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Effectiveness of an Evidence-based Assessment Instrument for Reducing Physical Restraint Use in General Adult Wards in Hong Kong A Cluster Randomized Controlled Trial

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Abstract

Background

Physical restraint is commonly applied in clinical setting. No evidence-based assessment instrument was solely evaluated its effectiveness in reducing restraint use in general adult ward settings. The study aimed to evaluate the effectiveness of an evidence-based assessment instrument in reducing physical restraint use in general adult wards, and to describe staff satisfaction.

Methods

A single-blinded cluster randomized controlled trial was conducted in eight general adult wards in Hong Kong. Wards were randomized to use the assessment instrument with usual documentation or usual documentation solely. The primary outcomes were daily restraint prevalence and restraint episode incidence, analysed using generalizing estimating equations to account for clustering and pre-specified covariates. Secondary outcomes included restraint duration, length of ward stay, restraint-related incidents, and staff satisfaction.

Results

A total of 1,961 eligible patient admissions in eight ward clusters, following adjusted analyses, found no statistically significant difference between the intervention and control wards in restraint prevalence (adjusted odds ratio = 0.787, 95% CI: 0.522-1.188, p = 0.255) or restraint episode incidence (adjusted incidence rate ratio = 0.971, 95% CI: 0.766-1.231, p = 0.811). Among patients who experienced restraint, duration and length of ward stay did not differ significantly between groups. Thirty-eight of 102 eligible nurses in intervention wards completed the post-implementation survey. Respondents reported moderate perceived usability and identified paperwork, complexity, and training needs as implementation barriers.

Conclusions

The instrument did not demonstrate a statistically significant reduction in physical restraint prevalence or restraint episode incidence during the study period. Further, development should address implementation barriers and evaluate the refined instrument within a longer and as a part of a multicomponent restraint-reduction intervention.

Trial Registration

The study protocol received Hong Kong Institutional Review Board (IRB) approval (Central IRB CIRB-2024-517-3: Feb 17th 2025).

Trial Registration Number: ChiCTR2500099134 (Mar 19th 2025)

Keywords

Assessment instrument; physical restraint; general adult wards; cluster randomized controlled trial; restraint decision wheel

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Background

Physical restraints limit body movement using means attached to a person's body that cannot be easily controlled or removed [1]. Despite centuries of use in clinical settings, particularly mental health care settings, physical restraint efficacy and safety remain questionable, with potential for adverse events and injuries [2,3,4].

In Hong Kong, physical restraint is not yet formally recognized as a nursing quality indicator. However, corporate and hospital guidelines direct healthcare providers to use restraint minimally, appropriately, and safely while respecting patient dignity and rights to prevent risks of harm [5,6].

Nurses face ethical dilemmas regarding restraint use without standardized assessment instruments. Major healthcare organizations including The Centers for Medicare & Medicaid Services and The Joint Commission recommend restraints only when patient harm is imminent and alternatives have failed [7,8]. As such, standard protocols are essential to support effective clinical decision-making [9].

Physical restraint prevalence in acute-care hospitals varies worldwide. Switzerland and Austria reported an 8.7% restraint rate between 2016 and 2018 [10]. The United States reported a 7% to 22% rate amongst elderly populations [11], and Hong Kong reported 10.19% regardless of the hospital groups in 2021-22 [12]. The prevalence in United Christian Hospital (UCH), an acute public hospital in Hong Kong was 11.76% in 2021.

Some common justifications for physical restraint use, including preventing injuries, managing fall risk, or preventing device tampering, appear reasonable. However, evidence increasingly demonstrates that physical restraint use is either ineffective or harmful [10, 13, 14, 15, 16]. Few studies showed that restraint use correlates with adverse outcomes including self-extubation, falls and fracture, increased aggression or agitation, longer hospital stays, elevated mortality rates, and negative emotional impacts on patients, families, and nurses [11, 17, 18, 19].

A systematic review identified a critical evidence-practice gap [20].While an evidence-based restraint decision wheel demonstrated effectiveness on reducing physical restraint use in intensive care settings, no comparable assessment framework guides restraint decisions in general adult wards. Current interventions addressing restraint reduction lack sufficient evidence quality.

Nurses rely on a simple observation record form listing restraint justifications without systematic decision-making guidance at UCH with 1,584 beds. This limitation urged development of an evidence-based assessment instrument to guide nurses in making appropriate, justified decisions while reducing unnecessary physical restraint in general adult wards.

Methods

The primary objective was to evaluate the effectiveness of the evidence-based assessment instrument in reducing prevalence physical restraint use based upon all eligible patient admissions and relevant ward-day observations in the randomized clusters. Patients who experienced physical restraint comprised as a secondary subgroup used only for analyses that were required restraint-specific data including restraint duration, type of restraint, repeated restraint episodes, and restraint-related incidents.

A single-blinded, cluster randomized controlled trial was conducted to evaluate whether an evidence-based assessment instrument reduced prevalence physical restraint use in eight general adult wards. It assessed process evaluation and user satisfaction with instrument implementation. The research question examined whether the structured assessment instrument effectively reduced prevalence restraint use in general adult wards. The alternative hypothesis stated that the evidence-based instrument would significantly reduce prevalence physical restraint use while improving clinical decision-making.

