluntarily use the sensory modulation room if they find it helpful.[54,55,57]

The most common resource need for sensory modulation interventions was the *space* and *equipment* to facilitate the intervention. Typically, 1 room on each unit was converted into the sensory modulation room, named the "comfort room" or "serenity room,"[54-59] and spatial modifications spanned ambient lighting, paint, wallpaper, and chalkboard walls. *Equipment* needs included musical instruments or CDs, sound machines and other auditory equipment to promote relaxation, comfortable furnishings, and other sensory modulation items.[54-56,58,59]

All 5 studies had high risk of bias for performance bias due to self-reported outcome measures and high risk of bias for confounding due to their NRCS design and lack of adjusted analyses.

Risk Assessment and Management Protocol

Seven studies (2 RCTs[60,66] and 5 pre-post[61-65]) compared interventions that incorporated a structured risk assessment and management protocol to usual care. Three of the studies did not report their dates of study conduct (published 2010-2022); the remaining 4 were conducted between 2002 and 2012. Both RCTs were conducted in Europe,[60,66]; 2 pre-post studies were conducted in the US,[61,64] 2 in Australia,[63,65] and 1 in Canada.[62] No study was conducted in a VA setting.

One cluster RCT was conducted in 14 wards (N = 2,364 total) across multiple hospitals in Switzerland; 4 wards were randomized to the intervention, 5 wards were randomized to wait-list control, and 5 wards were not randomized but preferred to implement the structured risk assessment intervention immediately (concurrent, non-randomized control) – we report results for only the randomized comparison.[60] The other cluster RCT, conducted in a single hospital in the Netherlands, randomized 2 wards (N = 36 beds total) to the intervention and 2 wards to the control group (practice as usual) and included all patients admitted to these units during the study period in the trial (N = 458).[66] The remaining 5 pre-post studies were all conducted in a single-hospital setting and evaluated outcomes before and after the implementation of a structured assessment protocol.[61-65]

Four studies (2 RCTs and 2 pre-post) evaluated wards that implemented the Brøset Violence Checklist, which is a 6-item instrument administered by clinical staff to predict conflict behaviors.[60-62,66] The 2 European RCTs (N = 2,822) compared wards where staff were trained to administer the Brøset Violence Checklist at admission to usual care wards.[60,66] One pre-post study reported outcomes before and after an 11-bed psychiatric intensive care unit started using the Brøset Violence Checklist. The study did not report a sample size.[62] Finally, 1 study compared outcomes before and after a 120-bed psychiatric hospital implemented the Brøset Violence Checklist, which it combined with other evidence-based strategies for reducing violence and aggression on the ward (N = 11,913 admissions).[61]

Three pre-post studies evaluated interventions that included investigator-developed or -modified risk assessment tools.[63-65] One pre-post study evaluated a risk assessment tool and management guideline developed by a hospital using a participatory action framework (N = 2,055).[63] Another pre-post study evaluated a risk assessment protocol that incorporated a modified version of the Agitation Severity Scale (N = 742).[64] Finally, a third pre-post study evaluated the Management of Acute Arousal Program protocol (N = 281).[65]

The central hypothesis of the studies using risk assessment tools was that their implementation would help staff to identify potentially aggressive patients to direct clinical efforts towards (*eg,* de-escalation techniques). All studies involved the intervention function *environmental restructuring,* as the implementation of the risk assessments changed the social context of how patients were managed in the unit. Risk assessments became part of standard care, both on admission and regularly during patients' stay, and were incorporated into clinical decision-making[65,66] and triaging patients to different risk categories to receive behavioral interventions and staff care tailored to their level of risk.[63,64] In addition to the risk assessments, studies made additional environment modifications such as increasing staff presence in the "milieu,"[61] having staff perform ward checks every 2-3 hours,[63] identifying patient-specific coping strategies on admission,[61] and introducing sensory modulation rooms.[61] Two studies also introduced greater clinical and administrative oversight associated with seclusion, restraint, and aggressive events (*eg,* clinical directors examined all seclusion and restraint events to determine if formal administrative review was needed,[61] and nurses involved in aggressive incidents were interviewed to see if they could have been prevented[62]).

All of the studies also involved elements of *education* and *training* to teach staff how to use the assessments[62,63,65,66] and act on their results (*eg,* treatment recommendations).[60,63,64] One study also implemented a 2-day training program based on a trauma-informed model of care to reduce staff behaviors that may worsen trauma-related behaviors in patients.[61] Should a seclusion event occur, 1 study offered patients the opportunity to debrief with a member of staff who had not been involved in the incident.[65] Some studies also included various elements of *persuasion* to encourage staff to use the tools,[63,65] to discuss preventive measures with patients and encourage them to engage with these measures,[60,63] to encourage specific treatments,[64] and to use the tools to problem solve as a clinical team.[60] One study encouraged patients to voluntarily take some time out.[65]

To further reduce the use of seclusion and restraint, 1 study *restricted* the length of time a patient could remain in seclusion without renewal of the order from 4 to 2 hours.[61] Another study only allowed the use of seclusion and restraint as a "last resort" for patients scoring above 9 on the modified Agitation Severity Scale combined with physician notification.[64] Finally, 3 studies used *enablement* to engage and encourage patients to be part of their own self-management in selecting strategies to support them.[63-65]

The central resource requirement for the 6 risk assessment studies was *documentation* needs to collect information on symptom severity and mental status via risk assessment scales,[60-66] and for post-event reviews of seclusion events.[61] *Time to perform documentation* was reported by 6 of the studies[60,62-65] with initial risk assessments occurring shortly after admission (*eg,* within 72 hours) and at regular intervals throughout the patient's hospitalization. *Time to perform checks on patients* was also included in 2 interventions.[61,63]

All 7 studies were high risk of bias for outcome ascertainment due to the self-reported nature of the outcomes. All 5 pre-post studies conducted crude analysis and thus were deemed high risk of bias for confounding bias.[61-64] In addition, in 2 studies it was unclear whether the comparator group was similar, [62,63] and in 2 studies it was unclear whether patients were selected at random.[62,64]

Comprehensive/Mixed (Protocols Without Empirical Data, KQ1)

All 6 intervention protocols captured under KQ1[39-45] were developed in the US, with 3 protocols [41-44] produced by VA hospitals. One protocol was published by the American Psychiatric Nurses Association,[39] 1 by New York City Health and Hospitals Corporation,[45] and 1 by Recovery Innovations Inc.[40] The protocols included comprehensive recommendations for staff education and training, culture change headed by organization leadership, as well as limitations on the use of seclusion and restraint with an emphasis on least-restrictive alternatives.

Most protocols included an element of *education*, with staff provided information on alternatives to seclusion and restraint and the organization's goal to reduce coercive and restrictive practices.[39-43,45] Patient education provided information on behaviors that require the use of seclusion and restraint and the criteria for discontinuation[41] as well as brochures for patients and families, including a voluntary treatment agreement.[42,43]

The use of *persuasion* was common across the protocols, with direct messaging from organization leadership to staff for commitment to recovery-oriented care and practices to reduce seclusion and restraint reported in 3[39,40,42,43] guidance documents. Other forms of persuasion entailed oversight and dissemination of performance improvement efforts to reduce the use of seclusion and restraint.[39, 40,45] The Code Green response protocol[41] emphasized that any employee concerned with a patient's potential for a behavioral emergency should notify the care team to trigger clinical consultation that may avert the need for restrictive practices.[44]

Five[39-41,44,45] protocols explicitly discussed the function of *training,* with all recommending de-escalation practices. Attention was also paid to the identification of patient risk factors[41] and sensory modulation training.[45] One protocol[45] involved a 2-day training program for staff which introduced the 6 core strategies to reduce seclusion and restraint, including primary and secondary prevention, leadership roles and responsibilities, key characteristics of trauma-informed care systems, use of data to inform practice, modifiable environmental factors, rigorous post-event debriefing, and consumer and family roles in the inpatient setting.

Some protocols incorporated *restriction* into their interventions, with the most common requirement being the use of least-restrictive alternatives prior to the initiation of seclusion and restraint.[39,41,44] The No Force First policy[40] included a mandate from the CEO that seclusion and restraint would no longer be permitted at any company facility. Other forms of restriction pertained to the time allowed for seclusion and restraint.[39,45] One protocol[41] also specified that a licensed independent practitioner must be notified within 1 hour of seclusion and restraint initiation if an order had not previously been entered into the electronic health record.

Five[39-44] protocols included *environmental restructuring* to modify the physical and social context of the inpatient unit. Three protocols[39,40,42,43] discussed the need to establish a work culture conducive to a reduction in seclusion/restraint, which included safety and recovery-oriented care. One[42,43] protocol stressed the need to develop "home-like, non-institutional, and

patient centered environments," while another[40] highlighted that the staff-patient relationship should be viewed as a partnership of "risk-sharing" rather than "risk management" control. Facility leadership were identified as responsible for ensuring policy compliance,[41] maintaining structures and resources for program implementation,[39] and promoting a therapeutic relationship between staff and patients.[42,43] Changes to the physical environment spanned the use of "quiet" or "comfort" rooms,[42-44] sensory tools,[41] and evaluations of light and noise levels[42,43] to promote a calming environment. Multiple protocols noted a change in social context via seclusion/restraint data reviews.[41,42,43] The Code Green response[44] protocol involved a stepwise modification to the physical environment including a paging system announcement of the Code Green, the removal of nonessential staff and patients from the area, a response team huddle, and movement of the patient to an enhanced monitoring location.

A consistent resource need across the 6 protocols was *staffing*. One protocol[45] created a new position entitled the Behavioral Health Associate who specialized in crisis prevention and de-escalation to take over some duties of hospital police, while 2 protocols [40,42,43] incorporated peer-support specialists onto the unit. Other staffing requirements included multidisciplinary care coordination[41] and the Code Green response team[44] headed by a response leader with the specification that therapeutic containment required at least 3 team members. *Documentation* needs were prevalent,[41-44] particularly in the electronic health record for seclusion/restraint event details that included record of which alternative interventions were deployed and their outcomes. One protocol[40] created an "electronic recovery record" for patients and staff to create wellness plans and track progress. Four protocols[40-44] maintained *staff debriefing* needs, with 2[42-44] specifically noting that debriefing must occur within 48 hours of a seclusion/restraint event. Three[40-43] protocols also defined *programming* needs such as morning recovery activities to create a sense of community[40] and recreational activities.[41,42,43]

Comprehensive/Mixed (Empirical Evaluations, KQ2)

Sixteen studies (2 RCTs,[31,69,82,83] 2 concurrent comparison,[68,76] and 12 pre-post)[67,70-75,77-80,84,85] conducted from 1992 to 2020 evaluated comprehensive/mixed approach interventions. Nine studies[67,70,73-75,77,78,80,85] were conducted in the US, of which 4 were in a VA Medical Center.[70,77,78,85] One VA study was a poster that presented minimal methodological details.[70] Five studies were conducted in Europe[68,69,76,79,82] and 2 in Australia.[72,84] Sample size varied across studies (range: 352 to 8,349 patients),[68,74,76,79,82,84,85] with several studies not reporting these data.[67,70,73,75,77,78,80] Unit or hospital characteristics were also inconsistently reported across studies (range of 15 to 437 beds).[70,73,74,78,80,84,85]

Comprehensive interventions were described as multicomponent and included a variety of intervention functions aimed at targeting multiple levels (hospital, staff, patients) and determinants (knowledge, capability, motivation, procedures of care [and self-care]) to prevent aggressive behaviors and subsequent use of coercive measures. The most common intervention functions targeted towards staff included *education*, *persuasion*, *training*, and *environmental restructuring*. The most common intervention functions targeted towards patients included *persuasion*, *environmental restructuring*, and *enablement*. Two studies (1 RCT[69] and 1 pre-post[72]) evaluated the Safewards intervention. We describe the intervention details and results for the Safewards protocol first followed by the results from the remaining comprehensive protocols.

Safewards

Two studies (1 RCT[69] and 1 pre-post [72]) evaluated the Safewards intervention, which consists of 10 components to reduce conflict and use of coercive measures on inpatient wards. These include: 1) published standard of behaviors for patients and staff, 2) advisory statements to handle flashpoints, 3) de-escalation training, 4) requirement to compliment patients at nurse shift change, 5) protectively identify and intervene when patients receive bad news from friends/family, 6) shared information between staff and patient (*eg*, favorite sports team), 7) regular group meetings for patients, 8) easily available sensory modulation tools, 9) reassurance following frightening incidence, and 10) display positive messages throughout the ward from discharged patients.[69] These components were coded as having elements of *education*, *persuasion*, *incentivization*, *training*, *environmental restructuring* (including restructuring of the social context), *modelling*, and *enablement*. The Safewards intervention was designed (in collaboration with expert nurses, service users, and carers)[69] to address determinants of conflict and containment identified in the Safewards Model.[31]

In the RCT, 31 wards at 15 hospitals within 100 km of central London were randomized to receive the Safewards intervention or a control condition. Control wards implemented an intervention to improve staff physical health (*eg*, healthy snacks and incentives to do physical activity).[69] Although staff in each group were not blind to the intervention they received, they were blind to the research hypothesis (*ie,* that Safewards would be more effective than the physical activity control). Both arms of the study were led to believe that the intervention they received would lead to lower rates of conflict and coercive measures. Thus, as described by the study authors, the comparator arm "controlled for both researcher attention and participant expectancy."[69] Randomization was at the ward level and the study did not provide data on number of patients in each unit. The pre-post study compared 8 wards in a large health district in Australia that implemented the Safewards intervention to a period before the units used the intervention.[72]

Both Safewards studies reported *equipment* resource needs to carry out the intervention, with sensory "crates" and "boxes" deployed on the units that contained stress toys and mp3 players with calming music.[69,72] An additional resource was related to *staffing,* since the Safewards intervention required nursing staff to actively engage with the care model and implement new activities.[69]

Both studies had high risk of bias; they relied on self-reported outcome data and had a high degree of missing data.

Other Comprehensive Protocols

Fourteen studies evaluated comprehensive/mixed protocols with different components that could include staff training, patient education, efforts to improve communication between staff and patients, interdisciplinary clinical team-based approaches, staff/team meetings to discuss cases and alternatives to restraints or seclusion, and proactively identifying patients at risk for restraint/seclusion, among others.[67,68,70,73-81,84,85] Seven studies[67,68,75,76,79,82,85] evaluated interventions that sought to improve or modify elements of ward culture (including staff attitudes towards patients and use of seclusion as a justified course of action), 2 studies explicitly mentioned evaluating interventions that were compliant with Joint Commission mandates,[74,77] and multiple studies noted Joint Commission mandates as a motivation for the development of an

intervention. Eleven protocols were implemented in a single hospital (with 1 to 5 inpatient units, offering 7 to 88 patient beds, where reported).[67,68,70,73-75,77,78,80,84,85] Two protocols were implemented in 2 hospitals (both in 2 units with bed capacity ranging from 19 to 45 each),[76,79] and 1 protocol (an RCT) was implemented in 15 hospitals with 28 inpatient units.[82] Patient sample sizes and characteristics were rarely reported.

Most interventions included the element of *education*. The content of staff education varied from informing staff on the content of intervention/alternative approaches to care (*eg,* recovery-oriented care),[70,82,84] clarifying appropriate indications for seclusion and alternatives to seclusion,[73,77,78,80] information on what agitates patients in their care and how they would prefer to be treated in moments of agitation,[73] and education on the ethical concerns and negative effects of seclusion.[68,80] Patient education involved content to support patients in their self-monitoring and self-care during periods of agitation[70,80] and to inform patients about the model of care (*eg, trauma informed)*.[67]

Many interventions also included the element of *training* to help patients and staff adopt the intervention and/or change their behavior to reduce aggressive episodes and seclusion events, respectively.[68,70,74-76,78,80,82,85] Staff-directed training could include training on preventing and managing patient aggression,[67,74,76,78,82] improving patient relationships,[75,76] improving ward culture,[67,82,85] and specific alternatives to seclusion.[67,75,78] One study provided staff with feedback on the quality of staff's care plans (designed with the study's new model, the Methodical Work Approach), and trained staff on how to used evidence-based principles of searching and reviewing the evidence to refine their care plans.[68] Patient-directed training was used to help patients develop detailed behavioral goals and support collaborative relationship building between staff and patients.[80] One study in a VA medical center provided patients with recovery and management training and social skills training.[70]

Persuasion was often used to reinforce education and/or training, as staff were encouraged by study leaders, hospital administration, or peer champions to change their behavior to align with the new protocols.[67,70,73,75,77-80,82] Two studies seemed to try to persuade staff to use the new protocol by engaging them in the design and implementation of the new processes.[70,77]

Interventions also implemented various forms of *environmental restructuring* to change physical or social context of the wards. Restructuring included adding new staff[70,73] or reorganizing existing staff to better support patient needs (*eg,* the multidisciplinary on-call Psy-BOC team to respond to escalating behaviors of concern),[67,84] introducing new structures (*ie,* calming room),[67,80] self-management plans,[67] or programming for patients,[67,70,85] and introducing new staff/ward processes such as behavioral risk and response assessments,[67,74-76] community meetings and shared meals with staff and patients,[67] regular staff meetings,[67,75,76,85] and staff performance feedback.[76,80] Should a seclusion event occur, processes of debriefing were put in place (often with senior clinicians or ward leadership) to identify factors contributing to the event, determine if alternatives to seclusion were attempted, and ultimately to determine if seclusion was justified.[67,74,75,77,80]

Some studies used the intervention function *enablement*, most commonly to engage and empower patients (and sometimes their families) to work collaboratively with staff towards their care and treatment goals (*eg,* selecting goals, identifying preferential interventions, opening lines of communication to refine over time, breaking down barriers of control-based care).[67,68,75,80,82,85]

One study adapted policies to allow for off-unit privileges earlier during hospitalization.[73] One study also noted efforts to empower staff in terms of decision-making during acute situations and celebrating staff initiatives for improved patient care.[67]

Finally, a few studies also included elements of *modelling* (*eg*, expert guidance and demonstration of the new behaviors)[70,84] and *restriction* (*eg,* clear boundaries for acceptable/not acceptable patient behavior [76] and procedures for when seclusion was allowed and for how long).[73]

Nine studies identified *staffing* as a resource need[67,68,70,73-75,80,84,85] with the incorporation of multidisciplinary teams reported by 2 studies.[84,85] Other staffing requirements included staff-led training and ongoing coaching,[80] coordination across hospital departments for patient programming,[70] and availability of staff to escort patients off-unit as part of the de-escalation process[73] or remaining with challenging patients as needed.[67] Ten studies cited *documentation* resource needs,[67,68,70,73-76,78,80,85] with 5 studies[70,74,75,78,80] including documentation of seclusion or restraint event details, debriefings, or review processes such as a record of which least restrictive alternative(s) were used and the outcome of these interventions. Six studies[67,73-76,85] introduced documentation to capture history of aggressive behavior and information on effective coping methods. Furthermore, 4 studies[67,70,80,85] reported *programming* needs. Group therapy was implemented by 2 studies,[70,80,85] with a VA study[70] providing 4-6 hours of programming per day which included offerings such as social skills training and occupational/resume building workshops.

Two studies (1 concurrent comparison[76] and 1 pre-post study[77]) conducted multivariate regression to account for confounders; the remaining 12 studies conducted crude analyses and thus were at high risk for cofounding bias. All studies used self-report data for outcomes and thus were at high risk for performance bias.[67,68,70,73-75,78-80,82,84,85]

EFFECT OF HOSPITAL/UNIT RESTRUCTURING

Based on evidence from 4 pre-post studies,[46-49] restructuring units to include architecturally positive attributes and open-door privileges may reduce episodes of seclusion, duration of seclusion, duration of restraint, and forced medication use (Table 4). We have low confidence in these findings because studies had serious methodological limitations (relied on self-reported outcome data and conducted crude analyses) and there was some inconsistency in findings between studies for episodes of seclusion, restraint, and patient outcomes. Studies provide insufficient evidence (no conclusion) regarding episodes of restraint, other patient outcomes, and staff outcomes. The studies did not evaluate a composite measure of coercion.

Seclusion

Three pre-post studies compared a period with hospital redesign (including 2 studies that implemented open wards) to a pre-hospital restructuring period.[46-48] One large study (N = 17,359 admissions) found episodes of seclusion significantly decreased (adjusted odds ratio [aOR] = 0.88, 95% CI [0.83, 0.92]; Appendix J shows detailed outcome data) during a 5-year period when the hospital implemented open wards.[46] The same study conducted a crude analysis and found hours of seclusion decreased after the hospital implemented open wards (mean 27.1 hours at the beginning of the period of study versus 18.2 hours at the end of the study, $p <$ .001).[46] A second small study (N = 144) found no difference in episodes of seclusion between the

10 months before and 10 months after a hospital restructured the wards into 3 different programs (including the introduction of open ward) (31 vs 32 events, p = not significant [NS]).[47] Despite no change in frequency of seclusion events, the same study found a significant reduction in duration of seclusion (unadjusted mean 5 vs 2.3 hours, $p = 0.02$). A third very small study ($N = 18$) found fewer seclusion events 3 to 6 months after the move to a purpose-built psychiatric intensive care unit than 3 to 6 months before the move (3 vs 14, $p = 0.001$)[48]. The same study found a decrease in the total duration of seclusion (531 vs 2,117 minutes, $p = 0.001$) but no difference in mean duration of seclusion (190 vs 153, $p = 0.288$).[48]

Restraint

Two pre-post studies reported episodes and duration of restraint.[47,49] One large study found a significant reduction in episodes (reductions ranged between 48% to 63% based on 3 definitions of restraint (p <0.001 for all) and duration (48% reduction, $p = 0.003$) of restraint after a hospital structurally modernized compared to a period before.[49] A small pre-post study found no difference in episodes or duration of restraint after the hospital restructured to include an unlocked day hospital program, transitional residential program, and intensive care unit (number of events: 114 vs 190, p = not reported [NR], and mean 11.1 vs 9.2 hours, p = NS, respectively).[47]

Composite Measure of Coercion

No study reported data on a composite measure of coercion.

Forced Medication Use

Two pre-post studies found the use of forced medications decreased in the period after the intervention compared to before.[46,49] One large pre-post study found the introduction of an open-door policy was associated with a reduction in administration of forced medication (aOR = 0.90, 95% CI [0.83, 0.98]).[46] The same study reported unadjusted decreases in cases with at least 1 forced medication (2.4% beginning of period vs 1.2% end of period, p <0.001) and mean number of forced medications (mean 2.3 beginning of period vs 1.2 end of period, $p = 0.003$).[46] The other pre-post study found forced medication use decreased 84.4% (p <0.001) after the hospital structurally modernized the inpatient psychiatric units.[49]

Patient Outcomes

One small pre-post study conducted in the US reported the crude number of suicide attempts (1 vs 0 events, p = NR), deaths (1 vs 0 events, p = NR), and patient-to-patient assaults (6 vs 6 events, p = NR) before compared to after hospital restructuring (including the introduction of an open day hospital unit) and found no difference.[47] A second very small study in the United Kingdom ($N = 18$) found less aggressive incidents and aggressive patients 3 to 6 months after the move to a purpose-built psychiatric intensive care unit than 3 to 6 months before the move (16 vs 36, $p = 0.01$ and 12 vs 16, p = NR, respectively).[48]

Staff Outcomes

One small pre-post study reported the crude number of patient-to-staff assaults (1 vs 1 events, p = NR) before compared to after hospital redesign to include an open ward and found no difference.[47]

Table 4. Summary of Findings for Hospital/Unit Restructuring

Outcome	Studies (Patients); Design	Methodological Limitations	Indirectness	Imprecision	Inconsistency	Other Issues	Overall Confidence	Summary of Findings
Seclusion episodes	3 (17,521); Pre-post	Serious limitations[a]	Direct	Precise	Inconsistent[b]	Sparse data	Low	May reduce episodes of seclusion
Seclusion duration	3 (17,521); Pre-post	Serious limitations[c]	Direct	Precise	Consistent	Sparse data	Low	May reduce duration of seclusion
Restraint episodes	2 (>144[d]); Pre-post	Serious limitations[c]	Direct	Precise	Inconsistent[e]	Sparse data	No conclusion	Insufficient evidence
Restraint duration	2 (>144 [d]); Pre-post	Serious limitations[c]	Direct	Precise	Consistent	Sparse data	Low	May reduce duration of restraint
Coercion composite	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Forced medication	2 (>17,359[d]); Pre-post	Serious limitations[a]	Direct	Precise	Consistent	Sparse data	Low	May reduce the use of forced medication
Patient outcomes	2 (162); Pre-post	Serious limitations[c]	Direct	Precise	Inconsistent	Sparse data	No conclusion	Insufficient evidence
Staff outcomes	1 (144); Pre-post	Serious limitations[c]	Direct	Precise	NA	Single Study	No conclusion	Insufficient evidence

Notes. [a] One pre-post study conducted adjusted analyses and 2 conducted crude analyses. All studies relied on self-reported outcome data; [b] One large and 1 very small pre-post study reported a reduction in outcomes, and 1 small pre-post study reported no difference in outcomes; [c] All studies used crude unadjusted analyses to evaluate this outcome; [d] Only 1 study reported sample size; [e] 1 study reported a reduction and another reported an increase.
Abbreviations. NA=not applicable.

EFFECT OF STAFF EDUCATION/TRAINING

Based on evidence from 3 pre-post studies,[50-52] training staff (*eg,* de-escalation, alternative strategies to seclusion and preventing violence) may reduce staff injuries and as-needed medication use (Table 5). We have low confidence in these findings because of methodological limitations (mostly unadjusted analyses) and inconsistent findings within and between studies. Studies provide insufficient evidence (no conclusion) for episodes of seclusion, episodes of restraint, other patient outcomes (*eg*, aggression), and composite measures of coercion. Studies did not report on duration of seclusion or duration of restraint.

Seclusion

Two studies (1 concurrent and 1 pre-post) found no difference in episodes of seclusion between patients in wards where staff received training (TeamsSTEPPS and City Nurses) compared to either a pre-period or concurrent comparison.[50,52] In a pre-post study, the rate of seclusion was similar before and after the TeamsSTEPPS intervention was implemented (5.9% vs 4.4%, $p = 0.349$).[52] However, an unadjusted pre-post analysis of the City Nurses intervention found a reduction in mean seclusion events per shift (mean 0.02 vs 0.01, $p = 0.02$).[50] Neither study reported duration of seclusion.

Restraint

One concurrent comparison study (Bowers et al) conducted a pre-post unadjusted analysis among the 3 intervention wards only and found that the City Nurses intervention reduced episodes of restraint per shift (mean 0.06 vs 0.03, $p = 0.02$).[50] A pre-post study (Forster et al) reported a 13.8% decrease (unadjusted) in episodes of restraint in the 12 months after the introduction of a training intervention (pre period 2,379 episodes per 2,560 admissions vs post period 2,380 episodes per 3,010 admissions, p = NR).[51] Neither study reported duration of restraint.

Composite Measure of Coercion

One study found no difference (City Nurse vs concurrent practice as usual comparison) in a measure of total containment as measured by the PCC-SR; the analyses adjusted for both patient characteristics and cluster effects of the ward. A pre-post unadjusted comparison in the same study (of just the 3 intervention wards) found a reduction in events per shift in the composite endpoint (mean 4.56 vs 3.74, $p < 0.001$).[50]

One pre-post study reported a 54.6% decrease in the duration of seclusion or restraint per episode after the introduction of a staff training intervention (13.9 vs 6.3 hours/episode, p = NR).[51]

Forced Medication Use

Patients in wards with staff trained in the City Nurse intervention received fewer as-needed medications ($p < 0.001$ compared to concurrent comparison and in pre-post analysis).[50] In the same study, an unadjusted pre-post analysis of intervention wards only found a reduction in administration in forced intramuscular medication (mean per shift 0.07 vs 0.04, $p = 0.003$).

Patient Outcomes

One concurrent comparison study (with a pre-post analysis) evaluated the City Nurse intervention and reported patient conflict, verbal aggression, physical aggression against objects, physical aggression against others, and physical aggression against self.[50] In adjusted analyses, there was no significant difference in these outcomes (as individual items or as a composite "total conflict" variable) for patients in wards where staff were trained compared to patients in concurrent control wards. In unadjusted pre-post analyses, there were significant reductions in conflict, verbal aggression, aggression against objects, and aggression against self ($p < 0.05$ for all).

Staff Outcomes

One pre-post study (Forster et al) reported a crude 18.8% decrease in staff injuries after the introduction of a training program compared to the 12 months before the intervention (48 vs 39 incidents, p = NR).[51]

Table 5. Summary of Findings for Staff Education/Training

Outcome	Studies (Patients); Design	Methodological Limitations	Indirectness	Imprecision	Inconsistency	Other Issues	Overall Confidence	Summary of Findings
Seclusion episodes	2 (>730); concurrent and pre-post	Serious limitations[a]	Direct	Precise	Inconsistent[b]	Sparse data	No conclusion	Insufficient evidence
Seclusion duration	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Restraint episodes	2 (>5,570); concurrent and pre-post	Some limitations[c]	Direct	Precise	Inconsistent[d]	Sparse data	No conclusion	Insufficient evidence
Restraint duration	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Coercion composite	2 (>5,570); concurrent and pre-post	Some limitations[c]	Direct	Precise	Inconsistent[d]	Sparse data	No conclusion	Insufficient evidence
Forced medication	1 (NR); concurrent and pre-post	Some limitations[c]	Direct	Precise	NA	Single study	Low	May reduce as-needed medication use and forced intramuscular medication use
Patient outcomes	1 (NR); concurrent and pre-post	Serious limitations[c]	Direct	Precise	NA	Single study	No conclusion	Insufficient evidence
Staff outcomes	1 (4,940); pre-post	Serious limitations[e]	Direct	Precise	NA	Single study	Low	May reduce staff injuries

Notes.[a] One study conducted adjusted analyses and a second conducted crude analyses. Both studies relied on self-reported outcome data; [b] One pre-post study reported no difference and 1 concurrent study with a pre-post analysis reported reduction; [c] Self-reported outcome data and unclear if comparator group is similar; [d] One study reported no difference with a concurrent comparison but a reduction with a pre-post comparison and a second pre-post analysis reported a reduction in the duration of seclusion or restraint. One pre-post study reported a reduction; [e] One pre-post study conducted unadjusted analyses.
Abbreviations. NA=not applicable.

EFFECT OF SENSORY MODULATION

Based on evidence from 2 concurrent comparison and 5 pre-post studies,[53-59] episodes of seclusion, but not duration of seclusion, may be reduced by sensory modulation rooms on inpatient wards (Table 6). Sensory modulation rooms may also reduce use of forced medication. We have low confidence in these findings due to serious methodological limitations, inconsistent findings across studies for some outcomes, and sparse reporting of data. Studies provide insufficient evidence (no conclusion) regarding episodes of restraint, composite measures of coercion, patient outcomes (*eg,* self-injury, patient-to-patient assault), and staff outcomes (patient-to-staff assault). Studies did not report on duration of restraint.

Seclusion

Five studies reported seclusion events with diverse findings. One study with a concurrent control[55] found a sensory modulation room reduced episodes of seclusion (percent change not quantitively reported, $p < 0.001$), and 2 pre-post studies found no difference after a unit implemented the room compared to a period before.[56,58] Azuela et al (a pre-post study) found no difference in seclusion episodes in the 2 years after unit A implemented the comfort room compared to the year before (median number seclusion events 8.5 vs 6.5, $p > 0.05$) but found a significant reduction in seclusion events in unit B after the comfort room was installed (median number seclusion events 14.5 vs 7.5, $p = 0.04$). Another pre-post study reported no seclusion events in the 4 months after the introduction of the sensory modulation room; however, this was no different from the 4 months before that observed 0 seclusion events.[57] The lack of use of seclusion at baseline in this study makes it difficult to assess the impact of the sensory modulation room.

The concurrent comparison study (Lloyd et al) found no difference in duration of seclusion.[55] In a pre-post comparison, Azuela et al found no difference in duration of seclusion for patients in unit A (median 126.8 vs 66.7 hours; $p > 0.05$) and a decrease in duration of seclusion for patients in unit B (360.3 vs 145.3 hours, $p = 0.02$).[53] A third pre-post study also found no differences in seclusion duration after the introduction of a sensory modulation room on the ward and possible increase in mean duration time, once outlier cases were accounted for.[58]

Restraint

One pre-post study reported no difference in the use of restraint in the 4 months before the introduction of a sensory modulation room compared to 4 months after (month 1 of pre period 0.39 events per 1,000 client days, months 2-4 of pre period 0 events, and month 1-4 post period 0 events).[57] The low baseline use of restraint in this study makes it difficult to assess the impact of the sensory modulation room. No other study reported data on episodes of restraint and no study reported data on duration of restraints.

Composite Measure of Coercion

One concurrent comparison study (Cummings et al) found no difference in rates of seclusion and restraint after the introduction of a sensory modulation room.[54] The study only reported a qualitative description of their findings and did not report summary data. A second pre-post study reported a reduction in the percent patient days where sedation, seclusion, or restraints were used (13.3% vs 1.6%, $p = 0.14$).[59]

Forced Medication Use

One study reported reductions in the number of benzodiazepines distributed per day (median 2.5 vs 1, $p < 0.001$), total amount of benzodiazepines distributed per day (median 4 mg vs 1 mg, $p < 0.001$), and number of patients given benzodiazepines per day (median 2 vs 1, $p < 0.001$) after the introduction of a sensory modulation room.[59] The study reported no difference in average benzodiazepine dose per patient day among those who received medication (mean 2 mg vs 2 mg, $p = 0.393$). The study did not report whether benzodiazepines were voluntarily taken by patients or forced. No other study reported forced medication use.

Patient Outcomes

One pre-post study reported a crude 12.1% increase in patient self-injurious behavior (4-month average of 2.32 events per 1,000 client days in pre period) and a 23.4% decrease in client-to-client assaults (4-month average of 3.98 events per 1,000 client days in pre period).[57] Another pre-post study administered the Essen Client Evaluation Schema (EssenCES) survey to residents and staff to understand their perception of ward climate and found no difference in Patient's Cohesion subdomain after the installation of the comfort rooms.[53] A third pre-post study reported a non-significant decrease in aggressive patient episodes 12 months after the implementation of a sensory modulation room compared to 12 months before (13.9 vs 19.6, p = NS).[56]

Staff Outcomes

Two pre-post studies reported on staff outcomes. One found a 48.1% decrease in client-to-staff assaults after implementation of the sensory modulation room (4-month average before intervention 2.32 events vs 1.20 events per 1,000 client days after intervention).[57] The second found no difference in the staff portion of the EssenCES (subdomains for experience of safety, therapeutic hold, and overall climate) or Professional Attitudes Towards Seclusion Questionnaire before compared to after comfort rooms were installed.[53] No other study reported staff outcome data.

Table 6. Summary of Findings for Sensory Modulation

Outcome	Studies (Patients); Design	Methodological Limitations	Indirectness	Imprecision	Inconsistency	Other Issues	Overall Confidence	Summary of Findings
Seclusion episodes	5 (>75[a]); concurrent and pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[c]	Sparse data	Low	May reduce episodes of seclusion
Seclusion duration	3 (>75[a]); concurrent and pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[d]	Sparse data	Low	No difference in duration of seclusion
Restraint episodes	1 (NR); pre-post	Serious limitations[b]	Direct	Precise	NA	Single study	No conclusion	Insufficient evidence
Restraint duration	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Coercion composite	2 (>321[e]); concurrent and pre-post	Serious limitations[b]	Indirect	Precise	Inconsistent[f]	Sparse data	No conclusion	Insufficient evidence
Forced medication	1 (321); pre-post	Serious limitations[b]	Indirect[g]	Precise	NA	Single study	Low	May reduce use of forced medication
Patient outcomes[h]	3 (>75[a]); pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[i]	Sparse data	No conclusion	Insufficient evidence
Staff outcomes[j]	2 (NR); pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[k]	Sparse data	No conclusion	Insufficient evidence

Notes. [a] One study reported sample size of number of patients with seclusion events only; [b] Self-reported outcome data and unadjusted analyses; [c] One study with a concurrent comparison reported a reduction in seclusion, 2 pre-post studies found no difference, 1 pre-post study reported 0 events pre and post, and 1 pre-post study reported inconsistent findings in different units that implemented a comfort room; [d] One concurrent comparison reported no difference in duration of seclusion, 1 pre-post study reported inconsistent findings in different units that implemented a comfort room, and 1 pre-post study reported a possible increase in duration once outlier cases were accounted for; [e] One study reported sample size; [f] One concurrent comparison qualitatively reported no difference in outcome and 1 pre-post study reported a reduction in the outcome; [g] Did not specify if medication was forced or voluntarily taken by patients; [h] Self-injury, aggressive episodes, client-to-client assault, and patient cohesion subdomain on the Essen Climate Evaluation Schema; [i] Three pre-post studies reported an increase, decrease, and no change on diverse patient outcome domains; [j] Client-to-staff assault, staff subdomains on the Essen Climate Evaluation Schema, and Professional Attitudes Towards Seclusion Questionnaire; [k] Two pre-post studies reported a decrease and no-difference on diverse staff outcome domains.
Abbreviations. NA=not applicable; NR=not reported.

EFFECT OF RISK ASSESSMENT WITH MANAGEMENT PROTOCOL

Comparisons of Risk Assessments with the Brøset Violence Checklist

Based on evidence from 2 RCTs and 2 pre-post studies,[60-62,66] episodes of seclusion, a composite measure (psychotropic medication use, seclusion, and restraint), and patient aggressive incidents may be reduced by risk assessment protocols that include the Brøset Violence Checklist (Table 7). We have low confidence in these findings due to serious methodological limitations, inconsistent findings for some outcomes, and sparse reporting of data. There is no evidence of differences in episodes of restraint and some evidence to suggest duration of restraint may increase (low confidence). The studies provide insufficient evidence regarding duration of seclusion (no conclusion). The studies did not evaluate use of forced medication or staff outcomes.

Seclusion

Three studies (1 RCT and 2 pre-post) found reductions in seclusion after wards implemented a risk assessment protocol that included the Brøset Violence Checklist.[61,62,66] A RCT found the number of seclusion incidents decreased 15% (p = NS) from the 10-week baseline period (relative risk [RR] = 1.19, 95% CI [0.76, 1.88]) to 30-week intervention period (RR = 1.01, 95% CI [0.74, 1.88]) for patients randomized to treatment wards compared to control wards. The same study found the number of patients exposed to seclusion increased 8% (p = NS) in the experimental wards compared to the control wards (10-week baseline period RR = 1.42, 95% CI [0.83, 2.48] vs 30-week intervention period RR = 1.71, 95% CI [1.12, 2.67]). A pre-post study found the use of seclusion decreased after the introduction of the Brøset Violence Checklist (30 episodes per month before intervention vs 22 episodes per month after intervention, p = NR).[62] A second pre-post study found a 52% decrease ($p < 0.001$) in seclusion events in the 12 months after the intervention compared to 12 months before (events 9.2/100 vs 4.4/100 admissions).[61]

Two studies (1 RCT and 1 pre-post) reported decreases in duration of seclusion for risk assessment interventions that included the Brøset Violence Checklist.[61,66] The RCT reported a 45% decrease ($p < 0.05$) in hours of seclusion per admission (10-week baseline period RR = 1.12, 95% CI [1.01, 1.19] vs 30-week intervention period (RR = 0.62, 95% CI [0.58, 0.66]). The pre-post study reported a 27% decrease in duration of seclusion per admission (p = NR), but mean duration of seclusion events increased (mean 337.7 vs 516.2 min, $p < 0.01$).[61]

Restraint

One pre-post study found rates of restraint decreased 6% after a Brøset Violence Checklist-based intervention was introduced compared to before (events 5.5/100 vs 5.1/100 per admission), although this finding was not significant ($p = 0.44$).[61] The same study reported a 52% increase in duration of restraints per admission (p = NR) and mean duration of restraint increased (mean 286 vs 445 min, $p < 0.01$).

