บทความวิจัย

Development and Pilot Evaluation of a Safety Restraint Device for Psychiatric Inpatients: Safety, Usability, and User Satisfaction

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Abstract

Introduction: It is important to develop a restraint device that is both safe and convenient to handle aggressive psychiatric patients, since injuries to both patients and staff frequently take place with outdated or poorly designed devices

Research objective: To develop a bed restraint device and evaluate its safety, ease of use, and user satisfaction among staff and patient caregivers.

Research methods: An exploratory sequential mixed-methods design was used, consisting of two phases. In Phase 1, the problems and needs of nurses using the original restraint device were assessed, and these findings guided the development of a prototype. In Phase 2, the prototype was evaluated for safety, ease of use, and satisfaction. The sample included 30 staff users and 30 patient caregivers. Data analysis involved descriptive statistics.

Results: No restraint-related injuries were reported (0 cases). The mean time required for restraint decreased from 10 - 15 minutes to 3.61 minutes when four staff members participated. Mean satisfaction scores were highest for staff (3.90, SD = .12) and caregivers (3.86, SD = .15).

Conclusions: The developed restraint device resulted in no restraint-related injuries, reduced both the time and number of staff required for restraint, and achieved high satisfaction among staff and caregivers.

Implications: Safety Restraint is effective and suitable for psychiatric wards. However, further research is needed before wider adoption**.**

Keywords: patient restraint device, psychiatric nursing, nursing innovation

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การพัฒนาและการประเมินผลเบื้องต้นของอุปกรณ์ผูกยึดผู้ป่วยจิตเวช: ความปลอดภัย ความสะดวกในการใช้งาน และความพึงพอใจของผู้ใช้

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บทคัดย่อ

บทนำ: การพัฒนาอุปกรณ์ผูกยึดที่มีความแข็งแรง ปลอดภัย และสะดวกต่อการใช้งานเป็นสิ่งจำเป็นในการดูแลผู้ป่วยจิตเวชก้าวร้าวรุนแรง พบอุบัติการณ์ ผู้ป่วยเกิดการบาดเจ็บจากการผูกยึด และบุคลากรถูกผู้ป่วยทำร้าย ขณะผูกยึดผู้ป่วยบนเตียง ด้วยอุปกรณ์ที่ชำรุด ไม่สะดวกต่อการใช้งาน

วัตถุประสงค์การวิจัย: เพื่อพัฒนาอุปกรณ์ผูกยึดผู้ป่วยบนเตียง และการประเมินผลด้านความปลอดภัย ความสะดวกในการใช้งาน และความพึงพอใจต่อการใช้งาน ของบุคลากรและผู้ดูแลผู้ป่วย

ระเบียบวิธีวิจัย: การวิจัยนี้เป็นการวิจัยแบบผสมผสานเชิงสำรวจตามลำดับ ดำเนินการเป็น 2 ระยะ ดังนี้ ระยะที่ 1 ศึกษาสภาพปัญหาและความต้องการกับพยาบาลผู้ใช้งานอุปกรณ์ผูกยึดแบบเดิม แล้วนำมาพัฒนาอุปกรณ์ต้นแบบ ระยะที่ 2 การประเมินผลด้านความปลอดภัย ความสะดวกในการใช้งาน และความพึงพอใจต่อการใช้งาน กลุ่มตัวอย่างบุคลากรผู้ใช้งาน 30 คน และผู้ดูแลผู้ป่วย 30 คน วิเคราะห์ข้อมูลด้วยสถิติเชิงพรรณนา

ผลการศึกษา: ไม่พบการบาดเจ็บจากการผูกยึด (0 ราย) ระยะเวลาเฉลี่ยที่ใช้ในการผูกยึดลดลงจาก 10 - 15 นาที เหลือ 3.61 นาที โดยใช้บุคลากรในการผูกยึด 4 คน และคะแนนความพึงพอใจเฉลี่ยของบุคลากรและผู้ดูแลอยู่ในระดับสูงสุดที่ 3.90 (SD = .12) และ 3.86 (SD = .15) ตามลำดับ

สรุปผล: ในการพัฒนาและประเมินประสิทธิผลของอุปกรณ์ผูกยึด โดยไม่ก่อให้เกิดการบาดเจ็บจากการผูกยึด ช่วยลดระยะเวลาและจำนวนเจ้าหน้าที่ที่ใช้ในการผูกยึด และได้รับความพึงพอใจในระดับสูงจากเจ้าหน้าที่และผู้ดูแล