From April 8 to June 5, 2025, wards in the Department of Medicine & Geriatrics (M&G), the Department of Orthopaedics & Traumatology (O&T), and the Department of Surgery (SUR), respectively, were randomly allocated to the intervention or control condition using a method of coin flipping. The case mix of two O&T wards includes patients with spinal conditions, those undergoing total joint arthroplasty, general fracture, wound-related conditions, and sports injuries. The two SUR wards primarily manage patients with upper or lower gastric intestine conditions, urology conditions, and head and neck conditions. The case mix of four M&G wards includes geriatric medical conditions, stroke, neurological disorders, and general medical conditions. Participants were allocated to either the intervention wards, which used the evidence-based assessment instrument and the existing record form, or the control wards, which used only the existing record form (appendix A & B). Patient admissions, therefore, were not individually randomized. All eligible adult patient admissions to participating wards during the study period received the care assigned to the ward to which they were admitted. Allocation occurred through centralized system under concealment by a third party at the Admission Registration Office based on the bed availability and patient's diagnosis according to the standard ward admission protocol. Ward nurses did not know which group the patient was allocated to until the patient was admitted. Patients were blinded, but nurses could not be blinded to the evidence-based assessment instrument due to study design requirements. Investigators responsible for data acquisition remained unblinded to understand the study purpose when entering respective study sites. The study followed CONSORT guidelines for cluster randomized controlled trial reporting [21].

Inclusion criteria

This study included all patients aged 18 and above admitted to general adult wards and nurses providing direct patient care.

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Exclusion criteria

No exclusion criteria applied because all hospitalized patients received treatment and care during the study period.

Intervention group

The intervention adopted an evidence-based assessment instrument developed by the principal and co-investigators, demonstrating excellent psychometric properties [scale-level content validity for relevance (S−CVI/Ave = 0.99), scale-level CVI for clarity (S−CVI/Ave = 0.99), and satisfactory face validity (S−FVI/Ave = 0.90) using the Delphi process [22, 23]. Inter-rater reliability was almost perfect, with a Fleiss' Kappa of 0.822 ($p < 0.001$).

This assessment instrument incorporated the restraint decision wheel framework [24], providing structured guidance for assessing risks, benefits and alternative strategies for managing challenging behaviors. Nurses in intervention wards received four identical briefing sessions on the instrument application and adopted this instrument to assess restrained patients at least every shift of duty according to the requirement of Hospital Authority guideline for physical restraint use [25].

The instrument is comprised of five levels [20]. The instrument can help nurses go through the decision process swiftly and come up to an appropriate action with proper documentation [20]. Level one evaluated mental/behavioral status across four categories including is a patient oriented, disoriented, restless, or aggressive. Disorientation is assessed using standardized cognitive tools such as the Montreal Cognitive Assessment (MoCA) or the Mini-Mental State Examination (MMSE), the Abbreviated Mental Test (AMT) or other orientation questions such as time, place, and person. Restlessness refers to anxiety or unease preventing relaxation [26], while aggression encompasses motor activity, verbal / physical aggression, and emotional distress [27]. This level identifies behavioral risks that may contribute to unsafe actions.

Level two evaluates restraint-free care feasibility based on medical device type categorized as non-life-threatening or life-threatening. Devices include peripheral intravenous catheters, wound drains, monitoring leads, oxygen therapy, drains / tubes / catheters, treatment infusions, and other. This level determines the clinical risk associated with unplanned device manipulation and helps justify whether additional safety measures or restraint minimization strategies are required.

Level three assesses mobility status comprises independent, ambulatory with aids, or dependent based on their ability to perform activities of daily living with reference to the Barthel Index.

Level four identifies restraint indications, including essential treatment / monitoring interruptions, self-harm, harm to others, or high risk of falls. This level requires nurse's clinical judgment to balance patient autonomy with considerations of previous levels. This level reinforces the principle that restraint should

be used only as a last resort after less restrictive strategies have been attempted and deemed insufficient.

Level five explores restraint-free alternatives and overall patient safety, including accompanying care, periodic reality orientation, sensor pad(s), proximity to nurse station, antipsychotic medications, medication review (during initial restraint use or as necessary), disguised tubes / lines / devices, and others. Nurses should evaluate and document all feasible alternatives.

Control group

The control group did not receive the evidence-based assessment instrument. Instead, they continued with standard practices regarding the physical restraint use. This group served as a baseline to compare the outcomes of the intervention group, allowing for an evaluation of the effectiveness of the evidence-based assessment instrument.

Feasibility of the study

A pilot study was conducted in four intervention wards from March 25 to April 7, 2025, to familiarize nurses with study workflows and to assess instrument application. Thirteen nurses in the intervention group provided verbal enquiries during the pilot. In late May 2025, nurses completed feasibility, acceptability, and user satisfaction evaluations of the assessment instrument. Eventually, no substantive modifications were made to the assessment tool and implementation procedures.

Outcomes

The primary outcomes were daily physical restraint prevalence and restraint episode incidence. The secondary outcomes were restraint duration, number of restraint episodes per patient, restraint type, restraint-related incidents, length of ward stay, and nurse satisfaction with the instrument.

Measurement instruments

Daily physical restraint prevalence was defined as the number of patients receiving physical restraint at noon divided by the total ward census at noon for each participating ward-day. Restraint episode incidence was defined as the number of new restraint episodes during each 24-hour period, analysed with the relevant patient-time denominator. Duration refers to cumulative restraint time in each episode. Accidental catheter removal means the instances in which patients unintentionally removed their own catheters. The patient falls refers to the number of fall incidents occurring during hospitalization. Length of ward stay is measured by time from ward admission to discharge.