Composite Measure of Coercion

One RCT reported a decrease in a composite measure of coercion that included use of psychotropic medication, seclusion, and restraint (3-month event rate 10% control vs -27% intervention, $p < 0.001$).[60] The study did not report duration of the composite measure and no other study reported a composite outcome.

Forced Medication Use

No study reported data on use of forced medication.

Patient Outcomes

Two RCTs[60,66] (Abderhalden et al and van de Sande et al) reported aggressive incidents/events and 1 RCT (Abderhalden et al) reported physical attacks.[60] In both RCTs, aggressive incidents significantly decreased for patients randomized to wards with structured risk assessment protocols using the Brøset Violence Checklist compared to control wards. Abderhalden et al reported severe aggressive events, defined as a score ≥9 on the Staff Observation Aggression Scale, declined in both treatment (RR = 0.59, 95% CI [0.41, 0.83]) and control wards (RR = 0.85, 95% CI [0.64, 1.13]), and the reduction was larger in the intervention wards ($p <$ 0.001). The same study reported a reduction in physical attacks for patients in wards randomized to intervention compared to control (-41% vs -7%, $p < 0.001$). Van de Sande et al reported a 68% reduction ($p < 0.05$) in aggressive incidents and a 50% reduction (p = NS) in number of aggressive patients in intervention compared to control wards.[66]

Staff Outcomes

No study reported staff outcomes.

Table 7. Summary of Findings for Risk Assessments with Brøset Violence Checklist

Outcome	Studies (Patients); Design	Methodological Limitations	Indirectness	Imprecision	Inconsistency	Other Issues	Overall Confidence	Summary of Findings
Seclusion episodes	3 (>12,371[a]); 1 RCT and 2 pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[c]	Sparse data	Low	May reduce episodes or incidents of seclusion
Seclusion duration	2 (12,371); 1 RCT and 1 pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[d]	Sparse data	No conclusion	Insufficient
Restraint episodes	1 (11,413); pre-post	Serious limitations[b]	Direct	Precise	NA	Single study	Low	No difference episodes of restraint
Restraint duration	1 (11,413); pre-post	Serious limitations[b]	Direct	Precise	NA	Single study	Low	May increase duration of restraint
Coercion composite	1 (NR); RCT	Serious limitations[b]	Indirect	Precise	NA	Single Study	Low	May reduce a composite measure of psychotropic medication use, seclusion and restraint
Forced medication	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Patient outcomes[e]	2 (>458[f]); 2 RCTs	Serious limitations[b]	Direct	Precise	Consistent	Sparse data	Low	May reduce aggressive incidents
Staff outcomes	0 (0)	NA	NA	NA	NA	NA	NA	No evidence

Notes. [a] One study did not report sample size; [b] All studies used self-reported outcome data. RCTs did not blind staff. Pre-post studies conducted unadjusted analyses; [c] RCT reported non-significant decrease in seclusion incidents and non-significant increase in number of patients exposed to seclusion, 1 pre-post study reported significant decrease in proportion of patients secluded, another pre-post study reported decrease in number of episodes of seclusion (p = NR); [d] RCT reported non-significant decrease. Pre-post study reported increase in mean duration of seclusion; [e] Aggressive incidents and physical attacks. [f] One RCT did not report sample size.
Abbreviations. NA=not applicable; NR=not reported; RCT=randomized controlled trial.

Comparisons of Investigator-developed Risk Assessments

Based on evidence from 3 pre-post studies,[63-65] there is no difference in duration of seclusion and staff satisfaction between interventions that include an investigator-developed risk assessment tool compared to usual care, but episodes and duration of restraint may be reduced by these interventions (Table 8). We have low confidence in these findings due to serious methodological limitations and sparse data. The studies provide insufficient evidence regarding episodes of seclusion and other patient outcomes (no conclusion). The studies did not evaluate a composite measure of coercion or use of forced medication.

Seclusion

One pre-post study found a decrease in seclusion per 1,000 occupied bed days in the 18 months after a hospital-developed risk assessment tool was implemented compared to the 24 months before (RR = 0.71, 95% CI [0.63, 0.80]).[63] A second pre-post analysis of an intervention that included the Modified Agitation Severity Scale found no difference in seclusion incidents in the 18 months before compared to 18 months after the intervention (22 vs 28 incidents, p = NR).[64] The same study found no difference in minutes in seclusion before compared to after the intervention (mean 132 vs 137 minutes). A third pre-post study found no difference in seclusion events or duration 6 months after the implementation of the Management of Acute Arousal Program compared to 6 months before (67 vs 64 incidents, $p = 0.51$; 312 vs 299 minutes, $p = 0.19$).[65]

Restraint

One pre-post study reported a 44.1% decrease in total incidents of restraint (68 vs 38 incidents, p = NS) in the 18 months after the introduction of a risk assessment tool compared to the 18 months before.[64] The same study reported a 44.4% decrease in average restraint minuets per incident (mean 18 vs 10 minutes, $p = 0.047$) The other study did not report restraint data.

Composite Measure of Coercion

No study reported data on composite measure of coercion.

Forced Medication Use

No study reported data on use of forced medication.

Patient Outcomes

A pre-post study reported non-significant decreases in aggressive events per 1,000 occupied bed days (RR = 0.78, 95% CI [0.47, 1.27]) and self-harm/suicide (RR = 0.69, 95% CI [0.26, 1.69]) after the introduction of a hospital-developed risk assessment.[63] A second pre-post study found no difference in an 8-item study developed patient safety survey (higher scores indicate positive responses; mean 12.2 vs 13.25, p = NS).[64]

Staff Outcomes

Two pre-post studies reported survey data on staff satisfaction and safety.[63,64] Harrington et al found significant differences on 2 of 6 items on a staff satisfaction survey conducted before and after implementation of the intervention. Staff were more likely to agree with the statement that

they are "satisfied with the practice of visual observations in the management of patients who have been identified as being "at risk'" and "visual observations provide optimum care for the patients at [this psychiatric unit]" after the intervention. Manning et al found no difference in a 6-item study-developed staff survey or on the Oldensburg Burnout Scale before and after the intervention (mean 36.17 vs 36.11, $p = 0.98$).[64]

Table 8. Summary of Findings for Investigator-developed Risk Assessments

Outcome	Studies (Patients); Design	Methodological Limitations	Indirectness	Imprecision	Inconsistency	Other Issues	Overall Confidence	Summary of Findings
Seclusion episodes	3 (3,149); pre-post	Serious limitations[a]	Direct	Precise	Inconsistent[b]	Sparse data	No conclusion	Insufficient
Seclusion duration	2 (1,094); pre-post	Serious limitations[c]	Direct	Precise	NA	Sparse data	Low	No difference in duration of seclusion
Restraint episodes	1 (742); pre-post	Serious limitations[d]	Direct	Precise	NA	Single study	Low	May reduce episodes of restraint
Restraint duration	1 (742); pre-post	Serious limitations[d]	Direct	Precise	NA	Single study	Low	May reduce duration of restraint
Coercion composite	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Forced medication	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Patient outcomes	2 (2,797); pre-post	Serious limitations[e]	Direct	Precise	Inconsistent[f]	Sparse data	No conclusion	Insufficient
Staff outcomes[g]	2 (2,797); pre-post	Serious limitations[e]	Direct	Precise	Consistent	Sparse data	Low	No difference in staff satisfaction

Notes. [a] All studies used self-reported outcome data; 1 study conducted adjusted analyses and 2 conducted crude analyses; [b] One study reported a decrease in events and 2 studies reported no difference; all studies evaluated different protocols; [c] Both studies used self-reported outcome data; 1 study conducted adjusted and 1 conducted crude analyses; [d] Study used self-reported outcome data and conducted crude analyses; [d] One study reported aggressive events and self-harm/suicide. A second study reported a patient safety survey; [e] Both studies used self-reported outcome data and reported crude analyses; [f] One study reported non-significant decreases in aggressive events and self-harm/suicide. A second study reported no difference in patient safety based on a hospital-developed patient survey; [g] Two studies reported staff satisfaction and 1 study reported a measure of staff burnout.
Abbreviations: NA=not applicable.

EFFECT OF COMPREHENSIVE/MIXED

Comparison of Safewards Intervention

Based on evidence from 1 RCT and 1 pre-post study,[69, 72] the Safewards intervention may reduce a composite measure of coercion (restraint and seclusion and/or forced medication use) and patient conflicts (Table 9). We have low confidence in these findings because studies had serious methodological concerns. The studies provide insufficient evidence (no conclusion) for staff outcomes. Studies did not report on seclusion, restraint (other than as a composite outcome), or use of forced medication.

Seclusion

No study reported data on seclusion, other than as a composite outcome.

Restraint

No study reported data on restraint, other than as a composite outcome.

Composite Measure of Coercion

One RCT[69] and 1 pre-post study[72] reported a reduction in a composite measure of coercion for patients in wards that implemented Safewards. In the RCT, the composite measure of containment (defined as actions taken by staff to manage unsafe patients such as coerced medication, seclusion, restraint, special observation, *etc*) was evaluated using the patient-staff conflict checklist (PCC), which is completed by the unit nurse in charge and measures 8 forms of containment. Among wards that experienced containment events, the rate of containment decreased by 26.4% (95% CI [9.9, 34.3%]) per shift for wards that implemented Safewards. The same study reported no difference in rates of shifts with 0 of containment events (RR = 1.04, 95% CI [0.83, 1.34]). In a primary analysis, the pre-post study used the PCC and defined containment as seclusion and/or restraint.[72] In a secondary analysis, containment was defined as seclusion, restraint, and forced medication. With both definitions there was a significant decrease in use of containment (RR = 0.88, 95% CI [0.82, 0.94] and RR = 0.27, 95% CI [0.14, 0.47], respectively). Neither study reported data on duration of containment.

Forced Medication Use

No study reported data on use of forced medications.

Patient Outcomes

One RCT found no difference in self-harm evaluated with the Self-Harm Antipathy Scale (adjusted mean difference = 0.23, 95% CI [-3.38, 3.83]).[69] The same RCT reported a reduction in conflicts as measured by the PCC, which evaluates 22 events such as verbal aggression (RR = 0.85, 95% CI [0.76, 0.94]). There was no difference in wards reporting shifts with 0 conflict events (RR = 1.14, 95% CI [0.92, 1.42]). In adjusted analyses, the pre-post study reported a decrease in conflicts reported via the PCC and physical aggression (aRR = 0.77, 95% CI [0.66, 0.89] and RR = 0.65, 95% CI [0.59, 0.72], respectively).[72]

Staff Outcomes

One RCT found no difference in the Ward Atmosphere Scale, which measures staff assessment of the ward culture and environment.[69] A pre-post study noted no difference in the Violence Prevention Climate Scale, which measures staff and patient perceptions of violence on the ward.[72]

Table 9. Summary of Findings for Safewards Intervention

Outcome	Studies (Patients); Design	Methodological Limitations	Indirectness	Imprecision	Inconsistency	Other Issues	Overall Confidence	Summary of Findings
Seclusion episodes	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Seclusion duration	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Restraint episodes	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Restraint duration	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Coercion composite	2 (NR[a]); 1 RCT and 1 pre-post	Serious limitations[b]	Indirect[c]	Precise	Consistent	None	Low	May reduce composite measures
Forced medication	0 (0)	NA	NA	NA	NA	NA	NA	No evidence
Patient outcomes	2 (NR[a]); 1 RCT and 1 pre-post	Serious limitations[b]	Direct	Precise	Consistent	None	Low	May reduce patient conflicts
Staff outcomes	2 (NR[a]); 1 RCT and 1 pre-post	Serious limitations[b]	Direct	Precise	Consistent	Sparse data[d]	No conclusion	Insufficient

Notes. [a] Studies did not report patient sample size; [b] Both studies had high risk of bias; [c] Both studies reported composite outcome "containment" that was measured by the same tool, the patient-staff conflict checklist shift report. The specific scope of events defined by containment may have varied; the RCT reported containment as "actions taken by staff to manage unsafe patients such as coerced medication use, seclusion, restraint, special observation, *etc*" and the pre-post reported containment as seclusion/restraint for the primary analysis and seclusion/restraint/forced medication use for the secondary analysis; [d] Two studies reported different measures of staff outcomes (ward culture/environment and violence on ward).
Abbreviations: NA=not applicable; NR=not reported; RCT=randomized controlled trial.

Comparison of Comprehensive/Mixed Interventions with Different Components

Based on evidence from 1 RCT, 2 concurrent comparison studies,[68,76] and 11 pre-post studies,[67,70,73-75,77-80,84,85] episodes of seclusion, duration of seclusion, duration of restraint, episodes of composite measures of coercion, and duration of composite measures of coercion may be reduced by comprehensive/mixed interventions (Table 10). There is no evidence of differences for episodes of restraints and use of forced medication. We have low confidence in all these findings due to serious methodological limitations (self-reported outcome data and crude analyses) and sparse data. Studies provide insufficient evidence (no conclusion) for other patient outcomes and staff outcomes.

Seclusion

Nine studies evaluated mixed interventions and reported on the incidence or number of seclusion events.[67,68,70,73,75,76,79,82,84] All 9 studies reported fewer seclusion events for patients in intervention compared to comparison (or pre-implementation) wards. Effect sizes, outcome measures (*eg,* comparisons of counts, RR or hazard ratios [HR]), and statistical testing varied between studies. For example, 1 VA pre-post study (reported in a poster) reported a 56.3% decrease (71 vs 31 events, p = NR) in seclusion in the 3 years before compared to after the intervention.[70] A pre-post study evaluating wards trained in moral case deliberation reported a reduction the proportion of patients secluded (16.7% vs 9.6%, $p = 0.034$) but no difference in frequency of seclusion (mean 2.2 vs 3.4, $p = 0.42$).[79] Whitecross et al found a 65.3% decrease (p = NR) in seclusion episodes per 1,000 bed days and a 55.7% decrease in monthly percent of admitted patients secluded after the introduction of a multidisciplinary team "on call" approach.[84] A crisis prevention management intervention resulted in 30% to 63% reduction (depending on unit) in episodes of seclusion.[75] Hellerstein et al reported a reduction in the average number of patients secluded for those in wards that received a multidisciplinary intervention (mean 3.1 vs 1.1, $p < 0.001$).[73] A concurrent comparison study found a higher chance of being secluded if patients where in a ward that did not receive the culture change intervention (HR Year 1 = 2.8 and HR Year 2 = 5.6, p = NR).[76] A pre-post study reported significant reductions in seclusion events over the course of the 13 years since they first implemented their multicomponent model.[67] Finally, a RCT (Valimaki et al) found fewer seclusion events in wards randomized to the intervention compared to control (RR = 0.72, 95% CI [032, 1.63], p group * year interaction = 0.003), and in a secondary analysis fewer patients who were placed in seclusion (RR = 0.76, 95% CI [0.40, 1.46], p group * year interaction = 0.37).[82]

Eight studies reported on the duration of seclusion[68,70,73,76,78,79,82,84] and reported inconstant findings. One pre-post study reported a 50% increase (p = NR) in seclusion hours in the 12 months after a VA Medical Center implemented a comprehensive training program.[78] A RCT showed no difference in length of seclusion for patients in wards randomized to the intervention (log transformed mean difference 0.16, 95% CI [-0.39, 0.71], p group * year interaction = 0.21). The remaining 6 studies reported reductions in duration of seclusion for patients in experimental compared to comparison wards, though not all were statistically significant. For example, Boumans et al found that patients in wards who received the mixed intervention had fewer hours of seclusion (mean difference -63.46 hours, p <0.01).[68] A pre-post study of a mixed intervention incorporating moral case deliberation reported fewer hours of seclusion, although this finding was non-significant (156.2 vs 39.8 hours, $p = 0.115$), and a significant reduction in the mean duration of seclusion events (73.9 vs 10.0 hours, $p = 0.05$).[79] A pre-post study of a

multicomponent intervention that included staff education, hospital-wide policy changes on the use of seclusion/restraint, and efforts to improve communication between patients and staff reported reductions in the total hours patients were secluded in a month (41.6 vs 2.7, p = 0.003) and the proportion of total patient time in seclusion (0.11 vs 0.007; *p* = 0.03) after the intervention.[73] Whitecross et al reported a 71.9% reduction in hours of seclusion per 1,000 bed days (270.4 vs 76.0 hours).[84] Finally, 1 VA pre-post study (reported in a poster) reported an 88% decrease in total hours of seclusion in the 3 years before compared to after the intervention (1204 vs 142 total hours).[70]

Restraint

Six studies evaluating mixed interventions reported on episodes of restraint and found inconsistent findings.[67,70,73,75,79,82] A RCT found the use of limb restraints increased from baseline to follow-up in usual care wards (5.4% vs 7.3%) and remained stable in intervention wards (8.6% vs 8.6%; *p* value group * year interaction < 0.001). The same study reported no difference in the proportion of limb restraint used, physical restraint events, or patients physically restrained.[82] A pre-post study conducted in 5 units reported a 20% to 97% reduction in restraint use after the units implemented a crisis prevention management intervention.[75] Stoll et al found that use of restraint decreased after 2 wards implemented a mixed intervention that incorporated moral case deliberation, though this finding was non-significant (3.2% vs 1.8%, *p* = NS).[79] The same study reported no difference in the frequency of restraint episodes among those exposed to restraint.[79] One pre-post study reported no difference in the number of patients restrained per month (mean 0.35 vs 0.32, *p* = NS) after the introduction of a multicomponent intervention.[73] A VA study (reported in a poster) reported a 10% increase (10 vs 11 events) in total patients restrained in the 3 years after compared to 3 years before the intervention.[70] Blair reported a decrease in restraint events over the course of 13 years since the implementation of a multicomponent engagement model; however, reporting of methods and outcomes in this study was sparse.[67]

Five studies also evaluated time in restraints.[70,73,78,79,82] A RCT found patients in intervention wards spent less time in limb restraints and physical restraint but these findings were not significant.[82] One pre-post study reported no difference in the total hours patients were in restraint per month (mean 1.7 vs 1 hours, *p* = NS) or the percentage of patient hours in restraints (0.005 vs 0.003; *p* = NS) after the introduction of a multicomponent intervention.[73] A VA study (poster) reported an 8% decrease in total hours in restraint. One pre-post study reported a 47% decrease in the total time patients spent restrained in the 12 months after the introduction of the intervention compared to the 12 months before (3387 vs 1812 hours, *p* = NR).[78] One pre-post study reported significant decreases in the number of hours in restraint overall and per episode (14.5 vs 86.8, *p* = 0.02 and 10.1 vs 55.2, *p* = 0.01, respectively) after the introduction of the moral case deliberation approach.[79]

Composite Measure of Coercion

Five pre-post studies[69,70,74,79,80,85] (including 2 studies conducted in the VA)[70,85] reported reductions in composite measures of coercion. In 4 studies, the composite only included episodes of seclusion and restraint,[70,74,79,80,85] and in 1 study the composite included seclusion, restraint, and forced medication use.[79] In 1 VA study, the incidence of the composite significantly decreased after the introduction of the intervention (mean monthly rate 3.17 vs 1.5, *p* = 0.03),[85] and a second VA study reported a 48% decrease in number of combined events in the 3 years

after the intervention compared to the same period before (81 vs 42 events, p = NR). A pre-post study qualitatively reported a 94% reduction in combined seclusion and restraint events (p = NR).[70,80] Another pre-post study reported a significant decrease in total number of episodes in the 12 months after compared to before the intervention (310 vs 148 episodes, $p < 0.01$).[74] Finally, another pre-post study reported a reduction in proportion of patients subject to seclusion, restraint, and forced medication use after the introduction of a mixed intervention that included moral case deliberation (17.2% vs 9.5%, $p = 0.02$).[79]

Three VA studies[70,77,78] reported reductions in a composite of total hours in seclusion and restraint. One VA pre-post study (McDonagh et al) reported an 86% decrease in total hours in seclusion and restraint during the 3 years post intervention compared to same period before (1,711 vs 245 total hours, p = NR).[70] A second VA pre-post study (Pollard et al) reported fewer monthly hours of seclusion and restraint after the introduction of a comprehensive intervention developed in response to the Joint Commission (182 vs.56 hours, $p < 0.001$).[77] A third VA pre-post study reported a 31% decrease in total hours in seclusion and restraint during the 12 months after the intervention was introduced compared to the 12 months before (3783 vs 2600 total hours, p = NR).[78]

Forced Medication Use

Two studies reported on use of forced medication.[79,82] One RCT found no significant differences in the number of patients who experienced forced medication or the total number of patients injected.[82] A pre-post study also found no difference in forced medication use after a hospital implemented a mixed intervention that included forced medications (4.8% vs 4.1%, $p = 0.93$).[79]

Patient Outcomes

Six studies reported patient outcomes including satisfaction with treatment ($N = 1$),[82] death ($N = 1$),[82] assaults/fights ($N = 5$),[70,73,74,77,84] injuries, and self-harm ($N = 2$).[74,84] Two pre-post studies were conducted in the VA.[70,77] One RCT found no difference in a measure of satisfaction (Client Satisfaction Questionnaire) or deaths between patients in wards randomized to treatment or control.[82] A pre-post study reported no difference in the number of patients involved in fights in the 67 months after compared to 20 months before the intervention (mean 0.5 vs 0.3, p = NS).[73] One pre-post VA study reported 3 patient injuries and 1 patient assault in the 3 year pre period and 0 injuries or assaults cumulative in the 3 year post period.[70] A second pre-post VA study reported a reduction in assaults or self-destructive events after the intervention (mean 1.07 vs 0.72 events per 24-hour period, $p = 0.004$).[77] One study reported a significant increase in assaults on patients in the 12 months after compared to before the intervention (67 vs 85 events, p <0.05) and no difference in self-destructive behavior (27 vs 24 events, $p > 0.05$).[74] Finally, another study reported unadjusted reductions in self-harm (change = -25%), physical aggression (change = -25.2%), and verbal aggression (change = -23.4%) after implementation of a multidisciplinary team approach.[84] No other study reported other patient outcomes.

Staff Outcomes

Six studies (3 VA studies[70,77,85] and 3 non-VA studies)[73,74,82] reported staff outcomes. Two pre-post studies[70,73] reported staff injuries, 1 study reported assaults on staff,[74] 1 reported critical incidents (defined as potential or actual assaultive or self-destructive events),[77] 1 study evaluated staff satisfaction,[85] and 1 reported team climate and nurse turnover rates.[82] In 1 pre-post study,

staff injuries significantly decreased after implementation of the intervention (mean injuries per month 0.7 vs 0.18, $p = 0.03$). [73] One pre-post VA study reported 3 staff injuries in the 3 years before the intervention compared to 0 injuries in the 3 years after the intervention (p = NR).[70] The same study reported 0 patients assaults on staff before the intervention compared to after the intervention.[70] Another pre-post VA study found significant reductions in the number of critical incidents (defined as potential or actual assaultive events occurring on the unit in the past 24 hour period) in the 28 months following the intervention compared to the 18 months before the intervention (mean 0.72 vs 1.07, $p = 0.004$).[77] One pre-post study found the number of assaults on staff significantly increased after compared to before the intervention (31 vs 83 events, $p < 0.01$).[74] A pre-post VA study evaluated a recovery-oriented model of care and found significant increases in overall staff satisfaction and in subdomains related to satisfaction with programming, staff collaboration, ability to handle situations without restraints, ability to provide group programming, and belief that patients should be involved in their care ($p < 0.05$ for all).[85] Finally, a RCT found no difference in nurse turnover or team climate between staff in units randomized to intervention or control wards.[82]

Table 10. Summary of Findings for Comprehensive Interventions

Outcome	Studies (Patients); Design	Methodological Limitations	Indirectness	Imprecision	Inconsistency	Other Issues	Overall Confidence	Summary of Findings
Seclusion episodes	9 (>12,913[a]); 1 RCT, 2 concurrent control; 6 pre-post	Serious limitations[b]	Direct	Precise	Consistent	None	Low	May reduce episodes of seclusion
Seclusion duration	8 (>12,913[a]); 1 RCT, 2 concurrent control; 5 pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[c]	None	Low	My reduce duration of seclusion
Restraint episodes	6 (>8,754 [a]); 1 RCT, 5 pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[d]	None	Low	No difference in restraint events
Restraint duration	5 (>8,754 [a]); 1 RCT, 4 pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[e]	Sparse data	Low	May reduce duration of restraint
Composite coercion episodes	5 (>4,125 [a]); 5 pre-post	Serious limitations[b]	Indirect	Precise	Consistent	None	Low	May reduce composite measures of coercion
Composite coercion duration	3 (NR); 3 pre-post	Serious limitations[b]	Indirect	Precise	Consistent	None	Low	May reduce duration of composite measure of coercion
Forced medication	2 (8,754); 1 RCT, 1 pre-post	Serious limitations[b]	Direct	Precise	Consistent[f]	None	Low	No difference in forced medication use
Patient outcomes	5 (>4,724[a]); 5 pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[g]	Sparse data	No conclusion	Insufficient
Staff outcomes	3 (>3,368 [a]); pre-post	Serious limitations[b]	Direct	Precise	Inconsistent[h]	Sparse data	No conclusion	Insufficient

Notes. [a] Several studies did not report patient level sample size; [b] Self-reported outcome data, unadjusted analyses, lack of blinding (RCT); 6 of 8 studies reported a reduction in duration of seclusion; [c] One RCT reported no difference, 1 pre-post study reported an increase, and 6 pre-post studies reported a decrease in duration of seclusion; [d] One RCT reported an increase in one restraint measure and no difference in 4 restraint measures, 2 pre-post studies reported a decrease in restraint, 2 pre-post study reported no difference in restraint, and 1 pre-post study reported an increase in restraint; [e] One RCT and 1 pre-post study reported no difference, 3 pre-post studies reported a decreased time; [f] One RCT found an increase in forced medication use for treatment compared to control ward patients, and 1 pre-post study found no decrease (p = 0.93); [g] Three pre-post studies reported reduction in assaults, 1 pre-post study reported an increase in assaults, and 1 pre-post study reported a large reduction in assaults; [h] One RCT reported no difference in nurse turnover or team climate, 2 pre-post studies reported decreases in staff injuries/critical incidents, 1 pre-post study reported increases in staff satisfaction, 1 pre-post study reported mixed results on staff assaults and injuries, and 1 pre-post study reported increases in staff assaults.
Abbreviations. NA=not applicable; RCT=randomized controlled trial.

DISCUSSION

We identified 48 reports that described 43 protocols (7 reports described 6 protocols without evaluation and 41 reports described 37 studies that reported comparative data). Interventions were multicomponent and targeted multiple levels, actors, and determinants of both patient and staff behavior. Four comparative studies evaluated hospital/unit restructuring, 3 evaluated staff education/training, 7 evaluated sensory modulation/rooms, 7 evaluated risk assessment interventions, and 16 evaluated comprehensive/mixed interventions. All 6 non-comparative protocols involved comprehensive/mixed interventions. Episodes of seclusion was the most frequently evaluated outcome, followed by episodes of restraint and composite outcomes of seclusion and restraint. Key findings include the following:

Hospital/unit restructuring

- Hospital/unit restructuring protocols involved implementing an open-door policy, outfitting rooms with natural light, and a culture shift towards patient-centered and recovery-oriented care (*ie*, intervention function *environmental restructuring)*.
- Restructuring units to include architecturally positive elements and restructuring services (including, in some cases, implementing an open-door policy) may reduce episodes of seclusion, duration of seclusion, duration of restraint, and use of forced medication (low confidence).
- It is unknown if restructuring units reduces episodes of restraint, other patient outcomes, and staff outcomes (insufficient evidence). The studies did not evaluate a composite measure of coercion.

Staff education/training

- Education/training interventions provided staff with de-escalation techniques and alternative strategies to seclusion and included intervention functions of *persuasion*, *education*, *training*, or *modelling*. *Staffing* was the primary resource associated with the interventions.
- Staff training (*eg,* de-escalation, alternative strategies to seclusion, and preventing violence) may reduce staff injuries and as-needed medication use (low confidence).
- It is unknown if staff training reduces episodes of seclusion, episodes of restraint, composite measures of coercion, and patient outcomes such as aggression (insufficient evidence). The studies did not evaluate duration of seclusion or restraint.

Sensory modulation

- Sensory modulation rooms involved creating a dedicated space to meet the multisensory needs of patients. The common intervention element was *environmental restructuring* followed by *education, persuasion, enablement,* and *restrictions*. *Space* and *equipment* to facilitate the intervention were the primary resources associated with sensory rooms.
- Sensory/comfort rooms may reduce episodes of seclusion and forced medication use but may not affect duration of seclusion (low confidence).

- It is unknown if sensory/comfort rooms reduce episodes of restraint, composite measures of coercion, patient outcomes (such as self-injury, patient-to-patient assault), and staff outcomes (patient-to-staff assault) (insufficient evidence). The studies did not report on duration of restraint.

Risk assessment and management protocols

- Risk assessment and management protocols involved using a structured tool to help staff identify potentially aggressive patients to direct clinical efforts. Risk assessment and management protocols included intervention functions of e*nvironmental restructuring, education,* and *training.* Resource requirements included *documentation* and *time staff spent to perform checks on patients*.
- Structured risk assessments that include the Brøset Violence Checklist may reduce episodes of seclusion, a composite measure of seclusion and, patient aggressive events (low confidence).
- There is no evidence of differences in episodes of restraint, and duration of restraint may increase for interventions that include the Brøset Violence Checklist (low confidence).
- It is unknown if incorporating the Brøset Violence Checklist reduces the duration of seclusion (insufficient evidence). The studies did not evaluate forced medication use or staff outcomes.
- Investigator-developed or -modified risk assessment tools may reduce episodes and duration of restraint but not duration of seclusion (low confidence).
- There is no evidence of differences in duration of seclusion or staff stratification for investigator-developed or -modified risk assessment tools (low confidence).
- It is unknown if investigator-developed risk assessment tools reduce episodes of seclusion or other patient outcomes (insufficient evidence). The studies did not evaluate composite measures of coercion or forced medication use.

Comprehensive/mixed interventions

- Comprehensive/mixed protocols included intervention functions of *education* and *training.* Protocols often included elements of *persuasion* to reinforce staff education and *environmental restructuring* to change physical or social context of the wards. The most common resource needs to implement mixed interventions were *documentation* and *staffing* followed by *programming*.
- The Safewards intervention may reduce a composite measure of coercion (restraint and seclusion and/or forced medication use) and patient conflicts (low confidence).
- It is unknown if the Safewards intervention impacts staff outcomes (insufficient evidence). The studies did not evaluate episodes or duration of seclusion, episodes or duration of restraint, or episodes of forced medication use.
- Other comprehensive interventions may reduce episodes of seclusion, duration of seclusion, duration of restraint, and episodes and duration of composite measures of coercion (low confidence).

- There is no difference in episodes of restraint or forced medication use for other comprehensive interventions (low confidence).
- It is unknown if other comprehensive interventions reduce other patient outcomes or staff outcomes (no conclusion).

STRENGTHS AND LIMITATIONS OF THE EVIDENCE BASE

There is great interest from policymakers, hospital administrators, staff, and patients for effective alternatives to seclusion. One of the most reassuring findings of this review is the number of protocols we found that attempted to address this need, and the diversity of intervention functions identified within protocols, suggesting that intervention designers are building complex solutions to address a complex practice problem. For example, 8 of the 9 intervention functions were identified in efforts to reduce staff's use of seclusion (*education*, *persuasion*, *incentivization, training*, *restriction*, *environmental restructuring*, *modelling*, and *enablement*), and 7 of the 9 intervention functions were identified in efforts to reduce patients' aggressive behavior (*education*, *persuasion*, *incentivization, training*, *restriction*, *environmental restructuring*, and *enablement*). It is reassuring that two-thirds of interventions targeted both patients and staff to reduce the likelihood of precipitating behavior requiring seclusion or any alternatives. In such protocols, patients were provided with education on how to manage distress more effectively and were often enabled to do so through efforts to change or re-shift the patient-staff dynamic from one of control to collaboration. Patient-focused interventions also often included environmental changes to support patients to manage their emotions (*eg,* access to a sensory room) along with social changes to the ward culture. While the evidence supporting the effectiveness of protocols to reduce seclusion (or their component intervention functions) is limited due to the quality of the empirical designs (discussed below), the ethos of the interventions aligns with contemporary perspectives of patient-oriented recovery-focused mental health care.

An important limitation of the evidence base is the sparse reporting of outcomes of interest to stakeholders; namely outcomes of patient aggression, patient and staff injuries, and patient and staff satisfaction. While the content of these interventions suggests face validity that they may be preferred by patients (and possibly staff) compared to seclusion, there is insufficient evidence to justify this claim. Although outcomes of seclusion, restraint, or composite of both combined with or without forced medication use were reported frequently, they were not consistently reported in the same study, which made it challenging to evaluate trade-offs between reducing seclusion and other interventions. For example, we found that protocols with sensory modulation rooms may reduce episodes of seclusion, but their impact on episodes of restraint was unknown due to insufficient evidence. Conversely, some studies only reported seclusion and restraint as a composite outcome, which did not allow for direct comparison with other studies that reported seclusion and restraint distinctly.

Although multiple interventions show promise to reduce seclusion, findings need to be interpreted with caution. Only 4 of 37 comparative studies used a RCT design. Of the remaining 33 studies, 5 used a concurrent comparison design (often with non-comparable units as comparison) and 28 used a pre-post design. Overwhelmingly, many of these pre-post evaluations were characterized as quality improvement projects in which a hospital or unit implemented an intervention to achieve an administrative or policy goal to reduce seclusion. While some studies were very explicit in defining their theoretical or empirical basis for the design of their protocol,

others were not and the rationale for the protocol appeared primarily driven by a hospital or policy recommendation or preference to reduce or eliminate seclusion. It is possible then, especially in the latter studies, that observed reductions in seclusion rates could be due to staff responding to administrative goals (or presumed pressure) rather than a specific mechanism of action being targeted by an intervention.[51,92]

A major limitation of the evidence was that all the studies relied on self-reported outcome data: staff were either the target or implementers of interventions and were also the outcome observers. In protocols with patient-directed interventions, they also implemented the intervention. Given that most interventions and quality improvement initiatives were explicit in their aims to reduce seclusion, it is feasible that staff could have either changed their behavior or measured their behavior differently to meet hospital or researcher expectations (*ie,* performance bias). Although it is difficult to change who observes and records coercion events for future studies, it is possible to modify or downplay intervention expectations to alleviate performance bias. For example, 1 RCT included in the review (of Safewards) randomized control wards to a physical activity program and led staff and patients in the unit to believe they were receiving the intervention condition (that would lead to reduced rates of seclusion), thereby countering potential for performance bias.[69] Another limitation of available evidence is inconsistent outcome reporting: some studies reported rates of seclusion per number of admissions, others reported raw counts of events (with limited data on sample size), and others did not clearly specify units of time for duration-related outcomes. With respect to analysis, most NRCSs conducted crude (unadjusted) analyses and did not adequately account for confounding.

STRENGTHS AND LIMITATIONS OF THE SYSTEMATIC REVIEW PROCESS

We followed contemporary standards for conducting systematic reviews. The systematic review was designed broadly to include all possible protocols to reduce seclusion but restricted to protocols that could be feasibly delivered in US health care settings. A strength of this review was our detailed coding of the intervention functions of the protocols. Coding in this way allowed us to see past intervention labels and key phrases to isolate the core of their hypothesized mechanisms of action (where reported) and who was being targeted. Our codes provided a structure to group the protocols into meaningful categories for subsequent syntheses and identified trends of intervention functions both within and across these categories. This coding can be used to inform future practice for units hoping to implement these interventions (or parts of them) or identify opportunities for future research (*eg,* untested or rarely used intervention functions).

This review has several limitations. We defined protocols as guidance documents or strategies as an alternative to seclusion. The operationalization of our definition of a protocol required the review team to make decisions about whether an intervention met our definition of a protocol; it is possible that we may have missed protocols in our operationalizing of our definition. Although we aimed to extract data on the resources needed to deliver an intervention, most studies did not explicitly document these data (*eg,* equipment or security needs), and we had to infer the resource needs based the description of the interventions. We sought to make minimal inferences and stay true to the data in the report. Finally, while we believe a strength of our review was the coding of interventions and grouping into conceptually similar categories, it is possible that the conclusions could change if groupings of interventions changed.

APPLICABILITY

Although we restricted the review to studies conducted in settings that may be most applicable to inpatient mental health units in the US, it is important to note that unique elements of interventions and contexts in which they were applied may not generalize to all inpatient psychiatric hospitals. A strength of many of the studies was the extent to which the protocols were tailored to the local context, designed with stakeholder engagement to support their implementation (*eg,* staff and/or patients were invited to participate in understanding the problem and building solutions to address the problem).[47,51,54] Safewards may offer the most generalizable intervention, given the comprehensive nature of the intervention and that evidence in support of the intervention comes from a RCT (it is well investigated, but few studies of Safewards met our review eligibility criteria). An important consideration in the applicability of these protocols is their associated resource needs. Although resource needs were less formally evaluated compared with clinical events, there is some evidence to suggest that they can at times be substantial and include increased personnel, equipment, and time for staff to complete training, deliver programming, or do additional documentation. Users of this report may consider implementing elements of the reviewed protocols (described in detail in Appendix H, with resource implications in Appendix I) that either map to shared clinical contexts (*eg,* the VA) or complement existing local protocols to reduce seclusion (*eg,* if staff education and training are already present, are there aspects of this that can be refined or additional elements such as staff modeling by expert peers or enablement of patients that can be added?).

IMPLICATIONS FOR VA POLICY AND PRACTICE

We identified 4 pre-post studies conducted in the VA.[70,77,78,85] All 4 studies evaluated comprehensive interventions that involved, at minimum, staff training and creating a patient-centered ward culture. Two studies specifically described protocols based on a recovery-oriented model of care, which align with the requirements in VHA Handbook 1160.06 ("inpatient mental health units also must provide a healing, recovery-oriented environment").[30,70,85] One of these studies was a conference poster presentation with limited information on methods and results.[70] The 4 studies relied on self-reported outcome data, and only 1 study conducted regression analysis to adjust for confounding.[77] All 4 studies reported large reductions in outcomes related to seclusion.