ข้อเสนอแนะ: Safety restraint (SR) เป็นอุปกรณ์ที่มีประสิทธิภาพสูง เหมาะกับการใช้งานหอผู้ป่วยจิตเวช อย่างไรก็ตาม ควรมีการศึกษาวิจัยเชิงทดลองแบบพหุสถาบัน เพื่อยืนยันประโยชน์ของอุปกรณ์ก่อนพิจารณาขยายผลและนำไปใช้อย่างแพร่หลายในสถานพยาบาลอื่น ๆ

คำสำคัญ: อุปกรณ์ผูกยึดผู้ป่วย การพยาบาลจิตเวช นวัตกรรมการพยาบาล

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Introduction

The global burden of mental illness continues to rise, placing increasing demand on psychiatric inpatient services worldwide.[1-2] Nationally, psychiatric inpatient admissions in Thailand rose from 11, 266 in 2012 to 14,223 in 2016; most patients were male, the largest group being of working age (23 - 59 years), followed by adolescents and young adults aged 15 - 22 years.[3] Acute psychosis, schizophrenia, alcohol withdrawal, and alcohol psychosis are among the most frequent diagnoses associated with severe agitation and aggression requiring inpatient care.[1-2]

Physical restraint remains a widely used acute management strategy in these cases, despite recognized ethical complexities and ongoing international efforts toward restraint reduction,[1,4] Physical violence in acute psychiatric wards poses major challenges, not only due to the risk of injury to patients and staff, but also because of the counter-therapeutic effects of coercive management strategies.[4-5] Core prevention strategies, including staff training, leadership commitment, and device improvement, have long been recognized as essential to reducing restraint-related harm.[6] Staff surveys consistently report that between 75% and 100% of nurses working on acute psychiatric units have experienced patient assault during their careers.[7] Common complications include compromised skin integrity, pressure ulcers, psychological distress, and disruption of the therapeutic relationship.[5,8] Qualitative evidence further confirms that patients frequently describe restraint experiences as distressing and dehumanizing, underscoring the need for redesign that prioritizes dignity.[9] Of the three core prevention strategies, staff training and leadership commitment have been studied extensively and are already embedded in many services[6]; by contrast, the physical design of the restraint device itself has received comparatively little empirical attention. This gap, together with the local audit findings described below, provided the rationale for the present study.

A 2022 - 2024 review at Phyathai Phaholyothin Hospital's Psychiatric Center examined 67 inpatients; 34.30% needed restraints, with 8.60% having skin injuries. Root cause analysis identified four issues: coarse cotton fabric causing skin trauma; slippery nylon straps difficult to fasten, sometimes causing device slippage and staff attacks; the black device's frightening appearance; and a lengthy, resource-intensive process requiring six staff and 10 - 15 minutes per episode, totaling 60 - 90 staff-minutes. Device design was the main modifiable risk factor, prompting this innovation study. Thailand’s Mental Health Act emphasizes physician approval, consent, and standards for restraint use.[10] NICE guidelines note poor device materials can cause harm.[11] This study aimed to develop and evaluate a new Safety Restraint device to reduce harm, shorten application time, and preserve patient dignity.

Research objectives

1. To identify problems and limitations of existing restraint equipment.

2. To design and develop a prototype restraint device that addresses identified shortcomings.

3. To evaluate the preliminary effectiveness, safety, usability, and user satisfaction of the SR device in terms of patient skin injury, staff injury, application time, number of staff required, device maintenance, and satisfaction among nursing staff and family caregivers.

