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SAFETY INCIDENTS IN SECLUSION AND RESTRAINT PRACTICES IN PSYCHIATRIC INPATIENT CARE

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To my family

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ABSTRACT

Safety incidents for patients and staff have been recognised during seclusion and restraint events in psychiatric inpatient care. This study aimed to identify safety incidents and their contributing risk factors in seclusion and restraint events in psychiatric inpatient care. The existing practices, incidents, and contributing risk factors were explored.

The study was conducted in three phases. In the first phase, focus groups were used to identify psychiatric nurses' experiences of nursing practices, safety incidents, and risk factors in seclusion and restraint events. In the second phase, existing practices, safety incidents and risk factors were explored using video observations of seclusion and restraint events. In the third phase, risk factors for falls in seclusion were modelled based on existing literature and the expertise of psychiatric nurses using sociotechnical probabilistic risk assessment.

Based on the findings of this study, existing practices of seclusion and restraint consist of nursing interventions to meet the needs of patients. The identified safety incidents included assaults, falls, medication errors, elopement, self-harm and others. Safety incidents were found to potentially affect both patients and nurses. The contributing risk factors for safety incidents in seclusion and restraint were unsafe acts of nurses and patients as well as latent conditions in the system. These unsafe acts and latent conditions were visible in the example of falls in seclusion.

Based on the knowledge generated, recommendations for improving safety in seclusion and restraint events in psychiatric inpatient care are suggested. Changes are needed in clinical nursing practice, in nursing education and training, in the support from nursing management, and in the broader organisation. According to the presented recommendations, there is a need to adopt a system-level approach to improve safety.

KEYWORDS: Psychiatric inpatient care, seclusion, restraint, psychiatric nursing, patient safety, occupational safety

TIIVISTELMÄ

Psykiatrisessa sairaalahoidossa on tunnistettu vaaratapahtumia potilaan eristämisen ja sitomisen yhteydessä. Tämän tutkimuksen tarkoituksena oli tunnistaa potilas- ja työturvallisuuteen liittyviä vaaratapahtumia ja niihin vaikuttavia tekijöitä potilaan eristämis- ja rajoitustilanteissa psykiatrisessa osastohoidossa. Tunnistamisessa tarkasteltiin nykyisiä eristämis- ja rajoittamiskäytäntöjä, vaaratapahtumia ja näiden riskitekijöitä.

Tutkimus toteutettiin kolmessa vaiheessa. Ensimmäisessä vaiheessa kerättiin psykiatristen sairaanhoitajien kokemuksia eristämiseen ja sitomiseen liittyvistä käytännöistä, vaaratapahtumista ja riskitekijöistä fokusryhmien avulla. Toisessa vaiheessa tarkasteltiin nykyisiä eristys- ja sidontakäytäntöjä, vaaratapahtumia ja riskitekijöitä videohavainnoimalla eristys- ja sidontatilanteita. Kolmannessa vaiheessa mallinnettiin sosioteknisellä todennäköisyysperusteisella riskianalyysilla eristämisessä tapahtuvien kaatumisten todennäköisyyttä ja riskitekijöitä hyödyntämällä olemassa olevaa kirjallisuutta ja psykiatristen sairaanhoitajien asiantuntemusta.

Tämän tutkimuksen tulosten perusteella eristämis- ja sitomiskäytännöt sisälsivät potilaiden tarpeisiin kohdennettuja hoitotyön interventioita. Eristämisessä ja sitomisessa havaittuja vaaratapahtumia olivat väkivalta, kaatumiset, lääkityspoikkeamat, itsensä vahingoittaminen, karkaamiset ja muut vaaratapahtumat. Vaaratapahtumat kohdistuivat sekä potilaisiin että hoitajiin. Eristämiseen ja sitomiseen liittyvien vaaratapahtumien riskitekijöitä olivat hoitajien ja potilaiden vaarallinen toiminta sekä järjestelmässä piilevät olosuhteet. Potilaan kaatumisen esimerkissä ilmenivät sekä vaarallinen toiminta ja järjestelmän piilevät olosuhteet.

Löydösten perusteella on tehty suosituksia eristämisen ja sitomisen turvallisuuden edistämiseksi psykiatrisessa laitoshoidossa. Turvallisuuden edistämiseksi tarvitaan muutoksia kliinisessä käytännössä, koulutuksessa, hoitotyön johtamisen tukemisessa ja organisaatiossa. Suositukset tulisi toteuttaa systeemiajatteluun perustuvalla lähestymistavalla.

AVAINSANAT: Psykiatrinen sairaalahoito, eristys, sidonta, psykiatrinen hoitotyö, potilasturvallisuus, työturvallisuus

Table of Contents

List of tables and figures

Tables

Figures

Abbreviations

AHRQ   Agency for Healthcare Research and Quality
APA   American Psychological Association
APNA   American Psychiatric Nurses Association
ECG   Electrocardiogram
ECTS   European Credit Transfer and Accumulation System
ICD-10   International Classification of Diseases 10th Revision
ILO   International Labour Organization
IOM   Institute of Medicine
NICE   National Institute for Health and Care Excellence
OSHA   The Occupational Safety and Health Administration
SCM   Swiss Cheese Model of Accident Causation
ST-PRA   Sociotechnical Probabilistic Risk Assessment
TENK   Finnish National Board on Research Integrity
TPS   The Toyota Production System
USD   United States dollar
WHO   World Health Organization

List of Original Publications

This dissertation is based on the following original publications, which are referred to in the text by their Roman numerals:

I   Varpula, J., Välimäki, M., Lantta, T., Berg, J. & Lahti, M. Nurses' perceptions of risks for occupational hazards in patient seclusion and restraint practices in psychiatric inpatient care: A focus group study. *International Journal of Mental Health Nursing*, 2020; 4: 703–715.

II   Varpula, J., Välimäki, M., Lantta, T., Berg, J., Soininen, P. & Lahti, M. Safety hazards in patient seclusion events in psychiatric care: A video observation study. *Journal of Psychiatric and Mental Health Nursing*, 2022; 29: 359–373.

III   Varpula, J., Lantta, T., Lahti, M., Berg, J., Soininen, P. & Välimäki, M. Nursing interventions during seclusion and mechanical restraint: A video-observation study in inpatient psychiatric care. Manuscript.

IV   Varpula, J., Välimäki, M., Pulkkinen, J. & Lantta, T. Patient falls in seclusion rooms in psychiatric inpatient care: A sociotechnical probabilistic risk modelling study. *Journal of Nursing Care Quality,* Early access 10.1097/NCQ.0000000000000683

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1   Introduction

Studies have raised concerns about the state of safety in psychiatric inpatient care settings (Brickell & McLean 2011; D'Lima et al. 2017; Thibaut et al. 2019,). Patients have reported feeling unsafe during their care (Pelto-Piri et al. 2019). Similar experiences have been reported by nurses working in psychiatric inpatient care (Kelly et al. 2016; Schwappach & Niederhauser 2019). The prevalence of safety incidents is high in psychiatric inpatient care: between 17.2% and 23.5% of patients have experienced a safety incident in this setting (Nilsson et al. 2020; Vermeulen et al. 2018). The outcomes of safety incidents can be significant. Although most patient safety incidents result in either no harm or only slight harm, some incidents can result in moderate or severe harm and even death (Marcus et al. 2018; Nilsson et al. 2020). Occupational safety injuries due to patient violence and aggression are the leading cause of physical injury to nurses (Kelly et al. 2016).