Consistent with requirements from VHA Handbook 1160.06 and the Design Guide for Inpatient Mental Health & Residential Rehabilitation Treatment Program Facilities,[93] the studies we identified found that modifying the environment (*eg,* sensory rooms) reduced seclusion. However, we note that open-door polices may not be relevant to the VA context. VA inpatient mental health units should continue to view the environment as a component of treatment and make modifications as needed. For units in established facilities, this means ensuring that there are opportunities for patient-patient and patient-staff social interaction, meaningful activities, and private spaces for relaxation. As the VA constructs new facilities, it should consider constructing smaller units (*ie,* number of patients) with well-designed layouts incorporating natural light, effective acoustics management, and green space.[94]

As the VA aims to implement less restrictive interventions to manage conflict behaviors in inpatient units, there are opportunities for system-level approaches to monitor and evaluate efforts. VA-wide improvement efforts have already been implemented towards standardized

documentation in the electronic health record, such as the Violence Risk Assessment; however, further opportunities exist which can include standardizing measures in the electronic medical record to document process (*eg,* use of seclusion) and outcomes (*eg,* aggression). Once data are uniformly reported in the electronic medical record, then it is possible to standardize reporting at system levels (*eg,* Medical Center, VISN, and national program offices) to evaluate trends and identify units with above/below average process and outcome measures. With standardized reporting of process and outcomes, VA could use its robust electronic medical record to conduct secondary database analyses to develop interventions to identify Veterans at high risk of being placed in seclusion or who exhibit conflict behaviors.

Although not covered in our review, several studies noted the importance of follow-up outpatient care as a feature of high quality inpatient mental health care. This is also highlighted in VHA Handbook 1160.08. Patients in inpatient mental health wards often have 1 or more readmissions after discharge. An aspect of care that was not covered by our review, but which could have an important role in reducing the use of seclusion, is to reduce the need for inpatient mental health care. As an integrated health system, the VA is positioned to ensure continuity between inpatient and outpatient mental health care.[95-97] For example, VA programs such as the Mental Health Intensive Case Management focus on patients who frequently use VHA mental health inpatient and emergency services, with the goal of reducing hospital use and improving patient functioning, reducing symptoms, and minimizing substance use.

IMPLICATIONS FOR RESEARCH

Multiple NRCSs and quality improvement studies have evaluated alternatives to seclusion. The literature had major methodological limitations, some of which may be easy to overcome. Most studies relied on data from medical records to conduct analysis and did not account for confounding variables. Future observational studies should account for confounders in their analyses by, at a minimum, conducting regression adjustment that includes patient characteristics that are also routinely captured in the electronic medical record. For hospitals that are part of large systems, there are opportunities to use electronic medical record data and quasi-experimental methods to compare units that do and do not implement interventions. Such larger studies should use more sophisticated methods to account for potential confounders such as propensity score matching or inverse probability weighting. Few studies reported outcomes by subgroups and there is an opportunity to use medical record data to identify effects of interventions for patients with specific diagnoses. There are also opportunities to improve the reporting of outcomes, such as reporting different forms of coercion as separate outcomes to allow practitioners and policy makers to understand the trade-offs (if any) between reducing seclusion and other forms of coercion. There are also opportunities to improve RCTs, such as conducting more RCTs with appropriate cluster randomized methods (design and analysis) and with appropriate attention and performance bias controls.[69] Comparative evaluations could be improved by detailed reporting of the elements of their protocols via the use of standardized reporting guidelines (*eg,* the template for intervention description and replication [TIDieR]).[98]

CONCLUSIONS

Despite numerous comparative studies, there are limited data on the benefits of seclusion and concern that the practice could cause harm. Restructuring units to include open wards or positive features, sensory/comfort rooms, structured risk assessments that include the Brøset Violence

Checklist, and comprehensive/mixed interventions may reduce seclusion. Restructuring units may also reduce the use of restraints and forced medication. There is no difference in episodes of restraint for other comprehensive interventions or structured risk assessments that include the Brøset Violence Checklist. It is unknown if sensory modulation rooms reduce episodes of restraint. It is unknown if staff training alone or investigator-developed risk assessment tools reduce seclusion. These findings may generalize to the VA, which is already implementing several strategies demonstrating reductions in seclusion (*eg,* unit restructuring and comprehensive/mixed interventions). The literature was marked by methodological limitations. Opportunities for future research and practice include standardizing reporting of process and outcome measures in electronic medical records and conducting analyses that account for confounders.

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APPENDIX A. SEARCH STRATEGIES

PUBMED

("Mental Disorders"[Mesh] OR "Psychiatry"[Mesh] OR "Hospitals, Psychiatric"[Mesh] OR "Mental Health"[Mesh] OR mental[tiab] OR mentally[tiab] OR psychiatr*[tiab] OR schizophren*[tiab] OR psychoti*[tiab]) AND ("Coercion"[Mesh] OR "Patient Isolation"[Mesh] OR "Commitment of Mentally Ill"[Mesh] OR Coerci*[tiab] OR Seclusion[tiab] OR Patient Isolation[tiab] OR Patient Immobili*[tiab] OR Compulsor*[tiab] OR Mentally Ill Commitment*[tiab] OR Involuntary Commitment*[tiab] OR (involunta*[tiab] NOT movement*[tiab]) OR ((lock[tiab] OR locked[tiab] OR locking[tiab] OR contained[tiab] OR containment*[tiab]) AND (door[tiab] OR doors[tiab] OR ward[tiab] OR wards[tiab] OR room[tiab] OR rooms[tiab]))) AND (Prevent* OR avoid* OR deter* OR delay*)

EMBASE

9/6/22, 1:58 PM Exported Print HTML | Embase

Embase®

Embase Session Results

No.	Query	Results
#16	#6 AND #14 AND #15	5,099
#15	prevent* OR avoid* OR deter* OR delay*	9,749,628
#14	#7 OR #8 OR #9 OR #10 OR #13	39,583
#13	#11 AND #12	10,668
#12	door OR doors OR ward OR wards OR room OR rooms	788,828
#11	lock OR locked OR locking OR contained OR containment*	464,247
#10	((((coerci* OR seclusion OR patient) AND isolation OR patient) AND immobili* OR compulsor* OR mentally) AND ill AND commitment* OR involuntary) AND commitment*	2,598
#9	'forensic psychiatry'	19,612
#8	'patient isolation'	2,640
#7	'coercion'	5,081
#6	#1 OR #2 OR #3 OR #4 OR #5	3,470,438
#5	mental OR mentally OR psychiatr* OR schizophren* OR psychoti*	2,117,527
#4	('mental hospital' OR psychiatric) AND hospital	194,047
#3	'psychiatry'	984,900
#2	mental AND disorder	357,808
#1	'mental disease'/exp OR 'mental disease'	2,648,036

COCHRANE

([mh "Mental Disorders"] OR [mh Psychiatry] OR [mh "Hospitals, Psychiatric"] OR [mh "Mental Health"] OR mental:ti,ab OR mentally:ti,ab OR psychiatr*:ti,ab OR schizophren*:ti,ab OR psychoti*:ti,ab) AND ([mh Coercion] OR [mh "Patient Isolation"] OR [mh "Commitment of Mentally Ill"] OR Coerci*:ti,ab OR Seclusion:ti,ab OR "Patient Isolation":ti,ab OR ("Patient" NEXT Immobili*):ti,ab OR Compulsor*:ti,ab OR ("Mentally Ill" NEXT Commitment*):ti,ab

OR ("Involuntary" NEXT Commitment*):ti,ab OR (involunta*:ti,ab NOT movement*:ti,ab) OR ((lock:ti,ab OR locked:ti,ab OR locking:ti,ab OR contained:ti,ab OR containment*:ti,ab) AND (door:ti,ab OR doors:ti,ab OR ward:ti,ab OR wards:ti,ab OR room:ti,ab OR rooms:ti,ab))) AND (Prevent* OR avoid* OR deter* OR delay*)

PSYCINFO

((MH "Mental Disorders"+) OR (MH Psychiatry+) OR (MH "Hospitals, Psychiatric"+) OR (MH "Mental Health"+) OR (TI mental OR AB mental) OR (TI mentally OR AB mentally) OR (TI psychiatr* OR AB psychiatr*) OR (TI schizophren* OR AB schizophren*) OR (TI psychoti* OR AB psychoti*)) AND ((MH Coercion+) OR (MH "Patient Isolation"+) OR (MH "Commitment of Mentally Ill"+) OR (TI Coerci* OR AB Coerci*) OR (TI Seclusion OR AB Seclusion) OR (TI "Patient Isolation" OR AB "Patient Isolation") OR (TI "Patient Immobili*" OR AB "Patient Immobili*") OR (TI Compulsor* OR AB Compulsor*) OR (TI "Mentally Ill Commitment*" OR AB "Mentally Ill Commitment*") OR (TI "Involuntary Commitment*" OR AB "Involuntary Commitment*") OR ((TI involunta* OR AB involunta*) NOT (TI movement* OR AB movement*)) OR (((TI lock OR AB lock) OR (TI locked OR AB locked) OR (TI locking OR AB locking) OR (TI contained OR AB contained) OR (TI containment* OR AB containment*)) AND ((TI door OR AB door) OR (TI doors OR AB doors) OR (TI ward OR AB ward) OR (TI wards OR AB wards) OR (TI room OR AB room) OR (TI rooms OR AB rooms)))) AND (Prevent* OR avoid* OR deter* OR delay*)

CINAHL

((MH "Mental Disorders"+) OR (MH Psychiatry+) OR (MH "Hospitals, Psychiatric"+) OR (MH "Mental Health"+) OR (TI mental OR AB mental) OR (TI mentally OR AB mentally) OR (TI psychiatr* OR AB psychiatr*) OR (TI schizophren* OR AB schizophren*) OR (TI psychoti* OR AB psychoti*)) AND ((MH Coercion+) OR (MH "Patient Isolation"+) OR (MH "Commitment of Mentally Ill"+) OR (TI Coerci* OR AB Coerci*) OR (TI Seclusion OR AB Seclusion) OR (TI "Patient Isolation" OR AB "Patient Isolation") OR (TI "Patient Immobili*" OR AB "Patient Immobili*") OR (TI Compulsor* OR AB Compulsor*) OR (TI "Mentally Ill Commitment*" OR AB "Mentally Ill Commitment*") OR (TI "Involuntary Commitment*" OR AB "Involuntary Commitment*") OR ((TI involunta* OR AB involunta*) NOT (TI movement* OR AB movement*)) OR (((TI lock OR AB lock) OR (TI locked OR AB locked) OR (TI locking OR AB locking) OR (TI contained OR AB contained) OR (TI containment* OR AB containment*)) AND ((TI door OR AB door) OR (TI doors OR AB doors) OR (TI ward OR AB ward) OR (TI wards OR AB wards) OR (TI room OR AB room) OR (TI rooms OR AB rooms)))) AND (Prevent* OR avoid* OR deter* OR delay*)

CAIRN.INFO

(Mental Disorders OR Psychiatry OR Psychiatric Hospitals OR Mental Health OR mental OR mentally OR psychiatr* OR schizophren* OR psychoti*)

AND
(Coercion OR Patient Isolation OR Commitment of Mentally Ill OR Coerci* OR Seclusion OR Patient Isolation OR Patient Immobili* OR Compulsor* OR Mentally Ill Commitment* OR Involuntary Commitment* OR ((lock OR locked OR locking OR contained OR containment*) AND (door OR doors OR ward OR wards OR room OR rooms)))

AND (Prevent* OR avoid* OR deter* OR delay*)

CLINICALTRIALS.GOV

(Coercion OR Patient Isolation OR Commitment of Mentally Ill OR Coerci* OR Seclusion OR Patient Isolation OR Patient Immobili* OR Compulsor* OR Mentally Ill Commitment* OR Involuntary Commitment*) AND (Mental Disorders OR Psychiatry OR Psychiatric Hospitals OR Mental Health OR mental OR mentally OR psychiatr* OR schizophren* OR psychoti*)

PROTOCOLS

The nominating partner made a request for protocols of alternative strategies to seclusion during a monthly VA National Psychiatry Chiefs call on August 12, 2022. Experts attending the call were encouraged to submit existing (and proposed) protocols or policies to reduce seclusion practices for adult patients in inpatient mental health units to the Providence EPC.

APPENDIX B. INTERVENTION FUNCTIONS

Intervention Function[a]	Definition
Education	Increasing knowledge or understanding
Persuasion	Using communication to induce positive or negative feelings or stimulate action
Incentivization	Creating expectation of reward
Coercion	Creating expectation of punishment or cost
Training	Imparting skills
Restriction	Using rules to reduce the opportunity to engage in the target behavior (or to increase the target behavior by reducing the opportunity to engage in competing behaviors)
Environmental restructuring	Changing the physical or social context
Modelling	Providing an example for people to aspire to or imitate
Enablement	Increasing means/reducing barriers to increase capability or opportunity[b]

Notes. [a] Intervention functions taken from Michie, S., van Stralen, M.M. & West, R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implementation Sci 6, 42 (2011). https://doi.org/10.1186/1748-5908-6-42. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/2.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.
[b] Capability beyond education and training; opportunity beyond environmental restructuring.

APPENDIX C. CRITERIA USED IN QUALITY ASSESSMENT

Question	Yes	No	Unclear
1. Design a. Randomized control trial b. Nonrandomized comparison of interventions			
2. Was the article free of discrepancies (*eg*., between text and tables)? Add note if no (high concern)			
3. Were patient eligibility criteria sufficiently clear? Add note if no (high concern)			
4. Was the alternative seclusion protocol (and comparator) sufficiently clear? Add note if no (high concern)			
5. Were outcomes adequately defined without problem? Add note if no (high concern)			
6. Was the setting sufficiently clearly defined? (Add note if no (high concern)			
7. Were there missing results data for ANY outcomes that occurred in inpatient setting? Were there missing results data for >20% of patients (or imbalance between study groups) for outcomes that occurred after discharge? Add note if yes			
8. Outcome assessment a. No (or inadequate) description of how seclusion and/or restraint (episodes or timing) was measured (unclear RoB) b. Independent or blind determination of seclusion and/or restraint (episodes or timing) (low RoB) c. Self-report (by staff) of seclusion and/or restraint (including that reported in records) (episodes or timing) (high RoB)			
9. If RCT, was there inadequate randomization method? Whether randomization was done at the level of the clinic/provider/or the patient, answer no (low RoB) unless there's an obvious flaw.			
10. If RCT, was there inadequate allocation concealment? Whether the randomization was done at the level of the clinic/provider/or patient, answer no unless there's an obvious flaw. If yes, add a note.			
11. If RCT, were staff blinded? Add note if no (high RoB)			
12. If observational study, eligible patients receiving care informed by alternative seclusion protocols were all selected or a random selection of patients was used (*ie*, no concerns about biased selection of alternative seclusion protocol patients). Add note if no (high RoB)			
13. If observational study, comparator group (or clinic/ward) was sufficiently similar (and selected patients were all included or a random sample were included). Add note if no (high RoB)			
14. If observational study, adjustment for confounders a. Crude analysis (unadjusted comparison between alternative seclusion protocol and standard seclusion protocol) (high RoB) b. Regression adjustment or patient matching (accounting for at least age, sex, and mental health diagnosis) (low RoB)			

Question	Yes	No	Unclear
c. Regression adjustment or patient matching (not accounting for at least 1 one of age, sex, and mental health diagnosis) (moderate RoB)			
d. Propensity score analysis (or equivalent) (low RoB)			

Abbreviations. RoB=risk of bias.

APPENDIX D. STUDIES EXCLUDED AT FULL TEXT

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7. Bar-shalita, T. Exploring the effectiveness of a sensory room in reducing seclusion, restraint and aggression at an acute psychiatric unit. 2022. *No outcomes of interest (protocol/study registration).*
8. Baumgardt J, Jäckel D, Helber-Böhlen H, et al. Preventing and reducing coercive measures- an evaluation of the implementation of the safewards model in two locked wards in Germany. *Front Psychiatry* 2019;10:340. *Not alternative to seclusion (explicit).*
9. Baumgardt J, Jäckel D, Helber-Böhlen H, et al. Corrigendum: preventing and reducing coercive measures- an evaluation of the implementation of the safewards model in two locked wards in Germany. *Front Psychiatry* 2019;10:340. *Duplicate.*
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APPENDIX E. QUALITY RATINGS FOR ALL ELIGIBLE STUDIES

Author, Year, PMID, Design	Free of Discrepancies	Clarity: Pop	Clarity: Int/Com	Clarity: Outcomes	Clarity: Setting	Missing Results	Outcome Ascertainment	RCT		Observational Study		
								Adequate Randomization	Adequate Allocation Concealment	Cohort Rep	Comparator Rep	Adjustment for Confounders
Hospital/Unit Restructuring												
Hochstrasser, 2018, Pre-post	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	Yes Regression adjustment (Low RoB)
Hunter,1993, 8444440, Pre-post	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	No Crude analysis[B] (High RoB)
Jenkins, 2014, No PMID, Pre-post	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	No Crude analysis[b] (High RoB)
Rohe, 2017, 26820456, Pre-post	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	No Crude analysis[b] (High RoB)
Staff Education/Training												
Bowers, 2008, 18844799, Concurrent	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Unclear	Yes Regression adjustment (Low RoB)
Forster, 1999, 10565060, Pre-post	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	No Crude analysis[b] (High RoB)
Haefner, 2021, 32749904, Pre-post	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	No Crude analysis[b] (High RoB)
Sensory Modulation												
Lloyd, 2013, No PMID, Concurrent	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Unclear	No Crude analysis[b] (High RoB)
Cummings, 2010, 20349887, Pre-post	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Unclear	No Crude analysis[b] (High RoB)
Azuela, 2018, No PMID, Pre-post	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	No Crude analysis[b] (High RoB)
Novak, 2012, 23014117, Pre-post	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	No

Author, Year, PMID, Design	Free of Discrepancies	Clarity: Pop	Clarity: Int/Com	Clarity: Outcomes	Clarity: Setting	Missing Results	Outcome Ascertainment	RCT		Observational Study		
								Adequate Randomization	Adequate Allocation Concealment	Cohort Rep	Comparator Rep	Adjustment for Confounders
												Crude analysis[b] (High RoB)
Sivak, 2012, 22439145, Pre-post	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	No Crude analysis[b] (High RoB)
Smith, 2013, 24305908, Pre-post	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	No Crude analysis[b] (High RoB)
Zimmermann, 2020, No PMID, Pre-post	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Unclear	No Crude analysis[b] (High RoB)
Risk Assessment												
Abderhalden, 2008, 18700217, RCT	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	No (Low RoB)	No (Low RoB)	NA	NA	NA
van de Sande, 2011, 22016437, RCT	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	No (Low RoB)	No (Low RoB)	NA	NA	NA
Blair, 2017, 26897657, Pre-post	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	No Crude analysis[b] (High RoB)
Clarke, 2010, 20712684, Pre-post	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Unclear	Unclear	No Crude analysis[b] (High RoB)
Harrington, 2019, 31206989, Pre-post	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Unclear	No Crude analysis[b] (High RoB)
Manning, 2022, 36006571, Pre-post	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Unclear	Yes (Low RoB)	No Crude analysis[b] (High RoB)
Trauer, 2010, No PMID, Pre-post	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	Yes Regression adjustment (Low RoB)
Comprehensive/Mixed												
Bowers, 2015, 26166187, RCT	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes[d] (High RoB)	Self-report[a] (High RoB)	No (Low RoB)	No (Low RoB)	NA	NA	NA

Author, Year, PMID, Design	Free of Discrepancies	Clarity: Pop	Clarity: Int/Com	Clarity: Outcomes	Clarity: Setting	Missing Results	Outcome Ascertainment	RCT		Observational Study		
								Adequate Randomization	Adequate Allocation Concealment	Cohort Rep	Comparator Rep	Adjustment for Confounders
Valimaki, 2022, 36040740, RCT	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	No (Low RoB)	No (Low RoB)	NA	NA	NA
Boumans, 2014, 23890418, Concurrent	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	No Crude analysis[b] (High RoB)
Noorthoorn, 2014, Concurrent	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB))	NA	NA	Yes (Low RoB)	Yes (Low RoB)	Yes Regression adjustment (Low RoB)
Blair, 2015, 25751828, Pre-post	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Unclear	Unclear	No Crude analysis[b] (High RoB)
Dickens, 2020, 32691495, Pre-post	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes[e] (High RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	Yes Regression adjustment (Moderate RoB)
Hellerstein, 2007, No PMID, Pre-post	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	No Crude analysis[b] (High RoB)
Khadivi, 2004, 15534024, Pre-post	Yes (Low concern)	No (High concern)[c]	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	No Crude analysis[b] (High RoB)
Lewis, 2009, 19291492, Pre-post	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Unclear	Yes (Low RoB)	No Crude analysis[b] (High RoB)
McDonagh, 2019, No PMID, Pre-post	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Unclear	Unclear	No Crude analysis[b] (High RoB
Pollard, 2007, 17102932, Pre-post	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	Yes Regression adjustment (Moderate RoB)
Richmond, 1996, 8936879, Pre-post	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Unclear	No Crude analysis[b] (High RoB)

Author, Year, PMID, Design	Free of Discrepancies	Clarity: Pop	Clarity: Int/Com	Clarity: Outcomes	Clarity: Setting	Missing Results	Outcome Ascertainment	RCT		Observational Study		
								Adequate Randomization	Adequate Allocation Concealment	Cohort Rep	Comparator Rep	Adjustment for Confounders
Stoll, 2022, 35650555, Pre-post	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	No Crude analysis[b] (High RoB)
Taxis, 2002, 11901660, Pre-post	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Unclear	Unclear	No Crude analysis[b] (High RoB)
Whitecross, 2020, 32391731, Pre-post	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Yes (Low RoB)	No Crude analysis[b] (High RoB)
Zuehlke, 2016, 27845534, Pre-post	Yes (Low concern)	No (High concern)[c]	Yes (Low concern)	Yes (Low concern)	Yes (Low concern)	No (Low RoB)	Self-report[a] (High RoB)	NA	NA	Yes (Low RoB)	Unclear	No Crude analysis[b] (High RoB)

Notes. [a] Self-report of seclusion and/or restraint events of timing of events (including that reported in records); [b] Conducted unadjusted analysis; [c] Unclear sample size, unclear total number of patients or minimal details on patient population; [d] ≥36% missing data on the patient-staff conflict checklist, which was the primary outcome and a tool completed by a ward nurse at the end of each shift to document patient behavior and ward containment measures; [e] 36% missing data on the patient-staff conflict checklist, which was the primary outcome and a tool completed by a ward nurse at the end of each shift to document patient behavior and ward containment measures. Intervention was described as being compliant with JCAHO but limited details on core component of the intervention of agitation.
Abbreviations. con=control; int=intervention; pop=population; RCT=randomized controlled trial; rep=representativeness; RoB=risk of bias.

APPENDIX F. DESIGN DETAILS

Author, Year, PMID, Country	Study Design	Study Dates	Setting	Inclusion Criteria	Exclusion Criteria
Hospital/Unit Restructuring					
Hochstrasser, 2018, 29331599, Switzerland	Pre-post	Jan 2010 to Dec 2015	Single hospital; 15 adult inpatient psychiatric units	Patients ≥18 years of age and admitted to 1 of 15 wards during the study period with capacity for seclusion	NR
Hunter, 1993, 8444440, United States	Pre-post	Mar 1989 to Dec 1990	Single hospital; 2 22-bed locked adult inpatient psychiatric units	Patients admitted to either unit with capacity for seclusion	NR
Rohe, 2017, 26820456, Germany	Pre-post	Jan 2005 to Dec 2014	Single hospital; 10 inpatient psychiatric units	Patients admitted to the 10 units with a capacity for seclusion	NR
Jenkins, 2014, No PMID, United Kingdom	Pre-post	Feb 2011 to Feb 2012	Single hospital; 2 10-bed inpatient psychiatric units (pre-post ward move)	Patients admitted to either unit with capacity for seclusion	NR
Staff Education/Training					
Bowers, 2008, 18844799, United Kingdom	Concurrent control	July 2004 to Jan 2006	Eight acute inpatient psychiatric wards in large metropolitan area	Project advertised to 13 wards, of which 3 applied to participate and were interviewed. Two wards were accepted with an additional ward introduced 9-months into the intervention phase.	NR
Forster, 1999, 10565060, United States	Pre-post	Jan 1995 to Dec 1996	Single hospital; 4 acute adult inpatient psychiatric units	Patients admitted to the 4 units with a capacity for seclusion	NR
Haefner, 2021, 32749904, United States	Pre-post	Oct 2018 to Feb 2019	37-bed adult inpatient psychiatric unit	Patients admitted to the unit with capacity for seclusion	NR
Sensory Modulation					
Lloyd, 2013, No PMID, Australia	Concurrent control	Jan to Dec 2011 (Intervention	Single hospital; 2 20-bed acute adult inpatient psychiatric units	Patients admitted to 2 units with capacity for seclusion	NR

Author, Year, PMID, Country	Study Design	Study Dates	Setting	Inclusion Criteria	Exclusion Criteria
		started July 2011)			
Cummings, 2010, 20349887, United States	Concurrent control	NR	Single hospital; 2 acute inpatient psychiatric units	Patients admitted to either unit with capacity for seclusion	NR
Azuela, 2018, No PMID, New Zealand	Pre-post	Sept 2014 to Aug 2016	Two acute adult inpatient mental health services	Patients admitted to either service with capacity for seclusion	NR
Novak, 2012, 23014117, Australia	Pre-post	NR	Single hospital; 40-bed acute inpatient psychiatric unit	Patients admitted to the unit with capacity for seclusion	NR
Sivak, 2012, 22439145, United States	Pre-post	Jul 2010 to Mar 2011	Single hospital; 2 adult inpatient psychiatric units	Patients admitted to either unit with capacity for seclusion	NR
Smith, 2013, 24305908, United Kingdom	Pre-post	Sept 2010 to Dec 2012	Single hospital; 15-bed male inpatient psychiatric intensive care unit	Patients admitted to the unit with capacity for seclusion	NR
Zimmermann, 2020, No PMID, United States	Pre-post	Jan 2019 to Mar 2020	16-bed acute adult inpatient psychiatric unit	Patients admitted to the unit with capacity for seclusion	NR
Risk Assessment					
Abderhalden, 2008, 18700217, Switzerland	RCT	Jun 2002 to Apr 2004	Fourteen adult inpatient psychiatric units from 324 across 32 psychiatric hospitals.	Wards where most patients had an acute psychiatric disorder; patients were admitted directly onto the ward; usually discharged in 3 months; 18-65 years old; the ward admitted all potential patients and was not specialized for the treatment of specific disorders.	NR
van de Sande, 2011, 22016437, Netherlands	RCT	NR	Single hospital; 36 beds across 4 adult inpatient psychiatric units	Patients admitted to the 4 units with capacity for seclusion	NR

Author, Year, PMID, Country	Study Design	Study Dates	Setting	Inclusion Criteria	Exclusion Criteria
Blair, 2017, 26897657, United States	Pre-post	Oct 2010 to Sept 2012	Single hospital; 120-bed adult inpatient psychiatric service	Patients admitted to the psychiatric service with capacity for seclusion	NR
Clarke, 2010, 20712684, Canada	Pre-post	NR	Single hospital; 11-bed psychiatric intensive care unit	Patients admitted to the psychiatric intensive care unit with a capacity for seclusion who provided verbal, documented consent	NR
Harrington, 2019, 31206989, Australia	Pre-post	Oct 2005 to Apr 2009	Single hospital; 25-bed acute adult inpatient psychiatric unit	Patients admitted to the unit with capacity for seclusion	NR
Manning, 2022, 36006571, United States	Pre-post	NR	Single acute adult inpatient psychiatric unit	Patients admitted to the unit with capacity for seclusion	Patients with a very short length of stay and those deemed inappropriate for the intervention by a clinician (*eg.*, active alcohol withdrawal or similar medication treatments)
Trauer, 2010, No PMID, Australia	Pre-post	Jan 2006 to Jan 2007	Single hospital; 2 22-bed adult inpatient psychiatric units	Patients admitted to either unit with capacity for seclusion	(Post hoc) all admissions in which the patient had been admitted to the ground floor ward, or had been transferred to or from it, were excluded. Data analysis occurred for only 1 ward, the first floor ward.

Author, Year, PMID, Country	Study Design	Study Dates	Setting	Inclusion Criteria	Exclusion Criteria
Comprehensive/Mixed					
Bowers, 2015, 26166187, United Kingdom	RCT	NR	15 hospitals; 31 acute adult inpatient psychiatric units	Acute psychiatric wards for adults of any gender	Wards with specialist function, who planned major changes, or where ≥2 criteria were met: no permanent ward manager in post, a locum consultant solely responsible for inpatient care, >30% nursing staff vacancy rate
Välimäki, 2022, 36040740, Finland	RCT	Jan 2015 to Dec 2017	15 hospitals; 28 inpatient psychiatric units	Wards that are Finnish speaking, have at least 1 psychiatric ward, are open 24/7, and are able to use coercive measures defined in the Finnish Mental Health Act	NR
Boumans, 2014, 23890418, Netherlands	Concurrent	Apr 2008 to Jun 2010	Single hospital; 4 adult inpatient psychiatric units (21-bed intensive care, 7-bed acute intensive care, 20-bed specialized care, and 18-bed forensic unit)	Patients admitted to the 4 units with a capacity for seclusion	NR
Noorthoorn, 2014, No PMID, Netherlands	Concurrent	Jan 2003 to June 2005	Two hospitals; 1 45-bed and one 38-bed adult inpatient psychiatric unit	Patients admitted to either unit with capacity for seclusion	NR
Blair, 2015, 25751828, United States	Pre-post	2000 to 2013	Single hospital; inpatient psychiatry service	Patients admitted to the psychiatry service with capacity for seclusion	NR
Dickens, 2020, 32691495, Australia	Pre-post	Apr 2019 to Jan 2020	One health district; 142 beds across eight adult inpatient psychiatric units	All inpatient mental health units within the health district; patients admitted to the 8 units with capacity for seclusion	Units with current or past utilization of Safewards interventions; units non-

Author, Year, PMID, Country	Study Design	Study Dates	Setting	Inclusion Criteria	Exclusion Criteria
					responsive to research requests
Hellerstein, 2007, 17890979, United States	Pre-post	Sept 2000 to Apr 2006	Single hospital; 24-bed General Clinical Research Inpatient Unit; 12-bed Schizophrenia Research Unit; 22-bed Washington Heights Community Service Unit	Patients admitted to the 3 units with a capacity for seclusion	NR
Khadivi, 2004, 15534024, United States	Pre-post	2000 to 2001	Single hospital; 3 acute adult inpatient psychiatric units	Patients admitted to the 3 units with capacity for seclusion	NR
Lewis, 2009, 19291492, United States	Pre-post	2004 to 2006	Single hospital; 88 beds across 5 adult inpatient psychiatric units; 1 general acute unit and four specialty-based service lines	Patients admitted to the 5 units with capacity for seclusion	NR
McDonagh, 2019, No PMID, United States	Pre-post	2009 to 2018	Single (VA) hospital; 1 adult inpatient psychiatric unit	Patients admitted to the unit with capacity for seclusion	NR
Pollard, 2007, 17102932, United States	Pre-post	Oct 1998 to Jul 2002	Single (VA) hospital; 1 acute adult inpatient psychiatric unit	Patients admitted to the unit with capacity for seclusion	NR
Richmond, 1996, 8936879, United States	Pre-post	Feb 1992 to Feb 1993	Single (VA) hospital; 4 30-bed adult inpatient psychiatric units (three locked and one unlocked)	Patients admitted to the 4 units with capacity for seclusion	NR
Stoll, 2022, 35650555, Switzerland	Pre-post	Jun 2019 to Sept 2020	Two hospitals; 1 19-bed closed acute geriatric inpatient psychiatric unit and one 19-bed open acute adult inpatient psychiatric unit	Patients admitted to either unit with capacity for seclusion	

Author, Year, PMID, Country	Study Design	Study Dates	Setting	Inclusion Criteria	Exclusion Criteria
Taxis, 2002, 11901660, United States	Pre-post	Jun 1996 to Feb 2000	Single hospital; 86-bed acute adult inpatient psychiatric unit	Patients admitted to the unit with capacity for seclusion	NR
Whitecross, 2020, 32391731, Australia	Pre-post	Aug 2016 to Jul 2017 (Intervention started Feb 2017)	Single hospital; 58-bed adult inpatient psychiatric unit	Patients admitted to the psychiatry service with capacity for seclusion	NR
Zuehlke, 2016, 27845534, United States	Pre-post	Oct 2012 to Sept 2013	Single (VA) hospital; 15-bed adult inpatient psychiatric unit	Patients admitted to the unit with capacity for seclusion	NR

Abbreviations. NR=not reported; RCT=randomized controlled trial; VA=Veterans Affairs.

APPENDIX G. BASELINE DATA

Author, Year, PMID, Country, Design	Group Names	N Total Units; N Patients	Race/ Ethnicity, %	Age, Mean (SD) or %	Male, %	Clinical Diagnosis, %
Hospital/Unit Restructuring						
Hochstrasser, 2018, 29331599, Switzerland, Pre-post	2015	15; 2803	NR	46.3 (16.5)	45.9%	**ICD-10** F0 organic, including symptomatic, mental disorders: 4.5% F1 mental and behavioral disorders due to psychoactive substance use: 22.5% F2 schizophrenia, schizotypal and delusional disorders: 19.9% F3 mood (affective) disorders: 28.6% F4 neurotic, stress-related and somatoform disorders: 15.3% F6 disorders of adult personality and behavior: 6.6% Other psychiatric diagnosis: 1.6% No psychiatric diagnosis: 1.0%
	2014	15; 2922	NR	45.4 (16.5)	49.7%	**ICD-10** F0 organic, including symptomatic, mental disorders: 4.8% F1 mental and behavioral disorders due to psychoactive substance use: 22.5% F2 schizophrenia, schizotypal and delusional disorders: 19.2% F3 mood (affective) disorders: 30.9% F4 neurotic, stress-related and somatoform disorders: 12.1% F6 disorders of adult personality and behavior: 8.0% Other psychiatric diagnosis: 1.5% No psychiatric diagnosis: 1.0%
	2013	15; 2989	NR	45.8 (16.5)	47.9%	**ICD-10** F0 organic, including symptomatic, mental disorders: 5.9% F1 mental and behavioral disorders due to psychoactive substance use: 24.4% F2 schizophrenia, schizotypal and delusional disorders: 17.9%

Author, Year, PMID, Country, Design	Group Names	N Total Units; N Patients	Race/ Ethnicity, %	Age, Mean (SD) or %	Male, %	Clinical Diagnosis, %
						F3 mood (affective) disorders: 30.4% F4 neurotic, stress-related and somatoform disorders: 10.9% F6 disorders of adult personality and behavior: 7.5% Other psychiatric diagnosis: 1.2% No psychiatric diagnosis: 1.9%
	2012	15; 2873	NR	45.8 (17.1)	49.2%	**ICD-10** F0 organic, including symptomatic, mental disorders: 5.4% F1 mental and behavioral disorders due to psychoactive substance use: 23.7% F2 schizophrenia, schizotypal and delusional disorders: 18.6% F3 mood (affective) disorders: 30.1% F4 neurotic, stress-related and somatoform disorders: 10.3% F6 disorders of adult personality and behavior: 8.2% Other psychiatric diagnosis: 1.6% No psychiatric diagnosis: 2.1%
	2011	15; 2848	NR	46.9 (17.6)	47.1%	**ICD-10** F0 organic, including symptomatic, mental disorders: 6.2% F1 mental and behavioral disorders due to psychoactive substance use: 25.9% F2 schizophrenia, schizotypal and delusional disorders: 18.2% F3 mood (affective) disorders: 27.0% F4 neurotic, stress-related and somatoform disorders: 11.8% F6 disorders of adult personality and behavior: 7.0% Other psychiatric diagnosis: 1.8% No psychiatric diagnosis: 2.1%
	2010	15; 2924	NR	45.9 (16.9)	47.1%	**ICD-10** F0 organic, including symptomatic, mental disorders: 5.1% F1 mental and behavioral disorders due to psychoactive substance use: 26.7%

Author, Year, PMID, Country, Design	Group Names	N Total Units; N Patients	Race/ Ethnicity, %	Age, Mean (SD) or %	Male, %	Clinical Diagnosis, %
						F2 schizophrenia, schizotypal and delusional disorders: 20.3% F3 mood (affective) disorders:27.8% F4 neurotic, stress-related and somatoform disorders:9.9% F6 disorders of adult personality and behavior: 6.6% Other psychiatric diagnosis: 1.6% No psychiatric diagnosis: 2.1%
Hunter, 1993 8444440, US, Pre-post	After hospital restructuring	2; 78	White: 56.1% Black: 26.7% Hispanic: 13.9% American Indian: 0.0% Other: 2.3%	44	50%	**Diagnostic Tool NR** Schizophrenic disorder: 51.4% Major affective disorder: 20.6% Organic brain syndrome: 4.1% Personality disorder: 3.1% Mental retardation: 1.2% Other: 19.6%
	Before hospital restructuring	2; 66	White: 50.1% Black: 29.6% Hispanic: 18.1% American Indian: 0.2% Other: 1.6%	44	50%	**Diagnostic Tool NR** Schizophrenic disorder: 44.4% Major affective disorder: 22.9% Organic brain syndrome: 2.0% Personality disorder: 4.7% Mental retardation: 0.6% Other: 25.4%
Rohe, 2017, 26820456 Germany, Pre-post	Architecturally positive redesign	10; NR	NR	NR	NR	NR
	Pre-intervention (practice as usual)	10; NR	NR	NR	NR	NR
Jenkins, 2014, No PMID, United Kingdom, Pre-post	Purpose-built psychiatric intensive care unit	1; 18	NR	41.6 (12.8)	100%	**ICD-10** F1 mental and behavioral disorders due to psychoactive substance use: 0% F3 Mood disorders: 6% F6 Behavior and personality disorders: 0% F20 Schizophrenia, schizotypal and delusional disorders: 12%

Author, Year, PMID, Country, Design	Group Names	N Total Units; N Patients	Race/ Ethnicity, %	Age, Mean (SD) or %	Male, %	Clinical Diagnosis, %
						F42 OCD: 0%
	Old unit	1; 18	NR	40.2 (12.7)	83.4%	**ICD-10** F1 mental and behavioral disorders due to psychoactive substance use: 1% F3 Mood disorders: 3% F6 Behavior and personality disorders: 1% F20 Schizophrenia, schizotypal and delusional disorders: 12% F42 OCD:1%
Staff Education/Training						
Bowers, 2008, 18844799, UK, Concurrent	City Nurses intervention – escalation training	3; NR	NR	NR	NR	NR
	Concurrent control (practice as usual)	3; NR	NR	NR	NR	NR
	Pre-intervention (practice as usual)	8; NR	NR	NR	NR	NR
Forster, 1999 10565060, United States, Pre-post	Staff training	4; 3010	NR	NR	NR	NR
	Pre-intervention (practice as usual)	4; 2560	NR	NR	NR	NR
Haefner, 2021, 32749904, United States, Pre-post	Post-test	1; 342	NR	18-25: 27.2% 26-35: 29.5% 36-45: 24.0% 46>: 19.3%	54.1%	**Diagnostic Tool NR** Schizophrenia: 31.3% Schizoaffective disorder: 17.8% Depression: 9.1% Bipolar: 25.4% Psychotic disorder: 16.4%
	Pre-test	1; 388	NR	18-25: 21.9% 26-35: 38.4% 36-45: 19.1% 46>: 20.1%	52.3%	**Diagnostic Tool NR** Schizophrenia: 30.4% Schizoaffective disorder: 14.2% Depression: 10.6%