Research Framework

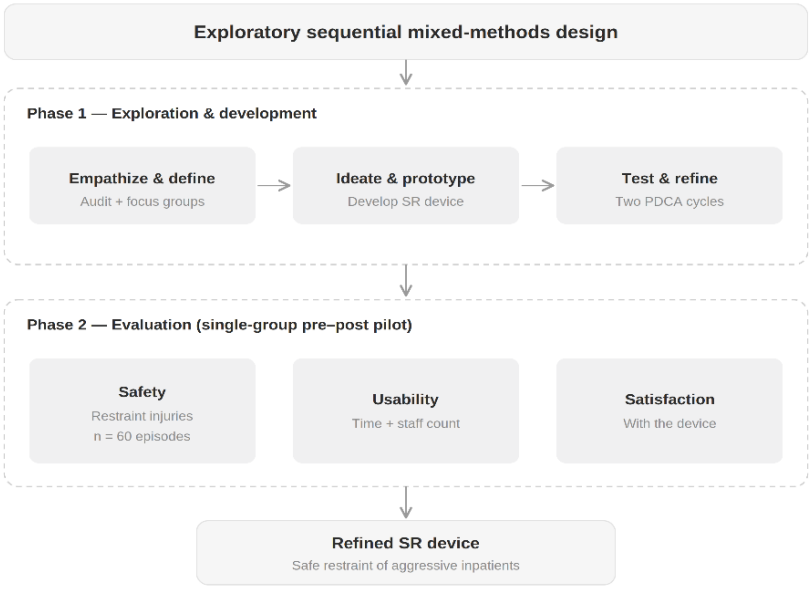


Figure 1. Exploratory sequential mixed-methods framework for the development and evaluation of a safety restraint device.

Research methodology

Study Design

This study employed an exploratory sequential mixed-methods design, comprising iterative device development and a pilot evaluation against a historical baseline, using Design Thinking together with the PDCA quality cycle across two phases. Phase 1 (Exploration and Development) examined the problem and user needs through a clinical audit and focus groups with psychiatric nurses experienced with the previous device and then developed the Safety Restraint device using Design Thinking, refining the prototype through two PDCA cycles of testing with aggressive psychiatric inpatients. Phase 2 (Evaluation) used a single-group, pre–post pilot evaluation to assess preliminary effectiveness in terms of safety (restraint-related injury) across 60 restraint episodes, usability (application time and number of staff required for restraint), and satisfaction with the device. Integration occurred at the design and interpretation stage: the qualitative pain points identified in Phase 1 were translated into specific device modifications (Table 1), which were then evaluated

quantitatively in Phase 2. This connecting (building) point of integration–rather than a side-by-side joint display–is characteristic of an exploratory sequential design.

Setting and Participants

The study took place at the Psychiatric Center (Let's Talk), Floor 5, Building 4, Phyathai Phaholyothin Hospital, Bangkok, Thailand. Three participant groups were recruited between March and June 2025.

Group A: psychiatric inpatients aged 13 - 65 admitted for severe aggression (PAS ≥ 5), with a physician's order for four-limb restraint for ≥ 1 hour and providing informed consent. Exclusions: skin lesions, wounds, dermatological issues at restraint sites, unstable physical illness, or refusal of consent. All eligible restrained patients during the study were enrolled consecutively, for a total of 60 episodes.

Group B: included nursing staff and healthcare providers registered nurses, practical nurses, or healthcare assistants in the psychiatric inpatient unit who had used the SR device at least 3 times. Excluding were staff who hadn't used it. Thirty participants enrolled.

Group C: family caregivers. Inclusion: the primary caregiver, aged 20 years or older, of a patient restrained with the SR device who has observed at least one restraint episode. Exclusion: caregivers unable to communicate in Thai. Thirty participants were enrolled.

For Groups B and C, the sample size was estimated using G*Power (one-sample t-test, effect size .5 (a conventional medium effect)[12], alpha .05, power .95), yielding a minimum of 54 participants. Therefore, 60 were enrolled to allow for attrition.

The Safety Restraint Device

The Safety Restraint (SR) is a six-component system with chest, pelvis, bilateral arm, and bilateral leg restraints. It features Perma Nano Zinc Oxide fabric, certified as bacteriostatic maintaining antimicrobial and structural properties for over 150 laundering cycles[13], and conforming to Thai Industrial Standard (TIS) 996 - 2533, with a tensile strength of 225.0 kg[14]. Straps use adjustable PVC locks for quick, secure fastening. The soft inner surface and pastel colors aim to reduce skin trauma and psychological distress.

Ethical Considerations

Ethical approval was obtained from the Phyathai-Paolo Hospital Group Institutional Review Board (COA. 007/2025, IRB Protocol No. IRB 001-2568, approved on February 17, 2025). The study followed international guidelines for human subject protection and GCP standards. Written consent was obtained from all patients or their legal representatives. Data were anonymized with coded records, stored securely, and accessible only to the research team; they will be destroyed after one year. Phyathai Phaholyothin Hospital will handle adverse events medically and financially.

Data Collection

Phase 1 Explored the problem and user needs via a clinical audit and focus groups. Qualitative data came from semi-structured interviews with 6 nursing staff, conducted privately, lasting around 45 minutes, audio-recorded, and transcribed verbatim. Trustworthiness was ensured through independent coding by two researchers, consensus on discrepancies, member checks, peer debriefing, and an audit trial.