Seclusion and restraint are coercive measures currently used in psychiatric inpatient care to manage patient violence and aggression (Gerace & Muir-Cochrane 2019). However, ethical concerns questioning the appropriateness of these measures have been raised (Haugom et al. 2019; Zheng et al. 2020). Over the last decades, both research (Goulet et al. 2017) and international recommendations (Council of Europe Committee on Social Affairs, Health, and Sustainable Development 2019) have supported the reduction of seclusion and restraint. Still, despite efforts made, seclusion and restraint contintue to be used in most psychiatric inpatient care facilities (Laukkanen et al. 2020a). The World Health Organization's (WHO 2021a) guidance on community mental health services regarding the promotion of person-centred and rights-based approaches states that "*coercive practices such as restraint and seclusion cause harm to physical and mental health and can lead to death*" (WHO 2021a, p. 216). Previous studies have identified safety incidents during seclusion and restraint for patients (Cusack et al. 2018; Kersting et al. 2019) and for healthcare professionals (Renwick et al. 2016).

Efforts to improve safety in psychiatric care have focused on prevention, risk assessment, and management of violence, suicide, and self-harm (Svensson 2022). Safety research in psychiatric inpatient care is also regarded as under-researched compared to other healthcare settings (Svensson 2022; Thibaut et al. 2019). Studies

have focused on seclusion and restraint as ways to manage violence and self-harm (Steinert & Lepping 2009; Steinert et al. 2010) as well as on reducing seclusion and restraint to improve safety (Bell & Gallacher 2016; Jayaram 2016), but not on improving the safety of seclusion and restraint practices in psychiatric inpatient care.

The knowledge of safety incidents occurring in seclusion and restraint in psychiatric inpatient care has been limited to specific safety incidents and risk factors. Studies have primarily relied on data from incident reporting systems (Kersting et al. 2019). However, relying only on data from incident reporting data can result in under-detection of safety incidents and risk factors (Christiaans-Dingelhoff et al. 2011; Roine et al. 2018). Incident reporting data rely on and are limited to staff (Reilly et al. 2019) and patient reporting (Villar et al. 2021). Therefore, to better understand safety incidents and their contributing risk factors, combining various kinds of data, viewpoints, methods, and data sources is needed (Van Dael et al. 2021).

The aim of this doctoral study was to identify safety incidents and their contributing risk factors in seclusion and restraint events in psychiatric inpatient care. Existing practices, incidents, and contributing risk factors were synthesised using the Swiss Cheese Model of Accident Causation (SCM) (Reason 2008 p.101–102) to gain an in-depth understanding of safety incidents in seclusion and restraint in psychiatric inpatient care, which was used as the basis for generating recommendations to improve seclusion and restraint practices.

The study was conducted in the field of nursing science. Nursing is understood here as the process of achieving health (Peplau 1988 p. 5–16; Roper et al. 2001 p. 122–140) in the complex interdependent relationships of people and their environment (Bender 2018; Neumann & Fawcett 2011). The term people refers to secluded and restrained patients and the nurses who care for them during seclusion and restraint events. Patients subjected to seclusion and restraint suffer predominantly from psychotic disorders, substance use or mood disorders (Miodownik et al. 2019). The environment in this study is the seclusion rooms located in the psychiatric inpatient care units (Laukkanen et al. 2021). Seclusion and restraint are carried out in a locked room with limited furniture (Pettit et al. 2017) for safety (Mental Health Act 1116/1990). Safety is a central element of health (Peplau 1988 p. 78) and is regarded as a human right (WHO 2017). This study explores safety through its absence, mainly in the light of safety incidents.

2 Review of the Literature

2.1 Psychiatric inpatient care

2.1.1 Organisation of psychiatric inpatient care services in Finland

Psychiatric inpatient care in Finland is organised as part of mental health services. The delivery of psychiatric inpatient care is regulated by The Ministry of Social Affairs and Health (Finnish Institute for Health and Welfare 2020). The delivery of mental health and substance abuse services for the treatment and rehabilitation of individuals with mental health disorders is responsibility of the wellbeing service counties (Finnish Government 2023). There are in total 21 self-governing wellbeing services counties with an addition of the capital, city of Helsinki which is responsible for organising these services by itself. Psychiatric inpatient care is organized by the wellbeing services counties in psychiatric hospitals. According to the Mental Health Act (1116/1990), patients must be cared for in mutual understanding as much as possible, using medically acceptable methods.

In 2021, Finland had 2,657 psychiatric hospital beds, approximately 48 per 100,000 inhabitants (Linnanranta 2022). This is less than the European Union average of 73 hospital beds per 100,000 inhabitants (WHO 2021a). In Finland, most (n = 2,160) of the hospital beds are under the management of the wellbeing services counties. The rest are in state-run forensic hospitals (n = 443) and a psychiatric hospital for prisoners (n = 54). Over half (n = 1,258) of the hospital beds are for acute care. The occupancy rate of psychiatric hospital beds is over 90% (Linnanranta 2022).

Patients are admitted to psychiatric inpatient care based on a referral process under the Mental Health Act (1116/1990). First, any physician working in public or private health services can make a referral (M1) to an observation based on an evaluation that the criteria of involuntary treatment potentially exist (Valvira 2019). The criterion for involuntary treatment requires that three preconditions are met: the individual has a mental illness or mental disorder that requires treatment, leaving the patient untreated would worsen the psychiatric condition or pose a threat to the health or safety of the individual or the health and safety of others, and all other mental

health services would be inadequate. After the patient is referred to psychiatric inpatient care, a psychiatrist evaluates whether the patient fills the criterion for involuntary treatment. If not, the patient is discharged. If the criterion is not filled but the patient would benefit from psychiatric inpatient care, the patient can start voluntary treatment. If the criterion for involuntary treatment is met, the patient stays in psychiatric inpatient care for an observation period of three days. Based on the observation, the criterion for involuntary treatment is assessed again. If the criterion is not met, the patient is discharged or can stay for voluntary treatment. If the criterion is met, a statement (M2) is made by a psychiatrist. The medical director makes the decision (M3) on involuntary treatment in a psychiatric unit. The decision for involuntary treatment is valid for up to three months and is renewed if necessary (Mental Health Act 1116/1990).