Author, Year, PMID, Country, Design	Group Names	N Total Units; N Patients	Race/ Ethnicity, %	Age, Mean (SD) or %	Male, %	Clinical Diagnosis, %
						Bipolar: 25.0% Psychotic disorder: 19.3%
Sensory Modulation						
Lloyd, 2013, No PMID Australia, Concurrent	Sensory modulation room	1; NR	NR	NR	NR	NR
	Concurrent control (practice as usual)	1; NR	NR	NR	NR	NR
Cummings, 2010, 20349887, United States, Concurrent	Comfort room	1; NR	NR	NR	NR	NR
	Concurrent control (practice as usual)	1; NR	NR	NR	NR	NR
	Pre-intervention (practice as usual)	1; NR	NR	NR	NR	NR
Azuela, 2018, No PMID, New Zealand, Pre-post	Sensory modulation room	2; NR	NR	NR	NR	NR
	Pre-intervention (practice as usual)	2; NR	NR	NR	NR	NR
Novak, 2012, 23014117, Australia, Pre-post	Sensory room	1; NR	NR	NR	NR	NR
	Pre-intervention (practice as usual)	1; NR	NR	NR	NR	NR
	Study	1; 75[a]	NR	Under 20: 12.0% 20–39: 64.7% 40–59:13.3% 60 or over: 0.0%	17.3%	**Diagnostic Tool NR** Schizophrenia/other psychoses: 33.3% Manic episode or bipolar affective disorder: 24.0% Depression: 8.0% Borderline personality disorder: 5.3% Other: 4.0%

Author, Year, PMID, Country, Design	Group Names	N Total Units; N Patients	Race/ Ethnicity, %	Age, Mean (SD) or %	Male, %	Clinical Diagnosis, %
						Missing: 25.3%
Sivak, 2012, 22439145, United States, Pre-post	Comfort room	5; NR	White 81.4%	Range 18-79 50-59: 36.6%	NR	NR
	Pre-intervention (practice as usual)	5; NR	NR	NR	NR	NR
Smith, 2013, 24305908, United Kingdom, Pre-post	Sensory room	1; NR	NR	NR	100%	NR
	Pre-intervention (practice as usual)	1; NR	NR	NR	100%	NR
Zimmermann, 2020, No PMID, United States, Pre-post	Serenity room	1; 321	NR	NR	NR	NR
	Pre-intervention (practice as usual)	NR	NR	NR	NR	NR
Risk Assessment						
Abderhalden, 2008, 18700217, Switzerland, RCT	Intervention wards	4; NR	NR	39.0 (13.1)	54.4%	**ICD-10** F0 organic, including symptomatic, mental disorders: 3.8% F1 mental and behavioral disorders due to psychoactive substance use: 26.2% F2 schizophrenia, schizotypal and delusional disorders: 33.4% F3 mood (affective) disorders: 15.5% F4 neurotic, stress-related and somatoform disorders: 14.3% F6 disorders of adult personality and behavior: 4.0% Other: 2.7%
	Waitlist control (practice as usual)	5; NR	NR	38.0 (14.3)	55.2%	**ICD-10** F0 organic, including symptomatic, mental disorders: 4.3% F1 mental and behavioral disorders due to psychoactive substance use: 24.2% F2 schizophrenia, schizotypal and delusional disorders: 35.7%

Author, Year, PMID, Country, Design	Group Names	N Total Units; N Patients	Race/ Ethnicity, %	Age, Mean (SD) or %	Male, %	Clinical Diagnosis, %
						F3 mood (affective) disorders: 15.3% F4 neurotic, stress-related and somatoform disorders: 11.5% F6 disorders of adult personality and behavior: 5.0% Other: 4.1%
	Preference arm (practice as usual)	5; NR	NR	41.7 (15.9)	47.5%	**ICD-10** F0 organic, including symptomatic, mental disorders: 1.7% F1 mental and behavioral disorders due to psychoactive substance use: 27.0% F2 schizophrenia, schizotypal and delusional disorders: 26.5% F3 mood (affective) disorders: 21.4% F4 neurotic, stress-related and somatoform disorders: 21.9% F6 disorders of adult personality and behavior: NR Other: 1.4%
	Study	14; 2364	NR	39.5 (14.2)	53.4%	**ICD-10** F0 organic, including symptomatic, mental disorders: 3.3% F1 mental and behavioral disorders due to psychoactive substance use: 24.3% F2 schizophrenia, schizotypal and delusional disorders: 31.0% F3 mood (affective) disorders: 16.2% F4 neurotic, stress-related and somatoform disorders: 14.3% F6 disorders of adult personality and behavior: 3.2% Other: 2.8%
van de Sande, 2011, 22016437, Netherlands, RCT	Structured risk assessment – intervention period	2; 207	Ethic minority: 34%	38	65%	**Diagnostic Tool NR** Psychotic disorder: 66.0% Personality disorder: 28.0% Drug misuse first diagnosis: 9.0%
	Structured risk assessment - baseline	2; 80	Ethic minority: 39%	38 (13)	66%	**Diagnostic Tool NR** Psychotic disorder: 74.0% Personality disorder: 25.0% Drug misuse first diagnosis: 4.0%

Author, Year, PMID, Country, Design	Group Names	N Total Units; N Patients	Race/ Ethnicity, %	Age, Mean (SD) or %	Male, %	Clinical Diagnosis, %
	Control (practice as usual) – intervention period	2; 251	Ethic minority: 31%	39.4	55%	**Diagnostic Tool NR** Psychotic disorder: 49.0% Personality disorder: 8.0% Drug misuse first diagnosis: 3.0%
	Control (practice as usual) – baseline	2; 90	Ethic minority: 18%	40 (11)	60%	**Diagnostic Tool NR** Psychotic disorder: 57.0% Personality disorder: 6.0% Drug misuse first diagnosis: 3.0%
Blair, 2017, 26897657, United States, Pre-post	Evidence-based principles to reduce seclusion / restraint	1; 8029	Black: 16.5% Spanish/Hispanic: 23.6% White: 55.3% Other: 4.6%	> = 12yo: 5.0% 13–65: 87.2% > = 66: 7.8%	51.5%	NR
	Pre-intervention (practice as usual)	1; 3884	Black: 15.9% Spanish/Hispanic: 23.9% White: 56.3% Other: 3.9%	> = 12yo: 4.9% 13–65: 85.9% > = 66: 9.2%	50.3%	NR
Clarke, 2010, 20712684, Canada, Pre-post	Brøset Violence Checklist	1; NR	NR	NR	NR	NR
	Pre-intervention (practice as usual)	1; 48 (pilot trial)	NR	NR	NR	NR
Harrington, 2019, 31206989, Australia, Pre-post	Risk assessment (Clinical Risk Management Initiative)	1; 965	NR	Range 18-65	NR	**ICD-10** Schizophrenia, schizoaffective disorder, or psychosis: 51.8%
	Pre-intervention (practice as usual)	1; 1090	NR	Range 18-65	NR	**ICD-10** Schizophrenia, schizoaffective disorder, or psychosis: 50.5%

Author, Year, PMID, Country, Design	Group Names	N Total Units; N Patients	Race/ Ethnicity, %	Age, Mean (SD) or %	Male, %	Clinical Diagnosis, %
Manning, 2022, 36006571, United States, Pre-post	Risk assessment (Modified Agitation Severity Scale)	1; 389	NR	NR	NR	NR
	Pre-intervention (practice as usual)	1; 352	NR	NR	NR	NR
	Study	1; 742	Asian: 0.7% Black or African American: 11.1% Indigenous: 8.6% White: 74.2% Other: 3.9% Unknown: 1.5% Hispanic: 3.8% Non-Hispanic: 96.2%	35.76 (12.43)	50.1%	NR
Trauer, 2010, No PMID, Australia	The Management of Acute Arousal Program	1; 132	NR	36.3	62%	ICD-10 Schizophrenia: 32.3% Psychosis: 8.5% Schizoaffective: 14.0% Bipolar:10.4% (Hypo)mania: 3.7% Any personality disorder: 23.8% Borderline pers. disorder: 11.0% Adjustment disorder: 4.9% Anxiety disorder: 3.0% PTSD: 1.8%

Author, Year, PMID, Country, Design	Group Names	N Total Units; N Patients	Race/ Ethnicity, %	Age, Mean (SD) or %	Male, %	Clinical Diagnosis, %
						Stress:1.2% Eating disorder: 1.8% Intentional self harm: 3.7% Depression: 23.2% Tobacco: 42.7% Drug misuse: 30.5% Alcohol misuse: 18.3% Suicidal ideation: 10.4%
	Pre-intervention (practice as usual)	1; 149	NR	38.4	59%	ICD-10 Schizophrenia: 38.8% Psychosis: 10.6% Schizoaffective: 8.5% Bipolar: 10.1% (Hypo)mania: 4.3% Any personality disorder: 18.6% Borderline pers. disorder: 5.8% Adjustment disorder: 3.2% Anxiety disorder: 2.7% PTSD: 2.7% Stress: 4.3% Eating disorder: 0.5% Intentional self harm: 1.1% Depression: 14.9% Tobacco: 31.4% Drug misuse: 16.0% Alcohol misuse: 8.5% Suicidal ideation: 2.1%
Comprehensive/Mixed						
Bowers, 2015, 26166187, UK, RCT	Safewards	16; NR	NR	NR	NR	Diagnoses NR
	Control wards (physical health program)	15; NR	NR	NR	NR	Diagnoses NR
	Intervention wards	13; 4163	NR	41.5 (6.5)	49%	Diagnoses NR

Author, Year, PMID, Country, Design	Group Names	N Total Units; N Patients	Race/ Ethnicity, %	Age, Mean (SD) or %	Male, %	Clinical Diagnosis, %
Välimäki, 2022, 36040740, Finland, RCT	Control wards (practice as usual)	15; 4186	NR	40.0 (5.1)	56%	Diagnoses NR
	Study	27; 8349	NR	40.6 (5.7)	53%	Diagnoses NR
Boumans, 2014, 23890418, Netherlands, Concurrent	Methodological Work Approach	1; 134	NR	39.5 (12.4)	79.9%	**DSM-IV** Emotional disorder: 8.2% Bipolar disorder: 8.2% Psychotic disorder: 59.0% Substance use disorder: 41.8% Other disorders: 11.2% Axis 1 unspecified disorders: 11.9% Personality disorders: 33.6% Intellectual disabilities: 3.7%
	Control (practice as usual)	3; 544	NR	38.0 (12.8)	61.8%	**DSM-IV** Emotional disorder: 22.2% Bipolar disorder: 4.8% Psychotic disorder: 41.0% Substance use disorder: 27.8% Other: 14.3% Axis 1 unspecified disorders: 19.1% Personality disorders: 39.2% Intellectual disabilities: 5.7%
Noorthoorn, 2014, No PMID, Netherlands, Concurrent	Intervention	1; 768	NR	45.6 (14.8)	43%	**DSM-IV Axis 1** Psychosocial problem: 3.0% Anxiety disorder: 16.0% Depressive disorder:28.0% Bipolar I disorder: 7.0% Psychotic disorder: 17.0% Dementia and brain disorder: 3.0% Undetermined: 28.0% **DSM-IV Axis 2** Cluster A personality disorder: 5.4% Personality disorder NAO:4.0% Undetermined: 17.0% No information: 75%

Author, Year, PMID, Country, Design	Group Names	N Total Units; N Patients	Race/ Ethnicity, %	Age, Mean (SD) or %	Male, %	Clinical Diagnosis, %
	Pre-intervention (practice as usual)	1; 702	NR	38.8 (11.7)	46%	**DSM-IV Axis 1** Psychosocial problem: 3.0% Anxiety disorder: 21.0% Depressive disorder: 18.0% Bipolar I disorder: 10.0% Psychotic disorder: 22.0% Dementia and brain disorder: 3.0% Undetermined:24.0% **DSM-IV Axis 2** Cluster A personality disorder:9.3% Personality disorder NAO: 9.0% Undetermined: 31.0% No information: 50.0%
Blair, 2015, 25751828, United States, Pre-post	Engagement Model	NR; NR	NR	NR	NR	NR
	Pre-intervention (practice as usual)	NR; NR	NR	NR	NR	NR
Dickens, 2020, 32691495, Australia, Pre-post	Safewards	8; NR	NR	NR	NR	NR
	Pre-intervention (practice as usual)	8: NR	NR	NR	NR	NR
Hellerstein, 2007, 17890979, United States, Pre-post	Comprehen-sive intervention	3; NR	NR	NR[b]	49-67%	NR
	Pre-intervention	NR	NR	NR	NR	NR
Khadivi, 2004, 15534024, United States, Pre-post	Comprehen-sive intervention	3;NR	NR	NR	NR	NR

Author, Year, PMID, Country, Design	Group Names	N Total Units; N Patients	Race/ Ethnicity, %	Age, Mean (SD) or %	Male, %	Clinical Diagnosis, %
	Pre-intervention (practice as usual)	3;NR	NR	NR	NR	NR
Lewis, 2009, 19291492, United States, Pre-post	Crisis Prevention Management program	5; NR	NR	NR	NR	NR
	Pre-intervention (practice as usual)	5; NR	NR	NR	NR	NR
McDonagh, 2019, No PMID, United States	Recovery-oriented programming	1; NR	NR	NR	NR	NR
	Pre-intervention (practice as usual)	1; NR	NR	NR	NR	NR
Pollard, 2007, 17102932, United States, Pre-post	Report study-level only	1; NR	NR	NR	NR	NR
	Pre-intervention (practice as usual)	1; NR	NR	NR	NR	NR
Richmond, 1996, 8936879, United States, Pre-post	Comprehen-sive intervention	3; NR	NR	NR	NR	NR
	Pre-intervention (practice as usual)	3; NR	NR	NR	NR	NR
Stoll, 2022, 35650555, Switzerland, Pre-post	Moral case deliberation	2; NR	NR	NR	NR	NR
	Pre-intervention (practice as usual)	2; NR	NR	NR	NR	NR

Author, Year, PMID, Country, Design	Group Names	N Total Units; N Patients	Race/ Ethnicity, %	Age, Mean (SD) or %	Male, %	Clinical Diagnosis, %
Taxis, 2002, 11901660, United States, Pre-post	Comprehen-sive intervention	1; NR	NR	NR	NR	NR
	Pre-intervention (practice as usual)	1; NR	NR	NR	NR	NR
Whitecross, 2020, 32391731, Australia, Pre-post	Psychiatric behavior of concern team	1; 89	NR	37.3 (9.8)	62.9%	**Diagnostic Tool NR** Primary Diagnosis Schizophrenia or other psychosis: 68.5% Affective disorder: 15.7% Personality disorder or other: 15.7% Secondary Diagnosis Alcohol abuse/dependence: 1.1% Drug abuse/dependence: 51.7% ID/ABI/Developmental disorder: 4.5%
	Pre-intervention (practice as usual)	1; 108	NR	36.6 (9.7)	62.0%	**Diagnostic Tool NR** Primary Diagnosis Schizophrenia or other psychosis: 69.4% Affective disorder: 18.5% Personality disorder or other: 12.0% Secondary Diagnosis Alcohol abuse/dependence: 5.6% Drug abuse/dependence: 58.3% ID/ABI/Developmental disorder: 6.5%
Zuehlke, 2016, 27845534, United States, Pre-post	Recovery-oriented program of care	1; NR	NR	NR	NR	NR
	Pre-intervention (practice as usual)	1; NR	NR	NR	NR	NR
	Study	1; 352	NR	NR	NR	NR

Notes. [a] Report sample for patients experiencing a seclusion event, including repeat patients. The unique number of patients was not reported; [b] 4% of population was aged 13-18.
Abbreviations. ABI=acquired brain injury; ICD-10=International Classification of Diseases 10th Revision; ID=intellectual disability; NR=not reported; S/R=seclusion and restraint.

APPENDIX H. PROTOCOL DETAILS

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
Hospital/Unit Restructuring						
Hochstrasser, 2018, Switzerland, Pre-post	Department of Adult Psychiatry, University of Basel	Open-door policy with recovery oriented care	No	Not explicit; cite previous evidence	An open-door policy will reduce frequency of seclusion and forced medication	**Environment:** • Six previously closed psychiatric wards were permanently opened in August 2011 • Processes for monitoring seclusion and forced medication • Additional changes included more patient-centered and recovery-oriented care, family and caregiver involvement, new psychotherapy concepts, implementation of a primary nursing care delivery model, and other elements
	NA	Pre-intervention (practice as usual)	NA	NA	NA	NA
Hunter,1993, United States, Pre-post	Greater Bridgeport Community Mental Health Center	After hospital restructuring	No	Response to staffing shortages and shifts in patient population. Modeled off the Massachusetts Mental Health Center day hospital-inn program. Various consultations and meetings at all levels of the hospital (staff/management, units, disciplines)	NR	**Environment:** • Two 22-bed locked wards were transformed into an unlocked day hospital program, transitional residential program, and intensive care unit with close monitoring and 24-hour nursing care. Patients are triaged to the appropriate level of supervision and nursing care. • Residential program is supervised, activities designed to prepare patients to return to the community. **Education:** • Day hospital patients provided education on how to administer their own medications. **Incentivization:** • Intensive unit has clearly defined privileges (not specified) **Restriction:** • Therapeutic environment of intensive unit designed to create a structured social milieu with clear expectations.
	NA	Before hospital restructuring	NA	NA	NA	NA
Jenkins, 2014, United	NHS mental health hospital	Purpose built psychiatric	No	Three years prior, an independent assessment by the Psychiatric Intensive Care Advisory Service (a	It was hypothesized that a new and improved ward environment would	**Environment:**

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Kingdom, Pre-post		intensive care unit		collaboration between the National Association for Psychiatric Intensive Care Units and the Royal College of Psychiatrists' Center for Quality Improvement) highlighted environmental difficulties within the old unit, and recommended development of a new ward. Specific methods to design new ward not reported.	be associated with a reduction in arousal and aggression levels overall as measured by formal reports and continuous monitoring records.	• Ensuite facilities created for bedrooms with separate Section 136 facilities (areas to assess patients detained by the police) • Gender-specific areas and a seclusion area conforming to Department of Health guidelines • Seclusion area located more proximally to the nursing station • Greater access to therapeutic activity space with a designated activities room and development of specific visiting areas • Increased levels of visibility as measured by all areas of the ward being visible from the staff base, clear lines of sight and observation systems available in all doors and windows • Increased privacy for patients as all bedrooms are singles
	NA	Old unit	NA	NA	NA	**Environment:** • Furniture was used to partition bedrooms in an attempt to achieve privacy in shared bedrooms
Rohe, 2017, Germany, Pre-post	University Hospital in Tübingen	Architecturally positive redesign	No	Response to structural and therapeutic limitations of former unit built in 1894. Specific methods used to inform design of new building not reported.	NR	**Environment:** • A new building with floors able to serve as open or closed wards, design features to allow natural light in rooms, warm/light tones were used for coloring to increase feelings of warmth and friendliness. • Areas with open space, large lounge, and social areas
	NA	Pre-intervention (practice as usual)	NA	NA	NA	NA
Staff Education and Training						
Bowers, 2008, United Kingdom, Concurrent	City Nurses project	City Nurses intervention – escalation training	No	Replication study of City Nurses project which showed significant reductions in patient aggression, conflict, absconding and self-harm and improvements in ward atmosphere and nurse–patient interaction (Bowers et al	Increases in staff appreciation of patients, skills in managing patients, and rules and routines of ward life is associated with reduced conflict and containment.	**Persuasion:** • Changes and the methods by which they were achieved were negotiated with staff, with feedback on outcomes periodically provided to the wards • Appointed City Nurses worked with wards to increase staff's positive appreciation of patients. **Modeling:** • Two City Nurses clinical experts worked with the wards' staff 3 days per week to demonstrate low-conflict, low-containment, high-therapy nursing.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
				2006,[4] Brennan et al. 2006,[5] Flood et al 2006).[6]		
		Concurrent control (practice as usual)	NA	NA	NA	NA
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Forster, 1999, United States, Pre-post	John George Psychiatric Pavilion	Staff training	No	Multidisciplinary local hospital work group consisting of physicians, psychologists, nurses, social workers, and administrators, to evaluate hospital policy regarding the use of S/R. The committee met biweekly to develop policy recommendations.	Structured S/R programs including interdisciplinary committees and mandatory staff education are associated with a reduction in S/R by shaping staff attitudes towards less restrictive alternatives.	**Education:** • The use of S/R was added to the weekly staff meeting agenda. **Persuasion:** • Policy changes received the full support of the hospital administration. • Administrators participated in training sessions and emphasized that the goal of the program was to reduce S/R and reduce staff injuries. • Progress of the effort was disseminated hospital wide. **Training:** • Mandatory full day trainings all staff with any patient contact. The course had 3 goals: (1) awareness of the factors leading to patient agitation and violence; (2) promote the knowledge/ use of less restrictive measures; and (3) to increase safe staff reactions to violence. • The program emphasized optimal containment techniques practiced to minimize the risk of patient or staff injury. Inappropriate uses of restraint were discussed, and participants role-played verbal interventions as less restrictive alternatives to physical containment.
		Pre-intervention (practice as usual)	NA	NA	NA	NA

[4] Bowers L, Flood C, Brennan G, et al. (2006) A trial to reduce conflict and containment on acute psychiatric wards: city nurses. *Journal of Psychiatric and Mental Health Nursing* 13, 165–172.

[5] Brennan G, Flood C, & Bowers L. (2006) Constraints and blocks to change and improvement on acute psychiatric wards – lessons from the City Nurses project. *Journal of Psychiatric and Mental Health Nursing* 13, 475–482.

[6] Flood C, Brennan G, Bowers L, et al. (2006) Reflections on the process of change on acute psychiatric wards during the City Nurses project. *Journal of Psychiatric and Mental Health Nursing* 13, 260–268.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
Haefner, 2021, United States, Pre-post	Department of Defense (DoD) and the Agency for Healthcare Research and Quality	De-escalation training (TeamSTEPPS)	No	TeamSTEPPS integrates teamwork in the delivery of health care designed to improve patient safety in high-risk environments. Jean Watson's Theory of Human Care (Watson, 2012)[7] formed the framework of the project.	TeamSTEPPS moves nursing staff away from using seclusion by using verbal de-escalation and encourages patients to regain emotional control and reduce aggressive behavior	**Education:** • Posters summarizing the TeamSTEPPS training placed at the nurses' station, the staff lounge, and the report room. • Nurses received a laminated card with the de-escalation process to attach to her/his identification badge. **Persuasion:** • Unit leadership communicated support of the project. • Staff were encouraged to use verbal de-escalation to manage aggressive behavior rather than seclusion. • Staff were encouraged to have a more authentic engagement with the patients to reduce patients' aggressive behavior. **Training:** • Two-step education program aimed at increasing the nurses' knowledge of verbal de-escalation. Three self-learning TeamSTEPPS computer modules followed by in-class demonstrations of de-escalation techniques.
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Sensory Modulation						
Lloyd, 2013, Australia, Concurrent	Queensland Health Seclusion and Restraint Committee	Sensory modulation room	No	SM room was designed in following specifications described by Champagne and Stromberg (2004)[8] and implemented in an acute inpatient setting following the recommendation of the Queensland Health Seclusion and Restraint committee.	1) Patients would report reduced distress after use of the SM environment. 2) The unit in which SM was introduced would have reduced frequency and duration of seclusion for the period after the introduction of SM compared with the period prior to	**Education**: • Provided staff education and exposure to the SM room. • An SM Open Day was held to introduce patients to SM with opportunity to experience various modalities within the approach. **Persuasion:** • Staff / patients were encouraged to use the SM for early intervention when they became aware of increasing patient distress. **Training:** • Phase 1 included an SM Open Day where patients and staff were introduced to SM; Phase 2 was

[7] Watson J. (2012). Human caring science: A theory of nursing (2nd ed.). Jones & Bartlett Learning.

[8] Champagne T, & Stromberg N. (2004). Sensory approaches in inpatient psychiatric settings. Innovative alternatives to seclusion and restraint. *Journal of Psychosocial Nursing, 43*(9), 35–44.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
					the introduction of SM whereas the twin ward where SM was not available would show no such change	basic SM training provided to ward staff over several weeks; Phase 3 included on-going one-on-one coaching with a trainer made available to staff by appointment. **Environment:** • A psychiatric intensive care room was converted into a SM room which included equipment and stimuli. **Enablement:** • Access and modification to SM room was tailored to patients following a post-admission sensory screen to identify the sensory stimulation likely to be calming. • Patients themselves or staff could request use of the SM room.
		Pre-intervention (practice as usual) concurrent control	NA	NA	NA	NA
Cummings, 2010, United States, Concurrent	New Hampshire Hospital	Comfort room	No	Hospital leadership aimed to reduce the use of S/R. The comfort room project started from suggestions from a patient and a staff member. A quality improvement team was formed to oversee the project.	The addition of a comfort room will reduce the use of S/R.	**Education:** • Patients shown the comfort room on admission. **Persuasion:** • Patients are encouraged to use the room as needed and • bring their own music into the room. • Nursing staff at the unit were asked to make suggestions to hospital leadership on project implementation. • Nurse managers empowered nursing staff to assist patients in managing their distress without the use of seclusion or restraint. **Restriction:** • Staff may enter the comfort room any time a patient demonstrates unsafe behavior. • Comfort room monitored by staff via video. **Environment:** • Comfort room door locked from the outside to allow patients to leave the room at will. • Comfort room walls painted light blue and decorated with wallpaper and seascape artwork. Dimmer light switch allowed patients to control brightness of the room.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
						• Multisensory reclining chair; oak entertainment center with television, DVD/VCR and CD player; calming music; books, puzzles, weighted blankets, stress balls and magazines **Enablement:** • When a patient shows signs of distress, the nurse enters a dialogue with the patient to determine the meaning of the behavior. If the patient is in distress, then the nurse may offer the comfort room as a first step in helping the patient progress to a calmer space.
		Concurrent control (practice as usual)	NA	NA	NA	NA
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Azuela, 2018, New Zealand, Pre-post	Dissertation produced at the Auckland University of Technology	Sensory modulation room	No	The SM program was designed based on existing guidelines (Azuela & Robertson, 2016;[9] Champagne, 2008;[10] Sutton & Nicholson, 2011).[11]	NR	**Persuasion:** • Project champions lead the implementation of SM room and had regular contact with the research team. • Project champions were linked with a peer support group. **Training:** • SM training focused on knowledge of clinical principles; therapeutic use of self; use of assessments; selection of sensory modulation activities; displaying supportive attitudes when using a sensory room; and development of personal safety plans with service users. **Environment:** • SM tools included (*eg,* weighted blankets, stress balls, scented sprays, and music player) • The units received support in the setting up of SM rooms and other environmental modifications within the units.

[9] Azuela G, & Robertson L (2016). The effectiveness of a sensory modulation workshop on health professional learning. *The Journal of Mental Health Training, Education and Practice, 11*(5), 317-331. doi:10.1108/JMHTEP-08-2015-0037

[10] Champagne T. (2008). *Sensory modulation & environment: Essential elements of occupation* (3rd ed.). Southampton, MA: Champagne Conferences & Consultation.

[11] Sutton D, & Nicholson E (2011). *Sensory modulation in acute mental health wards: A qualitative study of staff and service users' perspectives*. Auckland, New Zealand: Te Pou o Te Whakaaro Nui.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Novak, 2012, Australia, Pre-post	Study Researchers	Sensory room	No	The theoretical basis for sensory rooms emerged from the trauma-informed care, sensory modulation, self-management and recovery literature.[12] Authors cited the design followed "best practice principles"[13]	The introduction of the sensory room would: (1) reduce distress reported by consumers who used the room; (2) reduce disruptive and disturbed behaviors demonstrated by consumers who used the room; and (3) reduce rates of seclusion and aggression on the unit.	**Education:** • Staff were educated about the room • Consumers were routinely educated about the room and encouraged to use it when they felt distressed or needed 'time-out' **Persuasion**: • Staff encouraged to offer time in the room to patient at the first sign of distress or agitation. • Patients encouraged to use the room when they felt distressed **Environment:** • An existing interview room was converted into a sensory room. The design included a homely environment with scenic pictures, comfortable furnishings and a range of sensory modulation items including weighted blanket, music, magazines/books, rocking chair, scents and a fit ball
	NA	Pre-intervention (practice as usual)	NA	NA	NA	NA
Sivak, 2012, United States, Pre-post	Delaware Psychiatric Center	Comfort room	No	The New York Office of Mental Health website (MacDaniel, 2009)[14] details specific information in the development of comfort rooms which was used as a template.	Use of the comfort rooms would be effective in decreasing client behaviors that could result in the use of seclusion or restraint. Within 4 months of instituting the comfort rooms, there would be 0	**Education:** • Hospital administrators formed a committee, presented the initiative to internal / external stakeholders • Information about comfort rooms shared via newsletters • Weekly ward meetings with staff and patients to discuss committee progress

[12] MacDaniel M, Van Bramer J, and Hogan MF. Comfort rooms: a preventative tool to reduce the use of restraint and seclusion in facilities that serve individuals with mental illness (2009). New York, NY: New York State Office of Mental Health; National Executive Training Institute (NETI). Training curriculum for reduction of seclusion and restraint. Draft curriculum manual (2003). Alexandria, VA: National Association of State Mental Health Program Directors, National Technical Assistance Center for State Mental Health Planning; Champagne T and Stromberg N (2004). Sensory approaches in inpatient psychiatric settings: innovative alternatives to seclusion and restraint. *Journal of Psychosocial Nursing and Mental Health Services*; 42: 1–8.

[13] MacDaniel M, Van Bramer J, and Hogan MF. Comfort rooms: a preventative tool to reduce the use of restraint and seclusion in facilities that serve individuals with mental illness (2009). New York, NY: New York State Office of Mental Health

[14] MacDaniel M. (2009, February). Comfort rooms: A preventative tool used to reduce the use of restraint and seclusion in facilities that serve individuals with mental illness. Retrieved from the New York Office of Mental Health website: http://www.omh.state.ny.us/omhweb/resources/publications/comfort_room/

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
					use of S/R at the hospital. Within 4 months of instituting the comfort rooms, there would be a 50% reduction in client-to-client assaults and self injurious behavior.	• Staff instructed to suggest comfort room use to clients prior to engaging in any behaviors that could result in negative outcomes. **Persuasion:** • Clients reminded of the importance of keeping the comfort room in good condition. • Staff suggest patients use comfort room prior behaviors that led to seclusion or restraint. • Policies governing the use of comfort rooms were developed with agreement of the patient committee members. **Incentivization:** • Contest to name the comfort room. Winner received $5 coupon for the hospital's canteen and acknowledged publicly. **Restriction:** • Patients read the comfort room agreement form and initial the form prior to use. If unable/unwilling to initial the agreement form the use of the comfort room was not allowed. **Environment:** • Wall murals voted by patients painted in each room • Chalkboard painted walls in each room to enable drawing • Drop ceilings to decrease noise level; light panels with sky scenes to improve ambiance • Recliner, rocking chair, foam chair, lap desk, television and DVD player, drawing tools, paper games and puzzles, aromatherapy **Enablement:** • Client survey to identify items to include in the comfort rooms • Clients could volunteer to use the rooms for up to 30 minutes when they feel anxious or angry.
		Pre-intervention (practice as usual)	NA	NA	NA	NA

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
Smith, 2013, United Kingdom, Pre-post	Study Researchers	Sensory Room	No	Based on prior evidence that sensory rooms can reduce the use of seclusion on inpatient units and result in decreased patient distress. Introduction to sensory room occurred after consultation with both staff and patients.	NR	**Environment:** • The sensory room has light blue painted walls, laminate flooring, and 1 window which has a black out roller blind. • The following equipment was placed in the room: a large floor mounted bubble tube, an optic mat, a light/image emitting projector, 2 lying bean bags, 2 sitting bean bags, a variety of cushions, an iPod dock/iPod, and drawers containing magazines, stress relief toys, chewing gum, and educational materials promoting relaxation and healthy living.
	NA	Pre-intervention (practice as usual)	NA	NA	NA	NA
Zimmermann, 2020, United States, Pre-post	Dissertation produced at Brandman University and implemented at Mohave Mental Health	Serenity room	No	The serenity room was based on the comfort room model, established from The Theory of Comfort (Alligood & Tomey, 2010).[15]	Serenity room decreases the use of S/R in patients who are experiencing increased anxiety, anger, and aggression.	**Education:** • 35 staff were provided education on the use of the serenity room. • Patients made aware of the sensory room as a treatment option **Environment:** • Serenity room was painted, decorated, and furnished with a desk, rocking chair, and oversized bean bag, and sensory items like kinetic sand, stretch balls, and fidget spinners.
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Risk Assessment						
Abderhalden, 2008, Switzerland, RCT	Developers of the The Brøset Violence Checklist (Almvik &Woods 1999)[16]	Structured risk assessment (BVC)	No	Implemented validated Swiss version of the Brøset Violence Checklist (BVC)	Risk assessments can reduce the frequency and severity of patient aggression and use of coercive measures.	**Education:** • Staff were provided explicit recommendations for interventions based on risk assessment scores. **Persuasion:** • Staff discussed preventive measures with patients from a list provided on the risk assessment form. • High risk patients received multidisciplinary team consultation to discuss the need for immediate intervention. **Environment:**

[15] Alligood MR, & Tomey AM. (2010). *Nursing Theorists and Their Works.* Maryland Heights: Mosby Elsevier.

[16] Almvik R & Woods P. (1999) Predicting inpatient violence using the Brøset Violence Checklist (BVC). *International Journal of Psychiatric Nursing Research* 4, 498–505.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
						• A structured short-term risk assessment (BVC) administered during the first 3 days of hospitalization. • The BVC requires nurses to rate 6 patient behaviors (confusion, irritability, boisterousness, verbal threats, physical threats, and attacks on objects) and to perform an overall subjective assessment of the risk of imminent violence. Ratings were conducted twice daily.
		Wait-list control (practice as usual)	NA	NA	NA	NA
		Preference arm (practice as usual)	NA	NA	NA	NA
van de Sande, 2011, Netherlands, RCT	Developers of the The Brøset Violence (Almvik & Woods 1999)[g], past trial by Abderhalden et al. (2008), and study investigators	Structured risk assessment (BVC)	No	Implemented BVC. Sought to extend work Abderhalden et al (2008)[17] by exploring the added value of using the checklist during a patient's stay in addition to once during admission.	Structured short-term risk assessment can improve clinical decision-making and can result in timely de-escalation actions, avoiding coercive interventions.	**Training:** • All psychiatric nurses and doctors on the wards were trained to use the risk assessment instruments. **Environment:** • Patients were monitored daily by nurses using risk assessment scales. • Daily scales included the Crisis Monitor, BVC and the Kennedy–Axis V (short version) to identify risks of loss of control. • Weekly scales included the Kennedy–Axis V (full version), the Brief Psychiatric Rating Scale, the Dangerousness Scale and the Social Dysfunction and Aggression Scale were used to evaluate changes in mental state. • The Crisis Monitor scale ratings were discussed by the multidisciplinary team daily and at weekly clinical meetings. **Environment:** • Risk assessment scales incorporated into short-term clinical decision making, intervention planning and evaluation. • The Crisis Monitor scores guided discussions on how to deal with observed changes in risks, such

[17] Abderhalden C, Needham I, Dassen T, Halfens R, Haug HJ, Fisher JE. Structured risk assessment and violence in acute psychiatric wards: randomised controlled trial. Br J Psychiatry 2008; 193: 44–50.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
						as timely verbal de-escalation, behavioral limit-setting, and observation.
		Control (practice as usual)	NA	NA	NA	NA
Blair, 2017, United States, Pre-post	Developers of the BVC (Almvik & Woods 1999),[18] supplemented by Hartford Hospital, Connecticut	Structured risk assessment (BVC)	No	Implemented a previously validated risk assessment tool (BVC) in combination with other evidence-based strategies for reducing violence/aggression (*eg.,* staff education, trauma informed care, assessment of S/R practices, *etc*)	Use of prevention strategies of aggression can reduce use of S/R.	**Training:** • Staff completed a 2-day training based on a trauma-informed model of care intended to reduce staff behaviors that can exacerbate ‘‘trauma reactions’’ in patients. **Restriction:** • Physician renewal orders required for S/R increased from 4 to 2 hours. **Environment:** • BVC used daily documentation completed by a physician on arrival and by nursing staff during each shift. • Introduced new nursing assignments to maximize staff presence in the milieu. • Required that the Medical Director and the Director of Nursing examine all S/R events. • Environmental enhancements included assessing the patient’s ‘‘sensory diet’’ on admission to identify personalized coping strategies to reduce aggression. • Created comfort rooms with calming lights, sensory items, and music.
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Clarke, 2010, Canada, Pre-post	Developers of the The Brøset Violence Checklist (Almvik &Woods 1999)	Structured risk assessment (BVC)	No	Implemented previously validated risk assessment tool (BVC) developed by Almvik &Woods (1999)[19]	The BVC may assist health-care workers in the prevention of or reduction in the impact of violence through an early identification of patients with the potential for violence for which least restrictive	**Education:** • Participating staff members were oriented to the use of the risk assessment tool by the research nurse in brief 15-min sessions, either in a group or individually. **Environment:** • BVC was completed by general duty nursing staff on each shift for the first 72 hours of admission. Nurses completed a form for each patient assigned to them on that shift.

[18] Almvik R. & Woods P. (1999) Predicting inpatient violence using the Brøset Violence Checklist (BVC). *International Journal of Psychiatric Nursing Research* 4, 498–505.