Figure 2. The Safety Restraint (SR) device and its six components

Phase 2: Quantitative data were collected using a structured restraint-episode record form (CVI = .89; inter-rater Cohen's kappa = .91) that captured age, body mass index, medication score, Braden Scale score, PAS aggression score, restraint points, restraint duration, application time, and skin assessment; and a 30-item satisfaction questionnaire developed from the literature and reviewed for content validity by three experts (CVI = .93), following Thai clinical device evaluation methodology.[15] Internal consistency of the satisfaction questionnaire was assessed using Cronbach's alpha (nursing staff: α = .82; family caregivers: α = .78). Pilot testing with 6 staff and 6 caregivers, none of whom took part in the main study, led to minor wording adjustments. The final questionnaire used a 4-point Likert scale[16]: 3.26 - 4.00 = highest satisfaction; 2.51 - 3.25 = good; 1.76 - 2.50 = moderate; 1.00 - 1.75 = needs improvement.

Data Analysis

In Phase 2, quantitative findings on safety, usability, and satisfaction were analyzed using descriptive statistics (frequencies, percentages, means, and standard deviations) to summarize the clinical characteristics of restraint episodes and participants' ratings.

Results

Phase 1: Problem Identification and Device Development involved reviewing clinical records and staff focus groups (6 nurses) to identify 4 pain points with the restraint device. Prototype I was developed and tested; its evaluation found three main issues, which were fixed in Prototype II (Table 1).

Table 1 Problem Identification and Solutions for Prototype Development

Pain Point 1	Pain Point 2	Pain Point 3
Problem: Joint areas were not durable; straps tended to loosen and break. Device appearance was unattractive.	**Problem:** Dark color was perceived as intimidating; patients reported increased fear during application.	**Problem:** The fabric is rough and irritating to skin. After washing, the fabric lost its shape and stiffened, reducing the restraint's effectiveness.
Solution: Joints redesigned with durable, aesthetically refined materials.	**Solution:** Changed to pastel colors to reduce patient anxiety.	**Solution:** Material changed to Perma Nano Zinc Oxide fabric

Phase 2: Evaluation

2.1 Participant Characteristics

The study included 60 restraint episodes involving psychiatric patients. There were 33 female patients (55%) and 27 male patients (45%). Most patients were between 20 and 39 years old (26 patients, 43.30%), followed by those aged 40 to 59 (22 patients, 36.70%), 60 and older (8 patients, 13.30%), and 13 to 19 years old (4 patients, 6.70%). Nearly half of the patients (29, 48.30%) had a BMI below 18.50 kg/m². Sixteen patients (26.70%) had a BMI in the normal range of 18.50 to 22.90 kg/m², and 15 patients (25%) were in the overweight range of 23 to 24.90 kg/m².

Most restraint episodes used a 2-point restraint on both arms (37 episodes, 61.70%). There were also 16 episodes (26.70%) with a 5-point restraint, which included both arms, both legs, and a chest strap, and 7 episodes (11.70%) with a 4-point restraint on both arms and both legs. On average, restraint was applied for 3.61 minutes, and 4 staff members assisted in each episode. No patient skin injuries were reported across the 60 episodes, suggesting that the SR device did not cause restraint-related injuries in this group.

2.2 User Satisfaction: Nursing Staff and Healthcare Personnel

Table 2: Nursing Staff and Healthcare Personnel Satisfaction with the SR Device (n = 30)

Item	M	SD	Interpretation
1. Effectiveness of the SR Device	3.79	.20	Highest
2. Safety of the SR Device in Clinical Use	3.81	.12	Highest
3. Overall Staff Satisfaction	3.90	.12	Highest

Note. Cronbach's alpha = .82.

Table 2 presents satisfaction scores from 30 nursing staff and healthcare workers. The overall average was 3.90 (SD = .12), indicating high satisfaction. The top-rated items were ease of application (item 23: M = 4.00, SD = .00) and device appearance (item 21: M = 4, SD = .00), showing successful resolution of Phase 1 design issues. The effectiveness domain averaged 3.79

(SD = .20), and safety was 3.81 (SD = .12). The lowest-rated item was friction reduction (item 16: M = 3.50, SD = .81), still in the high satisfaction range but with the greatest variability.

2.3 User Satisfaction: Family Caregivers

Table 3: family caregivers' satisfaction with the SR Device (n = 30)

Item	M	SD	Interpretation
1. Effectiveness of the SR Device	3.76	.17	Highest
2. Safety of the SR Device in Clinical Use	3.71	.21	Highest
3. Overall Family Caregiver Satisfaction	3.86	.15	Highest

Note. Cronbach's alpha = .78.