2.1.2   Patients in psychiatric inpatient care

Most patients in Finnish psychiatric inpatient care have severe mental illnesses. According to the International Classification of Diseases (ICD-10), the most common diagnoses of patients in 2019 included mood disorders, schizophrenia, and schizotypal and delusional disorders (Kyrölä & Järvelin 2020). The numbers of patients and periods of treatment for the most common diagnoses in Finnish psychiatric inpatient care are described in Table 1. Most patients treated in psychiatric inpatient care are between the ages of 25 and 34, followed by patients aged 18–24, 35–44, and 45–54. In the age groups 25–34, 35–44, and 45–54, there are more male patients than female (Kyrölä & Järvelin 2020).

Table 1. The most common diagnoses of patients treated in Finnish psychiatric inpatient care (Kyrölä & Järvelin 2020).

Diagnosis	Patients	Hospital stays
F30-F39 Mood [affective] disorders	8,623 (35.7%)	12,486 (33.0%)
F20-F29 Schizophrenia, schizotypal and delusional disorders	8,004 (33.1%)	12,239 (32.4%)
F40-F48 Anxiety, dissociative, stress-related, somatoform and other nonpsychotic mental disorders	2,772 (11.5%)	3,499 (9.3%)
F10-F19 Mental and behavioural disorders due to psychoactive substance use	2,097 (8.7%)	2,698 (7.1%)
F90-F98 Behavioural and emotional disorders with onset usually occurring in childhood and adolescence	1,306 (5.4%)	1,757 (4.7%)

2.1.3   Psychiatric inpatient care environment

The current global psychiatric inpatient care environment is characterised by closed wards, a lack of privacy due to shared rooms, and overcrowding of patients (Weber et al. 2022). Patients have experienced the psychiatric inpatient environment to be unpleasant due to worn-out facilities (Molin et al. 2016a; Weber et al. 2022), a prison-like environment, and high levels of disturbances (Weber et al. 2022). Psychiatric nurses have reported similar experiences (Molin et al. 2016b). Many of the existing psychiatric hospitals in Finland were built in the first half of the 20th century. These hospitals are often located close to nature and distant from the general public (Ahola 2015). Many new psychiatric hospitals have been planned and built in recent years, and the approach to these has differed from that of the older ones. They are being built in close proximity to other healthcare services (Suomen sairaalatekniikan yhdistys [Finnish Association of Hospital Technology] 2020).

The Finnish Mental Health Act (1116/1990) states that seclusion and restraint must be carried out in a room designed for this purpose. According to a survey (Laukkanen et al. 2021), there are 176 seclusion rooms in Finland. Of these rooms, 35.2% are used only for seclusion, 25.6% only for mechanical restraints, and 39.2% for both. The sizes of the seclusion rooms vary. The average size of seclusion rooms in Finland is 10.96 square meters. The smallest is five square meters, and the largest is 49 square meters. Almost all (95.5%) of the seclusion rooms have a window. Seclusion rooms were also found to include safety equipment such as cameras (84.1%), windows in the doors (79%), and sound connection to the nurses' station (64.2%). The voice connection was found to be two-way in 84.1% of those seclusion rooms with the voice connection. Other safety equipment included a call button (54%) and an openable hatch in the door (17.6%). Very few (5.7%) rooms were found to have padded walls or ceilings. Less than 20% had a toilet and a sink or shower in the room. In most (76.1%) of the seclusion rooms, the toilet, sink, and shower were near the room. Less than 10% of the rooms had no access to a toilet, sink or shower or these were far away. Seclusion rooms were found to be mostly bare, with very few comforting elements. The most notable comforting elements were a bed, bedding, a clock, and a soft cube as a table. In some seclusion rooms, there was the possibility to listen to the radio (45.5%), sit in an armchair (22.7%), or watch television (16.5%) (Laukkanen et al. 2021).

2.1.4   Nursing in psychiatric inpatient care

In Finland, nursing is delivered by licenced health professionals: either registered nurses or practical nurses (Valvira 2021). Registered nurses in Finland usually have a bachelor's degree from a university of applied sciences, which is made up of a scope of 210 European Credit Transfer and Accumulation System (ECTS) credits

(Finnish Nurses Association 2022). Practical nurses have a vocational education with a scope of 180 competence points. Practical nurses in psychiatric inpatient care have focused on the competence area of mental health and substance abuse work (Finnish National Agency of Education 2017). Nurses constitute the largest workforce in Finnish psychiatric and mental health care (Korkeila 2021). In this study, the term nurse refers to both registered and practical nurses.

Psychiatric nursing is the specialised nursing care of individuals with psychiatric and mental disorders. The aim of psychiatric nursing is the holistic care of patients, incorporating both psychosocial and physical aspects (American Psychological Association [APA] 2022). The nurse-patient relationship is central to psychiatric nursing (Hartley et al. 2020) and therapeutic interaction (Moreno-Poyato et al. 2016). In the nurse-patient relationship, patients are recognised as vulnerable individuals who need understanding, support, and motivation to recover (Sahlberg et al. 2019). According to patients and nurses, the foundations for the nurse-patient relationship are mutual respect, trust, empathy, and an individualised approach (Moreno-Poyato et al. 2016; Thibeault 2016).

Safety is a significant part of psychiatric nursing (American Psychiatric Nurses Association [APNA] 2022). Psychiatric nurses can improve the safety experience of patients by fostering a good relationship between the patients and the staff (Kanerva et al. 2016). Similarly, patients have experienced that safety in psychiatric inpatient care stems from a good relationship between the patient and staff, and staff being available, responsive and kind (Cutler et al. 2020). The APNA also emphasises patient engagement and fostering a recovery-oriented environment to enhance safety in psychiatric inpatient care (Phoenix 2013). Risk assessment is another critical safety measure for psychiatric nurses. Most (95.7%., n=374) psychiatric nurses have conducted risk assessments in their clinical practice. Risk assessment focuses mostly on the patient's risk of harming themselves or others (Higgins et al. 2016). In upholding safety in psychiatric inpatient care, seclusion and restraint are used as a last resort (Power et al. 2020). It is these last-resort practices that serve as a lens through which psychiatric nursing is explored in this study.

2.1.5   Coercive measures in psychiatric inpatient care

Seclusion and restraint are coercive measures used in Finnish psychiatric inpatient care to manage the safety of patients, healthcare professionals, and others (Mental Health Act 1116/1990). The reasons for using seclusion and restraint in Finnish psychiatric inpatient care include agitation and disorientation, violence and threat of violence, aggression, and damaging of property (Keski-Valkama et al. 2010).