[19] Almvik R. & Woods P. (1999) Predicting inpatient violence using the Brøset Violence Checklist (BVC). *International Journal of Psychiatric Nursing Research* 4, 498–505.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
					interventions can be employed.	• Nurses involved in each aggressive incident were interviewed post incident to determine whether it could have been prevented.
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Harrington, 2019, Australia, Pre-post	Study researchers	Risk assessment (Clinical Risk Management Initiative; CRMI)	No	A model for managing clinical risk to replace standard visual observation. This model was based on clinical engagement principles and was developed using a participatory action research framework involving staff and consumer focus groups. The model was piloted and refined before full implementation.	The model would be associated with a decrease in adverse events and an increase in staff satisfaction levels.	**Education:** • Extensive education program describing changes to patient care and the expectations of staff • Staff explain to medium risk patients planned management strategies • The Patient Safety Plan described: possible early warning signs indicating change to risk; possible activities to decrease exacerbation of risk (identified by patient); and management strategies. **Persuasion:** • All clinical staff encouraged to regularly engage with medium risk patients, regular assessment, planning, and prevention • Patients asked to identify and participate in activities to decrease exacerbation of risk • Regular staff meetings allowed for feedback to improve the CRMI and to provide support and clarification when needed. **Training:** • Staff trained on how to conduct the risk assessment **Environment**: • The CRMI established a tailored risk review process in which risk assessments were at designed periods. Patients were categorized into 'low,' 'medium', or 'high' risk status. Risk assessments for every patient were documented at weekly for discussion at multidisciplinary clinical review meetings. • Members of the clinical team performed routine ward checks with low-risk patients every 2-3 hours. Change in mental status or risk was reported to contact nurse or shift leader. • Medium-risk patients were allocated a contact nurse who was responsible for engaging in regular risk assessment.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
						• High-risk patients were managed in the High Care Area or in the Low Dependency Unit with 1:1 nursing. **Enablement:** • The patient safety plan was completed in collaboration with patients whenever possible.
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Manning, 2022, United States, Pre-post	Study researchers	Risk assessment (modified Agitation Severity Scale; MASS)	No	Implemented a modified version of the Agitation Severity Scale (Strout, 2011)[20] (MASS). Modifications were made to allow for rapid clinical assessment and linking the scale to a treatment protocol.	Rapid clinical assessment of agitation can inform clinical decision making to avoid aggressive and violent behavior and reduce involuntary medication administration and S/R practices.	**Education** • A list of non-pharmacologic interventions compiled based on published guidelines and with input of nursing staff **Persuasion** • Medication use was encouraged as second line treatment. • Staff were encouraged to employ behavioral interventions to reduce agitation: speak with patient about frustration, encourage patient to channel feelings into activity, identify wants and feelings, redirect attention and offer choices, encourage relaxation techniques, offer fluids/food, and encourage self-time out. **Training** • Physicians and nursing staff were trained in the use of the MASS and Agitation Treatment Scale. **Restriction** • Seclusion or restraint were only a last resort and required notification of the physician. • MASS agitation scores determined which interventions were appropriate: very mild score = behavioral intervention; mild score = oral medication; moderate score = intramuscular injection; high score = seclusion/restraint. **Environment** • Treatment protocol incorporated 4 pharmacologic tracks based on agitation score upon admission. Preference was for behavioral intervention followed by oral medication, intramuscular medication and then seclusion or restraint as a

[20] Strout TD. Development of an agitation rating scale for use with acute presentation behavioral management patients [Doctoral dissertation, Connell School of Nursing]. Boston College. 2011. https://dlib.bc.edu/islandora/object/bc-ir%3A101860/datastream/PDF/download/citation.pdf

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						treatment of last resort. Seclusion or restraint also required notification of the physician. • Agitation scores entered directly into the electronic medical record that corresponded with a management strategy. **Enablement** • Patients were encouraged to use coping skills and relaxation techniques
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Trauer, 2010, Australia, Pre-post	Study researchers	Management of Acute Arousal Program (MAAP): assessment, psychosocial interventions, pharmacological interventions, and debriefing.	No	Developed based on prior research showing that enhanced management of problem behaviors and improved monitoring results in lower rates of seclusion[21]	The expectation was that there would be a reduction in seclusion in the 6 months of the intervention compared with the 6 months before its introduction.	**Education:** • 24 to 48 hours after an episode of MAAP, patients were offered a debriefing with a member of staff who had not been involved in the episode. • Ward staff were also given manuals and pocket-sized reference materials, and regular opportunities to meet with senior staff to review the operation of the program. **Persuasion:** • Time-out: the patient is asked to go voluntarily to an area in the unit for a specific period of time away from others • A Practice Development Nurse was appointed for the 6 month implementation to provide training and ongoing support and monitoring. • Senior clinicians on the ward would ask about the initiation of any MAAP episodes at an informal check-in with shift leaders and staff. **Training:** • All clinical staff were trained in MAAP in 2 sessions. The training included all elements of MAAP and use of the documentation system. • Training was also provided to new staff as required. **Environment**: • Ward nursing staff initially assessed patients displaying agitated or aggressive behavior using the Fremantle Arousal Scale. According to the level of arousal, a psychosocial intervention was applied,

[21] D'Orio BM, Purselle D, Stevens D, and Garlow SJ (2004). Reduction of episodes of seclusion and restraint in a psychiatric emergency service. *Psychiatric Services*. 55:581583; Schreiner, G.M., Crafton, C.G. and Sevin, J.A. (2004) Decreasing the use of mechanical restraints and locked seclusion. *Administration and Policy in Mental Health*. 31: 449463.

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						selecting from an ordered list: ventilation, redirection, time-out, restraint, or seclusion • Each MAAP episode was initiated as required and continued until a low level of arousal was reestablished. • 'As required' or PRN medications could be given at any stage. **Enablement** • Ventilation: patients provided opportunities express fears, frustration anger, anxiety and triggers. • Redirection: staff explored with the patient solutions to assist them in gaining control including distraction.
	NA	Pre-intervention (practice as usual)	NA	NA	NA	NA
Comprehensive/Mixed						
Bowers, 2015, United Kingdom, RCT	Study researchers	Safewards	No	The Safewards Model was developed by Bowers (2014)[22] to explain variable rates of conflict and containment and identify a large number of 'staff modifiers' that can impact on the likelihood of conflict or containment incidents. The model enabled the creation of a list of interventions that could enhance the staff modifiers and thereby reduce conflict and containment rates. Panels of expert nurses, service users, and carers identified the top intervention strategies to be included in pilot studies which were subsequently reduced into a package of 10 interventions.	Wards randomized to Safewards vs control would show fewer conflicts and less constraints defined as (coerced medication, seclusion, restraint, and special observation).	**Education:** • Advisory statements (called 'soft words') on handling flashpoints were hung in the nursing office and changed every few days. **Persuasion:** • Staff required to say something good about each patient at nursing shift handover. • Staff encouraged to scan for potential bad news a patient might receive from friends, relatives or staff, and intervening promptly to talk it through. • Staff provided reassuring explanations to all patients following potentially frightening incidents. • A display of positive messages about the ward from discharged patients was introduced. **Training:** • A de-escalation model used by the best de-escalator on the staff (as elected by the ward) expanded the skills of the remaining ward staff. **Environment:** • Structured, innocuous, personal information was shared between staff and patients (*eg.*, music

[22] Bowers L, 2014. Safewards: a new model of conflict and containment on psychiatric wards. *J. Psychiatr. Ment. Health Nurs*. 21, 499–508.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
						preferences, favorite films) via a 'know each other' folder kept in the day room. • A crate of distraction and sensory modulation tools to use with agitated patients included stress toys, music players with soothing music, light displays, and textured blankets. **Modeling:** • A de-escalation model used by the best de-escalator on the staff (as elected by the ward concerned) expanded the skills of the remaining ward staff. **Enablement:** • Publicized standards of behavior by and for patients and staff were mutually agreed upon. • A regular patient meeting to bolster, formalize, and intensify inter-patient support
		Control wards (physical health program)	NA	Wards in the control condition implemented a set of interventions directed at improving staff physical health. Staff on the control wards were told that improvements in their own physical health would lead to them delivering care more effectively, and thereby reduce conflict and containment.	Improvement in physical health was predicted by the Safewards Model to have no impact on conflict and containment.	**Education:** • Desk exercise poster placed in ward office • Staff completed diet assessment and feedback was provided. **Incentivization:** • Staff participated in pedometer-based competitions. **Environment:** • Supplies of health snacks, exercise magazines, and health promotion literature were available in ward offices. **Enablement:** • Linkages to local sports and exercise facilities were made.
Valimaki, 2022, Finland, RCT	Study researchers	VIOLIN (Violence Intervention)	No	Informed by previous research (The EUNOMIA [European Evaluation of Coercion in Psychiatry and Harmonization of Best Clinical Practice] study (Fiorillo 2011)[23]) that developed trainings for professionals on the management of aggressive behaviors and improved	Patient condition, treatment environment and ward culture may affect patient behavior. The use of coercive methods can be prevented with staff education about user-	**Education:** • Program contents were taught to staff via lectures, seminars, workshops, and site visits. • Knowledge on evidence-based studies demonstrating how to fill possible quality gaps shared with staff members. Strengths, weaknesses, opportunities, and threats related to unit changes were captured.

[23] Fiorillo A, De Rosa C, Del Vecchio V, et al. How to improve clinical practice on involuntary hospital admissions of psychiatric patients: suggestions from the EUNOMIA study. *Eur Psychiatry*. 2011;26(4):201-207. doi:10.1016/j.eurpsy.2010.01.013

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				communication between community and hospital teams. Present study (VIOLIN) was designed to improve treatment culture and reduce the need for coercive methods. A pilot study was undertaken with staff members, patients, and relatives in 1 hospital ward prior to present study to ensure acceptability, understandability, usefulness, and feasibility of the intervention.	centered, humane approaches as well as collaboration between patients, family members and staff members.	• Information packages including intervention materials were made available to staff to support competency. **Persuasion:** • Support available from the project team included monthly monitoring and support calls or emails to prompt and encourage change in staff members. **Training:** • Hands-on-support was provided by the trial team. The contact persons worked with staff to help them gain confidence in the new ideas of the intervention. The understanding of the intervention was reviewed using an interim evaluation. **Enablement:** • Local meetings involving staff members, patients, relatives, and the trial team specified detailed areas to be developed and the specific steps to be taken. Possible barriers and facilitating factors for change were identified.
		Control Wards (practice as usual)	NA	NA	NA	NA
Boumans, 2014, Netherlands, Concurrent	Vincent van Gogh psychiatric hospital	Methodical Work Approach	No	The Methodical Work Approach (Coussens 2010; Tiemens et al 2010; Winkelaar 2001)[24] is part of the professional training of almost all mental health personnel in the Netherlands and Belgium. The approach entails a systematic, transparent, and goal-driven way of working with cyclic evaluation and adjustment of the working process. A new format was developed for the treatment in which problems, goals, and means could be specified per life domain. These life domains were derived from the Camberwell Assessment of Needs Short Appraisal	Implementation of the Methodical Work Approach would lead to a reduction in the use of seclusion	**Education:** • The program included education on the negative effects of coercive measures and feedback to all ward teams about their use of these measures. **Persuasion:** • In the team members' daily reports, and during meetings and consultations, staff were encouraged to describe their interventions in relation to the goals and means in the life domains listed in the treatment plan. • All staff members on the ward were actively involved in intervention preparation and were invited to the expert group to redesign the treatment process. **Training:** • Training program included 3 sessions attended by all multidisciplinary team members. During these sessions the principles of the Methodical Work Approach were introduced, and the 5 phases of the

[24] Coussens A. (2010). Methodisch Werken in De Gezondheidszorg. Garant: Antwerpen & Apeldoorn; Tiemens, B., Kaasenbrood, A. & De Niet, G. (2010). Evidence Based werken in de GGZ. Houten: Bohn Stafleu van Loghum; Winkelaar, P. H. (2001). Methodisch Werken: Inleiding Tot Methodisch Handelen Met En Voor Mensen. Leusden: De Tijdstroom.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
				Schedule (Andresen et al. 2000)[25] and were clustered into a suitable framework with the following domains: daily living activities; social, financial, sexual, or psychiatric problems; and substance-use disorders. A domain 'existential questions' was added because of apparent needs in the specific patient group.		treatment process were explained. The procedure for the treatment process, as designed by the expert group, was demonstrated and integrated in the routine of the ward. • During the first training program the teams started to practice with the formulation of care plans using the Methodical Work Approach and were given feedback on the quality of the plans. • A second training program of the Methodical Work Approach lasted 3 days and the application of the approach into daily practice was elaborated on and illustrated with examples of patient care. • The program also included a workshop on the principles of evidence-based practice. The search for means to achieve goals was discussed and nurses learned how to ask 'answerable questions', as well as how to execute a search strategy in the literature. Guidelines were given to the nurses for deciding whether and how to use the evidence they found to modify their plans. **Environment:** • The Methodical Work Approach involves 5 phases: (i) translation of problems into goals; (ii) search for means to realize the goals; (iii) formulation of an individualized plan by matching specific means to individual needs and preferences; (iv) implementation of the plan; and (v) evaluation and readjustment. The 5 phases of the Methodical Work Approach can apply to several aspects of the treatment process: the therapeutic relationship, the treatment process, and/or the conditions for treatment. **Enablement:** • A key element of the Methodical Work Approach is the individual plan, which describes the goals of the patient, as well as the specific means to achieve these goals. Both goals and means are chosen in line with the patient's individual needs and references. The resulting procedure was as follows: the coordinating nurse assisted with the formulation of patient goals for specific life domains. When the family was involved, the coordinating nurse enquired about the family's vision on the goals of the patient and invited the

[25] Andresen R, Caputi P, & Oades LG (2000). Interrater reliability of the Camberwell assessment of need short appraisal schedule. *Australian and New Zealand Journal of Psychiatry*, 34 (5), 856–861.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
						family to participate in the treatment process. The multidisciplinary team then met with the patient and family to outline the short- and long-term goals and the means to achieve these. All decisions made at the meeting were recorded in the treatment plan. Progress was regularly evaluated and discussed with the patient and family. When delays were observed, possible causes were sought at all levels of the treatment process, and adjustments to the plan made accordingly. At follow up meetings the team evaluated, together with the patient and family, whether the goals had been reached and whether continuation of treatment at the ward was still indicated.
		Control (practice as usual)	NA	NA	NA	NA
Noorthoorn, 2014, Netherlands, Concurrent	NR	Intervention	No	Based on the assumption that seclusion did more harm as being traumatic and the assumption that restraint in general reflected more the relation between staff and clients, a project was started to abandon seclusion and diminish other forms of restraint in three years. The project was accompanied by a process evaluation built on and supported by a project leader and a researcher to supply data to the staff of the experimental ward.	NR	**Training:** • Team training aimed at prevention of aggression, dealing with conflict and restoring relationship with patient. Individual coaching provided as follow-up to team training. **Environment:** • A proactive approach in detecting behavior preceding aggression was implemented by using information from the patient, the family, and community nurses in developing means to deal with patient behavior, described within a specified signaling plan. • Family participation was appreciated as a main component of treatment. • At regular intervals researchers provided feedback on the numbers of restraint measures implemented to the team. • After an involuntary admission, dangerousness criteria as formulated within the home environment were re-evaluated within the context of the admission. • Team cohesion was stimulated by frequent team meetings. • During first admission, information was gathered to compile specified signaling plans (*ie*, plans aimed at early detection of behavior preceding aggression). **Restriction:**

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
						• Clear boundaries and limitations with respect to acting out behavior were communicated at admission. **Enablement:** • Agreement with the patient on treatment and signaling plan was valued as an important means in early detection of behavior preceding aggression. • All staff members had an important input in developing treatment plans.
		Control (practice as usual)	NA	NA	NA	NA
Blair, 2015, USA, Pre-post	Salem Health Psychiatric Center	Engagement Model	No	In 2001, based on the Sanctuary approach of Sandra Bloom (1997), the authors' hospital initiated the Engagement Model (Murphy & Bennington-Davis, 2005). The goal of this model was to implement an acute care, inpatient psychiatric recovery model that provided a safe and healing environment founded on trauma-informed care. Positive therapeutic alliances would be built with patients and efforts were directed toward individualization of treatment, with maximization of patient involvement. Management and staff desired to shift power and control from staff to patients as much as possible and reduce or eliminate the need for S/R.	NR	**Education:** • Community meetings are an opportunity to educate patients about the trauma-informed model of care. **Persuasion:** • Spontaneous interventions are welcomed and staff are encouraged to think "outside the box" when exploring alternatives. **Training:** • Annual Professional Assault Crisis Training required for all psychiatric, ED, float pool, and Security Services staff members. • Security staff earn mastery in the use of de-escalation techniques. **Environment:** • Admission screening tools provide information about individual patient trauma history, triggers, history of assault or aggression, and strategies the patient finds helpful for self-calming. • Twice daily community meetings are led by patients with staff guidance to discuss community expectations, issues, and concerns. Non-threatening, recovery-focused discussion questions are asked. The community guidelines and nonviolence policy are read at each meeting. • A special community meeting can be to address brewing problems or debrief an incident that has already occurred. These meetings can be requested by staff or patients. • Staff have developed a more defined low stimulus protocol for intrusive or disruptive patients, increased the use of spontaneous staff "huddles"

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
						for problem solving, and promoted greater individual initiative in creating early self-management plans for challenging cases. • Management team performed a root cause analysis on all incidents of S/R, with subsequent all-staff review in a nonjudgmental forum. • One staff member remains with a more challenging patient, engaging with him or her on a consistent basis until he or she begins to stabilize. • Rooms may be made available where patients can go for a quieter atmosphere. • Groups focused on active practice of relaxation or distraction techniques may be held in side rooms. • Staff have been offered the opportunity to eat free family-style meals with patients. Staff receive traditional 30-minute lunch breaks at a different time. • Staff spend less time in the nursing station or offices. An increased staff presence in the milieu can take the form of simply sitting and chatting with patients or reading a newspaper in the day area during downtime. • Two small side rooms are used as patient television viewing areas, so that the main day area promotes conversation and personal interactions. **Enablement:** • Managers offer themselves as resources rather than as the ultimate decision makers. • Ongoing recognition of unit successes and individual staff initiatives related to improved patient care is encouraged. • Staff to feel empowered in terms of decision making when acute situations occur. • Therapy staff have met twice per week with each patient to discuss patient-identified strengths, goals, progress, and treatment team recommendations. • When requests are reasonable and not dangerous, they are included in choice options including allowance for pet visits, use of music/headphones at times that are outside of the normal unit guidelines, loosening of American Dietary Association restrictions, authorized use of

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						computers, or supervised use of guitar or karaoke equipment.
	NA	Pre-intervention (practice as usual)	NA	NA	NA	NA
Dickens, 2020, Australia, Pre-post	Study researchers	Safewards	No	Safewards intervention was developed by Bowers et al. (2014).[26] A plan for Safewards implementation was devised with a group of select staff from each participating ward who volunteered or were nominated by the unit manager to facilitate the application of the interventions on their unit.	The introduction of Safewards would be associated with significant reductions in reported (i) conflict; (ii) serious conflict (physical violence); (iii) containment; (iv) highly coercive containment (seclusion, restraint, forced medication) after controlling for potential confounding variables; and (v) with significant improvements in the measured violence prevention climate.	**Education:** • Safewards was introduced to nursing staff via hour long ward in-service sessions. **Training:** • 12-week implementation phase included train-the-trainer sessions for clinical nurse consultants, introductory in-service education sessions, and educational materials were provided.
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Hellerstein, 2007, United States, Pre-post	New York State Psychiatric Institute (NYSPI)	Comprehensive intervention	No	In the year 2000, NYSPI initiated an institute-wide program to reduce rates of restraint and seclusion. A multidisciplinary group of physicians, nurses, mental health aides, and quality management personnel convened to review the literature, identify characteristics of NYSPI patients who were restrained or secluded, and to compare NYSPI with other institutions to determine factors contributing	Intervention would 1) reduce the number of patients placed in restraint or seclusion 2) reduce the length of time patients spend in seclusion or restraint and 3) achieve these reductions without increasing adverse outcomes as measured by patient-related staff	**Education:** • Clinical staff educated about appropriate indications for S/R. Staff discussions focused on situations that could potentially require the use of S/R and how clinicians could find alternatives. • The Coping Agreement Questionnaire collected information on what agitates patients, how they respond when upset, and how they would prefer to be treated while on the unit. Also elicits family input on coping methods. **Persuasion:**

[26] Bowers L, Alexander J, Bilgin H, et al. (2014). Safewards: the empirical basis of the model and a critical appraisal. *Journal of Psychiatric and Mental Health Nursing*, 21, 354–364.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
				to higher rates of restraint and seclusion use.	injuries, elopements, and fights and assaults.	• Staff encouraged to discontinue restraints or open the seclusion room door if the patient was sleeping. • Clinical staff used individual patients' responses on the Coping Agreement Questionnaire to help them find ways to deal with agitation. **Restriction:** • The time a patient could remain in S/R after an initial physician's order before a second order was required was decreased from 4 to 2 hours. • Clinical director must evaluate all patients who had 2 or more consecutive episodes of restraint or seclusion. • Clinical practices were changed, so that if security personnel were called to deal with an agitated patient restraint and seclusion were no longer an automatic result. **Environment:** • Additional staff were assigned to escort small groups of patients to the hospital's enclosed garden. • Staff members could escort an individual patient off-unit if it was thought to be likely to help him or her become calmer. **Enablement:** • Policies were changed to allow for off-unit privileges earlier during hospitalization.
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Khadivi, 2004, United States, Pre-post	Bronx Lebanon Hospital Center	Comprehensive intervention	No	Designed to be compatible with the mandates of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to respect patients' autonomy by minimizing the use of S/R in psychiatric and nonpsychiatric settings.	NR	**Education:** • Staff education provided on early recognition of agitation and clinical intervention. **Training:** • Staff trained to recognize of signs of agitation among patients and engage in early clinical intervention. *N.B. All staff members had previously been trained on assault prevention measures; however, this training varied and specific training on violence prevention was not given during the study period.* **Environment:**

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
						• History of inpatient violence was collected within the admission form. • Continuous nursing monitoring was implemented to minimize the duration of episodes of S/R. • Post episode debriefing of the staff and the patient took place with a review of each episode by the senior nurse and a physician.
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Lewis, 2009, United States, Pre-post	Henry Phipps Psychiatric Clinic	Crisis Prevention Management (CPM) program	No	A group of psychiatric nurses created an evidenced-based performance improvement program informed by the Public Health Prevention Model (Huckshorn, 2004).[27] The model uses primary, secondary, and tertiary prevention strategies to decrease the use of S/R. A committee comprised of nurses from all of the inpatient units developed a vision for patient care delivery.	Changing the culture of patient care is believed to be a necessity for any real S/R reduction efforts.	**Persuasion:** • Each unit had nurses who "championed" the new model, reinforced that S/R hinder recovery; pushed peers to become more proactive and creative with [alternative] interventions. • All staff in the department attended a day-long workshop designed to facilitate cultural change through presentations, discussion, and staff input into the development of various aspects of the model. • Signs were posted on the unit and verbal reminders were given to move staff closer to the patients. • When implementing the Comfort Cart the nurse assisted the patient and stayed with them to offer support, participate, and offer feedback. **Training:** • Psychiatric Emergency Training included information on primary, secondary, and tertiary interventions. Presented performance improvement measures, aspects of relationship building, verbal de-escalation techniques, and research findings. • Nurse Managers were trained to serve as "on-call clinicians" for debriefing process. **Environment:** • Daily Safety Focused Community Meetings were modified to add specific content stressing the importance of feeling and being safe in the milieu. • The Phipps Aggression Screening Tool was implemented at admission to identify individuals at

[27] Huckshorn KA (2004). Reducing seclusion and restraint use in mental health settings: Core strategies for prevention. *Journal of Psychosocial Nursing, 42*(9), 22–33.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
						increased risk for violent behavior. Staff utilized the responses to plan care. • Twice a day, several hours after shift report, all nursing staff met briefly to discuss any current or potential safety issues. • A witnessing debriefing process included an immediate post event debriefing led by the "on-call witness." to gather data regarding the triggers and contributing factors in the event, what interventions were attempted, and what barriers were present to impede the success of the interventions. A chart review, a patient interview, and a case conference with the nursing team involved in the incident occurred. The conference was used to identify contributing factors, alternative actions, and changes necessary to prevent future events. A key component of a successful witnessing process is establishing a non-punitive environment where staff is encouraged to share their thoughts, feelings, and opinions. • Staff can implement and evaluate interventions more effectively by sharing what is (or is not) working well for a patient. **Enablement:** • The Personal Safety Plan is initiated on admission to gather information delineating the patient's response to distress and identify what interventions will be most helpful for him to stay in control. It sets the expectation that the individual is a partner in his health care team. If the individual was unwilling to participate, information was obtained from family, care providers, or previous records.
		Pre-intervention (practice as usual)	NA	NA	NA	NA
McDonagh, 2019, United States, Pre-post	Ralph H Johnson VA Medical Center	Recovery-oriented programming	Yes	Identified reducing S/R is a national priority and movement towards recovery-oriented/patient centered care as a VHA priority	NR	**Education:** • Staff education provided • Recovery-oriented curriculum developed including self-help resource book/worksheet **Persuasion:** • Frontline staff were included from the beginning in policy design/implementation. • Established a "commitment to resilience" to inspire innovative solutions within a dynamic environment.

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						• Developed a "pre-occupation with failure" and did not accept the current S/R rate **Training:** • Various trainings provided to patients (eg., illness management, recovery training, social skills training) **Environment:** • Therapeutic Assistants were hired. • Coordination with various departments to put on 4-6 hours of daily programming (Nutrition service, VA police, Human resources, Dental Service, Chaplin Service, Voluntary service, SC State Department of Veteran's Affairs) • Programming included recovery groups, substance use disorder/post-traumatic stress disorder/depression groups, illness management and recovery training, social skills-training, recreation therapy, nutrition group, safety outside the hospital, occupational,, oral hygiene, non-secular groups, various entertainment activities, VA benefits, discharge planning and individual/family meetings. **Modeling:** • Deference to expertise as staff relied on local subject matter experts for guidance/Integration of peer support specialists
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Pollard, 2007, United States, Pre-post	VA Puget Sound Health Care System	Comprehensive intervention	Yes	Local quality improvement initiative (formal and informal) initiated in response to the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) 2000 standards[28] for the utilization of S/R	NR	**Education:** • Facility policies and procedures for the use of S/R were updated to reflect the emphasis on expanded leadership involvement in S/R usage. • Videotapes were prepared to serve as stimuli for discussions regarding risks of restraint, alternatives to restraint, and the senior leadership commitment to a restraint free environment. **Persuasion:** • Explored staff concerns about the new standards through informal discussion and focus groups..

[28] Joint Commission on Accreditation of Healthcare Organizations: Comprehensive Accreditation Manual for Hospitals: The Official Handbook. Oakbrook Terrace, Illinois, Joint Commission Resources, 2000.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
						Positive feedback provided to staff from both senior unit management and facility leadership on the use of alternatives. • Aggregated and trended data were presented and discussed monthly at the facility clinical executive committee meeting. • Staff discussions regarding alternatives to the use of S/R occurred. **Environment;** • Mental health and nursing leadership were tasked with reviewing all episodes of behavioral restraints for appropriateness and for meeting specified documentation requirements. The committee was also tasked with identifying of opportunities for improvement of care and patient safety.
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Richmond, 1996, United States, Pre-post	Fort Lyon VAMC	Comprehensive intervention	Yes	In November 1991 the medical center implemented a facility wide training program on prevention and management of disturbed behavior with the aim of reducing the number of S/R hours and reducing job-related injuries due to managing assaultive behavior.	NR	**Education:** • Nursing staff educated on the need to use least restrictive alternatives to keep patients out of S/R. **Persuasion:** • Staff were instructed to use and document the effectiveness of least restrictive measures on all patients exhibiting disruptive behavior. **Training:** • Staff training on prevention and management of disturbed behavior included early assessment of disrupted behavior, intervention using least restrictive alternatives and a team approach to using physical restraint if least restrictive alternatives are ineffective. • Alternatives included: one-to-one verbal intervention, time out, relaxation techniques, physical/diversional activity, changing the medication regimen or medication as needed.
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Stoll, 2022, Switzerland, Pre-post	Study Researchers	Moral case deliberation	No	Used the framework of clinical ethics support to help practitioners consider the use of coercion by determining the morally most justifiable course	With monthly moral case deliberation 1) formal coercive measures in general and seclusion,	**Persuasion:** • Monthly moral case deliberation meetings occurred in which staff addressed concrete, past, or anticipated moral challenges related to coercion.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
				of action (Hem et al., 2015).[29] Moral case deliberation, a form of clinical ethics support, was specifically adopted for the intervention (Molewijk et al., 2008)[30]	isolation, and coerced medication in particular will become a) less frequent and b) less intense; and 2) health practitioners will show higher moral attentiveness, estimate the intensity of coercion more accurately, exhibit a more negative attitude towards coercion, and disapprove coercion more often than before.	• Health practitioners meet to reflect collaboratively and systematically on concrete clinical cases . • Moral case deliberation took approximately 60 minutes and was structured by one of several conversation methods, chosen according to the purpose of the session. Methods could focus on the process (*eg*, self-refection, teambuilding, skills training) or the product (*eg*, solutions, compromises, answers). • Instead of giving normative recommendations, a trained facilitator focused on the quality of the deliberation process and the meaningfulness of the moral issues.
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Taxis, 2002, United States, Pre-post	Study researchers	Comprehensive intervention	No	Intervention developed via discussion groups with nurses and a review of the literature with concerns including (1) lack of alternatives employed prior to restraining patients, (2) a culture that was resistant to change and (3) issues regarding safety when implementing restraint and seclusion. Audits of events of S/R to alternatives identified. Leadership sought to create a culture shift 'from control to collaboration' to reduce use of S/R. A comprehensive change program was recommended.	NR	**Education:** • Staff education included lectures, skill-building interactive activities, and group discussions. Content included collaboration and de-escalation techniques, 1:1 discussions, diversional activities, ethical considerations, use of medication, and skills for improved documentation, among others. • Patient education was designed to empower the patient in self-monitoring and self-care during upsetting event (*eg*, anger reduction strategies) **Persuasion:** • Staff encouraged to develop individualized plans with patients. • A large story board that had graphs and charts with this information was placed in a prominent location on the unit. **Training:** • Treatment planning teams were trained and encouraged to develop individualized plans for all patients.

[29] Hem MH, Pedersen R, Norvoll R, Molewijk B. Evaluating clinical ethics support in mental healthcare: a systematic literature review. *Nurs Ethics*. 2015;22(4):452–66.

[30] Molewijk AC, Abma TA, Stolper M, Widdershoven G. Teaching ethics in the clinic The theory and practice of moral case deliberation. *J Med Ethics.* 2008 Feb;34(2):120-4.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
						• Nursing employees completed a training program that emphasized the ethical aspects of work-related boundaries, successful interaction styles to assist the patient in self-monitoring and utilization of adaptive problem-solving skills. • The assault program was a developed to give structured individual attention to the patient and focus on the development of nonviolent coping skills. This program included detailed behavioral goals and required a collaborative and educational exchange between a staff member and the patient. **Environment:** • A larger paradigm shift from a culture of control to collaboration. The goal of these changes was to create an environment that fostered the treatment of all persons with respect, dignity, and mutuality. • A 23-item audit tool was developed that addressed the issues of justification of S/R, assessment, care during and after the procedure, and documentation. The nurse who released the patient from S/R was assigned the audit tool. • Quarterly reports were compiled that tracked incidents and trends by shift, unit, and patient which were distributed to unit nurses. • Environmental alterations included the Oasis Room, which was renovated with carpet, comfortable furniture, and reading material. The room was designed to provide patients with a quiet pleasant environment to practice calming techniques. • Events of S/R was evaluated by the nurse project manager to determine appropriateness of the event, attempts to use less restrictive alternatives prior to the incident, care during the incident, and care immediately after the incident. **Enablement:** • Creating behavioral goals required a collaborative and educational exchange between a staff member and the patient. • There was a consistent emphasis from the project manager and the management team that the staff maximize collaborative exchanges and de-emphasize control tactics.

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		Pre-intervention (practice as usual)	NA	NA	NA	NA
Whitecross, 2020, Australia, Pre-post	Study researchers	Psychiatric behavior of concern (Psy-BOC) team	No	After experiencing a substantial increase in aggression in 2016, the service sought to examine the causes and design a new response approach. The "Plan, Do, Study, Act" (PDSA) methodology was used to understand the need for, design, and refine a multidisciplinary team-based response (Taylor et al., 2014).[31]	Implementation of Psy-BOC would reduce restrictive intervention (e.g., seclusions and security involvement) use and harmful behavior occurrence on the unit.	**Education:** • Created and distributed "A Behaviors of Concern (Psy-BOC) Call Psychiatry" guideline to educate staff. **Environment:** • A rostered multidisciplinary team was made available during business hours (triage psychiatry or registrar assistance provided after business hours support) with expertise in behavioral management to assist the treatment team in managing behavioral deterioration. Disciplines represented included medical, nursing, psychology, social work, occupational therapy, art and music therapy, and consumer and carer peer support. • A Psy-BOC call signaled a need for support in responding to an escalating behavior of concern. The call was sent vias SMS to the rostered Psy-BOC team members. **Modeling:** • The Psy-BOC team modelled how to respond during de-escalation to build staff and patient capacity and contributed to behavior management planning.
		Pre-intervention (practice as usual)	NA	NA	NA	NA
Zuehlke, 2016, United States, Pre-post	Long Beach VA	Recovery-oriented program of care	Yes	The VHA has embraced/endorsed the recovery-oriented care model with prior research showing efficacy of recovery interventions in quality-of-care improvements (U.S. Department of Veterans Affairs, Veterans Health Administration, 2013).[32]	Recovery-based models of care and the fostering of empowerment and hope may yield more positive patient outcomes.	**Training:** • The staff recovery intervention education was an 8-week training designed to be brief, basic, and applicable to everyday nursing on an inpatient unit. Each 20-min session presented a new recovery-oriented skill and included role playing. **Environment:** • Interdisciplinary recovery team meetings occurred weekly and included inpatient leadership, peer

[31] Taylor MJ, McNicholas C, Nicolay C, et al. Systematic review of the application of the plan–do–study–act method to improve quality in healthcare. *BMJ Qual Saf* 2014; 23: 290–298.

[32] U.S. Department of Veterans Affairs, Veterans Health Administration. (2013). Handbook 1160.06. *Inpatient Mental Health Services Handbook*. Retrieved from http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID2937

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
						specialists, and a rotating group of frontline nursing staff. These meetings allowed for the discussion of recovery-based improvements on the unit. • Patients gave input to programmatic changes during weekly community meetings. • Recovery-oriented group programming (psychoeducational, recreational, peer-support, and process therapy groups) were increased during the weekdays and added to the weekends. • A certified peer specialist was added to the inpatient unit as an integrated team member who met with patients individually for recovery goal development, assisted patients with accessing resources, and led support group. **Enablement:** • Treatment planning process was modified to include more direct patient participation. Patients were provided a worksheet about goals, objectives, strengths, and preferences, which was incorporated into the treatment plan.
		Pre-intervention (practice as usual)	NA	NA	NA	NA
APNA statement, 2018[a]	American Psychiatric Nurses Association (APNA)	Position Statement on S/R	No	NR	NA	**Education:** • Opportunities for professional growth and learning to develop a treatment approach that promotes individual safety, as well as autonomy and a sense of personal control **Persuasion:** • Oversight of S/R as part of an organization's performance improvement effort with data open for inspection by internal and external regulators • Advocate for policies at federal, state, and organizational levels that will protect individuals from needless trauma associated with S/R. • Argue that individuals have the right to be treated with respect and dignity and in a safe, humane, culturally sensitive and developmentally appropriate manner that respects individual choice and maximizes self-determination. **Training:** • Opportunities for professional growth and learning to develop a treatment approach that promotes

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						individual safety, as well as autonomy and a sense of personal control. • Healthcare organizations must make commitments to assure that staff are adequately trained and currently competent to perform treatment processes, milieu management, de-escalation techniques and S/R. **Restriction:** • S/R must never be used for staff convenience or to punish or coerce individuals. • S/R must be used for the minimal amount of time necessary and only to ensure the physical safety of the individual or others, and when less restrictive measures have proven ineffective. **Environment:** • Create a work culture that supports minimal S/R use and that will enable the vision of elimination to be realized. • Support evidence-based practice through research on the variables associated with the prevention and management of behavioral emergencies. • Effective administrative and clinical structures and processes must be in place to prevent behavioral emergencies and to support the implementation of alternatives.
Ashcraft, 2012[a]	Recovery Innovations Inc.	No force first (NFF) policy	No	Leadership moved towards a recovery-oriented model following "dismal outcomes produced by the traditional approach to service delivery"	NA	**Education:** • Design and implement self-directed education to reduce reliance on “compliance oriented” services such as medication monitoring. **Persuasion:** • Changing the mission statement from one that focused on stabilization to one that embodied a commitment to recovery. • NFF is stressed during new employee selection and orientation. • NFF policy defined the use of force and coercion as a treatment failure. • Critical incidents were tracked and reported with feedback provided to staff and stakeholders. • The leadership team held open forums for staff members to express their fears associated with elimination of S/R Leadership replaced fears with the recovery values of hope, choice, and empowerment.

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						• Weekly e-mails presented stories and videos of the downside of using force. **Training:** • Staff training in effective de-escalation techniques and the NFF process. • Support the training of law enforcement personnel, families, and guardians in the NFF process. • Staff are trained that the only restrictive intervention allowed in the facility is emergency forced psychotropic medication. • Debriefing reports are reviewed with quality management personnel as part of the ongoing training. **Restriction:** • President and chief executive officer mandated that S/R practices would no longer be used and that the NFF policy would be implemented companywide. • Force of any kind is used only as a last resort, even when people may appear to be a danger to themselves or others. • Use involuntary inpatient treatment only for individuals who present a clear danger to self or others and only after choice-based voluntary alternatives were attempted. **Environment:** • Characterize staff-patient relationships as "risk-sharing" partnerships instead of "risk management" control • Development of a recovery culture that stresses the importance of helping to develop meaning, purpose, and spirituality in people's lives • Over 50% of staff members are peer support specialists, who understand the trauma caused by S/R.
Clement, 2021[a]	Clement J. Zablocki VA Medical Center	Least restrictive means, documentation & staff training	Yes	To produce a policy that maintains the Medical Center's alignment with The Joint Commission's standards related to the use of S/R	NA	**Education:** • Education provided on least restrictive interventions that should be considered before initiating restraints (*eg*, decreasing stimulation). • Patient and family are educated on behaviors that require the use of S/R and least restrictive alternatives. • Criteria for discontinuing restraints is communicated to the patient.

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						Persuasion: • Staff are expected to be active participants in care planning and to engage in skillful communication with team members to ensure S/R minimization. • Providers should recognize individual manifestations of fatigue, anxiety, and increasing stress, and intervene as soon as possible. • Staff should deploy active listening, reality orientation, or affirm disorientation based on the situation and provide family or visitor support. **Training:** • Individuals ordering S/R must have previously completed requirements for education on S/R policy. • Staff caring for patients in S/R must demonstrate competency on (1) Strategies to identify staff and patient behaviors, events, and environmental factors that may trigger the use of S/R (2) De-escalation techniques (3) Safe use of restraints (4) Application of hospital approved types of restraints (5) Safe use of seclusion. • Staff who perform and document patient assessments when S/R are used must demonstrate competency in (1) Assessments needed to identify risks for patients and staff related to S/R (2) Identification of alternatives to S/R, requirements for continued monitoring, and assessment and reassessment needs of patients (3) Skills to manage emergency responses related to S/R. **Restriction:** • S/R use is limited to clinically justified situations or when warranted by patient behavior that threatens the physical safety of the patient, staff, or others. • S/R may not be used for coercion, discipline, convenience, or retaliation and may not be based solely on a patient's history of dangerous behavior. • Alternatives should be used or considered prior to S/R. • If S/R is employed, the least restrictive intervention is used to protect the patient, staff, or others. • If S/R is initiated or discontinued by a nurse without an initial order, a licensed independent practitioner must be notified within 1 hour and an order must be

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						entered in the electronic health record within 6 hours. • As needed, PRN orders, or trials of S/R are not acceptable. • Time limited orders must be entered in the electronic health record and are not to exceed 4 hours. **Environment:** • Decrease stimulation and promote a calm environment, via noise reduction strategies, evaluation of light levels, calming music or TV and aromatherapy. Provide opportunity for physical activity, distraction, or diversional activities • Promote comfort and evaluate need for adequate pain management. Ensure basic needs are met and sensory aids are in place • Medical Center Director and Associate Director for Patient Care Services are responsible for ensuring policy compliance. • Registered Nurses caring for patients are responsible for plus performing and/or supervising patient monitoring, application and removal of S/R and provision of nursing care. • Restraint and Seclusion committee are responsible for analyzing S/R data to identify opportunities for improvement, recommend action plans to improve S/R processes, and decrease S/R.
Iwamasa, 2017[a]	VHA Seclusion and Restraint Reduction Workgroup	Seclusion and Restraint Reduction Toolkit	Yes	In 2017, a Seclusion and Restraint Reduction Workgroup convened and used the National Association of State Mental Health Program Directors' Six Core Strategies Approach to Reduce the Use of Seclusion and Restraint (Huckshorn, 2004,[33] 2006)[34] as the framework for developing this toolkit. Also included existing VHA tools and resources that do not necessarily fit neatly	NA	**Education:** • Facility leaders complete a self-assessment of current S/R practices and a plan for making the zero S/R vision a practice reality by analyzing other successful organizations. • Staff education should include debriefing with each patient after each restraint episode. • Toolkit includes information brochure for patients/families, and a voluntary treatment agreement. **Persuasion:** • Facility plans contain clear expectations, outcomes, and timelines. Facility leadership requests

[33] Huckshorn KA (2004; Sept). Reducing the use of seclusion and restraint in mental health systems: A public health prevention approach with interventions. *Journal of Psychosocial Nursing and Mental Health Services.* (September Special Issue; Guest Editor), 42, 22–33.
[34] Huckshorn KA (2006) Re-designing State mental health policy to prevent the use of seclusion and restraint. *Administration and Policy in Mental Health,* 33, 482– 491.