Table 3 shows satisfaction from 30 caregivers, with a mean score of 3.86, indicating high satisfaction. Caregivers rated device safety (item 20: M = 4), hospital safety (item 26: M = 3.93), and confidence in safety (items 27 - 28: M = 3.90) highly. The effectiveness domain scored 3.76, and safety 3.71. The lowest item was item 18 (non-irritating material: M = 3.53), yet it was still rated highly.

Discussion

The findings support an exploratory sequential mixed-methods framework using iterative Design Thinking and PDCA-guided development with a single-group, pre–post pilot evaluation for creating restraint equipment in clinical settings. In Phase 2, 30 nurses and 30 family caregivers of patients with severe aggression participated in a single-group, pre–post pilot evaluation. During 60 restraint episodes, there were no patient or staff injuries, and the mean application time decreased by approximately 64 - 76% compared to baseline. The pre-intervention baseline reported an 8.6% skin-complication rate, two staff assaults, and application times of 10 - 15 minutes with six staff. Notably, no patient skin injuries were recorded in this pilot. Perma Nano Zinc Oxide fabric with a fine-weave inner lining was used to address friction-related skin trauma; the result aligns with this mechanism and NICE guidance on restraint device materials contributing to injuries[11], as well as Duxbury et al.[5] who reported that structured, evidence-based programs reduced restraint injury rates. No staff assaults from device slippage occurred; slippery nylon straps previously caused injuries, but the new adjustable PVC locking mechanism was designed to prevent this. These results are consistent with qualitative evidence that nurse staff see device design as key to safe, ethical restraint use.

Several explanations should be considered before attributing improvements to the device. First, the comparison was against a non-concurrent baseline, so secular changes in ward practice from 2022 - 2024 to 2025 cannot be excluded. Second, staff knew a new device was being

evaluated, which may have increased attentiveness, affecting application times and skin injury rates. Third, the device's introduction included briefing and hands-on practice, confounding training effects with device effects. Fourth, with only 60 episodes, the study had limited power to detect rare events; a baseline skin-complication rate of 8.60% would predict about seven events, so observing none, while noteworthy, is not conclusive (95% CI: 0 - 3.50%). Finally, satisfaction scores from staff and caregivers might be inflated, as they knew the device was developed within their own institution. The observed change is plausible but should be considered an upper-bound estimate until confirmed by controlled studies.

Reducing application time from 10 - 15 minutes to 3.61 minutes and staff from 6 to 4 has practical safety and workload benefits. Per-episode staff-minutes dropped from 60 - 90 to about 18.10, a 70 - 80% reduction. Shorter application times may lower staff exposure to aggressive behavior and psychological stress. User satisfaction was high: nurses rated ease and appearance at 4, and family caregivers rated safety features between 3.90 and 4. While high ratings suggest good safety and usability, they don't prove it. The large SD for friction reduction (.81) indicates uneven experience, needing further design focus. The aesthetic redesign to pastel fabric aimed to improve comfort and reduce fear; high aesthetic ratings support this, indicating color and texture are important in restraint device design.

Limitation

This study has limitations, including being a single-site pilot with 60 restraint episodes, 30 staff, and 30 caregivers, limiting generalizability. No control group was used; outcomes were compared to a historical baseline (2022 - 2024), which may not be comparable, so causality cannot be established, and co-interventions like staff training may have influenced results. No significance testing was performed. Additionally, the research team developed, delivered, and evaluated the device, risking bias due to enthusiasm for the innovation, which could have affected care and attention.

Implications for Practice

Until controlled studies confirm its safety, the SR device may be used in acute psychiatric inpatient units when restraint-related skin injuries or device slippage are identified through incident review. Implementation should include structured, competency-based training for staff applying restraint, standardized documentation of application details and skin assessments, a laundering and inspection protocol with removal if straps or joints fail, and ongoing adverse event monitoring within the hospital’s risk system. Restraint should be used only as a last resort, for the shortest time possible, with physician approval and documented consent from the patient or legal representative, per the Mental Health Act and standards.

Implications for Future Research

Future research should employ multicenter randomized controlled trials with stratified randomization and adequate sample sizes, systematically collect patient-reported outcomes (e.g., comfort, dignity, and psychological impact) using validated instruments to address current gaps, conduct long-term monitoring of device durability, maintenance costs, and outcome sustainability, and include comprehensive cost-effectiveness analyses covering both direct and indirect cost domains.

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