Seclusion is a coercive measure that involves the patient being isolated in a locked room designed for this purpose (Bowers et al. 2007; Mental Health Act

1116/1990). The decision to seclude a patient is made by a physician. Nurses can also implement seclusion in high-risk situations, and the physician is informed immediately afterwards. A register study found that in 2017 seclusion was used in 109 units in Finland. Seclusion was used a total of 4,006 times with a mean duration of 2.88 days (Laukkanen et al. 2020a). The evidence regarding the effectiveness of seclusion is questionable (Chieze et al. 2019; Sailas & Fenton 2000). However, the use of seclusion has been linked with patients having negative experiences, including distress and feelings of punishment (Chieze et al. 2019). Patients have also reported negative experiences related to the physical seclusion room environment (Askew et al. 2019) and the lack of comforting elements there (van der Venne et al. 2021). According to psychiatric nurses, seclusion can improve safety when other alternatives do not work or are insufficient (Gerace & Muir-Cochrane 2019). However, nurses have reported psychosocial distress (Haugom et al. 2019) and regret when using seclusion (Happell & Koehn 2010).

Mechanical restraint is a coercive measure that involves a patient being restrained to a bed with belts, straps, or other equipment to prevent movement (Bowers et al. 2007). According to the Finnish Mental Health Act (1116/1990), a patient can be mechanically restrained to a bed with belts and straps if other measures, such as seclusion, are insufficient. In 2017, mechanical restraints were used by 106 psychiatric units in Finland. There was a total of 2,113 mechanical restraint events, with a mean duration of 16.8 hours (Laukkanen et al. 2020a). Similar to seclusion, the effectiveness of mechanical restraint has not been established. Instead, more negative experiences have been associated with mechanical restraint than with seclusion due to the more invasive nature of mechanical restraint (Chieze et al. 2019). Nurses have reported feelings of frustration and failure when using mechanical restraint, even if it was used as a last resort (Manzano-Bort et al. 2021). Both seclusion and mechanical restraint have been considered detrimental to the therapeutic relationship (Chieze et al. 2019).

Chemical restraint is the intramuscular injection of sedating medication without the patient's consent (Bowers et al. 2007). According to the Finnish Mental Health Act (1116/1990), a patient can be injected with medication against their will to ensure safety. In 2017 chemical restraint was used in 95 units in Finland. There was a total of 2187 events of chemical restraint (Laukkanen et al. 2020a). Chemical restraints have been reported effective in sedating and reducing agitation, aggression, and violence (Muir-Cochrane et al. 2020). Chemical restraint has been experienced as unfavourable and as an act of violence by the patients. Nevertheless, some patients regard chemical restraint as less coercive than other alternatives. On the other hand, nurses regard chemical restraint as justified due to the lack of effective alternatives. (Muir-Cochrane & Oster 2021.)

Physical restraint is the physical holding of the patient to prevent them from moving (Bowers et al. 2007). The Finnish Mental Health Act (1116/1990) determines that a patient can be restrained by force if necessary. In 2017 physical restraint was used in 83 units in Finland. There was a total of 1,064 psychiatric restraint events with an average duration of 0.88 hours (Laukkanen et al. 2020a). However, this might not reflect the total number of physical restraints, as these measures are used during seclusion and not necessarily reported separately. Patients have reported negative experiences regarding physical restraints (Chieze et al. 2019). Physical restraint is experienced as traumatic (Guzmán-Parra et al. 2019), especially by patients with experiences of childhood physical or sexual abuse (Hammer et al. 2011). As with other types of restraints, physical restraint is regarded by staff as a "necessary evil" due to a lack of alternatives (Wilson et al. 2017). In this study, the focus is on seclusion and restraint. Restraint in this study encompasses mechanical restraint as well as physical and chemical restraint when they are used inside a seclusion room.

Reducing seclusion and restraint in psychiatric inpatient care is a global movement (United Nations [UN] 2008, Council of Europe Committee on Social Affairs, Health, and Sustainable Development 2019). In the Finnish National Mental Health Strategy and Programme for Suicide Prevention 2020–2030, the continuation of the reduction of seclusion and restraint is emphasised (Ministry of Social Affairs and Health 2020 p. 28). In Finland, psychiatric inpatient care units have adopted the use of different strategies such as Safewards (Bowers 2014), Six Core Strategies (Asikainen et al. 2020) and VIOLIN (Violence Intervention) (Välimäki et al. 2022a) to reduce seclusion and restraint. However, while these strategies reduce their use, seclusion and restraint are still used routinely in psychiatric inpatient care in Finland (Kyrölä & Järvelin 2020), Europe (O'Donovan et al. 2022), and other countries such as Hong Kong (Välimäki et al. 2022b) and the United States (Staggs 2015).

Psychiatric nursing has been extensively studied concerning the use of seclusion and restraint. Nurses perceive the practices as undesirable and as negative aspects of their work (Doedens et al. 2020). Despite their negative perceptions of seclusion and restraint, nurses perceive the practices to be necessary (Doedens et al. 2020; Laukkanen et al. 2019; Pettit et al. 2017; Power et al. 2020; Vedana et al. 2018). Similar perceptions have been found in nurse managers (Laukkanen et al. 2020b). Because of the pressure to reduce the use of seclusion and restraint in psychiatric inpatient care, the use of these measures is sometimes experienced by psychiatric nurses as a failure to do their job (Muir-Cochrane et al. 2018).

2.2   Patient and occupational safety in psychiatric inpatient care

2.2.1   Definitions of safety

Patient safety is defined as freedom from harm or danger produced by medical care (Agency for Healthcare Research and Quality [AHRQ] 2023). The Institute of Medicine (IOM 2001) has defined patient safety as "freedom from accidental injury". Based on these definitions, safety is a condition, a state. The WHO (2022) defines patient safety as "the prevention of errors and adverse effects associated with health care". Occupational safety is defined by the International Labor Organization (ILO 2001) as "the protection of workers against work-related sickness, disease and injury".

Safety has also been defined more broadly as a way of doing things and a separate discipline (Emanuel et al. 2008). Hollnagel (2014) proposes that safety is when things work as they should. Much of the research on safety focuses on the investigation, identification, and assessment of *un-safety*, the outcomes of unsafe care and safety incidents (Jha et al. 2010). Safety research terminology consists of multiple concepts, some of which are overlapping. The concepts and their definitions used in this doctoral dissertation are in Table 2. This study focuses on the absence of safety, particularly on safety incidents. A safety incident is an occurrence, condition, or situation where safety is absent, which results or could result in harm to either a patient or staff (Canadian Centre for Occupational Health and Safety [CCOHS] 2019; WHO 2022).

Table 2.   Concepts used in safety research.