Author, Year, Country, Design	Producer	Label	VA Protocol	Methods to Produce Protocol	Hypothesis	Intervention Function Content
				into the 6 core strategy categories.		feedback patients and families regarding the use of S/R. • All strategies are directed at persuading clinicians to reduce S/R with the goal of providing recovery-oriented services. • Effective debriefing can help to foster the belief that the event was clinically driven event to assist the patient with regaining control vs punitive. • Self-control strategies should be incorporated within treatment plans using a collaborative approach between staff and Veterans. **Environment:** • Facility leadership ensures the unit environmental design provides opportunities for relaxation and promotes space for therapeutic staff and Veteran interactions. • Leadership to work towards developing a culture of safety. Facility executives should provide guidance, direction, participation, and ongoing review of processes within the facility as they relate to patient care, the facility's mission, philosophy of care and guiding values that demonstrate congruence to obtaining a zero S/R environment. • Use of comfort rooms, meditation, relaxation, and sensory modulation • Toolkit includes a design guide which emphasizes home-like, non-institutional, and patient-centered environments that imbue healing, familiarity, and a sense of being valued. • Inpatient staff should collaborate with quality management to access data and run reports used to assess process improvement efforts. • Implement a regular data review workgroup meeting schedule and review and update existing S/R policies as needed. • Mental health environment of care checklist focuses on the removal of environmental hazards that could increase the risks of self-harm. **Enablement:** • Input from patients and their families is critical to understanding existing problems and developing approaches which align with mission of reducing S/R.

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VA Northern California HCS[a]	VA Northern California Health Care System: Mather Behavioral Health Inpatient Care Unit	"Code green" response	Yes	NR	NA	**Persuasion:** • Any staff member concerned with a patient's potential for perpetrating a behavioral emergency should notify other staff. Clinical consultation may help to avert an escalation to a behavioral emergency. • During a code green, the team leader creates a plan which involves verbal intervention (if anyone in the response group as a positive relationship with the patient they should be assigned responsibility for the verbal de-escalation) and show of support/force in which the patient is given the reason for the team response and offered a clear behavioral options. **Training:** • All staff complete training on prevention and management of behavioral emergencies and disruptive behavior. The training course will include information on hospital policies, verbal intervention strategies and physical control techniques. **Restriction:** • Code green is initiated only after appropriate clinical measures and de-escalation strategies have been ineffective. • If the patient is unable to regain control a "therapeutic containment" is performed using appropriate techniques. Only non-offensive physical interventions are authorized in behavioral emergencies. To prevent injury to staff and the patient, physical restraint should not be attempted with fewer than 3 team members. **Environment**: • Any VA employee observing a behavioral emergency may initiate a code green. If a professional staff member of a mental health program is present, they should assume this responsibility. The procedure is initiated by accessing the overhead paging system, then announcing "code green, (dayroom, group room, north corridor, *etc*)." • Upon becoming aware of the code green, available staff, police, and other employees in the vicinity should converge on that location but "stand away" from the patient unless instructed otherwise. All nonessential personnel should be removed

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						(including patients and visitors) as well as all potentially injurious objects. • Quiet Room is a safe area with enhanced monitoring to escort patients with escalating anxiety or aggression. • During a code green, the team leader creates a plan which involves task assignment and transfer of responsibility. (The team leader may request another team member take the lead if he/she feels the patient would respond better or if another staff member has more experience.) **Enablement:** • A debriefing should follow within 48 hours of the completion of any code green procedure. The purpose of the debriefing is to focus on needed areas of improvement in managing such incidents and to allow staff to ventilate feelings.
Wale, 2011[a]	New York City Health and Hospitals Corporation (HHC)	Seclusion and Restraint Reduction Initiative	No	In 2007, to continue the culture change from a medical model to a patient-centered rehabilitation and recovery-oriented service system, HHC launched the S/R Reduction Initiative. The goals of the initiative included further reductions in S/R use and continued culture change to make the psychiatric inpatient and emergency services more patient centered and trauma informed. Interdisciplinary change teams that would oversee the initiative at each facility were established. Teams included all disciplines, peer counselors, hospital security staff, and training and quality-improvement personnel.	NA	**Education:** • Guideline on the use of sensory modulation tools and techniques was distributed along with a sensory modulation staff training course. • HHC issued corporate guidelines to assist facilities with the revisions to facility-specific policies and procedures to bring them in line with changes in The Joint Commission and Centers for Medicaid and Medicare Services regulations. **Persuasion:** • HHC contracted with Office of Technical Assistance (OTA) faculty to provide consultation. At each site, the consultants met with the facility's behavioral health leadership team, quality-improvement staff, nursing leadership, and frontline staff to get a thorough picture of the facility's efforts to reduce the use of S/R. The consultants reviewed S/R documentation in a random sample of facility records. They then prepared summary reports of their findings, and their analysis of hospital strengths and priority areas recommended for improvement. **Incentivization:** • A competition was announced with a prize for the facility demonstrating the greatest improvement in a year. **Training:**

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						• "Creating Violence Free and Coercion Free Mental Health Treatment Environments for the Reduction of Seclusion and Restraint" training from the OTA included 3 2-day training sessions. Participants were introduced to 6 core strategies that have been proven to reduce S/R use including concepts of primary and secondary prevention, leadership roles and responsibilities, key characteristics of trauma-informed care systems, using data to inform practice, environmental factors that can be modified to create a safer or calmer environment, rigorous post-event debriefing, and consumer and family roles in the inpatient setting. • Train-the-trainer models for crisis prevention and management were developed including sixteen highly interactive sessions to develop crisis de-escalation skills using a graded system of alternatives. • HHC hired sensory modulation experts to train staff. • Training modules for hospital police to clarify their role when asked to respond to a patient who is agitated or in crisis. **Restriction:** • A 2-hour maximum limit on an S/R order for adults **Other:** • HHC facilities were asked to submit S/R data to the corporate office before the project was officially announced so that a baseline could be analyzed. Since the kick-off, facilities have been submitting data on S/R use and patient and staff injuries with monthly data reviews. The data are also shared quarterly in a comprehensive data book with corporate and individual facility S/R trend charts.

Notes. [a] Protocol without evaluation study results.
Abbreviations. APNA=American Psychiatric Nurses Association; BPRS=Brief Psychiatric Rating Scale; BVC=Brøset Violence Checklist; CPM=crisis prevention management; CRMI=clinical risk management initiatives; DoD=Department of Defense; HHC=Health and Hospitals Corporation; JCAHO=Joint Commission on Accreditation of Healthcare Organizations; MAAP=Management of Acute Arousal Program; MASS=modified agitation severity scale; NFF=no force first; NYSPI=New York State Psychiatric Institute; OTA=Office of Technical Assistance; PDSA=plan, do, study, act; PRN=pro re nata; SM=sensory modulation; S/R=seclusion and restraint; VA=Veterans Affairs.

APPENDIX I: INTERVENTION RESOURCE NEEDS

Author, Year, PMID	Staffing Needs and Mix	Environment	Programming	Space Requirements	Equipment Needs	Documentation Needs	Time to Perform Checks on Patients	Time to Perform Documentation	Changes in Service Provision
Hospital/Unit Restructuring									
Hochstrasser 2018 29331599	NR	NR	NR	NR	NR	NR	NR	NR	NR
Hunter 1993 8444440	Housing program staffed by mental health workers; intensive unit staffed by nurses. Multidisciplina-ry team responsible for all day hospital and intensive care patients regardless of which unit they are located at any given time	NR	Group based recreation program with activities in a community setting intended to raise residents' level of functioning and promote their return to community living	NR	NR	Upon admission to acute day hospital patients are evaluated to determine intensive care unit or residential program placement	NR	NR	Patients transferred to different units maintained the same care team throughout their stay; Intensive inpatient unit restructured around group-based treatment
Rohe 2017 26820456	NR	NR	NR	NR	NR	NR	NR	NR	NR
Jenkins 2014 No PMID	NR	NR	NR	Ensuite facilities for bedrooms, greater privacy as each bedroom was a single, separate Section 136 facilities (areas to assess patients detained by the police), gender specific areas, visiting area,	NR	NR	NR	NR	NR

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				designated activities room and a seclusion area conforming to Department of Health guidelines.					
Staff Education/Training									
Bowers 2008 18844799	Two City nurses were appointed for the project who were clinical experts in acute inpatient care with long experience in practice development	NR	A structure of rules and routines for ward life was implemented	NR	NR	NR	NR	NR	NR
Forster 1999 10565060	Management of Assaultive Behavior team consisted of a multidiscipline-ry group who met biweekly; "charismatic leader" headed staff training program	NR	NR	NR	NR	NR	NR	NR	NR
Haefner 2021 32749904	Multidisciplina-ry team of registered nurses, psychiatric pharmacy technicians, psychiatric nurse practitioners, social workers, occupational therapists and activity therapists	NR	NR	NR	NR	NR	NR	NR	NR

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Sensory Modulation									
Lloyd 2013 No PMID	NR	NR	NR	Psychiatric intensive care room converted into sensory modulation room	$5,000 of sensory modulation equipment including bean bag chairs, musical instruments, therapy balls and aromatherapy	Screening form to determine which sensory modulation format would benefit the patient	NR	NR	NR
Cummings 2010 20349887	Multiple staff members including nursing staff, executive staff and managers, representatives from maintenance, engineering, staff development, and rehabilitation departments involved in brainstorming and setting up the comfort room over a 2 year period	NR	NR	Comfort room to promote a healthy, therapeutic, supportive, and safe environment; locked from the outside allowing patients to leave when they no longer felt distressed	Lighting with a dimmer switch, wallpaper, light blue wall paint, multisensory reclining chair, oak entertainment center with a television DVD/VCR and CD player, calming music, books, puzzles, weighted blankets, stress balls, and magazines.	After each instance of comfort room use, staff documented whether the episode was considered effective in reducing distress	NR	NR	NR
Azuela 2018 No PMID	NR	NR	NR	NR	NR	NR	NR	NR	NR
Novak 2012 23014117	NR	Sensory room created a homely environment including scenic pictures and comfortable furnishing	NR	An existing interview room was converted into a sensory room	Comfortable furnishings and a range of sensory modulation items including weighted blanket, music, magazines, books, rocking chair, scents, and fit ball	A sensory room assessment form was developed. Consumers rated their level of distress on a 10-point scale and clinicians rated 11 common behavioral disturbances before and after room use. Age diagnosis,	NR	NR	NR

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						duration of use, whether medication was used, what items were used in the room and whether seclusion was required was also documented			
Sivak 2012 22439145	Multidisciplina-ry team including financial office representative to approve costs, procurement office representative to assist with ordering, performance improvement department representative for data collection, a psychologist, activity department representative for comfort measures guidance, 2 direct-care RNs, 2 nursing supervisors, carpenter for comfort room construction, infection control nurse and safety manager	NR	NR	One room on each unit was converted into a comfort room; comfort rooms installed with drop ceilings for noise control and sky scene light panels to improve ambiance; chalkboard covered wall and mural wall voted on by clients placed in each comfort room	Recliner, rocking chair, foam chair, carpets, lap desk, television, and Blu-ray disc player in each comfort room	Comfort room use login sheet; comfort room agreement form signed by clients prior to each use; comfort room voluntary feedback form	NR	NR	NR
Smith 2013 24305908	NR	NR	NR	Sensory room was 5 meters by 2.5 meters with light blue painted walls, laminate flooring and	Large floor mounted bubble tube, an optic mat, a light/ image emitting projector, 2 lying bean bags, 2	NR	NR	NR	NR

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				one window with a black out roller blind	sitting bean bags, a variety of cushions, an iPod dock/ iPod and drawers containing; magazines, stress relief toys, chewing gum and educational materials promoting relaxation and healthy living				
Zimmermann 2020 No PMID	Human service workers and nursing staff responsible for supervising the use of serenity room	NR	NR	Serenity room to provide a safe environment for patients to self-soothe and practice alternative coping strategies	Rocking chair, oversized bean bag, curtains, inspirational quotes and chalkboard wall, built in desk area, sound machine, kinetic sand, stretch balls and strings, fidget spinners, inspirational books, liquid filled non-toxic floor tiles, Himalayan salt lamp night light, and squeeze balls	NR	NR	NR	NR
Risk Assessment									
Abderhalden 2008 18700217	Group staff meetings to discuss preventive measures for a small subgroup of high-risk patients	NR	NR	NR	NR	Structured short-term risk assessment for every new patient during the first 3 days of hospitalization and twice daily thereafter	NR	Short-term risk assessment completed within 3 days of admission and twice daily during the rest of the inpatient stay	NR
van de Sande 2011 22016437	NR	NR	NR	NR	NR	The Crisis Monitor for early recognition of patterns associated with escalation and symptom severity change; Brøset	NR	5 minutes per patient to administer daily Crisis Monitor; 15 minutes per patient to	NR

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						Violence Checklist and the Kennedy–Axis V (short version) scale to identify risks of loss of control; Kennedy–Axis V (full version), Brief Psychiatric Rating Scale (BPRS), Dangerousness Scale, Social Dysfunction and Aggression Scale to evaluate mental state changes and current patient behavior		administer weekly assessment measures	
Blair 2017 26897657	NR	NR	NR	NR	NR	Medical Director and the Director of Nursing examined all S/R events to determine if a formal administrative review was needed (based on severity and outcome). Review included questions on staff knowledge of the patient, the specific de-escalation intervention(s) used and the communication about the patient's status prior to the event.	Physician review frequency increased to every 2 h from every 4 h for patients over the age of 18	NR	NR
Clarke 2010 20712684	Six full-time nursing staff charged with the responsibility of completing the Brøset Violence Checklists	NR	NR	NR	NR	Brøset Violence Checklist completed by general duty nursing staff for each patient assigned to him or her on each shift	NR	Brøset Violence Checklist completed during each nursing shift for the first 72 h of admission	NR
Harrington 2019 31206989	Patients categorized as medium risk were allocated a contact nurse responsible for	NR	NR	Secure high-care area for high-risk patient population	NR	Risk assessment completed on admission, when mental status changed, or at a minimum of once per	Ward rounds conducted 2–3x an hour and at strategic times such as	Risk assessments were completed on admission, at first psychiatrist consultant review,	NR

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	ensuring that regular engagements occurred; patients in the high-risk category managed in either a secure high-care area with a staff: patient ratio of 2:5 or in the open ward with 1:1 nursing.					week to categorize patients as 'low', 'medium', or 'high' risk; Medium and high risk patients had risk reviews regularly throughout the day while low risk patients had risk reviews 1x per shift; Patient Safety Plan captured possible early warning signs for change in risk, activities to decrease exacerbation of risk and management strategies	shift change and meal time; Medium risk patients required an initial comprehend-sive engagement by contact nurse and subsequent reviews occurred no less frequently than 1x an hour; patients requiring 4+ engagements an hour were reviewed for change is risk status to high-risk' patients requiring only hourly engagements were considered for change to low-risk	and with change in mental status; Risk review conducted 1x per shift for low-risk patients; risk reviewed conducted regularly throughout the day for medium and high-risk patients	
Manning 2022 36006571	NR	NR	NR	NR	NR	Modified Agitation Severity Scale (MASS) to assess current severity of patient agitation	NR	One minute to score the Modified Agitation Severity Scale at time of admission and then twice daily per patient	NR
Trauer 2010 No PMID	Staff not involved in the MAAP event engaged in a patient debriefing; A Practice Development Nurse was appointed for	NR	NR	Time-out areas away from others were required for patients to voluntarily go when experiencing distress	NR	Nursing staff initially assessed patients displaying agitated or aggressive behavior using the Fremantle	Reassess-ments and variation in management occurred every 15 to 30 minutes	De-briefings occurred 24-48 hours after the MAAP event	NR

Author, Year, PMID	Staffing Needs and Mix	Environment	Programming	Space Requirements	Equipment Needs	Documentation Needs	Time to Perform Checks on Patients	Time to Perform Documentation	Changes in Service Provision
	the six month implementation to provide training and ongoing support and monitoring; Senior clinicians would perform informal check-ins with shift leaders and staff about MAAP initiation					Arousal Scale[35]; All assessments and interventions were recorded on specially designed forms.			
Comprehensive/Mixed									
Bowers 2015 26166187	Large number of research staff operated across multiple sites; completion was dependent on the support of nursing staff to engage with the trial and undertake new and additional activities	NR	NR	NR	Crate of distraction and sensory modulation tools including stress toys, mp3 players with soothing music, light displays, textured blankets, *etc*	NR	NR	NR	NR
Välimäki 2022 36040740	NR	NR	NR	NR	NR	NR	Physician review frequency increased to every 2 h from every 4 h for patients over the age of 18	NR	NR
Boumans 2014 23890418	Active involvement of staff for program preparation	NR	NR	NR	NR	Decisions documented in a care plan and goals regularly evaluated by a coordinating nurse	NR	NR	NR

[35] Castle DJ, and Alderton D. (2003) Management of acute arousal in psychosis. In: Castle DJ, Copolov DL, Wykes T. (eds). Pharmacological and Psychosocial Treatment in Schizophrenia. London: Martin Dunitz, pp. 89102.

Author, Year, PMID	Staffing Needs and Mix	Environment	Programming	Space Requirements	Equipment Needs	Documentation Needs	Time to Perform Checks on Patients	Time to Perform Documentation	Changes in Service Provision
Noorthoorn 2014 No PMID	NR	NR	NR	NR	NR	During a first admission, information was gathered to compile specified signaling plans (*ie*, plans aimed at early detection of behavior preceding aggression)	NR	NR	NR
Blair 2015 25751828	Managers offer themselves as resources to staff; staff expected to take initiative in creating early self-management plans; 1 staff member may remain with a more challenging patient, engaging with him or her on a consistent basis until he or she begins to stabilize; management team performed a root cause analysis on all incidents of S/R; increased staff presence on ward.	Staff eat family-style meals with patients; An increased staff presence in the milieu can take the form of sitting and chatting with patients over a cup of coffee, playing a game of cards with patients, or reading a newspaper or magazine in the day area during a downtime.	2x daily community meetings reinforce community structure, provides stability, emphasizes safety, invites openness, enhances cohesiveness and enables patients to be heard; A special community meeting can be held, to address problems or debrief an incident; Special groups focused on active practice of relaxation or distraction techniques .	Two small side rooms are used as patient television viewing areas, so that the main day area promotes conversation and personal interactions; Rooms may be made available where patients can go for a quieter atmosphere.	Music/ headphones, authorized use of computers, supervised use of guitar or karaoke equipment	Admission screening tools provide information about individual patient trauma history, triggers, history of assault or aggression, and strategies the patient finds helpful for self-calming.	NR	NR	NR
Dickens 2020 32691495	NR	NR	NR	NR	Sensory boxes funded from project resources, sourced and constructed by the project officer	NR	NR	NR	NR

Author, Year, PMID	Staffing Needs and Mix	Environment	Programming	Space Requirements	Equipment Needs	Documentation Needs	Time to Perform Checks on Patients	Time to Perform Documentation	Changes in Service Provision
Hellerstein 2007 17890979	Two staff members available to escort an individual patient off-unit to assist in de-escalation; Staff assigned to escort small groups to the hospital's enclosed garden	NR	NR	NR	NR	The Coping Agreement Questionnaire to determine what upset or agitated patients, how they responded when upset and how they preferred to be treated while on the unit; family were asked for input on effective coping methods	The time that a patient could remain in restraint or seclusion before an additional physician order was required decreased from 4 h to 2 h.	NR	NR
Khadivi 2004 15534024	NR explicitly; assumed additional staff time required for a) post episode debriefing of the staff and the patient; b) review of each episode by the senior nurse and a physician; and c) continuous nursing monitoring to minimize the duration of episodes of seclusion and restraint	NR	NR	NR	NR	NR explicitly; assumed additional documentation associated with a) new history of inpatient violence to admission form; b) continuous nursing monitoring c) post episode debriefing of the staff and the patient; d) review of each episode by the senior nurse and a physician	NR explicitly; assumed additional time associated with continuous nursing monitoring	NR explicitly; assumed additional time for documentation associated with a) new history of inpatient violence to admission form; b) continuous nursing monitoring c) post episode debriefing of the staff and the patient; d) review of each episode by the senior nurse and a physician	NR
Lewis 2009 19291492	An "on call witness" and "on call clinician" facilitated the multistep de-briefing process	A Family Style Meals program permitted patients and staff to sit and eat together; patient and staff art gallery; framed pictures of staff's pets on the unit	NR	Patient moved to their room, activity room or empty alcove for use of Comfort Cart	Comfort cart included stress balls, CD players with headphones, aromatherapy, art supplies, musical instruments, karaoke, games, and journal writing supplies.	The Phipps Aggression Screening Tool for identification of patients at risk for violent behavior; The Personal Safety Plan to identify interventions to prevent violence; The Patient Support Sheet to inform the observer of patients under observation on target	NR	Stage 1 of witnessing program for S/R debriefing occurred immediately after S/R episode, Stage 2 occurred within 24 hours of event.	NR

Author, Year, PMID	Staffing Needs and Mix	Environment	Programming	Space Requirements	Equipment Needs	Documentation Needs	Time to Perform Checks on Patients	Time to Perform Documentation	Changes in Service Provision
						symptoms, effective interventions, and reportable events; Witnessing program for S/R debriefing which included immediate post event debriefing to gather data on triggers and contributing factors, interventions, and barriers to success. Second stage of program involved a chart review, patient interview and case conference with nursing staff for root cause analysis.			
McDonagh 2019 No PMID	Hired 6 Therapeutic Assistants/ Peer support specialists to put on 4-6 hours of programming a day; involved representatives from other service lines to run group programming including police, human resources, chaplain, nutrition, and voluntary services.	NR	4-6 hours of programming per day included: Recovery groups (anger, relaxation, *etc*); SUD/PTSD/ Depression groups; Illness Management and Recovery Training; Social Skills Training; Recreation Therapy; Nutrition group; Safety outside the hospital; Occupational/ CV building; Oral Hygiene; Non-secular groups; Various entertainment activities; VA Benefits; Discharge planning; Individual/family meetings	NR	NR	Program indicators: Attendance Sheets, Recovery Services Checklist and Various psychometrics (PCL-5, BAM-R, BDI-2, etc); S/R monitoring included documenting day of week initiated, tour of duty initiated, number of episodes per patient, age and gender of patient, staff nurse initiating S/R, any injuries occurring to staff and/or patients, compliance with documentation standards and medication use	NR	NR	NR

Author, Year, PMID	Staffing Needs and Mix	Environment	Programming	Space Requirements	Equipment Needs	Documentation Needs	Time to Perform Checks on Patients	Time to Perform Documentation	Changes in Service Provision
Pollard 2007 17102932	NR	NR	NR	NR	NR	NR	NR	NR	NR
Richmond 1996 8936879	NR	NR	NR	NR	NR	Data collection form to identify which least restrictive alternative(s) were used and the outcome at the time of intervention with a disruptive patient	NR	NR	NR
Stoll 2022 35650555	NR	NR	NR	NR	NR	NR	NR	NR	NR
Taxis 2002 11901660	Core training content delivered by charge nurse to the non-licensed staff in the form of staff meetings and 1:1 sessions; Professional nurse became the coach for non-licensed personnel	NR	Specific programmatic changes made to address the needs of patients with Axis 2 diagnoses with a tendency to engage in self-harming incidents, manipulative, and attention-seeking behaviors	NR	NR	Each event of restraint or seclusion was evaluated by the nurse project manager to determine: (1) appropriateness of the restraint or seclusion, (2) any attempt to use an appropriate, less restrictive alternative prior, (3) care during the incident, and (4) care immediately after the incident; Quarterly report compiled to track incidents and trends by shift, unit, and patient; 23-item audit tool was created that addressed justification of the use of seclusion or restraint, assessment, care during the procedure, care immediately after the procedure and documentation.	NR	NR	NR

Author, Year, PMID	Staffing Needs and Mix	Environment	Programming	Space Requirements	Equipment Needs	Documentation Needs	Time to Perform Checks on Patients	Time to Perform Documentation	Changes in Service Provision
Whitecross 2020 32391731	A multidisciplinary team available on call to manage behavioral deterioration (medical, nursing, psychology, social work, occupational therapy, art and music therapy, and consumer and carer peer support professionals)	NR	NR	NR	NR	NR	NR	NR	NR
Zuehlke 2016 27845534	27 interdisciplinary team members consisting of psychiatry, nursing, psychology, social work, peer support, and occupational/recreational therapy; certified peer specialist added to the inpatient unit to meet with patients individually for recovery goal development, resource access and support group facilitation.	NR	Group programming included psychoeducational, recreational, peer-support, and process therapy groups which were increased during the weekdays and added during weekends.	NR	NR	Patients provided a worksheet on goals, objectives, strengths, and preferences which was incorporated into the treatment plan.	NR	NR	NR

Author, Year, PMID	Staffing Needs and Mix	Environment	Programming	Space Requirements	Equipment Needs	Documentation Needs	Time to Perform Checks on Patients	Time to Perform Documentation	Changes in Service Provision
APNA Statement, 2018[a]	Healthcare organizations and their nursing leadership groups must make commitments of adequate professional staffing levels, staff time and resources to assure that staff are adequately trained and currently competent to perform treatment processes, milieu management, de-escalation techniques and seclusion or restraint.	NR	NR	NR	NR	Oversight of seclusion and restraint must be part of an organization's performance improvement effort and these data must be open for inspection by regulatory agencies. Reporting requirements must be based on a common definition of seclusion and restraint and include specific data requirements.	NR	NR	NR
Ashcraft 2012[a]	Over 50% of RI staff members are peer support specialists, who through their own experience understand the trauma caused by the use of force and coercion.	Establishment of a noninstitutional environment. In the crisis centers, patients have their own key and home-cooked food; liberal property management processes are employed. Individuals keep their own phones,	Morning recovery activity designed to create an atmosphere of community by having people share and connect with one another through acceptance rituals. Design and implement, with service recipient input, self-directed programming,	NR	Computer stations provide access to e-mail.	Development of "electronic recovery record" for patients and staff to create electronic recovery and personal wellness plans and jointly document progress in an electronic "wellness journal."	NR	NR	In outpatient services, case management has been enhanced or replaced by peer recovery coaching.

Author, Year, PMID	Staffing Needs and Mix	Environment	Programming	Space Requirements	Equipment Needs	Documentation Needs	Time to Perform Checks on Patients	Time to Perform Documentation	Changes in Service Provision
		and families and friends are welcome to visit.	including education and self-advocacy to reduce reliance on "compliance oriented" services.						
Clement, 2021[a]	Physicians, resident physicians, clinical psychologists, registered nurses and advanced practice registered nurses are required to actively participate in plans of care and multidisciplinary teams. The Restraint and Seclusion committee was created to review S/R data for usage and trends.	NR	Provide opportunity for physical activity, distraction, or diversional activities	NR	Play calming music or TV CARE Channel, provide aromatherapy	All orders for restraints and seclusion are entered in the electronic health record using approved hospital order sets. Documentation of restraint and seclusion included a description of circumstances leading to S/R, attempted alternatives with patient's response, revisions to the plan of care, patient injuries and death related to restraint use.	Assessment and reassessment of the patient regarding the need for restraint or seclusion was required with nurses conferring with providers for continued S/R use before the order expires. For behavioral cases, assessment of physical/psychological status occurred once every 4 hours and every 30 minutes for violent cases.	If an RN initiates/discontinues a seclusion or restraint episode, a licensed independent practitioner must be notified as soon as possible but no later than 1 hour afterward, and an order must be entered in the electronic health record within 6 hours.	NR
Iwamasa, 2017[a]	Facilities identify a peer support specialist as a seclusion/restraint reduction	Home-like non-institutional, and patient-centered environments	Provide patients with meaningful activities through interdisciplinary	Comfort rooms for meditation, music relaxation and	Equipment for sensory modulation and comfort rooms.	Data relating to S/R episodes must be inputted into the electronic health record. Toolkit provides de-briefing	NR	Debriefing must take place within 24-48 hours after the actual event.	NR

Author, Year, PMID	Staffing Needs and Mix	Environment	Programming	Space Requirements	Equipment Needs	Documentation Needs	Time to Perform Checks on Patients	Time to Perform Documentation	Changes in Service Provision
	champion for every unit. Facility leadership ensures adequate inpatient mental health staffing. Inpatient staff should collaborate with quality management staff to access data and run reports used to assess process improvement efforts. Facilities should establish an interdisciplina-ry data review workgroup.	that imbue healing, familiarity, and a sense of being valued. Environmental design provides opportunities for Veteran relaxation and promotes space for therapeutic staff and Veteran interactions.	collaborations including daily treatment planning, motivating patients to educational, therapeutic, and recreational activities. Incorporation of sensory modulation.	sensory modulation.		form that can be adopted by staff. Development of a national standardized restraint note. Facilities should consider use of standardized note titles as a process for collecting data while national templates are being developed.			
VA Northern California HCS[a]	Charge RN and/or an attending psychiatrist act as clinical consults when staff are concerned about a patient's behavior or potential for a behavioral emergency. The Code Green team leader has the most knowledge of the	NR	NR	Use of a quiet room, which is a safe area for enhanced monitoring of patients with escalating anxiety or aggression.	NR	A “Code Green Response Report” is completed in the electronic health record within 48 hours of the incident. The template includes all pertinent information related to the behavioral emergency response.	NR	NR	NR

Author, Year, PMID	Staffing Needs and Mix	Environment	Programming	Space Requirements	Equipment Needs	Documentation Needs	Time to Perform Checks on Patients	Time to Perform Documentation	Changes in Service Provision
	patient/situation and/or has the most training. If a therapeutic containment is to occur, at least 3 team members are required.								
Wale 2011[a]	New job title of Behavioral Health Associate who receives extensive crisis prevention and de-escalation training and performs some duties that had been assumed by hospital police.	NR	NR	NR	Purchase of sensory modulation equipment for each inpatient psychiatric unit which included rockers, weighted blankets and vests, and a rolling cabinet in which to store them.	Psychiatric emergency assessment form to be used in all the Psychiatric Emergency Services. This includes a trauma assessment, patient preferences regarding effective calming measures, triggers for agitation, and preferences regarding S/R use. Monthly data submissions to the corporate office are required.	NR	NR	NR

Notes. [a] Protocol without evaluation study results.

APPENDIX J. RESULTS

Results Summary: Seclusion

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Seclusion	Time in Seclusion
Hospital/Unit Restructuring				
Hochstrasser, 2018, Switzerland, Pre-post	Open-door policy with recovery-oriented care 14,435 patients (may include some admissions before policy which was implemented in Aug 2011) 2,803 patients in 2015	Pre-intervention (practice as usual) 2,924 patients in 2010	**Seclusion** OR (95% CI) open door policy: 0.88 (0.83 to 0.92) **Cases with at least 1 seclusion** Last year of post intervention follow-up (2015): 3.5% (97/2803) Baseline year (2010): 8.2% (239/2924) **Mean (SD) number of seclusion** Last year of post intervention follow-up (2015): 2.9 (3.4) Baseline year (2010): 5.1 (8.7)	**Mean (SD) hours of seclusion** Last year of post intervention follow up (2015): 18.2 (6.5) Baseline year (2010): 27.1 (16.4) One-way ANOVA p <0.001
Hunter, 1993, United States, Pre-post	After hospital restructuring 78 patients	Before hospital restructuring 66 patients	**No. seclusion events post (10 months) vs pre (10 months)** Post period no. events: 32 Pre period no. events: 31 Difference: p = NS	**Hours of seclusion episode** Post period mean (SD): 2.3 (2.8) Pre period mean (SD): 5.0 (8.4) Difference: p = 0.02
Jenkins, 2014, United Kingdom, Pre-post	Purpose built psychiatric intensive care unit 18 patients	Old unit 18 patients	**No. seclusion incidents post (3-6 months) vs pre (3-6 months)** Post period no. events: 3 Pre period no. events: 14 Difference: p = 0.001	**Total duration seclusion (minutes)** Post period: 531 Pre period: 2117 Difference: p = 0.001 **Mean (SD) duration of seclusion (minutes)** Post period: 190 (122) Pre period:153 (98) Difference: p = 0.288
Rohe, 2017, Germany, Pre-post	Architecturally positive redesign	Pre-intervention (practice as usual)	NR	NR

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Seclusion	Time in Seclusion
Staff Education/Training				
Bowers, 2008, United Kingdom, Concurrent and pre-post	City Nurse Intervention - Escalation Training 3 wards	Pre-intervention (practice as usual) and concurrent control (practice as usual) 5 wards	**Seclusion per shift (pre-post analysis only)** Post period mean (SD): 0.007 (0.098) Pre period mean (SD): 0.016 (0.125) Difference (among only intervention ward): p = 0.019	
Forster, 1999, United States, Pre-post	Staff training	Pre-intervention (practice as usual)	NR	NR
Haefner, 2021, United States, Pre-post	De-escalation training (TeamSTEPPS)	Pre-intervention (practice as usual)	**Seclusion events post (2 months) vs pre (2 months)** Post period no. events and rate: 15 (4.4%) Pre period no. events and rate: 23 (5.9%) Difference: p = 0.349	
Sensory Modulation				
Lloyd, 2013, Australia, Concurrent	Sensory modulation room NR	Concurrent control (practice as usual) NR	**Seclusion episodes pre (6 months) and post (6 months)** <u>Intervention ward</u> No. events (post): 53 No. events (pre): 157 <u>Comparator ward</u> No. events (post): 81 No. events (pre): 46 Significant decrease in rate of seclusion for intervention vs comparison ward (p <0.001)	**Duration of seclusion** "No evidence that the duration of seclusion episodes changed."
Cummings, 2010, United States, Concurrent	Comfort room	Concurrent control (practice as usual) Pre-intervention (practice as usual)	NR	NR
Azuela, 2018, New Zealand, Pre-post	Sensory modulation room N NR	Pre-intervention (practice as usual) N NR	**Seclusion episodes post (1 year) vs pre (1 year)**	**Seclusion duration post (1 year) vs pre (1 year)** Unit A Median (SD) hours (post): 68.75 (77.512)

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Seclusion	Time in Seclusion
			Comfort room was implemented in both Unit A and B; results were analyzed separately as pre-post Unit A total events (post): 81 Unit A total events (pre): 91 Unit A Median (SD) (post): 6.5 (3.4) Unit A Median (SD) (pre): 8.5 (3.9) p>0.05 Unit B total events (post): 115 Unit B total events (pre): 162 Unit B Median (post): 7.5 (6.2) Unit B Median (pre): 14.5 (3.6) p = 0.04	Unit A Median (SD) hours (pre): 126.80 (133.97) p>0.05 Unit B Median (SD) hours (post): 145.30 (196.8) Unit B Median (SD) hours baseline (pre): 360.30 (220.12) p = 0.02
Novak, 2012, Australia, Pre-post	Sensory room 75 patients[36]	Pre-intervention (practice as usual) 75 patients	**Seclusion episodes post (12 months) and pre (12 months)** Post period mean (SD): 18.2 (7.7) Pre period mean (SD): 17.2 (6.0) Difference: p = NS	NR
Sivak, 2012, United States, Pre-post	Comfort room NR	Pre-intervention (practice as usual) NR	**Seclusion episodes post (4 months) vs pre (4 months)** Pre intervention mean rate of seclusion/1000 days of client care before intervention (July through Oct 2010): 0 "Since the initiation of the comfort rooms, there has been no use of seclusion or restraint"	
Smith, 2013, United Kingdom, Pre-post	Sensory room NR	Pre-intervention (practice as usual) NR	**No. seclusion events post (3 months) vs pre (3 months)** Post period no. events: 37 (25 were repeat events by 6 patients) Pre period no. events: 27 (12 were repeat events by 4 patients Difference: NS; Authors notes "If the repeater seclusion were extracted as	**Seclusion duration post (3 months) vs pre (3 months)** Post range: 45 minutes to 16 hours 30 minutes Pre range: 40 minutes to 3 days Difference: NR

[36] Independent sample size is unclear. Study reports sample to experience seclusion events, which may have included the same individual multiple times.