Baseline restraint prevalence was measured on one pre-implementation day and was used only to describe the pre-intervention ward context. It was, however, not regarded as a reliable estimate of usual prevalence or as the principal basis for inference regarding intervention effectiveness.

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Process evaluation and satisfaction survey

A process evaluation and satisfaction survey assessed nine domains: (1) achievement of the assessment purpose, (2) ease of use, (3) clarity of instructions, (4) training adequacy, (5) guidance facilitation, (6) satisfaction with the instrument; (7) instrument acceptance, (8) implementation barriers, and (9) barrier solutions. A 6-point Likert scale evaluated domains one through seven, and two open-ended questions for domain 8 and 9. Face validity was established by one professor (IL) of an institute in questionnaire development and five advanced practice nurses serving as nursing education coordinators. The electronic survey was administered to nurses in the intervention group only near study completion using a cross-sectional approach.

Data Collection

Data were collected by co-investigators through retrospectively reviewing patient medical records upon discharge throughout the study period, as well as through surveys of nurses at the end of the study. Co-investigators were responsible for updating the prevalent number of restrained patients in the study sites daily. An executive officer who has obtained a bachelor degree in statistics and was not involved in the research study was responsible for the data input and analysis.

Sample Size Calculation

The required sample size for an individual randomized trial was estimated as 221 patients per arm to reduce physical restraint prevalence from 10.22% to 7.22%, with a two-sided significance level of 5% and 80% power with reference to other studies [28, 29] which targeted a small effect. As this study adopts a cluster randomized design, the sample size was adjusted for clustering using a design effect (DE), using a formula [$DE = 1 + (m -1)\rho$, where m is the average cluster size and ρ is the Intra-cluster Correlation Coefficient (ICC)], to account for clustering at the ward level. Assuming an average ward size of 50 patients and an ICC of 0.0007, the DE was calculated as 1.0343. After adjustment, the required sample size increased to approximately 229 participants per arm (458 in total). As most of the patients stay in the wards until discharge, the mortality rate is low in the study wards. After accounting for an anticipated attrition rate of 5%, the required sample size was inflated to approximately 241 per arm (482 in total). In other words, this yielded a total of 482 subjects per specialty, or 964 subjects across the two M&G sub-specialties.

All nurses at study sites were invited to participate in the satisfaction survey. Nurse participation in process evaluation and satisfaction surveys were voluntary. With approximately 26 nurses per ward and 104 total nurses, a sample size calculator provided by the online Smart Survey determined that 50 respondents were needed under a confidence level of 95% and a margin of error of 10%.

Data Analysis

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Primary effectiveness analyses compared intervention and control wards according to the randomized allocation. Daily restraint prevalence was analysed using generalized estimating equations (GEE) with a binominal distribution, logit link, and exchangeable working correlation structure to account for repeated observations within wards. Restraint episode incidence was analysed using GEE with a log link and an offset for the relevant exposure time. Adjusted estimates were presented as adjusted odds ratios (aOR) or adjusted incidence rate ratios (aIRR) with 95% confidence intervals. Analyses of restraint duration, type, repeated episodes and restraint-related incidents were limited to patients who experienced physical restraint and were considered secondary analyses. As patient-level clinical characteristics were not available for all non-restrained admissions, comparisons of characteristics among restrained patients were descriptive and were not interpreted as evidence of baseline comparability between randomized groups.

Results were reported as regression coefficients, adjusted Exp(B) (aOR) estimates, 95% confidence intervals, chi-square (X^2) statistics and p-values, with statistical significance set at $p < 0.05$. The principle of Intention-to-Treat was applied throughout the study. Data analysis was performed using SPSS 29.0.

Missing data including missing completely at random (MCAR), missing at random (MAR), and missing not at random (MNAR) were observed and handled. Mean imputation was used for normally distributed variables with minimal missing data. The mode was used for categorical data [30].

Ethical Considerations

The Institutional Review Board (IRB) approval (Central IRB CIRB-2024-517-3: Feb 17th 2025) was obtained from the Hospital Authority Central Institutional Review Board (Central IRB) prior to study initiation. The study complied with the Helsinki Declaration and the good clinical practice guidelines of the International Conference on Harmonisation.

All data and records were stored in a locked cabinet at the study institution. Non-identifiable data were stored on secured computers with restricted access. Research data were handled according to the Hospital Authority policies for storage, destruction, and medical record management. Investigators permitted trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s), providing direct access to source data / documents. The principal investigator and team were responsible for safekeeping personal and study data. All investigators and IRB/REC retained access right. Data would be destroyed five years after study completion.

Informed Consent

In routine care, when physical restraint was indicated, nurses explained the potential risks to patients and their relatives, and informed consent was obtained in accordance with Hong Kong Hospital Authority guideline. For research participation and data collection, a distinct consent model was

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implemented. Eligible patients or guardians or next of kin were invited to participate in data collection, with retrospective consent sought if a patient regained mental capacity [31]. While all eligible admitted patients in the participating wards were screened for potential inclusion under the cluster-level implementation, individual research participation remained voluntary. Patients who declined research participation did not influence their routine clinical care. Patient information was kept strictly confidential.