Concept	Definition	Source
Accident	An event that results in damage to the system	Galt et al. 2009
Adverse event	An injury resulting from or contributed to by medical care resulting in disability, prolonged hospitalisation or death	AHRQ 2019
Error	An act of doing something wrong or failing to do the right thing that results in an undesirable outcome or the potential for such	AHRQ 2019
Hazard	Any source that has the potential to cause harm to a human or the environment	Scheer et al. 2014
Latent condition	A weakness in the system	Reason 2008
Medical error	Error resulting from the medical treatment of the patient	Marcus et al. 2021
Medication error	Error resulting from the administration of medication	Marcus et al. 2021
Non-drug medical error	Error resulting from the treatment of the patient not related to medication	Marcus et al. 2021
Risk	The probability of exposure and the degree of damage	Scheer et al. 2014
Risk factor	An attribute that increases the likelihood of an accident	CCOHS 2019
Safety incident	An occurrence, condition or situation that results or could result in harm	CCOHS 2019
Second victim	An individual who causes or contributes to the adverse event	Ozeke et al. 2019
System	A set of elements, including human or non-human, that interact to achieve a goal	Galt et al. 2009
Unsafe act	An error conducted by the sharp-end worker	Reason 2008

2.2.2   Safety incidents in psychiatric inpatient care

The prevalence of safety incidents in psychiatric inpatient care varies; in a Swedish medical record review study, 17.2% of records (N = 2552) included a safety incident. (Nilsson et al. 2020). A study by Cullen et al. (2019) identified an incidence rate of 13.48 safety incidents per 100 patient days in general psychiatric inpatient care units and 7.11 per 100 patient days in Veterans Health Administration psychiatric inpatient care units. In a survey of nurses and psychiatrists, 75% (n = 205) reported being involved in at least one safety incident during their career (Martens et al. 2016). Safety incidents in psychiatric inpatient care can be classified into nine distinct categories: assaults, self-harm, sexual assaults, falls, adverse drug events, medication errors, elopement, contraband, and others (Marcus et al. 2021).

Assaults occur when patients use violence and aggression towards staff or other patients (Marcus et al. 2021). The prevalence of aggression has been reported in a systematic review to range between 8 and 76% (Weltens et al. 2021). A systematic review by Thibaut et al. (2019) reported a higher use of verbal assaults (57.4%) than physical assaults (43.2%) in psychiatric inpatient care. Patient factors associated with assaults include physical aggression, male gender, age, threats (Derscheid et al. 2021), history of aggression, interactions with patients and staff, a diagnosis of a psychotic or bipolar disorder, and substance abuse. Other contributing factors for aggression are ward factors, such as high bed occupancy, an unsafe and restrictive environment, smoking, and lack of privacy on the ward. Staff factors associated with aggression are male gender, presence of temporary or unqualified staff, and dissatisfied and exhausted staff. (Weltens et al. 2021.)

Self-harm has been reported to occur during psychiatric inpatient care with a rate of 2.54 per 1,000 bed days in adult psychiatric inpatient care units. The outcomes of self-harm range from mild harm (60%, n = 268) to severe self-harm (8%, n = 34) (James et al. 2012) to suicides and suicide attempts (Holth et al. 2018). Antecedents for self-harm in psychiatric inpatient care are psychotic symptoms such as hallucinations (James et al. 2012; Timberlake et al. 2020), conflicting behaviour and conflict with staff (James et al. 2012), depression and anxiety (Subica et al. 2016), and the use of containment measures (James et al. 2012).

Sexual assault in psychiatric inpatient care concerns both the staff and patients as victims and as perpetrators (Berland & Guskin 1994; Bowers et al. 2014; Nijman et al. 2005). In a study by Nijman et al. (2005), as much as 68% of psychiatric nurses have experienced sexual harassment, and 3% have experienced sexual assaults in the last year. In another study, 13% of patients expressed sexual behaviour towards staff or other patients during their hospitalisation (Bowers et al. 2014). Furthermore, 36% out of 255 directors of psychiatric units have dealt with allegations of sexual assault conducted by staff towards patients in a six-year period (Berland & Guskin 1994).

The incidence of falls in psychiatric inpatient care ranges from 0.8 falls per 1,000 patient days (Heikkilä et al. 2022) to 7.97 falls per 1,000 patient days (Yates & Tart 2012) in general psychiatric care. A higher incidence (17.7 falls per 1,000 patient days) of falls has been reported in geropsychiatric inpatient care (Oepen et al. 2018). Falls can result in minor to severe injuries and even death (Turner et al. 2020). Specific risk factors have been identified for falls, such as mood disorders (Lavsa et al. 2010) and psychosis (Poster et al. 1991). The commonly used medications in psychiatric inpatient care, such as psychotropic medication (Knight & Coakley 2010), sedatives, antidepressants (Vaughn et al. 1993), and cardiovascular medication (Lavsa et al. 2010) have been recognised as risk factors for falls.

Adverse drug events in psychiatric inpatient care are the side effects or adverse reactions to medication (Vermeulen et al. 2021). In 11,403 admission days, 94 adverse drug events were reported in one study (Vermeulen et al. 2021). In another study, in the course of six months, the majority of patients (86%, n = 343) reported adverse drug events, most of which (76%, n = 240) were mild. An incidence rate of 42 per 1,000 patients was found for adverse drug events in psychiatric inpatient care (Ayani et al. 2016).

Medication errors are errors in delivering medication to the patient, including the wrong medication, dose or route, or a delayed or missed dose (Marcus et al. 2021). The incidence rate of medication errors has been reported to be 17.5 per 1,000 patient days (Ayani et al. 2016). Medication errors and adverse drug events are related, as medication errors may result in adverse drug events (Marcus et al. 2021). In one study, 42% of medication errors resulted in adverse drug events (Ayani et al. 2016).

Elopement in psychiatric inpatient care refers to a patient leaving a closed psychiatric inpatient ward or facility without permission (Marcus et al. 2021). Around 1 to 15 patients elope from psychiatric hospitals annually (Exworthy & Wilson 2010). Reasons for elopement have been identified as patients feeling unsafe, withdrawal from substances, conflict with staff, non-compliance to medication, and feelings of confinement (Brumbles & Meister 2013).

Contraband in psychiatric inpatient care refers to when a patient is in possession of potentially dangerous item such as a sharp object, substance, or a rope-like item (Marcus et al. 2018; Marcus et al. 2021).

2.2.3   Safety incidents in seclusion and restraint

A systematic literature search was conducted to identify safety incidents in seclusion and restraint events in existing studies. The search was performed in February 2022 in three major bibliographic databases (PubMed, CINAHL, PsycINFO). The search terms were developed using the PICO framework (Miller & Forrest 2001), with a wide range of subject headings, keywords and phrases. The search terms used are

described in Appendix 1 (Table 1) and the formation of the articles in the PRISMA flow chart is shown in Appendix 2 (Figure 1). The included articles are presented in Appendix 3 (Table 2).

The search identified 17 studies reporting safety incidents during seclusion and restraint in psychiatric inpatient care. Most of the studies identified safety incidents related to the use of mechanical and physical restraint. Three studies (Haj Salem et al. 2013; Saint-Martin et al. 2008; Visaggio et al. 2018) identified safety incidents in seclusion events and two studies (Bauer et al. 2016; Nielssen et al. 1997) looked at safety incidents in the use of chemical restraint.