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Seclusion	Time in Seclusion
			anomalies, the rates of seclusion would be seen to have been reduced."	**Mean (SD) duration of seclusion (minutes) post (3 months) vs pre (3 months)** Post period: 3 hours 59 minutes (3 hours 40 minutes) Pre period: 7 hours 30 minutes (17 hours 25 minutes) Difference: NR "This may look as if the mean duration of time in seclusion decreased considerably after the sensory room had been introduced. However these results are skewed by some extreme values of very long seclusion time periods, with two long seclusion episodes in [the pre period] of 2 days, 6 hours and 3 days, and in [the post period], there was one seclusion episode of 16 hours 30 minutes. With these three outliers removed from the data set, the mean duration in [the pre period] (n = 25) was 2 hours 46 minutes (SD = 2 hours 50 minutes) and in [the post period] (n = 36) it was 3 hours 37 minutes (SD = 3 hours 7 minutes). Therefore the average length of time in seclusion had actually increased, not decreased following the introduction of the sensory room."
Zimmermann, 2020, United States, Pre-post	Serenity room	Pre-intervention (practice as usual)	NR	NR
Risk Assessment				
Abderhalden, 2008, Switzerland, RCT	Structured risk assessment (BVC)	Control (practice as usual)	NR	NR
van de Sande, 2011, Netherlands, RCT	Structured risk assessment (BVC) 20 beds and 207 patients during intervention period	Control (practice as usual) 16 beds in control wards and 251 patients during intervention period	**Seclusion incidents** 30-week intervention RR (95% CI): 1.01 (0.74 to 1.88) 10-week baseline RR (95% CI): 1.19 (0.76 to 1.88)	**Hours in seclusion** 30-week intervention RR (95% CI): 0.62 (0.58 to 0.88) 10-week baseline RR (95% CI): 1.12 (1.01 to 1.19) % change in risk ratio in baseline to intervention period: -45% (p <0.05)

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Seclusion	Time in Seclusion
			% change in baseline risk ratio to intervention period risk ratio: -15% (p = NS) **No. secluded patients** 30 week intervention RR (95% CI): 1.71 (1.12 to 2.67) 10 week baseline RR (95% CI): 1.42 (0.83 to 2.48) % change in risk ratio of no. of patients exposed to seclusion to risk ratio in intervention period: 8% (p = NS)	
Blair, 2017, United States, Pre-pos	Structured risk assessment (BVC) 8,029 admissions	Pre-intervention (practice as usual) 3,884 admissions	**Seclusion episodes post (12 months) vs pre (12 months)** Proportion of patients secluded (post): 4.4% (213/8,029 admission) Proportion of patients secluded (pre): 9.2% (358/3884 admission). Difference (12 months post intervention): -52% (p <0.001)	**Duration of seclusion per admission post (12 months) vs pre (12 months)** Difference (12 months post intervention): -27% (p = NR) Duration of seclusion per admission in 12 months before intervention: NR **Minutes in seclusion post (12 months) vs pre (12 months)** Mean (SD) (post): 516.2 Mean (SD) (pre): 337.7 (NR) Difference: p <0.01
Clarke, 2010, Canada, Pre-post	Structured risk assessment (BVC) N NR	Pre-intervention (practice as usual) N NR	**Episodes of seclusion** 2 months after intervention: 22 episodes/month 3 months intervention phase: 12 episodes/month 2 months before intervention: 30 episodes/month p = NR	
Harrington, 2019, Australia, Pre-post	Risk assessment (Clinical Risk Management Initiative)	Pre-intervention (practice as usual)	**Seclusion per 1,000 occupied bed days post (18 months) vs pre (24 months)** Difference in rates (95% CI): -12.8 (-17.2 to -8.43)	

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Seclusion	Time in Seclusion
	965 admissions post-implementation	1,090 admissions in pre period	Pre-Intervention rate (95% CI): 43.7 40.6 to 46.9) RR (95% CI): 0.71 (0.63 to 0.80; p < 0.001)	
Manning, 2022, United States, Pre-post	Risk assessment (modified Agitation Severity Scale) 389 patients	Pre-intervention (practice as usual) 353 patients	**Seclusion incidents post (18 months) vs pre (18 months)** Post: 28 Pre: 22 Difference: p = NS	**Mean (SD) minutes in seclusion post (18 months) vs pre (18 months)** Post: 137 (97) Pre: 132 (141) Difference: p = NS
Trauer, 2010, Australia, Pre-post	The Management of Acute Arousal Program 188 admissions	Pre-intervention (practice as usual) 164 admission	**No. seclusion events post (6 months) vs pre (6 months)** Post period no. events: 67 Pre period no. events: 64 Difference: 0.51	**Mean (median) duration of seclusion (minutes) post (6 months) vs pre (6 months)** Post period: 312 (235) Pre period: 299 (230) Difference: 0.19
Comprehensive/Mixed				
Bowers, 2015, United Kingdom, RCT	Safewards	Control wards (physical health program)	NR	NR
Välimäki, 2022, Finland, RCT	Intervention wards 8 wards, 13 units, 335 nurses, 238 hospital beds, 4,163 patients	Control wards (practice as usual) 7 wards, 15 units, 313 nurses, 235 hospital beds, 4,186 patients	**No. seclusion events at ward level/total patients intervention vs control** Baseline n (proportion) intervention: 629/4163 (15.1) Baseline n (proportion) control: 580/4186 (13.9) RR (95% CI) after intervention 0.72 (0.32 to 1.63; p = 0.42) p-value for group * time: 0.003 **No. secluded patients at ward level/total patients intervention vs control** Baseline n (proportion) intervention: 342/4163 (8.2) Baseline n (proportion) control: 354/4186 (8.5)	**Length per seclusion event on ward level, geometric mean, min intervention vs control** Log-transformed mean difference (95% CI) 0.16 (-0.39 to 0.71; p = 0.56) Baseline geometric mean intervention: 1,378 Baseline geometric mean control: 1,614 p-value for group*time: 0.21

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Seclusion	Time in Seclusion
			RR after intervention (95% CI) 0.76 (0.40 to 1.46; p = 0.41) P-value for group * time: 0.37	
Boumans, 2014, Netherlands, Concurrent	Methodological work approach 134 patients	Control (practice as usual) 544 patients	**Seclusion episodes per 1,000 patient days** <u>Change over time in incident of seclusion comparison ward time series</u> Coefficient (SE): -0.22 (0.36, p = NS) <u>Difference experimental vs comparison ward</u> Coefficient (SE): -0.55 (0.20, p <0.01)	**Hours in seclusion per 1,000 patient days** <u>Change over time in incident of seclusion comparison ward time series</u> Coefficient (SE): 0.84 (28.85, p = NS) <u>Difference experimental vs comparison ward</u> Coefficient (SE): -63.46 (17.25, p <0.01)
Noorthoorn, 2014, Netherlands, Concurrent control	Intervention 45-bed ward; 768 patients (1,392 admissions)	Control (practice as usual) 38-bed ward; 702 patients (1,138 admissions)	**Seclusion episodes** <u>Intervention Ward</u> No. episode over study period: 39 episodes (30 patients) Seclusion per 1,000 admissions (1st year): 6.7 Seclusion per 1,000 admissions (2nd year): 4.6 Seclusion per 1,000 admissions (3rd half year): 0.7 <u>Comparison Ward</u> No. episode over study period: 130 episodes (79 patients) Seclusion per 1,000 admissions (1st year): 14.7 Seclusion per 1,000 admissions (2nd year): 21.4 Seclusion per 1,000 admissions (3rd half year): 26.1 Seclusion occurred more in comparison wards: p = 0.001 Hazard ratio for being secluded (comparison ward vs intervention	**Seclusion days** <u>Intervention Ward</u> Seclusion days per 1,000 patient days (2003): 8 days Number of seclusion days per 1,000 patient days (2004): 3 days <u>Comparison Ward</u> Number of seclusion days per 1,000 patient days (2003): 17 days Number of seclusion days per 1,000 patient days (2004): 19 days “Duration of seclusions did not differ between wards”

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Seclusion	Time in Seclusion
			ward): year 1: 2.8 (p = NR), year 2: 5.6 (p = NR)	
Blair, 2015, United States, Pre-post	Engagement model NR	Pre-intervention (practice as usual) NR	Annual no. seclusion events post (2002-2013) vs pre (2000) Post no events (2001-2013): 2013: 13 2012: 30 2011: 7 2010: 3 2009: 19 2008: 2 2007: 0 2006: 0 2005: 0 2004: 1 2003: 3 2002: 10 2001: 53 Pre no events (2000): 101 Difference: NR	NR
Dickens, 2020, Australia, Pre-post	Safewards	Pre-intervention (practice as usual)	NR	NR
Hellerstein, 2007, United States, Pre-post	Comprehensive intervention NR	Pre-intervention (practice as usual) NR	**No. patients secluded month post (67 months) vs pre (20 months)** Pre period mean (SD): 3.1 (1.4) Post period mean (SD): 1.0 (1.1) P-value for difference: <0.0001	**Total hours patients secluded month** Pre period mean (SD): 41.6 (52) Post period mean (SD): 2.7 (4.5) P-value for difference: 0.003 **% of total patients hours in seclusion** Pre period mean (SD): 0.11 (0.14) Post period mean (SD): 0.007 (0.01) P-value for difference: 0.03
Khadivi, 2004, United States, Pre-post	Comprehensive intervention	Pre-intervention (practice as usual)	NR	NR
Lewis, 2009, United States, Pre-post	Crisis Prevention Management program	Pre-intervention (practice as usual)	**Episodes of seclusion**	

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Seclusion	Time in Seclusion
	NR	NR	"Three of the 4 units had a decrease in the use of seclusion ranging from 30–63%."	
McDonagh (PowerPoint), 2019, United States, Pre-post	Recovery-oriented programming NR	Pre-intervention (practice as usual) NR	**No. episode of seclusion** Post period (3 years): 31 Pre period (3 years): 71 56.3% decrease (p = NR)	**Total hours in seclusion** Post period (3 years): 142 Pre period (3 years): 1205 88%.3% decrease (p = NR)
Pollard, 2017, United States, Pre-post, Medium	Comprehensive intervention	Pre-intervention (practice as usual)	NR	NR
Richmond, 1996, United States, Pre-post	Comprehensive intervention NR	Pre-intervention (practice as usual) NR	NR	**Hours in Seclusion Post (12 months) vs Pre (12 months)** Pre period: 395.55 total seclusion hours Post period: 788.2 total seclusion hours 50% increase in seclusion hours
Stoll, 2022, Switzerland, Pre-post	Moral Case Deliberation NR	Pre-intervention (practice as usual) NR	**Proportion of patients secluded** Post period: 9.6% (*N* = NR) Pre period: 16.7% (*N* = NR) Difference: p = 0.034 **Frequency seclusion episodes among those in seclusion** Post period mean (SD): 3.4 (6.6) Pre period mean (SD): 2.2 (2.5) Difference: p = 0.42	**Time in seclusion** Post period mean (SD): 39.8 (95.2) Pre period mean (SD): 156.2 (268.8) Difference: p = 0.115 **Hours seclusion per episode** Post period mean (SD): 10.0 (12.6) Pre period mean (SD): 73.9 (102.3) Difference: p = 0.05
Taxis, 2002, United States, Pre-post	Comprehensive intervention	Pre-intervention (practice as usual)	NR	NR
Whitecross, 2020, Australia, Pre-post	Psychiatric behavior of concern team 1356 episodes of care	Pre-intervention (practice as usual)	**Seclusion episodes per 1,000 occupied bed day post (6 months) vs pre (6 months)** Mean 6 months before intervention: 19.2 Difference (6 months post): -65.3% (p = NR)	**Seclusion hours per 1,000 occupied bed days post (6 months) vs pre (6 months)** Mean 6 months after intervention: 76.0 Mean 6 months before intervention: 270.4 Difference (6 months post): -71.9%

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Seclusion	Time in Seclusion
			Proportion of admitted patients secluded post (6 months) vs pre (6 months) Mean 6 months before intervention: 14.7% Difference (6 months post): -55.7% (p = NR)	
Zuehlke, 2016, United States, High, Pre-post	Recovery-oriented program of care	Pre-intervention (practice as usual)	NR	NR

Abbreviations. ANOVA=analysis of variance; no.=number; NR=not reported; NS=not significant; OR=odds ratio; RoB=risk of bias; SD=standard deviation; VA=Veteran Affairs.

Results Summary: Restraint

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Restraint	Time in Restraint
Hospital/Unit Restructuring				
Hochstrasser, 2018, Switzerland, Pre-post	Open-door policy with recovery-oriented care	Pre-intervention (practice as usual)	NR	NR
Hunter, 1993, United States, Pre-post	After hospital restructuring 78 patients	Before hospital restructuring 66 patients	**No. restraint events post (10 months) vs pre (10 months)** Post period no. events: 190 Pre period no. events: 114 Difference: p = NR	**Hours of restraint episode** Pre period mean (SD): 11.1 (25.9) Post period mean (SD): 9.2 (9.3) Difference: p = NR
Jenkins, 2014, United Kingdom, Pre-post	Purpose-built psychiatric intensive care unit	Old unit	NR	NR
Rohe, 2017, Germany, Pre-post	Architecturally positive redesign NR	Pre-intervention (practice as usual) NR	**Patients restrained per month and per occupied bed** Post period mean (SE): 0.035 (0.003) Pre period mean (SE): 0.069 (0.004) 50.1% decrease (p <0.001) **Days with fixations per month and per occupied bed** Post period mean (SE): 0.081 (0.011) Pre period mean (SE): 0.222 (0.019) 63.3% decrease (p <0.001) **Caring restraints per month and per occupied bed** Post period mean (SE): 0.012 (0.002) Pre period mean (SE): 0.024 (0.002) 48.4% decrease (p = 0.001)	**Duration (unit NR) of with fixations per month and per occupied bed** Post period mean (SE): 0.962 (0.157) Pre period mean (SE): 2.015 (0.240) 48.4% decrease (p = 0.003)
Staff Education/Training				
Bowers, 2008, United Kingdom, Concurrent and pre-post	City Nurse Intervention - Escalation Training	Pre-intervention (practice as usual) and concurrent	**Restraint per shift (pre-post analysis only)** Post period mean (SD): 0.031 (0.180) Pre period mean (SD): 0.057 (0.257)	NR

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Restraint	Time in Restraint
		control (practice as usual)	Difference (among intervention wards only) p = 0.0172	
	3 wards	5 wards		
Forster, 1999, United States, Pre-post	Staff training	Pre-intervention (practice as usual)	**Rates of restraint post (12 months) vs pre (12 months)**	
	3,010 admissions	2,560 admissions	Post period: 2,380 episodes per 3,010 admissions Pre period: 2,379 episodes per 2,560 admissions 13% decrease (p = NR)	
Haefner, 2021, United States, Pre-post	De-esclation training (TeamSTEPPS)	Pre-intervention (practice as usual)	NR	NR
Sensory Modulation				
Lloyd, 2013, Australia, Concurrent	Sensory modulation room	Concurrent control (practice as usual)	NR	NR
Cummings, 2010, United States, Concurrent	Comfort room	Concurrent control (practice as usual) Pre-intervention (practice as usual)	NR	NR
Azuela, 2018, New Zealand, Pre-post	Sensory modulation room	Pre-intervention (practice as usual)	NR	NR
Novak, 2012, Australia, Pre-post	Sensory room	Pre-intervention (practice as usual)	NR	NR
Sivak, 2012, United States, Pre-post	Comfort room NR	Pre-intervention (practice as usual) NR	**Mean Restraint Episodes Post (4 months) vs Pre (4 months)** Post intervention per 1000 days of client care (Dec 2010 to Mar 2011): 0 Pre intervention per 1000 days of client care (July through Oct 2010): 0.37 per 1000 days of client care in July and 0 events in Aug, Sep, and Oct. p = NR	NR

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Restraint	Time in Restraint
Smith, 2013, United Kingdom, Pre-post	Sensory room	Pre-intervention (practice as usual)	NR	NR
Zimmermann, 2020, United States, Pre-post	Serenity room	Pre-intervention (practice as usual)	NR	NR
Risk Assessment				
Abderhalden, 2008, Switzerland, RCT	Structured risk assessment (BVC)	Control (practice as usual)	NR	NR
van de Sande, 2011, Netherlands RCT	Structured risk assessment (BVC)	Control (practice as usual)	NR	NR
Blair, 2017, United States, Pre-post	Structured risk assessment (BVC) 8,029 admissions	Pre-intervention (practice as usual) 3,884 admissions	**Restraint events post (12 months) vs pre (12 months)** Proportion of patients secluded 12 months after intervention: 5.1% (412/8029 admission) Proportion of patients secluded 12 months before intervention: 5.4% (213/3884 admission) Difference (12 months post intervention): -6% (p = 0.44)	**Duration of restraint per admission post (12 months) vs pre (12 months)** Duration of restraint per admission in 12 months before intervention: NR Difference (12 months post intervention): -52% (p = NR) **Minutes in restraint post (12 months) vs pre (12 months)** Mean (SD) 12 months after intervention: 445.0 (NR) Mean (SD) 12 months before intervention: 286.7 (NR) Difference p <0.01
Clarke, 2010, Canada, Pre-post	Structured risk assessment (BVC)	Pre-intervention (practice as usual)	NR	NR
Harrington, 2019, Australia, Pre-post	Risk assessment (Clinical Risk Management Initiative)	Pre-intervention (practice as usual)	NR	NR
Manning, 2022, United States, Pre-post	Risk assessment (modified Agitation Severity Scale) 389 patients	Pre-intervention (practice as usual) 353 patients	**Restraint episodes** 18 months before intervention: 68 incidents 18 months after intervention: 38 incidents Difference: -44% (p = NS)	**Minutes in restraint per episode** Mean (SD) minutes 18 months before intervention: 18 (22) Mean (SD) minutes 18 months after intervention: 10 (22)

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Restraint	Time in Restraint
				Difference: -44.4% (p = 0.047)
Trauer, 2010, Australia, Pre-post	The Management of Acute Arousal Program	Pre-intervention (practice as usual)	NR	NR
Comprehensive/Mixed				
Bowers, 2015, United Kingdom, RCT	Safewards	Control wards (physical health program)	NR	NR
Välimäki, 2022, Finland, RCT	Intervention wards 8 wards, 13 units, 335 nurses, 238 hospital beds, 4,163 patients	Control wards (practice as usual) 7 wards, 15 units, 313 nurses, 235 hospital beds, 4,186 patients	**No. limb restraint events/total patients Intervention vs control** Follow-up n (proportion) intervention: 353/4089 (8.6) Follow-up n (proportion) control: 300/4092 (7.3) Baseline n (proportion) intervention: 360/4163 (8.6) Baseline n (proportion) control: 226/4186 (5.4) RR (95% CI) baseline 1.51 (0.45 to 5.14) RR (95% CI) after intervention 1.39 (0.49 to 3.98; p = 0.53) P-value for group*time: <0.001 **No. patients on whom limb restraints used/total patients** Baseline n (proportion) intervention: 172/4163 (4.1) Baseline n (proportion) control: 126/4186 (3.0) RR (95% CI) 1.59 (0.57 to 4.41; p = 0.36) P-value for group time: 0.06 **No. patient physical restraint events/total patients** Baseline n (proportion) intervention: 38/4163 (0.9) Baseline n (proportion) control: 27/4186 (0.7)	**Length per limb restraint event, geometric mean, min** Baseline geometric mean min. Intervention: 1345 Baseline geometric mean min control: 851 Log-transformed mean difference (95% CI) 0.42 (−0.62 to 1.46; p = 0.42) P-value for group * time: 0.26 **Length per physical restraint event, geometric mean, min** Baseline geometric mean Intervention: 28 Baseline geometric mean control: 25 Log-transformed mean difference (95% CI) −1.33 (−3.52 to 0.86; p = 0.21) p-value for group * time: 0.16

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Restraint	Time in Restraint
			RR (95% CI) 5.04 (0.94 to 26.96; p = 0.06) p-value for group * time: 0.05 **No. of patients physically restrained/total patients** Baseline n (proportion) intervention: 23/4163 (0.6) Baseline n (proportion) control: 11/4186 (0.3) RR (95% CI) 4.74 (1.14 to 19.78; p = 0.03) p-value for group * time: 0.25	
Boumans, 2014, Netherlands, Concurrent	Methodological work approach	Control (practice as usual)	NR	NR
Noorthoorn, 2014, Netherlands, Concurrent control	Intervention	Control (practice as usual)	NR	NR
Blair, 2015, United States, Pre-post	Engagement model	Pre-intervention (practice as usual)	Annual No. restraint events post (2002-2013) vs pre (2000) Post no mechanical (manual where reported) events (2001-2013): 2013: 0 (40) 2012: 0 (13) 2011: 0 2010: 1 2009: 4 2008: 0 2007: 0 2006: 0 2005: 0 2004: 0 2003: 0 2002: 5 2001: 7 Pre no events (2000): 28 Difference: NR	NR

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Restraint	Time in Restraint
Dickens, 2020, Australia, Pre-post	Safewards	Pre-intervention (practice as usual)	NR	NR
Hellerstein, 2007, United States, Pre-post	Comprehensive intervention NR	Pre-intervention (practice as usual) NR	**No. patients restrained month post (67 months) vs pre (20 months)** Post period mean (SD): 0.32 (0.5) Pre period mean (SD): 0.35 (0.6) Difference: p = NS	**Total hours patients restrained month** Pre period mean (SD): 1.7 (5.2) Post period mean (SD): 1.0 (1.1) P-value for difference: NS **% of total patients hours in restraint** Pre period mean (SD): 0.005 (0.014) Post period mean (SD): 0.003 (0.007) Difference: p = NS
Khadivi, 2004, United States, Pre-post	Comprehensive intervention NR	Pre-intervention (practice as usual) NR	NR	NR
Lewis, 2009, United States, Pre-post	Crisis Prevention Management program NR	Pre-intervention (practice as usual) NR	**Episodes of restraint** "Each unit experienced a decrease in the use of restraint ranging from 20–97%."	NR
McDonagh (report), 2019, United States, Pre-post	Recovery Programming NR	Pre-intervention (practice as usual) NR	**No. episode of restraint** Post period (3 years): 11 Pre period (3 years): 10 10% increase (p = NR)	**Total hours in restraint** Post period: 102.5 Pre period: 111.3 8% decrease over time Decreasing trend line (p = NR)
Pollard, 2017, United States, Pre-post	Comprehensive intervention	Pre-intervention (practice as usual)	NR	NR
Richmond, 1996, United States, Pre-post	Comprehensive intervention NR	Pre-intervention (practice as usual) NR	NR	**Hours in restraint post (12 months) vs pre (12 months)** Post period: 1812.31 total restraint hours Pre period: 3387.87 total restraint hours 47% decrease in restraint hours

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Restraint	Time in Restraint
Stoll, 2022, Switzerland, Pre-post	Moral Case Deliberation NR	Pre-intervention (practice as usual) NR	**Proportion of patients restrained** Post period: 1.8% (n = NR) Pre period: 3.2% (n = NR) Difference: p = NS **Frequency restraint episodes among those in restraint** Post period mean (SD): 1.5 (0.6) Pre period mean (SD): 1.7 (0.08) Difference: p = 0.91	**Hours in restraint among patients restrained** Post period mean (SD): 14.5 (12.1) Pre period mean (SD): 86.8 (45.3) Difference: p = 0.02 **Hours restraint per episode** Post period mean (SD): 10.1 (9.9) Pre period mean (SD): 55.2 (24.7) Difference: p = 0.01
Taxis, 2002, United States, Pre-post	Comprehensive intervention	Pre-intervention (practice as usual)	NR	NR
Whitecross, 2020, Australia, Pre-post	Psychiatric behavior of concern team	Pre-intervention (practice as usual)	NR	NR
Zuehlke, 2016, United States, High	NR	NR	NR	NR

Abbreviations. No.=number; NR=not reported; NS=not significant; OR=odds ratio; RoB=risk of bias; SE=standard error; SD=standard deviation; VA=Veteran Affairs.

Results Summary: Composite Measures

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Composite Measure	Time in Composite Measure
Hospital/Unit Restructuring				
Hochstrasser, 2018, Switzerland, Pre-post	Open-door policy with recovery-oriented care	Pre-intervention (practice as usual)	NR	NR
Hunter, 1993, United States, Pre-post	After hospital restructuring	Before hospital restructuring	NR	NR
Jenkins, 2014, United Kingdom, Pre-post	Purpose built psychiatric intensive care unit	Old unit	NR	NR
Rohe, 2017, Germany, Pre-post	Architecturally positive redesign	Pre-intervention (practice as usual)	NR	NR
Staff Education/Training				
Bowers, 2008, United Kingdom, Concurrent and pre-post	City Nurse intervention - escalation training 3 wards (pre-post analysis) 2 wards (concurrent analysis)[37]	Pre-intervention (practice as usual) and concurrent control (practice as usual) 5 wards	**Total Containment[38] (pre-post analysis only)** Post period mean (SD): 3.740 (2.337) Pre period mean (SD): 4.560 (2.264) Difference (among intervention wards only): p < 0.001 Concurrent control analysis: Intervention compared to concurrent control: "no significant change"	NR
Forster, 1999, United States, Pre-post	Staff training 3,010 admissions	Pre-intervention (practice as usual) 2,560 admissions	NR	Duration of seclusion or restraint per episode Post period (1996): 6.3 hours/episode Pre period (1995): 13.9 hours/episode 54.6% decrease (p = NR)
Haefner, 2021, United States, Pre-post	De-escalation training(TeamSTEPPS)	Pre-intervention (practice as usual)	NR	NR

[37] One of the 3 intervention wards ("Ward 5") was excluded from analysis as it was at the same hospital as "Ward 3" and had a short intervention period.
[38] Containment defined as a composite of means by which ward staff "keep patients safe, including extra medication given at nurses discretion, special observation, and manual restraint."

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Composite Measure	Time in Composite Measure
Sensory Modulation				
Lloyd, 2013, Australia, Concurrent	Sensory modulation room NR	Concurrent control (practice as usual) N NR	NR	NR
Cummings, 2010, United States, Concurrent	Comfort room NR	Concurrent control (practice as usual) NR Pre-intervention (practice as usual)	**Seclusion and restraint episodes during 9-month period** "The ANOVA showed no significant changes in seclusion and restraint use with the addition of a comfort room."	NR
Azuela, 2018, New Zealand, Pre-post	Sensory modulation room	Pre-intervention (practice as usual)		NR
Novak, 2012, Australia, Pre-post	Sensory room	Pre-intervention (practice as usual)	NR	NR
Sivak, 2012, United States, Pre-post, High	Comfort room	Pre-intervention (practice as usual)	NR	NR
Smith, 2013, United Kingdom, Pre-post	Sensory room	Pre-intervention (practice as usual)	NR	NR
Zimmermann, 2020, United States, Pre-post	Serenity room 172 patients	Pre-intervention (practice as usual) 149 patients	**Percent of days sedation, seclusion, or restraint** Post period (61 days) 1/61 days (1.6%) Pre period (60 days): 8/60 days (13.3%) Difference: p = 0.014	NR
Risk Assessment				
Abderhalden, 2008, Switzerland, RCT	Structured risk assessment (BVC) 4 wards	Control (practice as usual) 5 wards	**Composite of psychotropic medication, seclusion, and restraint** Rates of change intervention (3-months) vs control (3-months): -27% vs 10% (p < 0.001)	NR
van de Sande, 2011, Netherlands, RCT	Structured risk assessment (BVC)	Control (practice as usual)	NR	NR
Blair, 2017, United States, Pre-post	Structured risk assessment (BVC)	Pre-intervention (practice as usual)	NR	NR

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Composite Measure	Time in Composite Measure
Clarke, 2010, Canada, Pre-post	Structured risk assessment (BVC)	Pre-intervention (practice as usual)	NR	NR
Harrington, 2019, Australia, Pre-post	Risk assessment (Clinical Risk Management Initiative)	Pre-intervention (practice as usual)	NR	NR
Manning, 2022, United States, Pre-post	Risk assessment (modified Agitation Severity Scale)	Pre-intervention (practice as usual)	NR	NR
Trauer, 2010, Australia, Pre-post	The Management of Acute Arousal Program	Pre-intervention (practice as usual)	NR	NR
Comprehensive/Mixed				
Bowers, 2015, United Kingdom, RCT	Safewards 16 wards	Control wards (physical health program) 15 wards	**Composite of 8 forms of containment[39] as reported on the patient-staff conflict checklist intervention vs control** Baseline mean (SD) overall event rate intervention: 1.26 (1.93) Baseline mean (SD) overall event rate control: 1.39 (1.94) Ward count rate ratio (95% CI): 0.77 (0.66, 0.90; p = 0.004) Shifts with no containment event rate ratio (95% CI): 1.04 (0.83, 1.34; p = 0.71) Among wards experiencing containment events: 26.4% (9.9–34.3) reduction in events	NR
Välimäki, 2022, Finland, RCT	Intervention wards	Control wards (practice as usual)	NR	NR
Boumans, 2014, Netherlands, Concurrent	Methodological work approach	Control (practice as usual)	NR	NR
Noorthoorn, 2014, Netherlands, Concurrent	Intervention	Control (practice as usual)	NR	NR

[39] Defined as actions taken by staff to manage unsafe patients such as coerced medication, seclusion, restraint, special observation, etc.

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Composite Measure	Time in Composite Measure
Blair, 2015, United States, Pre-post	Engagement model	Pre-intervention (practice as usual)	NR	NR
Dickens, 2020, Australia, Pre-post	Safewards 8 wards 142 beds	Pre-intervention (practice as usual) 8 wards 142 beds	**Containment (seclusion and restraint)** 4-week post intervention adjusted rate ratio (95% CI): 0.88 (0.82 to 0.94) Baseline phase (4-week prior to intervention) mean (SD) rates of containment: 6.8 (5.8) **Highly coercive containment (seclusion, restraint and forced medication)** 4-week post intervention adjusted rate ratio (95% CI): 0.26 (0.14 to 0.47) Baseline phase (4-week prior to intervention) mean (SD) rates of containment: 6.8 (5.8) **Containment-free days** Pre vs Post period: 14.5% vs 4.9%	NR
Hellerstein, 2007, United States, High	Comprehensive intervention	Pre-intervention (practice as usual)	NR	NR
Khadivi, 2004, United States, Pre-post	Comprehensive intervention 1,602 admissions	Pre-intervention (practice as usual) 1,766 admissions	**Composite of seclusion and restraint post (12 months) vs pre (12 months)** 12 months post intervention number of episodes: 148 12 months pre intervention number of episodes: 310 % change in events in 12 months after intervention vs months before: -52% ($p < 0.001$)	NR
Lewis, 2009, United States, Pre-post	Crisis Prevention Management program	Pre-intervention (practice as usual)	NR	NR
McDonagh (report), 2019, United States, Pre-post	Recovery-oriented programming NR	Pre-intervention (practice as usual) NR	**Episodes of seclusion and restraint** Episodes in post period (3 years): 42 Episodes in pre period (3 years): 81 48% decrease	**Total hours in seclusion and restraint** Total hours in post period (3 years): 245 Total hours in pre period (3 years): 1,711 86% decrease

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Composite Measure	Time in Composite Measure
Pollard, 2017, United States, Pre-post	Comprehensive intervention NR	Pre-intervention (practice as usual) NR	NR	**Monthly seclusion and restraint hours post (18 months) vs pre (28 months)** Post period mean (SD): 55.64 (44.57) Pre period mean (SD): 182.48 (114.22) Difference: p <0.001 **Hours of seclusion and restraint per patient post (18 months) vs pre (28 months)** Post period mean (SD): 2.72 (2.18) Pre period mean (SD): 8.58 (6.07) Difference: p <0.001
Richmond, 1996, United States, Pre-post	Comprehensive intervention NR	Pre-intervention (practice as usual) NR	NR	**Total hours in seclusion and restraint post (12 months) vs pre (12 months)** Post period: 2600.51 total combined hours Pre period: 3783.42 total combined hours 31% decrease in combined hours
Stoll, 2022, Switzerland, Pre-post	Moral Case Deliberation NR 405 total both periods	Pre-intervention (practice as usual) NR	**Proportion of patients subject to formal coercion (seclusion, restraint, and forced medication)** Pre period: 17.2% (*N* = NR) Post period: 9.6% (*N* = NR) Difference: p = 0.024	NR
Taxis, 2002, United States, Pre-post	Comprehensive intervention NR	Pre-intervention (practice as usual) NR	**Incidence of seclusion and restraint** Baseline: NR “overall reduction in the incidence of restraint and seclusion was 94%” p = NR	NR
Whitecross, 2020, Australia, Pre-post	Psychiatric behavior of concern team	Pre-intervention (practice as usual)	NR	NR

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Episodes of Composite Measure	Time in Composite Measure
Zuehlke, 2016, United States, High	Recovery-oriented model of care NR 352 total both periods	Pre-intervention (practice as usual) NR	**Incidence of seclusion and restraint per month post (12 months) vs pre (12 months)** Post period mean (SD) rate: 1.50 (1.17) Pre period mean (SD) rate: 3.17 (2.37) Difference; p = 0.03	NR

Results Summary: Patient Outcomes

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Patient Injuries	Aggressive Incidents	Patient Satisfaction	Forced Medication
Hospital/Unit Restructuring						
Hochstrasser, 2018, Switzerland, Pre-post	Open-door policy with recovery-oriented care 14,435 patients (may include some admissions before policy which was implemented in Aug 2011) 2,803 patients in 2015	Pre-intervention (practice as usual) 2,924 patients in 2010	NR	NR	NR	**Forced medication** aOR (95% CI) open door policy: 0.90 (0.83 to 0.98) **Cases with at least 1 forced medication** Last year of post intervention follow up (2015): 1.2% (35/2803) Baseline year (2010): 2.4% (70/2924) p <0.001 **Mean (SD) number of forced medication** Last year of post intervention follow up (2015): 1.2 (0.5) Baseline year (2010): 2.3 (3.2) p = 0.003
Hunter, 1993, United States, Pre-post	After hospital restructuring 78 patients	Before hospital restructuring 66 patients	Number of patient-patient assaults Post N events: 6 Pre N events: 6 Number of patient-staff assaults Post N events: 1 Pre N events: 1 Death Post N events: 0 Pre N events: 1 Suicide attempt Post N events: 0	NR	NR	NR

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Patient Injuries	Aggressive Incidents	Patient Satisfaction	Forced Medication
			Pre N events: 1 p = NR for all; only report "There were no differences in the number of patient-to-patient assaults or patient assaults on staff"			
Jenkins, 2014, United Kingdom, Pre-post,	Purpose built psychiatric intensive care unit 18 patients	Old unit 18 patients	NR	No. aggressive incidents post (3-6 months) vs pre (3-6 months) Post period no. events: 16 Pre period no. events: 36 Difference: p = 0.001 No. aggressive patients post (3-6 months) vs pre (3-6 months) Post period no. events: 12 Pre period no. events: 16 Difference: NR	NR	NR
Rohe, 2017, Germany, Pre-post	Architecturally positive redesign NR	Pre-intervention (practice as usual) NR	NR	NR	NR	**Forced medication** Post period mean (SE): 0.006 (0.001) Pre period mean (SE): 0.04 (0.004) 84.4% decrease (p <0.001)
Staff Education/Training						
Bowers, 2008, United Kingdom, Concurrent and pre-post	City Nurse Intervention - Escalation Training 3 wards (pre-post analysis)	Pre-intervention (practice as usual) and concurrent control (practice as usual) 5 wards	NR	**Conflict total per shift (pre-post analysis only)** Post period mean (SD): 3.828 (3.636) Pre period mean (SD): 4.799 (3.933) Difference: p < 0.001	NR	**Given PRN medication (pre-post analysis only)** Post period mean (SD): 0.76 (0.95) Pre period mean (SD): 0.97 (1.15) Difference: p = 0.001

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Patient Injuries	Aggressive Incidents	Patient Satisfaction	Forced Medication
	2 wards (concurrent analysis)[40]			**Verbal aggression (pre-post analysis only)** Post period mean (SD):0.443 (0.766) Pre period mean (SD): 0.561 (0.912) Difference: p = 0.001 **Physical aggression against objects** Post period mean (SD):0.089 (0.323) Pre period mean (SD): 0.135 (0.405) Difference: p = 0.002 **Aggression against others** Post period mean (SD): 0.061 (0.288) Pre period mean (SD): 0.104 (0.366) Difference: p = 0.001 **Aggression against self** Post period mean (SD): 0.084 (0.414) Pre period mean (SD): 0.075 (0.313) Difference: p = 0.232 Concurrent control analysis (for all conflict items): "On the primary outcome measures of total conflict and		Concurrent control analysis: significantly fewer PRN (p <0.001) **Given intramuscular medication (enforced)** Post period mean (SD): 0.04 (0.22) Pre period mean (SD): 0.07 (0.27) Difference: p = 0.003

[40] One of the 3 intervention wards ("Ward 5") was excluded from analysis as it was at the same hospital as "Ward 3" and had a short intervention period.

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Patient Injuries	Aggressive Incidents	Patient Satisfaction	Forced Medication
				total containment, no significant change occurred on the experimental or control wards. The majority of conflict and containment items were also unchanged"		
Forster, 1999, United States, Pre-post	NR	NR	NR	NR	NR	NR
Haefner, 2021, United States, Pre-post	De-esclation training (TeamSTEPPS)	Pre-intervention (practice as usual)		**Aggressive incidents obtained via chart review** Post period events (39 charts reviewed): 11.4% Pre period events (67 charts reviewed): 17.3% Difference: p = 0.024		
Sensory Modulation						
Lloyd, 2013, Australia, Concurrent	Sensory modulation room NR	Concurrent control (practice as usual) NR	NR	NR	NR	NR
Cummings, 2010, United States, Concurrent	Comfort room NR	Usual care without comfort room NR	NR	NR	NR	NR
Azuela, 2018, New Zealand, Pre-post	Sensory modulation room NR	Pre-intervention (practice as usual) NR	NR		The Essen Climate Evaluation Schema (EssenCES) was used to determine staff's and service users'	

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Patient Injuries	Aggressive Incidents	Patient Satisfaction	Forced Medication
					perceptions of their inpatient unit's climate. **Unit A** Patient's Cohesion: Post: mean (SD) 3.21(.75) Pre: mean (SD) 3.00(.78) p = 0.17 **Unit B** Patient's Cohesion: Post: mean (SD) 3.20(.75) Pre: mean (SD) 3.07(0.64) p = 0.33	
Novak, 2012, Australia, Pre-post	Sensory room 75[41]	Pre-intervention (practice as usual) 75	NR	**Aggressive episodes post (12 months) and pre (12 months)** Post period mean (SD): 13.9 (7.8) Pre period mean (SD): 19.6 (13.1) Difference: p = NS	NR	NR
Sivak, 2012, United States, Pre-post	Comfort room NR	Pre-intervention (practice as usual) NR	**Self-injurious behavior post (4 months) vs pre (4 months)** Post intervention: 12.1% increase Pre intervention 4-month average rate 2.32 /1,000 days of client care	**Client to client assaults post (4 months) vs pre (4 months)** Post intervention: 23.4% decrease Pre intervention 4-month average rate 3.98 /1,000 days of client care	NR	NR

[41] Independent sample size is unclear. Study reports sample to experience seclusion events, which may have included the same individual multiple times.