The satisfaction questionnaire was anonymous with voluntary nurse participation. A disclaimer letter outlining the study purpose was attached to the survey. Nurses who completed and returned the survey were considered to have provided informed consent. This study was approved from the Hospital Authority Central Institutional Review Board (Central IRB).

Results

A total of 1,963 eligible patient admissions occurred in the eight randomized ward clusters during the study period, including 986 patients to the intervention groups and 977 to the control groups. Two admissions in intervention wards were excluded from the primary analyses because of incomplete outcome documentation in patients' medical record. Therefore, 1,961 admissions were included in the primary analyses of restraint prevalence and restraint episode incidence. Participants in the intervention and control groups were not interchangeable, and each group received only the assessments relevant to its assigned condition. See CONSORT flow diagram (figure 1).

Demographic data and baseline characteristics (table 1)

Significant demographic differences emerged between groups. The intervention group exhibited a substantially higher proportion of males (70.3% vs 47.0%, X^2=19.04, df=1, p<0.001) and a lower proportion of non-smokers (62.5% vs 72.3%, X^2=6.9, df=2, p=0.032). Emergency admissions were significantly more prevalent in the intervention group (87.7% vs 78.4%, X^2=9.54, df=4, p=0.049).

Unadjusted and adjusted mean daily restraint prevalence between the intervention and control wards during the study period (table 2 and figure 2)

During the study period, the unadjusted mean daily restraint prevalence was higher in the control wards than in the intervention wards (14.89% vs 12.10%). At the ward level, mean daily prevalence ranged from 8.83% to 15.46% in intervention wards and from 7.11% to 27.05% in control wards. In the adjusted between-group analysis, nevertheless, the intervention was not shown a statistically significant difference in daily restraint prevalence compared with the control group (aOR = 0.787, 95% CI: 0.522 – 1.188, p = 0.255).

The mean number of patients newly received physical restraint within a 24-hour period was 1.87 (SD =

1.59, 95% CI: 1.29 – 2.45) across study wards. The proportion of admissions with at least one newly given restraint episode was 17.4% (172 / 986) in intervention wards comparing to 17.0% (166/977) in control wards. Similarly, the adjusted GEE analysis found no statistically significant difference in restraint episode incidence between groups (aIRR = 0.971, 95% CI: 0.766 – 1.231, p = 0.811). Total ward occupancy increased restraint odds by 12.4% per patient present (aOR = 1.124, p = 0.003), while a newly initiated restraint in the prior 24 hours dramatically increased noon restraint counts by 83.1% (aOR = 1.831, p < 0.001).

Restraint prevalence comparing between the single pre-implementation measurement day and during the intervention period (figure 2)

On the single pre-implementation measurement day, restraint prevalence was 14.67% in intervention wards and 7.57% in control wards. During the intervention period, the mean daily prevalence was 12.10% and 14.89%, respectively.

Frequency of physical restraint use during the same hospital admission (table 3)

Most patients in both study groups experienced one restraint episode during the same hospital admission, accounting for 161 patients (97.0%) in control wards and 165 patients (95.9%) in intervention wards. Repeated restraint episodes occurred in a small proportion of patients, with two restraint episodes reported in 5 patients (3.0%) in control wards and 6 patients (3.5%) in intervention wards, while three restraint episodes were reported in one patient (0.6%) in intervention wards only. The distribution of restraint frequency did not differ significantly in both groups ($X^2 = 1.03$, df = 2, p = 0.596).

Duration of physical restraint use (table 3)

The mean duration of restraint per episode was slightly lower in intervention wards [133.66 hours (SD = 208.64)] compared to control wards without statistically significant difference [152.63 hours (SD = 191.45)] (t = 0.822, p = 0.412, 95% CI: -26.47 - 64.40).

Length of ward stay (table 3)

The mean length of ward stay was 9.46 days (SD = 13.75) in control wards, while that was 7.85 days (SD = 7.8) in intervention wards, with no significant difference in both groups (t = 1.33, 95% CI: -0.771 - 3.991, p = 0.184,).

Type of restraint (table 3)

Among restrained patients, the waist / abdominal belt was the most commonly used restraint in control wards (57.1%, n = 44) and intervention wards (65.6%, n = 61) without statistically significant difference ($\chi^2 = 3.17$, $p = 0.075$). Safety vests were the second most frequently used restraint, accounting for 36.4% (n = 28) in control wards and 28% (n = 26) in intervention wards without statistically significant

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difference (χ^2 = 0.19, p = 0.660). Other types of restraint used were similar in both groups without statistically significant difference.

Restraint-related incidents (table 3)

Restraint-related incidents were infrequent in both groups, but catheter-related incidents were the most frequently reported, occurring in 16 episodes (9.4%) in control wards and 14 episodes (7.8%) in intervention wards. Fall-related incidents were reported in two episodes (1.2%) in control wards and none in intervention wards. The distribution of recorded incident types did not differ significantly between groups (X^2 = 0.8, df = 1, p = 0.371).

Handling of missing data (table 4)

The proportion of missing data for variables collected among restrained patients ranged from 1.0% to 5.0%, with the highest level observed for educational level and duration of restraint use to the lowest for history of falls within the previous 90 days. Mode imputation was performed for marital status, educational level, smoking status, and history of falls in the previous 90 days. The Fall Risk Assessment score at admission and upon being restrained were imputed using mean values according to their observed distribution. All imputed values were incorporated into the final analytical dataset. Sensitivity analyses using alternative model specifications for primary outcomes yielded results consistent with the main analysis.