Seclusion

Two of the studies on safety incidents in seclusion were case studies. They investigated the death of patients during seclusion in psychiatric inpatient care. The mechanism of death was smothering in both case studies (Haj Salem et al. 2013; Saint-Martin et al. 2006). In the study by Haj Salem et al. (2013), a patient's death resulted from ingesting a medical nebuliser. In the study by Saint-Martin et al. (2006), the patient's death resulted from ingesting pellets of toilet paper. In both studies, the cause of death was considered suicide (Haj Salem et al. 2013, Saint-Martin et al. 2006). Visaggio et al. (2018) reported only the outcomes of safety incidents in seclusion. These included patient injuries (n = 11, 3.5%) and staff injuries (n = 6, 1.9%). The specific safety incidents causing the injuries were not reported. In conclusion, the studies identified only a few safety incidents in seclusion events, And the contributing factors to these safety incidents were not identified.

Mechanical restraint

The safety incidents reported for patients in mechanical restraints were pulmonary embolism (Dickson & Pollanen 2009; Hirose et al. 2021; Lee et al. 2019), deep vein thrombosis (DVT) (Funayama & Takata 2020; Ishida et al. 2014), subdural hematoma (Bauer et al. 2016), somatic complaints (Gildberg et al. 2015), aspiration pneumonia (Funayama & Takata 2020), skin abrasions (Funyama & Takata 2020), and unspecified injuries (Vedana et al. 2018; Visaggio et al. 2018). The safety incidents reported for staff were violence (Gildberg et al. 2015) and unspecified injuries (Vedana et al. 2018; Visaggio et al. 2018).

The association between mechanical restraint and deep vein thrombosis was significant in the studies by Funayama and Takata (2020) (p = 0.01, OR 6.0) and by Ishida et al. (2014) (p = 0.003, OR 1.22 per day), which both reported an increased risk for sedated patients and patients with comorbidities. Hirose et al. (2021) found a significant association between pulmonary embolism and mechanical restraint with

a duration over 15 days (p = 0.02, OR 3.24). The association was significant between mechanical restraint and aspiration pneumonia (p = 0.01, OR 4.1) (Funayama & Takata 2020). According to the experiences of nurses, the risk for safety incidents for staff is heightened when too few staff participate in mechanical restraints (Vedana et al. 2018).

The outcomes of safety incidents in mechanical restraint were death (Daniels et al. 2007; Dickson & Pollanen 2009; Lee et al. 2019), injuries for patients (n = 3, 3%), and injuries for staff (n = 9, 8,9%) (Visaggio et al. 2018). In a study by Vedana et al. (2018), nurses reported frequent staff injuries when using mechanical restraints. The studies on safety incidents in mechanical restraint focused on specific safety incidents or specific risk factors.

Physical restraint

Safety incidents in physical restraint were pulmonary thromboembolism (Fujita et al. 1999), assaults and violence (Lancaster et al. 2008; Moyo & Robinson 2012; Renwick et al. 2016), falls, and unspecified incidents (Moyo & Robinson 2012). The use of physical restraint was associated with staff injuries due to assaults (p = <0.001, OR 4.22) (Lancaster et al. 2008) and resisting restraints (Renwick et al. 2016). The safety incidents occurred during the holding (54.55%), initiation (27.27%), and exit (18.18%) stages (Moyo & Robinson 2012).

The outcomes of safety incidents in physical restraints for patients were death (Fujita et al. 1999) and injuries (4% n = 27) (Lancaster et al. 2008). For staff, the outcomes from safety incidents in physical restraints were injuries (Vedana et al. 2018), with an injury rate of 17% (n = 116) (Lancaster et al. 2008). Of 544 injuries in psychiatric care, 27% were associated with physical restraint (Renwick et al. 2016).

Chemical restraint

Safety incidents associated with chemical restraints were related to the side effects of the medication (Bauer et al. 2016; Nielssen et al. 1997). Mild side effects included injection site pain, headache, dizziness, nausea (Bauer et al. 2016), and hypotension (Nielssen et al. 1997). More severe side effects were extra pyramidical symptoms (Bauer et al. 2016), delirium (Nielssen et al. 1997), dystonia (Bauer et al. 2016, Nielssen et al. 1997), and phlebitis (Nielssen et al. 1997).

2.2.4   Improving safety in psychiatric inpatient care

Improving safety is defined as the development and implementation of strategies and practices that improve the safety of patients (AHRQ 2022) and healthcare professionals (The Occupational Safety and Health Administration [OSHA] 2022). Improving safety in health care is a prerequisite for high-quality healthcare systems (WHO 2021b). In psychiatric inpatient care, safety improvements have focused on the prevention and management of aggression and violence (Thibaut et al. 2019), enhancing safety culture (Kuosmanen et al. 2019; Mahoney et al. 2012), patient transfers (Young & Wachter 2009), and reducing medication errors (Jayaram et al. 2011).

Interventions, strategies, and programmes have been developed and implemented in psychiatric inpatient care to reduce aggression and violence (Hermanstyne & Mangurian 2016; Kaunomäki et al. 2017; Slaming et al. 2021; Wolf et al. 2017). Studies have found limited effectiveness of non-pharmacological interventions due to methodological limitations (Hermanstyne & Mangurian 2016; Slaming et al. 2021; Wolf et al. 2017). Intervention studies by Kuosmanen et al. (2019) and Mahoney et al. (2012) found positive changes in safety culture after an educational intervention. To improve the safety of patient transfers, the Toyota Production System (TPS) principles have been utilised, resulting in improved safety and a decrease in failed transfers (Young & Wachter 2009). Responding to the challenges of medication errors in psychiatric inpatient care, Jayaram et al. (2011) implemented an error reporting system and a prescribing system for psychiatric inpatient care, which resulted in a decrease in the number of reported and total medication errors.

The focus of previous studies on safety in seclusion and restraint has been on reducing their use in psychiatric inpatient care (Goulet et al. 2017). However, efforts are needed to improve the safety of seclusion and restraint practices. Seclusion and restraint are still used in psychiatric inpatient care, and studies have reported safety incidents resulting from the use of seclusion and restraint (Kersting et al. 2019).

2.2.5   Various approaches to improving safety

In health care, various approaches have been developed to improve safety. These approaches can be roughly defined as the person-centred approach (Cross 2018), the transactional approach (Pedersen & Mesman 2021), and the system approach (Reason 2000). In the person-centred approach, the focus is on individuals. This means that to improve safety, the performance of individuals must be improved (Cross 2018). To improve individuals' performance, behavioural psychology methods are utilised. These methods include organising training, encouraging participants to follow safety guidelines and rules, rewarding nurses for good practice,

and punishing them for errors and mistakes (Leveson et al. 2020). The person-centred approach has been the central approach in health care for decades. However, improving individual performance has not led to sufficient improvements in safety (Clarkson et al. 2018). The transactional approach is founded on the principles of pragmatism, where the safety focus is on the situational factors and the habits of interprofessional clinicians. To improve safety according to the transactional approach is to generate shared safety habits and practices. The transactional approach also includes elements such as teamwork, technology, skills, and organisational factors as they influence the safety habits of professionals (Pedersen & Mesman 2021). The system approach focuses on the system in which the professionals work (Carayon et al. 2014; Cross 2018; Reason 2008 p.102). The system approach and its variations are regarded as the foundation for improving safety in health care (AHRQ 2021).