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Patient Injuries	Aggressive Incidents	Patient Satisfaction	Forced Medication
Smith, 2013, United Kingdom, Pre-post	Sensory room	Pre-intervention (practice as usual)	NR	NR	NR	NR
Zimmermann, 2020, United States, Pre-post	Serenity room 172 patients	Pre-intervention (practice as usual) 149 patients	NR	NR	NR	**No. benzodiazepines per day** Post period median (IQR): 1 (0 to 2) Pre period median (IQR): 2.5 (1 to 4) Difference: p < 0.001 **Total amount of benzodiazepines per day.** Post period median (IQR): 1mg (0 to 3) Pre period median (IQR): 4mg (2 to 6) P-value for Difference: p 0.001 **No. patients medicated per day** Post period median (IQR): 1 (0 to 1) Pre period median (IQR): 2 (1 to 3) Difference: p <0.001 **Benzodiazepines dose per day when distributed.** Post period median (IQR): 2 (1.5 to 3) Pre period median (IQR): 2 (1.5 to 2) Difference: p = 0.393

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Patient Injuries	Aggressive Incidents	Patient Satisfaction	Forced Medication
Risk Assessment						
Abderhalden, 2008, Switzerland, RCT	Structured risk assessment (BVC) 4 wards	Control (practice as usual) 5 wards	NR	**Severe (SOARS-R score ≥9) aggressive events** Intervention group change over 3-months RR (95% CI): 0.59 (0.41 to 0.83) Control group change over 3-months RR (95% CI): 0.85 (0.64 to 1.13) Difference: p < 0.001 **Physical attacks** Rates of change in intervention (3-months) vs control (3-months)l: -41% vs -7% (p < 0.001)	NR	NR
van de Sande, 2011, Netherlands, RCT	Structured risk assessment (BVC) 20 beds and 207 patients during intervention period	Control (practice as usual) 16 beds in control wards and 251 patients during intervention period	NR	**Aggression incidents** 10 week baseline RR (95% CI): 1.12 (0.72 to 1.76) 30 week intervention RR (95% CI): 0.36 (0.26 to 0.50) % change in risk ratio in baseline to intervention period: -68% (p < 0.05) **Aggressive patients, n** 10 week baseline RR (95% CI): 1.13 (0.57 to 3.10) 30 week intervention RR (95% CI): 0.62 (0.40 to 0.99) % change in risk ratio of no. of aggressive patients	NR	NR

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Patient Injuries	Aggressive Incidents	Patient Satisfaction	Forced Medication
				to risk ratio in intervention period: -50% (p < 0.10)		
Blair, 2017, United States, Pre-post	Structured risk assessment (BVC)	Pre-intervention (practice as usual)	NR	NR	NR	NR
Clarke, 2010, Canada, Pre-post	Structured risk assessment (BVC)	Pre-intervention (practice as usual)	NR	NR	NR	NR
Harrington, 2019, Australia, Pre-post	Risk assessment (Clinical Risk Management Initiative) 965 admissions post-implementation	Pre-intervention (practice as usual) 1090 admissions in pre period	**Self-harm/suicide attempt per 1,000 occupied bed days post (18 months) vs pre (24 months)** Pre intervention rate (95% CI): 0.81 (0.44 to 1.36) Difference in rates (95% CI): -0.25 (-0.84 to 0.34) RR (95% CI): 0.69 (0.26 to 1.69; p = 0.42)	**Aggression per 1,000 occupied bed days post (18 months) vs pre (24 months)** Pre intervention rate (95% CI): 2.54 (1.85 to 3.41) Difference in rates (95% CI): -0.55 (-1.64 to 0.53) RR (95% CI): 0.78 (0.47 to 1.27; p = 0.33)		
Manning, 2022, United States, Pre-post	Risk assessment (modified Agitation Severity Scale) 389 patients	Pre-intervention (practice as usual) 353 patients	NR	NR	**Patient safety survey post (18 months) vs pre (18 months)** Mean (SD) overall baseline score: 12.2 (6.38) Mean (SD) overall post score: 13.3 (8.43) Difference: p = NR	NR

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Patient Injuries	Aggressive Incidents	Patient Satisfaction	Forced Medication
Trauer, 2010, Australia, Pre-post	The Management of Acute Arousal Program	Pre-intervention (practice as usual)	NR	NR	NR	NR
Comprehensive/Mixed						
Bowers, 2015, United Kingdom, RCT	Safewards 16 wards	Staff Attention Control 15 wards	**Self-Harm Antipathy Scale** Intervention vs Control β (95% CI) 0.23 (-3.38 to 3.83; p = 0.90) Baseline mean (SD) overall event rate intervention: 78.79 (18.85) Baseline mean (SD) overall event rate control: 80/16 (21.1)	**Conflict composite of 22 events reported on the patient-staff conflict checklist intervention vs control** Ward count rate ratio (95% CI): 0.85 (0.76, 0.94; p = 0.001) Ward hurdle rate ratio[a] (95% CI): 1.14 (0.92, 1.43; p = 0.23) Baseline mean (SD) overall event rate control: 4.69 (4.60) Baseline mean (SD) overall event rate intervention: 5.22 (6.32)	NR	NR
Välimäki, 2022, Finland, RCT	Intervention wards 8 wards, 13 units, 335 nurses, 238 hospital beds, 4,163 patients	Control wards (practice as usual) 7 wards, 15 units, 313 nurses, 235 hospital beds, 4,186 patients	**Deaths Intervention vs Control** Baseline events control: 1 Baseline events intervention: 5 OR (95% CI) 4.59 (0.37 to 56.69;p = 0.23) p-value for group*time: 0.34	NR	**Treatment satisfaction Client Satisfaction Questionnaire (CSQ-8)** No difference	**No. of forced medication events/total patients intervention vs control** Follow-up n (proportion) intervention: 486/4089 (11.9%) Follow-up n (proportion) control: 481/4,092 (11.8%) Baseline n (proportion) intervention: 317/4163 (7.6) Baseline n (proportion) control: 414/4186 (9.9)

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Patient Injuries	Aggressive Incidents	Patient Satisfaction	Forced Medication
						RR (95% CI) 0.87 (0.41 to 1.83; p = 0.71) p-value for group * time: 0.56 **No. of patients injected/ total patients** Follow-up n (proportion) intervention: 292/4,089 (7.1) Follow-up n (proportion) control: 289/4,092 (7.1) Baseline n (proportion) intervention: 150/4163 (3.6) Baseline n (proportion) control: 295/4186 (7.1) RR (95% CI) 1.12 (0.53 to 2.36; p = 0.76) p-value for group * time: <0.001
Boumans, 2014, Netherlands, Concurrent	Methodological work approach	Control (practice as usual)	NR	NR	NR	NR
Noorthoorn, 2014, Netherlands, Concurrent control	Intervention	Control (practice as usual)	NR	NR	NR	NR
Blair, 2015, United States, Pre-post	Engagement model	Pre-intervention (practice as usual)	NR	NR	NR	NR
Dickens, 2020, Australia, Pre-post	Safewards	Pre-intervention (practice as usual)	NR	**Conflict** 4-week post intervention adjusted rate ratio (95% CI): 0.77 (0.66 to 0.89)	NR	NR

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Patient Injuries	Aggressive Incidents	Patient Satisfaction	Forced Medication
	8 wards 142 beds	8 wards 142 beds		Baseline phase (4-week prior to intervention) mean (SD) rates: 4.0 (6.2) **Physical aggression** 4-week post intervention adjusted rate ratio (95% CI): 0.65 (0.59 to 0.72) Baseline phase (4-week prior to intervention) mean (SD): 4.0 (6.2)		
Hellerstein, 2007, United States, Pre-post	Staff education, limits on seclusion time per order, coping questionnaire, off-unit privileges NR	Pre-intervention (practice as usual) NR	NR	**No. patients involved in fights post (67 months) vs pre (20 months)** Post period mean (SD): 0.3 (0.2) Pre period mean (SD): 0.5 (0.2) Difference: p = NS	NR	NR
Khadivi, 2004, United States, Pre-post	Risk assessment 1602 admissions	Pre-intervention (practice as usual) 1766 admissions	**Self-destructive behavior post (12 months) vs pre (12 months)** 12 months pre intervention number of episodes: 27 12 months pre intervention number of episodes: 24 % change in events in 12 months after intervention vs 12 months before: -11% (NS)	**Assaults on patients post (12 months) vs pre (12 months)** 12 months pre intervention number of episodes: 67 12 months pre intervention number of episodes: 85 % change in events in 12 months after intervention vs 12 months before: increase 26.8% (p <0.05)	NR	NR

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Patient Injuries	Aggressive Incidents	Patient Satisfaction	Forced Medication
Lewis, 2009, United States, Pre-post	Crisis Prevention Management program	Pre-intervention (practice as usual)	NR	NR	NR	NR
McDonagh (report), 2019, United States, Pre-post	Recovery Programming NR	Pre-intervention (practice as usual) NR	**Patient assault no injury** Pre period (3 years): 1 Post period (3 years): 0 Difference NR **Patient injury** Pre period (3 years): 3 Post period (3 years): 0 Difference NR	NR	NR	NR
Pollard, 2017, United States, Pre-post	Comprehensive intervention NR	Pre-intervention (practice as usual) NR	NR	Self-destructive events per 24-hour period pre vs post policy intervention: Pre mean (SD): 1.07 (0.41) Post mean (SD): 0.72 (0.32) Difference: p = 0.004	NR	NR
Richmond, 1996, United States, Pre-post	NR	NR	NR	NR	NR	NR
Stoll, 2022, Switzerland, Pre-post	Moral Case Deliberation NR	Pre-intervention (practice as usual) NR	NR	NR	NR	**Proportion of patients coerced medication** Pre period: 4.8% (n = NR) Post period: 4.1% (n = NR) Differnece: p = 0.93
Taxis, 2002, United States, Pre-post	Comprehensive intervention	Pre-intervention (practice as usual)	NR	NR	NR	NR
Whitecross, 2020,	Multidisciplinary team approach	Pre-intervention (practice as usual)	**Self-harm post (6 months) vs pre (6 months)**	**Physical aggression post (6 months) vs pre (6 months)**	NR	NR

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Patient Injuries	Aggressive Incidents	Patient Satisfaction	Forced Medication
Australia, Pre-post	1356 episodes of care total		No. 6 months before intervention: 20 Difference (6 months post): -25% (p = NR)	No. 6 months before intervention: 163 Difference (6 months post): -25.2% (p = NR) **Verbal aggression post (6 months) vs pre (6 months)** No. 6 months before intervention: 188 Difference (6 months post): -23.4% (p = NR)		
Zuehlke, 2016, United States, Pre-post	Recovery-oriented model of care	Pre-intervention (practice as usual)	NR	NR	NR	NR

Notes. [a] Test for difference (intervention vs control) in number of shifts with 0 events.
Abbreviations. aOR=adjusted odds ratio; no.=number; NA=not applicable; NR=not reported; NS=not significant; OR=odds ratio; RoB=risk of bias; SE=standard error; SD=standard deviation; VA=Veteran Affairs.

Results Summary: Staff Outcomes

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Staff Injuries	Satisfaction with Policy
Hospital/Unit Restructuring				
Hochstrasser, 2018, Switzerland, Pre-post	Open-door policy with recovery-oriented care	Pre-intervention (practice as usual)	NR	NR
Hunter, 1993, United States, Pre-post	After hospital restructuring 78 patients	Before hospital restructuring 66 patients	**Patient-to-staff assaults** Pre no. events: 1 Post no. events: 1	NR
Jenkins, 2014, United Kingdom, Pre-post	Purpose built psychiatric intensive care unit	Old unit	NR	NR
Rohe, 2017, Germany, Pre-post	Architecturally positive redesign	Pre-intervention (practice as usual)	NR	NR
Staff Education/Training				
Bowers, 2008, United Kingdom, Concurrent and pre-post	City Nurses intervention – escalation training	Concurrent control (practice as usual)	NR	NR
Forster, 1999, United States, Pre-post	Intensive staff training 3,010 admissions	Pre-intervention (practice as usual) 2,560 admissions	**Staff injuries post (12 months) vs pre (12 months)** Post period: 39 incidents Pre period: 48 incidents 18.8% decrease (p = NR)	NR
Haefner, 2021, United States, Pre-post	De-esclation training (TeamSTEPPS)	Pre-intervention (practice as usual)	NR	NR
Sensory Modulation				
Lloyd, 2013, Australia, Concurrent	Sensory modulation room N NR	Concurrent control (practice as usual) N NR	NR	NR
Cummings, 2010, United States, Concurrent	Comfort room	Concurrent control (practice as usual)	NR	NR

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Staff Injuries	Satisfaction with Policy
		Pre-intervention (practice as usual)		
Azuela, 2018, New Zealand, Pre-post	Sensory modulation room N NR	Pre-intervention (practice as usual) N NR	NR	The Essen Climate Evaluation Schema (EssenCES) was used to determine staff's and service users' perceptions of their inpatient unit's climate. **Unit A** Experienced Safety: Post: mean (SD) 2.94(0.67) Pre: mean (SD) 3.40 (0.84) P = 0.11 Therapeutic Hold: Post: mean (SD) 3.29 (0.65) Pre: M (SD) 3.33 (0.83) p = .59 Overall Climate: Post: mean (SD) 3.18 (0.60) Pre: mean (SD) 3.31 (0.76) p = .27 Overall Attitudes (measured Professional Attitudes Towards Seclusion Questionnaire (PATS-Q): Median (post): 2.87 (0.36) Median (pre): 2.89 (0.61) p = .47 **Unit B** Experienced Safety: Post: mean (SD) 3.31 (0.69) Pre: mean (SD) 3.33 (0.49) p = 1.00 Therapeutic Hold: Post: mean (SD) 3.73 (0.73) Pre: mean (SD) 3.41 (0.61) p = .02 Overall Climate: Post: mean (SD) 2.63 (0.90) Pre: mean (SD) 2.80 (0.71) p = .10 Overall Attitudes (measured PATS-Q): Median (post): 2.8857 (0.56)

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Staff Injuries	Satisfaction with Policy
				Median (pre): 2.75 (0.39) p = 0.70
Novak, 2012, Australia, Pre-post	Sensory room	Pre-intervention (practice as usual)	NR	NR
Sivak, 2012, United States, Pre-post	Comfort room NR	Pre-intervention (practice as usual) NR	**Client to staff assaults post (4 months) vs pre (4 months)** Post intervention: 48.1% decrease Pre intervention 4-month average rate 2.31 /1,000 days of client care	
Smith, 2013, United Kingdom, Pre-post	Sensory room	Pre-intervention (practice as usual)	NR	NR
Zimmermann, 2020, United States, Pre-post	Serenity room	Pre-intervention (practice as usual)	NR	NR
Risk Assessment				
Abderhalden, 2008, Switzerland, RCT	Structured risk assessment (BVC)	Control (practice as usual)	NR	NR
van de Sande, 2011, Netherlands, RCT	Structured risk assessment (BVC)	Control (practice as usual)	NR	NR
Blair, 2017, United States, Pre-post	Structured risk assessment (BVC)	Pre-intervention (practice as usual)	NR	NR
Clarke, 2010, Canada, Pre-post	Structured risk assessment (BVC)	Pre-intervention (practice as usual)	NR	NR
Harrington, 2019, Australia, Pre-post	Risk assessment (Clinical Risk Management Initiative) 965 admissions post-implementation	Pre-intervention (practice as usual) 1,090 admissions in pre period		**Staff survey post (18 months) vs pre (24 months)** Visual observations contribute to safe practice at [this psychiatric unit]. P-value for difference = 0.17 Visual observations create a safe environment for patients. P-value for difference = 0.17 I am personally satisfied with the practice of visual observations in the

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Staff Injuries	Satisfaction with Policy
				management of patients who have been identified as being 'at risk': Improve post intervention. P-value for difference = 0.01 The current way in which we do visual observations prevents adverse outcomes for staff. P-value for difference = 0.33 The current way in which we do visual observations prevents adverse outcomes for patients. P-value for difference = 0.12 Visual observations provide optimum care for the patients at [this psychiatric unit]. Improve post intervention. P-value for difference <0.001
Manning, 2022, United States, Pre-post	Risk assessment (modified Agitation Severity Scale) 389 patients	Pre-intervention (practice as usual) 353 patients	NR	**Nurse survey post (18 months) vs pre (18 months)** **"**No significant difference between study phases" **Oldenburg burnout scale post (18 months) vs pre (18 months)** Mean (SD) baseline: 36.17 (6.74) Mean (SD) post: 36.11 (8.29) Difference in overall score: p = 0.98
Trauer, 2010, Australia, Pre-post	The Management of Acute Arousal Program	Pre-intervention (practice as usual)	NR	NR

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Staff Injuries	Satisfaction with Policy
Comprehensive/Mixed				
Bowers, 2015, United Kingdom, High	Safewards 16 wards	Control wards (physical health program) 15 wards	NR	**Ward atmosphere scale intervention vs control (positive values represent improvements for intervention)** Order and organization β (95% CI) -0.32 (-0.79 to 0.16; p = 0.20) Baseline mean (SD) overall event rate control: 6.43 (2.53) Baseline mean (SD) overall event rate intervention: 7.19 (2.27) Programme clarity β (95% CI) 0.27 (-0.22 to 0.75; p = 0.28) Baseline mean (SD) overall event rate control: 7.18 (2.06) Baseline mean (SD) overall event rate intervention: 7.4 (2.04) Staff control β (95% CI) -0.19 (-0.57 to 0.18; p = 0.30) Baseline mean (SD) overall event rate control: 1.8 (1.40) Baseline mean (SD) overall event rate intervention: 1.83 (1.55)
Välimäki, 2022, Finland, RCT	Intervention wards 8 wards, 13 units, 335 nurses, 238 hospital beds, 4,163 patients	Control wards (practice as usual) 7 wards, 15 units, 313 nurses, 235 hospital beds, 4,186 patients	NR	**Nurse turnover rates** No difference **Team climate inventory** No difference
Boumans, 2014, Netherlands, Concurrent	Methodological work approach	Control (practice as usual)	NR	NR
Noorthoorn, 2014, No PMID, Netherlands, Concurrent	Intervention	Control (practice as usual)	NR	NR

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Staff Injuries	Satisfaction with Policy
Blair, 2015, United States, Pre-post	Engagement model	Pre-intervention (practice as usual)	NR	NR
Dickens, 2020, Australia, Pre-post	Safewards 8 wards 142 beds	Pre-intervention (practice as usual) 8 wards 142 beds	NR	**Violence Prevention Climate Scale (VPC-14)** Staff and patient perceptions regarding violence prevention: "Did not change"
Hellerstein, 2007, United States, Pre-post	Comprehensive intervention NR	Pre-intervention (practice as usual) NR	**No. patient related staff injuries post (67 months) vs pre (20 months)** Pre period mean (SD): 0.7 (1.0) Post period mean (SD): 0.18 (0.42) Difference: p = 0.003	NR
Khadivi, 2004, United States, Pre-post	Comprehensive intervention 1,602 admissions	Pre-intervention (practice as usual) 1,766 admissions	**Assault on staff post (12 months) vs pre (12 months)** 12 months pre intervention number of episodes: 31 12 months post intervention number of episodes: 83 % change in events in 12 months after intervention vs 12 months before: 167% (p <0.01)	NR
Lewis, 2009, United States, Pre-post	Crisis Prevention Management program	Pre-intervention (practice as usual)	NR	NR
McDonagh (report), 2019, United States, Pre-post	Recovery-oriented programming NR	Pre-intervention (practice as usual) NR	**Staff injury** Pre period (3 years): 3 Post period (3 years): 0 Difference NR **Staff assault no injury** Pre period (3 years): 0 Post period (3 years): 2 Difference NR	NR

Author, Year, Country, Design	Intervention Label, Sample Size	Comparator Label, Sample Size	Staff Injuries	Satisfaction with Policy
Pollard, 2017, United States, Pre-post	Comprehensive intervention NR	Pre-intervention (practice as usual) NR		**Critical incidents (potential or actual assaultive or self-destructive events occurring on the unit in 24-h period) post (18 months) vs pre (28 months)** Pre period mean (SD): 1.07 (0.41) Post period mean (SD): 0.72 (0.32) P-value for difference = 0.004
Richmond, 1996, United States, Pre-post	Comprehensive intervention	Pre-intervention (practice as usual)	NR	NR
Stoll, 2022, Switzerland, Pre-post	Moral Case Deliberation	Pre-intervention (practice as usual)	NR	NR
Taxis, 2002, United States, Pre-post	Comprehensive intervention	Pre-intervention (practice as usual)	NR	NR
Whitecross, 2020, Australia, Pre-post	Psychiatric behavior of concern team	Pre-intervention (practice as usual)	NR	NR
Zuehlke, 2016, United States, Pre-post	Recovery-oriented model of care 352 total both periods	Pre-intervention (practice as usual) 352 total both periods	NR	**Staff satisfaction** Pre period: NR Overall stratification higher in post vs pre period (p = 0.04) Increases in staff satisfaction for daily programming (p = 0.001), satisfaction with staff collaboration (p = 0.003), ability to handle acute situations without using restraints (p = 0.008), ability to provide group programming (p = 0.09, and belief that patients should have input into their mental health treatment (p = 0.005).

APPENDIX K. PEER REVIEW DISPOSITION

Comment #	Reviewer #	Comment	Author Response
Are the objectives, scope, and methods for this review clearly described?			
1	1	Yes	Thank you.
2	2	Yes	Thank you.
3	3	Yes	Thank you.
4	4	Yes	Thank you.
5	5	Yes	Thank you.
6	7	Yes	Thank you.
Is there any indication of bias in our synthesis of the evidence?			
7	1	No	Thank you.
8	2	No	Thank you.
9	3	No	Thank you.
10	4	No	Thank you.
11	5	No	Thank you.
12	7	Yes - Themes of self-report data as biased and RCTs as the only way to conduct research on IMH units is not realistic. It seems the authors do not have a clear understanding of the context of VHA IMH services.	Thank you for this comment although we disagree with the assertion that the synthesis is biased. Our careful attention to the methods of included studies and contextualizing findings based of these methods, represents the absence (rather than presence) of bias in the synthesis. We appreciate the challenges of conducting a randomized trial in inpatient mental health units, but note several included studies used this method. The results and discussion sections raise attention of readers to potential for deviations from what may be the causal relationship between the interventions and outcomes based on established epidemiological methods. While self-report data can be informative, they also hold the potential for bias due to lack of control and potential for self-observers to collect incorrect or biased assessments (especially if they are aware of the hypothesis of the study

Comment #	Reviewer #	Comment	Author Response
			and ideal outcomes to be obtained), and therefore it is important to interpret self-report data with caution. Self-report data could provide useful information that can be integrated into development of new programs or for more rigorous controlled trials.
Are there any published or unpublished studies that we may have overlooked?			
13	1	No	Thank you.
14	2	No	Thank you.
15	3	No	Thank you.
16	4	No	Thank you.
17	5	No	Thank you.
18	7	Yes - VHA uses PMDB as its primary intervention to prevent disruptive behavior. Nurse/staffing training related to therapeutic communication are also important in preventing disruptive behaviors. Those topics were not examined in this review.	The reviewer comment suggests we missed a program and not a study meeting the review eligibility criteria, specifically. The PMDB is required training at the VA but it is not inpatient specific. Additionally, we searched for studies of this program and have found only one (https://cdn.mdedge.com/files/s3fs-public/Document/September-2017/022080016.pdf). This study does not mention seclusion as a goal for the program (thus not meeting our definition of an eligible intervention) or report seclusion as an outcome. We therefore do not believe we have missed a study of the PMDB program.
Additional suggestions or comments can be provided below.			
19	1	None	Thank you.
20	2	Page 17, line 20: statement of "there are limited data on the benefits on seclusion." The focus of the report is on the effective strategies of reducing seclusion events and not examining the benefits of seclusion itself which would be a different focus of the report.	This was an error as it was meant to say there are limited data on the benefit of protocols to reduce seclusion. We have corrected it to read as follows: “Despite great interest from policymakers, providers and patients for effective alternatives to seclusion, there are limited data on the benefits of protocols designed to reduce seclusion in adult inpatient mental health wards”
21	3	When reading this overview - I have questions regarding patient population types in the reviewed publications. We are looking at effective ways to reduce seclusion in practice - but there is no layering if there were more	We appreciate the reviewer’s comment that layering of factors that could reasonably impact/change results is important to consider and would be helpful in guiding policy and recommendations. Unfortunately, a major limitation of the studies included in this review (called out in our report)

Comment #	Reviewer #	Comment	Author Response
		effective approaches with certain age groups, sexes, or admitting diagnoses. Is there any information/data on when event occurred in relation to time after admission. We would need to consider the acuteness of the psychiatric situation with the patient and the correlation to restraint/seclusion in relation to that. Do certain admitting diagnoses result in higher occurrences of these events? That would help drive possible interventions based upon that unique factor. Interventions to reduce the number or length of seclusion events is great information - but in what context and relation to the majority percentage of patient situations. The information is great and demonstrates the need for more in depth research with set parameters for evaluation - but it led to many more questions about demographics, diagnoses, and acuity. Another factor is the type of inpatient setting - is it a mixed milieu? How can we bucket results based upon similar settings?	is the lack of reporting of patient data and specific analyses taking patient data into consideration. Diagnosis were reported in only 9 studies, and no study reported subgroup analyses by patient demographics or acuity. The interventions were complex and involved tailoring strategies based on individual patient context, but results were reported at aggregate for all patients. The Discussion notes that future studies should make greater efforts to study effect modification based on demographics, diagnoses, or acuity.
22	4	pg. 13 line 10:"...studies excluded, incarcerated, while incarcerated is excluded, many patients on inpatient have criminal records e.g., assault	Thank you for this comment. We agree that some patients in included studies may have criminal records. In consultation with experts during the scoping process we exclude studies with incarcerated populations because the management of patients in a forensic unit may be different than a non-forensic inpatient mental health unit. We have added text to the Methods section to clarify the inclusion criteria: “For both KQ 1 and KQ 2, studies were excluded if they included incarcerated or institutionalized populations as these settings were deemed to be outside the scope of interest to our stakeholders.”
23	4	pg. 17 line 17: "...other coercive measures" again consider removing this staff stigmatizing language	In the Introduction we have added a clarification about the term coercion. The footnote reads: “A note on the use of the term ‘coercion’ this report. We use the term coercion without judgement or intention of implying clinician stigma. Rather, we use this term to be consistent with our observations of how the literature describes a group of measures that may be applied “against the patient’s will or in spite of his or her

Comment #	Reviewer #	Comment	Author Response
			opposition" (such as seclusion, restraint and forced medication) to manage patient care.(Chieze, 2021) If a study reported coercion as a composite outcome in their results (i.e., a combined outcome of seclusion and other coercive measures) we report the study definition of coercion, where possible."
24	4	pg. 18 line 9: restructure units to include open wards and sensory/comfort wards" VA does not use "open wards" patients may be on a voluntary or involuntary commitment-the latter typically associated with lack of insight into illness and need for tx.	Per our protocol (based on expert input) we included studies or interventions conducted in high income countries that evaluated environmental restructuring. Some environmental restructuring studies evaluated open door policies. We revised the text in this section to note that open doors were only considered in some of the hospital restructuring studies, among other architecturally positive or service reorganization elements. The decision to make a ward open depends on type of patient population. We also note that open door policies may not be relevant to the VA.
25	4	pg. 19 line 17:"coersive practices", this terminology is very controversial and may denote a negative connotation despite staff doing everything to prevent seclusion, staff are doing something unethical-suggest not using this term throughout this report.	Please see our reply to comment 23.
26	4	pg. 19, line 42: seclusion definition-use TJC and code of fed regs definition.	In the Introduction (pg. 19 line 42) we describe seclusion following the approach used in the literature.
27	4	pg. 19 line 47: "...seclusion may/may not be monitored"-this is not accurate, TJC requires all patients in seclusion to be monitored.	In the Introduction we note that how seclusion is implemented in practice varies. We revised the statement to no longer emphasize as an example that in practice patients in seclusion may or may not be monitored. with
28	4	pg. 21 line 9: "we worked with representatives from OMHSP...please add ONS (Office of Nursing Services) which I fall under.	We revised the text to acknowledge the affiliation of the Operations Partners and TEP. The Preface also lists all TEP members, their titles, and affiliations.
29	4	pg. 23, line 8: inclusion criteria: population consists of state statues of voluntary/involuntary commitments	We revised the inclusion criteria to note the patient population consists of Adults with psychiatric conditions admitted (voluntary / involuntary) and being treated in hospital inpatient units.
30	4	pg 24, line 30: "staffing" there is no mention of staffing ratios and staffing mix (particularly) RNs	Thank you. The word 'mix' was missed from KQ 2 and has been added.

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		and impact on seclusion (ANA position statement: Reduction of Patient R&S in Healthcare Settings.	
31	4	pg. 36 line 55: "light and noise levels" no mention of the temperature in the unit.	Light and noise was mentioned as it was a specific example of environmental restructuring in one of the protocols listed. While unit temperature could feasibly be considered (as part of the environment or sensory modulation rooms), it was not mentioned explicitly and is not reported here.
32	4	pg. 63 line 23: "bright light" could be overstimulating-would consider "natural lighting" per the Design Guide.	We have changed bright light to natural light.
33	4	pg. 69 line 16: " restructure units to include open unit" again this is not the policy or practice in VA an not a reasonable consideration. Would also offer that other patient care needs are considered and addressed (trauma informed care; pain; withdrawal; hunger, thirst; disturbing hallucinations; intrusive thoughts) as well as unit management philosophy /attitudes of staff (recovery care vs. custodial care). in addition to staff education levels (RNs-ADN, BSN, MSN, certifications etc) and staff ratio and mix (e.g. All RN staff and impact on reducing seclusion).	Please see reply to comment 24.
34	5	Minor edits listed below with page/line reference. One suggestion: Clarify early what is included in "coercion events" ... restraint, seclusion, meds, all of the above, something else. There is a lot about “composite measures for coercion” (also not well defined) and it’s not clear what elements would be included in those composite measures until page 15 and then only by inference in line 7.	We revised the Introduction to clarify the meaning of coercion (see footnote a). When studies define coercion or composite measures we report the definition. Where studies do not define coercion, we indicate that the definition is not reported.
35	5	Edit Suggestions: Page 12 Line 29 “reduce seclusion on patient and staff outcomes and the resource needs required to implemented” [change to implement]	Thank you, this change has been made.

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36	5	Page 13 Line 35 “seclusion, respectively.. Based on our coding of the interventions, we identified 5 intervention” [remove extra period]	Thank you, this change has been made.
37	5	Page 14 Line 43 “for some outcomes and spares reporting of data. Studies provide insufficient evidence (providing” [change spares to sparse]	Thank you, this change has been made.
38	5	Page 16 Line 19-20 “Despite great interest from policymakers, providers and patients for effective alternatives to seclusion, there are limited data on the benefits of seclusion.” [Is there a word missing here? Because not sure what this introduction to the discussion means (how the interest in alternatives relates to the benefits of seclusion) or how it ties into the paragraph that follows]	This was an error. We have corrected it to read as follows: “Despite great interest from policymakers, providers and patients for effective alternatives to seclusion, there are limited data on the benefits of protocols designed to reduce seclusion in adult inpatient mental health wards”
39	5	Page 16 Line 44 “Outcomes such as of patient aggression, patient/staff injuries, and patient/staff” [remove "of"]	Thank you, this change has been made.
40	5	Page 17 Line 51 “that aim implement all or parts of these interventions.” [add "to" after aim]	Thank you, this change has been made.
41	5	Page 22 Line 30 “organizations in US or Canada or implemented or intended to be implemented these countries.” [add "in" after intended to be implemented]	Thank you, this change has been made.
42	5	Page 37 Line 56 “2) advisory statements to handled flashpoints;” [change handled to handle]	Thank you, this change has been made.
43	5	Page 65 Line 36 “reduce the likelihood of a precipitating behavior requiring seclusion or any alternatives.” [I think the "a" needs to be removed to say "reduce the likelihood of precipitating behavior requiring seclusion or any alternatives"]	Thank you, this change has been made.
44	5	Page 65 Line 59 “restrain was unknown due to insufficient evidence” [should be "restraint" rather than restrain]	Thank you, this change has been made.
45	7	Thank you for reviewing efforts to reduce seclusion on IMH units. The following are	Please see reply to comment 24 above

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		comments provided to enhance the draft. P11. Line 21. “open-door policy” is confusing as VHA inpatient mental health units are locked. Does this mean internal doors on the unit? Or did your review include literature on non-VA voluntary private pay facilities? VA provides IMH care to a very different clinical population than those treated in private pay free-standing IMH units.	
46	7	P11. e23. The “ie,” here is confusing. Perhaps a word is missing? This occurs again on line 53. This phrase: environment restructuring intervention function, or intervention function environment restructuring, is not used in the clinical IMH setting in VHA. Thus, providing an operational definition for the reader would be important. Perhaps deleting the word “function” may help make this term more understandable to the reader.	We extracted protocol elements into 1 of 9 intervention functions defined by the behavior change wheel. “Environmental restructuring” represents 1 of the 9 intervention functions. We revised the text in the Executive Summary clarify our intent.
47	7	In the summary, it would have been helpful to describe more clearly interventions that focused on staff v. interventions focused on patients. The first paragraph of the discussion explained this better.	We have called out the target of the intervention functions (staff vs. patient vs. both) more explicitly in the Executive Summary
48	7	P 11 Line 47. Use of the term coercion is problematic as it has a negative connotation. Recommend stating that this term is what was used in the research you reviewed. Coercion implies that staff are threatening or forcing patients to do something they don’t want to do. That is not acceptable clinical care. Coercion is different from implementing seclusion or restraint for patient and staff safety purposes. VA must follow TJC requirements. Excerpt from TJC PC.03.05.01: Program: Hospital Chapter: Provision of Care, Treatment, and Services Introduction: N/A	See reply to comment 23 above.

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		Rationale: N/A Elements of Performance: 1. The hospital uses restraint or seclusion only to protect the immediate physical safety of the patient, staff, or others. 2. The hospital does not use restraint or seclusion as a means of coercion, discipline, convenience, or staff retaliation. 3. The hospital uses restraint or seclusion only when less restrictive interventions are ineffective. 4. The hospital uses the least restrictive form of restraint or seclusion that protects the physical safety of the patient, staff, or others. 5. The hospital discontinues restraint or seclusion at the earliest possible time, regardless of the scheduled expiration of the order. Please find a different term to use in this paper.	
49	7	P. 12 Line 21. Physical restraint is actually the intervention of last resort, as it requires VHA staff to actually put hands on the patient to prevent movement. Seclusion is the least restrictive type of restraint. However, external accreditation standards (e.g., TJC) results in seclusion being more staff-intensive (seclusion requires direct observation) as compared to restraint. That should be clarified here.	We revised the text to emphasized that that seclusion is increasingly seen as “an” intervention of last resort (i.e.., one of several, including restraint), not “the” intervention of last resort. For that reason, we have kept the sentence as is as we believe the intent is clear.
50	7	P. 13 Line 14. Operationally define behavioral change wheel.	We have added additional details on the behavior change wheel (already in the full report) in the Execute Summary.
51	7	P. 13 Line 52. In terms of discussing reduction of seclusion from transforming a unit from a locked inpatient unit to a residential unit, that is essentially changing the level of care from inpatient to residential, which are not comparable. We have locked units that treat patients who are committed (either voluntarily or but the state court) to receive acute inpatient mental health care. A residential program is not acute care.	See reply to comment 24 above.

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52	7	P. 14 Line 35. Unclear the operational definition of enablement.	The operational definition of enablement (along with the operational definition of the other 8 intervention functions) was not included Executive Summary as this would make the summary too cumbersome. The details of how each intervention function was defined is included in the full report and Appendix B.
53	7	P15 Line 38. Should “creates” be “crates?”	Thank you, this change has been made.
54	7	P. 17 Line 12. Again, “open” wards is a residential level of care which is different from IMH care. This summary seems like a suggestion to make acute inpatient units unlocked wards, which is not realistic. Patients who do not need acute inpatient care would be discharged to a lower level of care such as residential or outpatient mental health services. This comes up again on P. 18 Line 9.	See reply to comment 24 above.
55	7	P. 33 Line 49. Unclear how continuous video monitoring is described as a restriction. Monitoring patients when they are using items that can be used for self-harm or harm to others is a safety procedure. Similarly, unclear how requiring patients to sign an agreement (BTW unsure what the agreement is about) prior to using the sensory modulation rooms is a restriction.	The *restriction* intervention function is defined as the use of rules to reduce the opportunity to engage in the target behavior or competing behaviors (see Appendix B). In one study, patients were informed that they may use the space as long as they were safe, but they would be monitored on video and staff could enter the space (ie, they would lose the privilege of using the room) if they were displaying unsafe behavior. In another study, patients had to sign an agreement form to use the sensory modulation room. Those who were unable/unwilling to sign the agreement form were not allowed to use the sensory modulation room. We interpreted both cases as examples of rules put in place to encourage positive and safe behavior for patients. We have added a clarifying statement to the agreement form (“…patients who were unable or unwilling to sign the agreement form were not allowed to use the sensory modulation room”).
56	7	P. 33 Line 53. Also unclear how customizing a sensory modulation room is enablement. Does enablement = customization? Not sure what to make of this as a treatment plan, for example,	The *enablement* intervention function is defined as increasing means/reducing barriers to increase capability or opportunity. We interpreted the extra efforts made by protocols to tailor the rooms to the specific requests of patients on the ward at that present moment (based on

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		should be customized to the individual. So is all treatment enablement?	intake forms) and supports put in place for patients to voluntarily use the rooms as examples of increasing patients' psychological capability and reducing patients' social and physical barriers (ward culture and set up) to use the sensory modulation rooms.
57	7	P. 49. Risk Assessment. As I read through this, I think what is missing for me is that it is unrealistic to expect any changes in rates of seclusion and restraint simply based on risk assessment. What is key is what you DO with the risk assessment data. In other words, how is the risk assessment date utilized by staff. It is not simply conducting a risk assessment that is key. It's that treatment is customized base on risk assessment results. Additionally, it seems that this section focused on risk of violence. On IMH assessing risk for self-harm is equally important, if not more so, in reducing seclusion and restraint. It seems that got lost in this review.	We describe the risk assessment protocols as they are reported in the studies. We agree that the staff action in response to the risk assessment is key, although not all protocols were explicit with this in their descriptions of the intervention. Where studies reported subsequent management protocols (informed by the risk assessments) we captured this information and coded the appropriate intervention functions. We have revised the name for this group of studies to be "risk assessment and management protocols".
58	7	A major theme throughout the report is that self-report data is biased, which is interesting. It seems the assumption is that the best methodology for research on variables related to reducing seclusion and restraint can only be found in RCTs. There seems to be a lack of understanding of how having researcher observers on a unit might impact staff and patient behavior, not to mention to difficulty in accommodating such a presence on many inpatient units where space is a premium. Where would the observers be situated? Some units have not had episodes of seclusion or restraint for years—how is that coded? No suggestions are provided on how to better conduct applied research in this type of setting.	It is important to distinguish that bias from self-report data and non-RCT designs are different concepts. Self-reported outcomes (which are subjective and thus prone to performance bias) can still be used in RCTs. All studies in the review used self-reported data. Only 4 studies used an RCT design (which controls for factors associated with outcomes besides the intervention to give a more valid inference of treatment effect). We present the findings in the context of these potential biases so that decision-makers can have the full picture to inform their recommendations. We acknowledge the challenges with implementing more robust, unbiased methods in our discussion and provide suggestions for future research.
59	7	P. 67 Line 50. "Recommendations" should be replaced with "requirements." Policies do not recommend behaviors rather, they stipulate required services. This occurs again on Line 58.	Thank you, this change has been made.

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60	7	P. 68 Line 8. Again, there seems to be a lack of understanding that an open ward is not consistent with an acute inpatient level of care. An open ward is essentially residential care. This must be removed.	See reply to comment 24 above.
61	7	P. 68 Line 10. Unclear why there is emphasis on smaller units. There was nothing in this report that looked at size of unit (square footage), number of beds per room, and related that to rates of seclusion and restraint. Indeed, having more treatment space and space for patients to interact, along with well-designed layouts with natural light and effective acoustics management is important. But that is not what this paragraph states.	Our intent in listing unit size as a feature to consider for future wards was not about square footage but about how many patients are housed in a unit - which was based on evidence we found in the hospital restructuring studies. We have modified this statement to add this clarification and added additional details noted by the reviewer which is consistent with the evidence we found. The sentence now reads: “As VA constructs new facilities it should consider constructing smaller units (ie, number of patients) with well-designed layouts incorporating natural light, effective acoustics management, and green space”.
62	7	P. 68 Line 16. With the implementation of Cerner efforts to standardize documentation of seclusion and restraint may be proceeding more rapidly. FYI many facilities do conduct risk assessment (the Violence Risk Assessment Instrument was developed in VA) and certainly are required to conduct self-harm risk assessment. This section read as if VA does not currently do that.	Thank you for this comment. We agree that some efforts to standardize are underway. We have added “VA-wide improvement efforts have already been implemented towards standardized documentation in the electronic health record, such as the Violence Risk Assessment, however further opportunities exist which can include standardizing measures in the electronic medical record to document process (*eg,* use of seclusion) and outcomes (*eg,* aggression).”
63	7	A few typos here and there like extra periods, inserting a word out of place, wrong spelling of word, etc..	Thank you. We have reviewed the report for typographical errors and made the necessary corrections.