Staff satisfaction

The staff satisfaction survey achieved a 37.3% response rate (n=38, N=102). Respondents were predominantly female with professional backgrounds in RN or APN roles. Mean clinical experience since graduation varied from 6.35 to 16.8 years, and specialty-specific experience ranged from 4.7 to 15 years.

Regarding instrument acceptance and usability, mean satisfaction scores ranged from 3.55 to 4.13 on a 6-point Likert scale. Nurses demonstrated moderate agreement that the instrument facilitated restraint decision-making (mean: 3.89), minimized restraint use (mean: 3.63), provided clear instructions (mean: 3.95), and warranted clinical adoption (mean: 3.55) (figure 3 and 4).

Respondents also identified substantial barriers to implementation, including increased paperwork and duplicated documentation, instrument complexity and inefficiency, communication challenges with patients and families, insufficient training, and uncertainty about genuine effectiveness, particularly given the instrument's application only after restraint implementation. Another concern was the heightened workload associated with more frequent assessments.

Respondents proposed improvements, including instrument simplification with reduced documentation

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requirements, enhanced staff education, integration within existing clinical programs, reduced review frequency, and optimized observation frequencies (e.g., daily checks), to manage workload sustainably while maintaining implementation fidelity.

Discussion

The unadjusted and adjusted mean daily physical restraint prevalence did not show statistically significant difference between intervention and controls wards. The adjusted analysis of restraint episode incidence showed no statistically significant difference between both groups. Therefore, the primary adjusted analysis did not demonstrate the use of assessment instrument reduced daily restraint prevalence and the incidence of restraint episodes compared with conventional care during the study period. This study showed that the instrument did not effectively reduce physical restraint use in randomized ward clusters.

The result did not align with prior research showing structured decision-making tools and multidisciplinary protocols reduce reliance on physical restraints in hospital [32, 33]. During the study period, significant variation in mean daily restraint prevalence was observed across wards. This reflected how institutional, environmental, and patient factors influence physical restraint use [34]. Wards with higher proportions of cognitively impaired or agitated patients have elevated restraint rates [35]. Consistent with prior studies, cognitive impairment and high fall risk remained principal restraint drivers [36, 37]. Therefore, evaluating physical restraint reduction must account for contextual variability in clinical challenges and resource availability.

Despite non-significant result, there is no study to evaluate the effectiveness of an assessment instrument alone, adapted from Restraint Decision Wheel for intensive care [24] and designed for general adult wards [20], in achieving restraint reductions. Previous literature confirms that well-designed assessment instruments and restraint reduction interventions reduce inappropriate physical restraint use, improve patient outcomes, and provide structured decision-making frameworks [20, 38, 39]. Some studies also reported evidence-based interventions effectively reduce restraint rates [40, 41].

Figure 2 demonstrated the single pre-implementation prevalence measurement and the mean daily prevalence observed during the study period. These descriptive values indicated that prevalence changed over period in both groups, but the baseline measurement was based on a single day and the groups differed substantially at that time. Therefore, the differences were not interpreted as evidence of intervention effectiveness.

While ongoing restraint use declined, new restraint episodes were not influenced by the assessment instrument. The intervention group showed increased waist belt use and decreased safety vest use, reflecting patient- and context-specific triggers affecting initial restraint decisions.

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411 The evidence-based assessment tool did not significantly influence the duration of physical restraint.
412 Instead, restraint duration appeared to be primarily related to hospitalization characteristics. Longer
413 length of ward stay was strongly associated with prolonged restraint use. It implied that patients requiring
414 longer admissions may have greater clinical complexity or care needs. Additionally, discharge to other
415 hospital demonstrated significantly longer restraint duration, indicating that discharge deposition may
416 reflect underlying patient factors related to restraint use.

417 Most patients in both groups experienced only one restraint episode per admission, reflecting a possible
418 shift toward more restrictive use. Earlier release is linked to the structured instrument. Additionally,
419 adverse events, such as catheter dislodgement and falls, were infrequent and comparable, indicating that
420 physical restraint reduction did not compromise patient safety. This study offered comprehensive
421 assessment by evaluating duration, type, and associated events.

422 Ward-level operational metrics were found to be strongly driven by daily restraint counts. Total ward
423 occupancy increased restraint odds by 12.4%. A newly initiated restraint in the prior 24 hours
424 dramatically increased noon restraint counts by 83.1%. Emergency or unscheduled admissions often
425 enter wards in acute status without stabilized care plans leading to an increase in restraint likelihood [42].
426 It reflects systemic strain, including nurse-to-patient ratios, that drive an environmental-dependent
427 reliance on restraints [43]. Individual instruments alone may struggle to overcome systematic
428 environmental pressures when ward census and acute patient turnover surge.

429 This survey findings demonstrated notable interdepartmental differences in perceptions of the
430 assessment instrument for physical restraint decision-making. M&G (Block P) consistently reported the
431 highest mean scores across all domains (4.5-5.0), indicating a relatively strong acceptance, perceived
432 clarity, and intention to use the instrument in clinical practice. O&T and SUR showed moderate to
433 favorable evaluations, with mean scores generally ranging from 3.2 to 4.1. Although nurses valued the
434 instrument's moderately clear guidance, practical challenges such as extra paperwork, duplicated
435 documentation, and insufficient training pose barriers. Simplifying the instrument and aligning review
436 frequency with policy requirements may enhance sustainability and long-term impact.