The system approach to safety is the use of system-thinking principles, where the system is referred to as a combination and interaction of parts: people, materials, technology (soft- and hardware), environment, and the process as a whole, not as individual parts (Ackoff 1971; Ackoff 1994). The system approach is warranted in health care services because they form a complex sociotechnical system. Complex sociotechnical systems consist of diverse individuals including patients, professionals, and carers with different, sometimes even conflicting, objectives (Carayon et al. 2014). Constant change, hazardous procedures, and the interaction between technology and humans are all part of health care in the 21st century (Effken 2002). This means that the actions of individual healthcare professionals and their potential errors should not be considered the leading causes of safety incidents. Instead, these safety incidents are consequences of the interactions of system elements (Cross 2018). Improving safety based on the system approach focuses on changing the system design (Clarkson et al. 2018; Cross 2018; Leveson et al. 2020; Peters 2014; Reason 2000). The existing elements that make up a system and their interrelationships are considered when improving a system design. Changes are then made to the system design to improve safety (Clarkson et al. 2018). An essential aspect of the system approach is that the focus is not on the individual healthcare professional and their actions but on the more extensive system in which they work (Reason 2000; Reason 2008 p.101). Therefore, when improving the safety of health care, the focus is not solely on improving the performance of the individual. Instead, the focus is on the system and its design (Clarkson et al. 2018; Cross 2018; Leveson et al. 2020; Reason 2000). The system approach to safety improvement can be applied to systems of different scales (Royal Academy of Engineering 2017).

The approach utilised in this study is the SCM, developed and depicted by Reason (2008). This system approach model was chosen because of its simplicity and applicability to different settings (Watson et al. 2019). In the model, safety

incidents are assumed to occur in the conditions in which individuals work and exist (Reason 2000). This model fits this study, as safety incidents in seclusion and restraint in psychiatric inpatient care are not only considered to be the result of nurses' mistakes. Instead, they are thought to stem from personal and system factors impacting seclusion and restraint in psychiatric inpatient care.

3   Aims

This study aimed to identify safety incidents and their contributing risk factors in seclusion and restraint events in psychiatric inpatient care. The existing practices, incidents, and contributing risk factors were synthesised using the SCM (Reason 2008 p.101–102) to gain an in-depth understanding of safety incidents in seclusion and restraint events in psychiatric inpatient care.

The research questions were as follows:

1.   What is nursing practice at the sharp end (bedside) of seclusion and restraint in psychiatric inpatient care (phases I and II)?

2.   What safety incidents occur in seclusion and restraint in psychiatric inpatient care (phases I and II)?

3.   What risk factors (unsafe acts and latent conditions) contribute to safety incidents in seclusion and restraint in psychiatric inpatient care (phases I, II, and III)?

A summary of the study's aims and phases is presented in Figure 1.

Based on the synthesis of the knowledge gained from this study with SCM recommendations are proposed. The recommendations can be used as a foundation to improve safety in seclusion and restraint practices in psychiatric inpatient care.

Aim: To identify safety incidents in and their contributing factors in seclusion and restraint events in psychiatric inpatient care

Nursing practice at the sharp end of seclusion and restraint	Safety incidents in seclusion and restraint	Risk factors contributing to safety incidents in seclusion and restraint: patient falls in seclusion as an example
Phase: I, II	Phase: I, II	Phase: I, II, III

Synthesis with
Swiss Cheese Model of Accident Causation

Safety incidents in seclusion and restraint in psychiatric inpatient care

Recommendations to improve safety in patient seclusion and restraint in psychiatric inpatient care
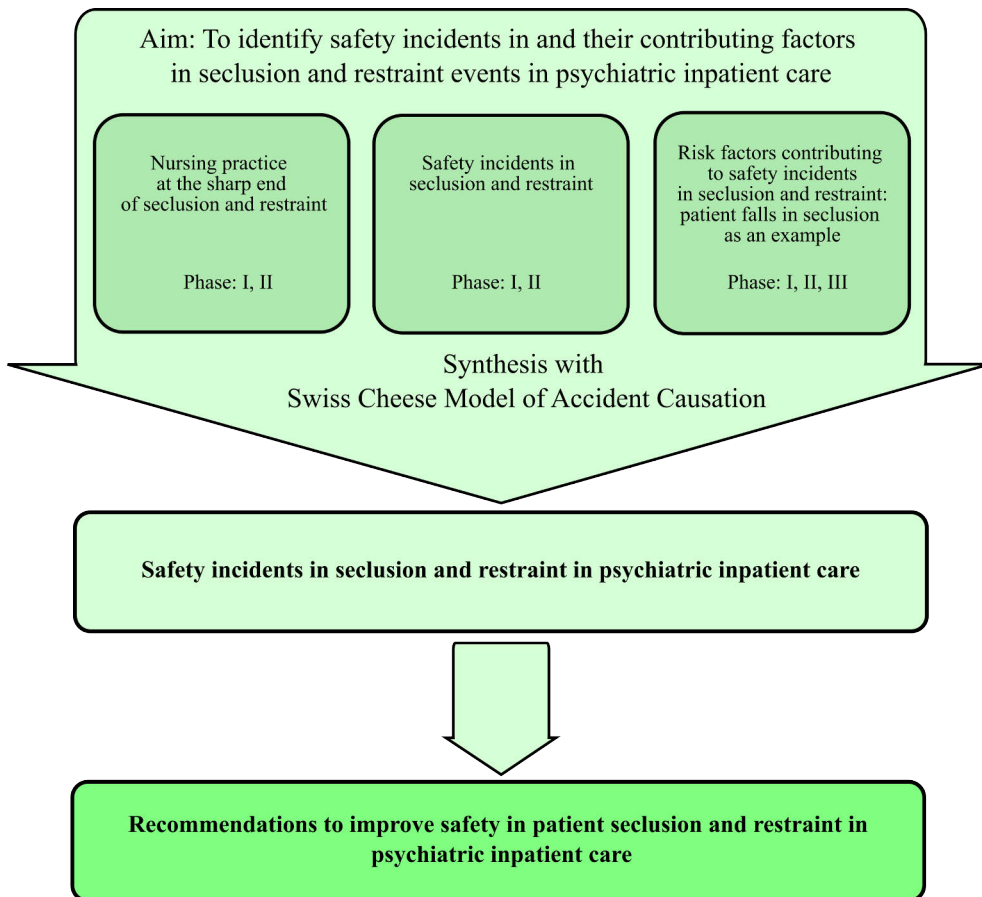
Figure 1. Summary of the study aims and phases.