437 Due to high patient heterogeneity and rapid patient turnover in acute wards, individual patient risk factors
438 account for the majority of variance in physical restraint decision-making rather than ward-level
439 clustering alone, resulting in a very low expected baseline ICC of 0.0007 [44]. Unlike long-term care
440 facilities where resident characteristics are highly static and create large ICC. Sample size in cluster RCT
441 are required to have extraordinarily sensitive to cluster size because the average cluster size in this study
442 is relatively large (m = 50 patients per ward). It led to an overly conservative ICC that would artificially
443 over-inflate the DE resulting in over-recruitment. An ICC of 0.0007 approximately reflects a subtle,
444 near-zero intra-ward correlation while still accounting for the study design that expanded the unadjusted

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individual sample size by 3.43% to preserve 80% statistical power [45].

Limitations

Several limitations warrant consideration. First, only eight wards were randomized would limit precision and the ability to account fully for ward-level differences in patient case mix, staffing, occupancy, and local clinical culture. Second, patient-level clinical and demographic data was not available for all non-restrained admissions, precluding a comprehensive assessment of patient-level baseline comparability between groups. Third, analyses restricted to restrained patients involved a post-randomization subgroup and could not evaluate the intervention effect among all eligible admissions. Fourth, restraint prevalence was measured at noon and may not capture variations in restraint use across a 24-hour period. Fifth, fluctuations in staffing levels and ward occupancy may have influenced implementation and outcomes. Staff movement between wards may cause contamination between both groups.

In addition, the short study period may be insufficient to reflect long-term sustainability of restraint practice changes. Finally, only 38 of 102 eligible nurses completed the satisfaction survey in intervention wards. The findings on acceptability and barriers may therefore create potential response bias and limits interpretation.

Implications

The study did not provide evidence that the assessment instrument reduced physical restraint prevalence or incidence in general adult wards. Nevertheless, the implementation findings identified practical elements that should be managed before further evaluation, including earlier application of other alternatives before restraint initiation, streamlined documentation, stronger training, and integration with existing workflows. Comprehensive interventions require effective assessment instrument, staff training, adequate nurse-to-patient ratios, and de-escalation practices [46]. Long-term sustainability needs continuous refinement, leadership support, and administrative integration. Further research should explore patient-centered perspectives, cost-effectiveness, specialty-specific adaptations, and clinical decision-support tools to reduce restraint use [10, 20, 47].

Conclusion

In this cluster randomized controlled trial, the evidence-based assessment instrument did not show a statistically significant reduction in daily physical restraint prevalence or restraint episode incidence compared with control care. Secondary outcomes among restrained patients, including restraint duration, length of ward stay, and recorded restraint-related incidents, also did not differ significantly between groups. Staff survey identified moderate acceptability but important barriers to implementation. Further research should refine the instrument and assess it as a part of a broader and other multicomponent intervention before evaluating the effect in reducing restraint use, patient safety or patient outcomes.

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Availability of data, code, and study materials:

The de-identified data and analytic code are available from the corresponding author upon request. The assessment instrument and the satisfaction survey questionnaire are available in the supplementary files. Study materials are available from the corresponding author upon reasonable request.

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Contributions

LFT had significant roles in designing, conceiving, conducting the study and writing the manuscript. KFS, CFN, TPC, KPL, and YKT contributed in data collection. FGK provided expert advice.

Ethics Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board (IRB) of the Hong Kong (Central IRB CIRB-2024-517-3: Feb 17th 2025). Informed consent was obtained from all individual participants included in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Figure 1: CONSORT Flow Diagram (overall)

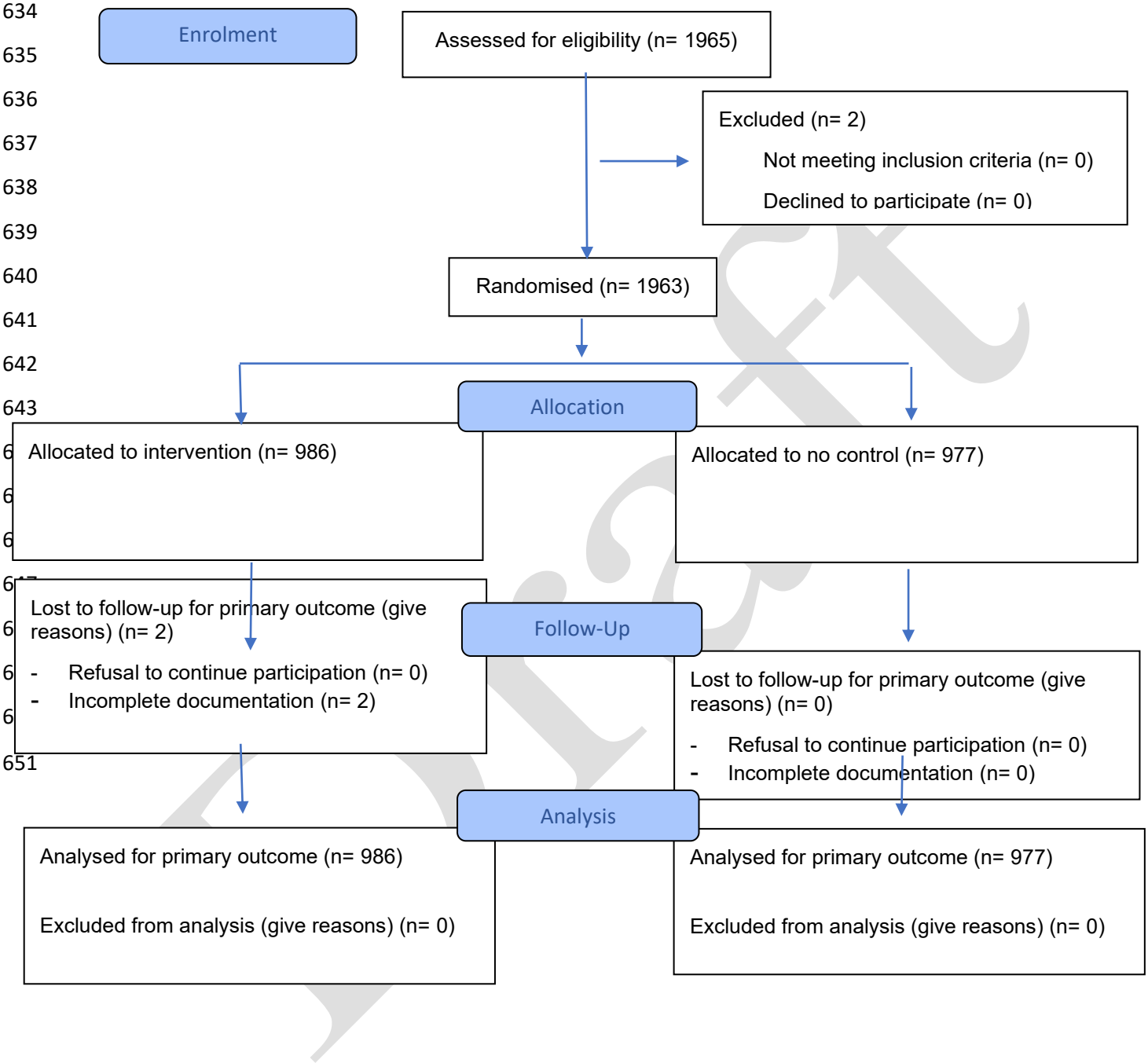


Figure 2. Physical restraint prevalence at baseline and during the study periods

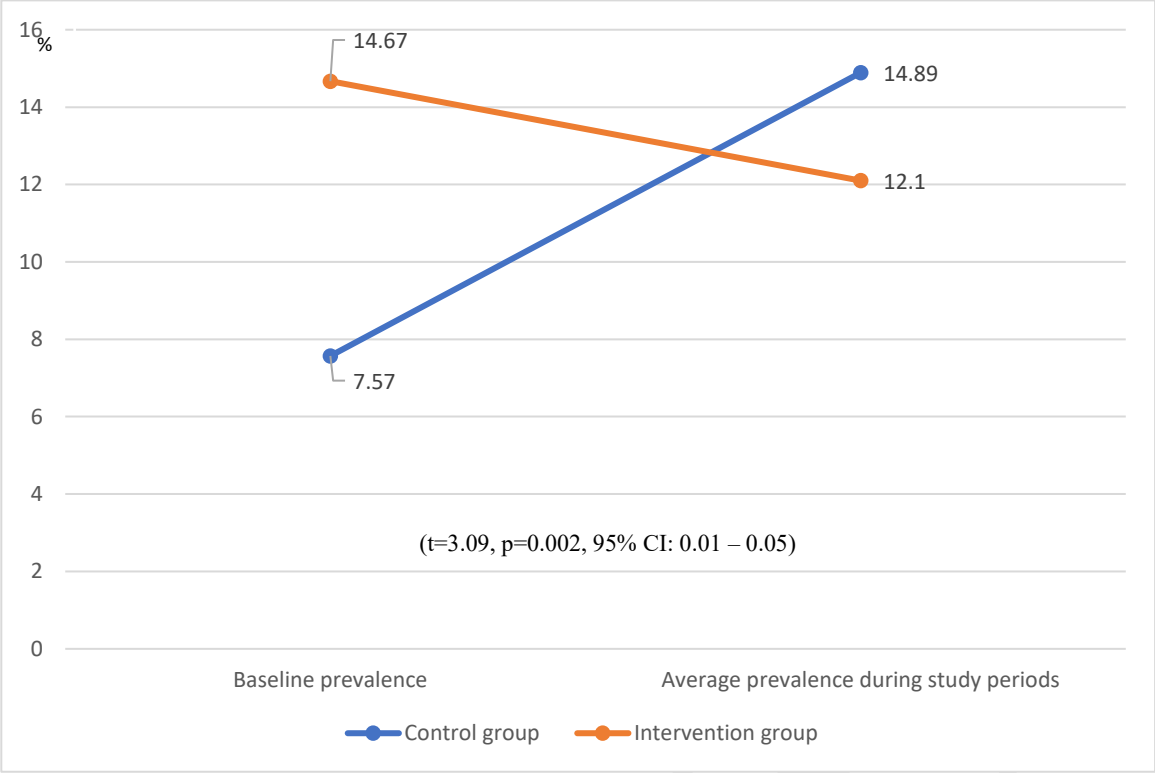
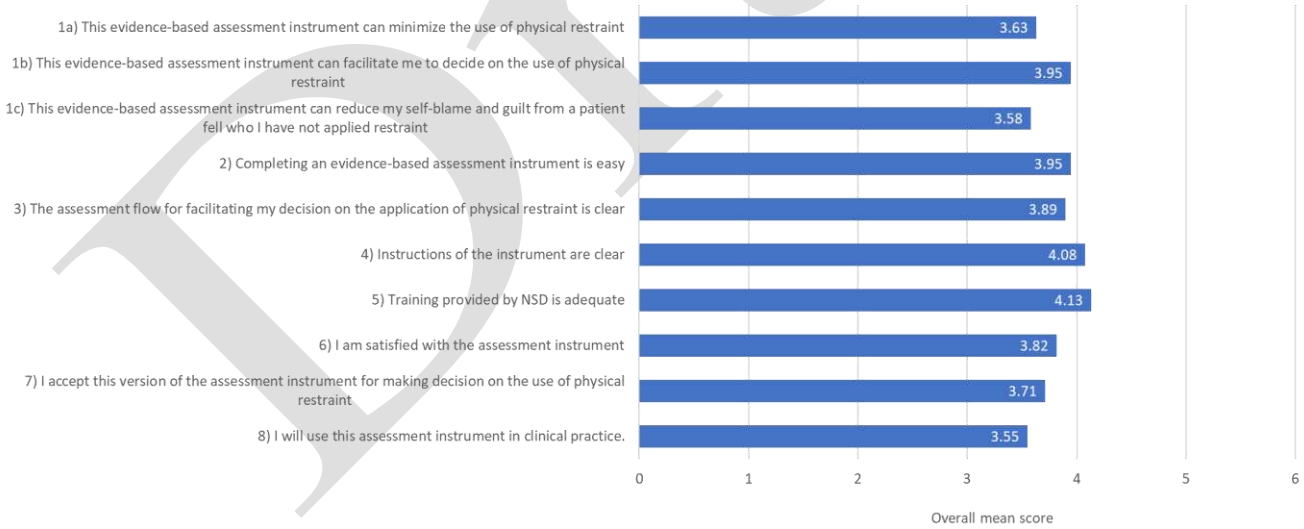
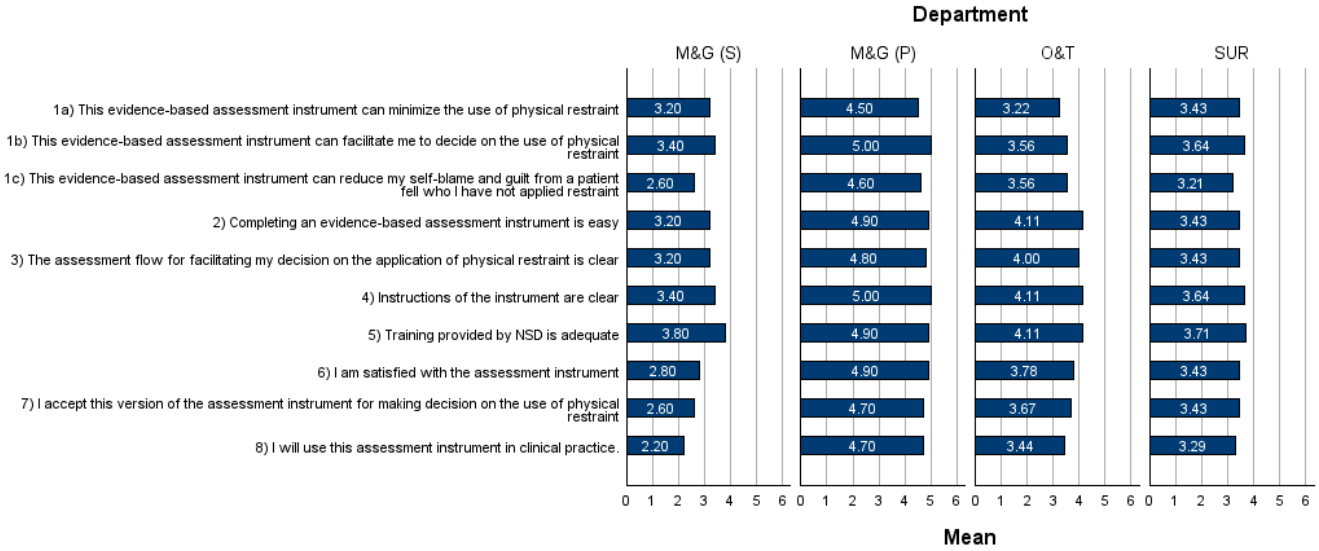


Figure 3. Overall means score of the survey



6-point Likert scale (1 – lowest; 6 – highest)

Figure 4. Sub-group analysis on means scores in three departments



Remarks: 6-point Likert Scale (1 – lowest; 6 – highest)

M&G(S) – Department of Medicine & Geriatrics (Block S); M&G(P) – Department of Medicine & Geriatrics (Block P); O&T – Department of Orthopaedics & Traumatology; SUR – Department of Surgery

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Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- AppendixA.RESTRAINTAssessmentpartonly2024v3V2.pdf
- AppendixB.Oldrecordform.pdf
- CONSORT2025editablechecklist.docx
- ResearchprotocolPRv4clean.docx