4 Materials and Methods

4.1 Theoretical framework

The theoretical framework of this study is the SCM (Reason 2008 p. 101–102). The model was chosen because of its simple, yet interpretative, nature. The simplistic nature allows for use of the model in assessing safety incidents and improving safety in different systems, from aviation to health care (Wiegmann et al. 2021). This study used the SCM to synthesise the findings of the three phases. Based on the synthesis, recommendations are made to improve safety in seclusion and restraint in psychiatric inpatient care.

The SCM is founded on the principles of the system approach (Reason 2000). Safety incidents can manifest as nurses' errors, and their causes and contributing factors are assumed to stem from the system. Systems contain factors that contribute to and cause safety incidents as well as factors that prevent them. In SCM, the factors that prevent safety incidents are defensive layers, illustrated in the model as slices of cheese (Reason 2000, 2008 p.101–102). These defensive layers constitute a variety of factors (Reason 2000). In the context of seclusion and restraint, the defensive layers can be, for example, the teamwork of the nurses, the safety equipment, and the established safety guidelines (Reason 2008 p.101). A completely safe system would include a slice of cheese without even the tiniest hole (Wiegmann et al. 2021). This would mean that the defensive layers are completely error-proof, and no safety incidents could be possible. In reality, no completely intact cheese slices exist, and no system is entirely safe. The holes in the individual cheese slices represent two different factors for safety incidents: unsafe acts and latent conditions (Reason 2000). These holes open and close continuously, representing the dynamic nature of the system (Wiegmann et al. 2021). Regarding seclusion and restraint, for example, when nurses enter the seclusion room, they are exposed to different safety incidents; a hole opens in the slice of cheese and closes when they exit the seclusion room. For patients, they can be exposed to specific safety incidents during seclusion or restraint, therefore the hole can be open in the slice of cheese during the duration of the seclusion or restraint.

Unsafe acts are actions committed by individuals working at the sharp end of the system, e.g., nurses whose work consists of direct interaction (Abolino & Mosier

2020; Reason 2000) with a secluded and restrained patient. Unsafe acts include slips and lapses, rule-based mistakes, knowledge-based mistakes, and violations (Reason 2008 p.38–45). Slips and lapses are when nurses misidentify something important in the patient's condition. Rule-based mistakes occur when nurses fail to apply a good rule when needed, such as constantly observing a mechanically restrained patient. Knowledge-based mistakes occur when nurses do not have sufficient knowledge, and conduct suboptimal actions in a specific situation. Violations are, for example, when nurses knowingly do not comply with the organisation's safety rules with the intention of reducing their workload.

Latent conditions are central to the system approach to safety. They shift the focus from solely identifying unsafe acts of individuals to examining the conditions in which the individuals operate (van Beuzekom et al. 2010). Latent conditions are weaknesses in the system (Lowe 2006; Reason 2000). They exist in the system and can result in safety incidents by themselves or when combined with unsafe acts (Reason 2000) or other elements of the healthcare system (Lowe 2006). Latent conditions can be identified and many of them can be repaired proactively (Reason 2000). In this study, the patient physiological condition is considered a latent condition, as patients themselves form a sub-system in the system of seclusion and restraint. Latent conditions in seclusion and restraint can be in the physical environment of the seclusion room, where materials and the design of the environment expose nurses or patients to safety incidents. An example of such a condition is when the material used for the floor has been designed to be easily cleaned but is slippery when wet.

4.2   Methodological approach

In this study, a multimethod approach was chosen. A multimethod approach is the use of various methods of inquiry (Fetters & Molina-Azorin 2017). A multimethod approach is suitable for this study because, to identify safety incidents and their contributing factors, there is a need to rely on more than one method of inquiry (Niglas 2010).

The study follows the multimethod approach defined by Morse (2003 p. 189-208), which is a combination of two or more methods in one project that are each conducted individually and are complete by themselves. This differs from a mixed methods approach, where the "mixing" of the methods in a specific design is at the core (Creswell & Plano Clark 2018 p. 35–38). Therefore, the multimethod approach of this study is evident. The individual research studies (papers I–IV), which focus on different aspects of safety in seclusion and restraint, were conducted separately, with the exception of papers II and III, which were conducted with the same data,

with different aims and separate reporting. The studies are complete as individual studies by themselves.

The individual studies are synthesised in this dissertation to form a larger whole. The individual studies' findings were synthesised with SCM (Reason 2008 p. 101–102) to form a bigger picture of safety incidents in seclusion and restraint events. This is used as the foundation for the recommendations to improve safety.

4.3   Methods

The methods used in the three phases are described in the following sub-chapters. More detailed descriptions of the methods used are described in the papers (I-IV). The methods used are summarised in Table 3 below.

Table 3.   A summary of research designs and methods used in the three study phases.

	Phase I (paper I)	**Phase II (papers II & III)**	**Phase III (paper IV)**
Design	Descriptive	Descriptive, explorative	Sociotechnical probabilistic risk assessment
Setting	Psychiatric hospital (n = 1), ward (n = 5)	Psychiatric hospital (n = 1), ward (n = 6)	Psychiatric hospital (n = 1)
Sampling	Purposive	Convenience	Purposive
Sample	Psychiatric nurse (n = 32)	Video recordings of seclusion and restraint (n = 36)	Psychiatric nurses (n = 6)
Data collection	Focus group	Non-participant video-observation	Exploration group, systematic literature search
Data analysis	Inductive content analysis	Inductive thematic analysis (paper II), Deductive content analysis (paper III)	Fault tree analysis

4.3.1   Designs

Phase I

The design of phase I (paper I) was descriptive. The design was chosen because it allowed for the description of experiences of those who had worked at the sharp end of seclusion and had knowledge of the safety incidents based on their experience (Bradshaw et al. 2017; Sandelowski 2010).

Phase II

In phase II (papers II & III), descriptive and explorative designs were utilised. A descriptive design was chosen (paper II) because it allowed for a detailed but concise description of events (Neergaard et al. 2009). Therefore, this design was suitable for describing unsafe acts and latent conditions in seclusion and restraint. The explorative design was chosen because the phenomenon of nursing in the sharp end has not been previously studied (Carpenter et al. 2011 p. 72–96).

Phase III

The design of phase III (paper IV) was developmental. Developmental designs are used when something new is generated (Richey & Klein 2005). The developmental design was considered as a suitable approach because a new model was generated using Sociotechnical Probabilistic Risk Assessment (ST-PRA) to model the risk (Marx & Slonim 2003) of patient falls in seclusion.

4.3.2   Settings and sampling

Phase I

In phase I (paper I), the study setting was one psychiatric hospital. The hospital represented a typical psychiatric hospital in Finland. The hospital had, in total, 100 hospital beds and approximately 150 psychiatric nurses. The hospital had different wards that specialised in the care of different psychiatric inpatient populations, such as psychogeriatric, psychosis, forensic and crisis patients. For this study, five wards were selected to represent the above-mentioned specialised wards. Seclusion and restraint were used as part of the care in all the selected study wards. Five different wards were chosen, as participants from different wards can provide different and unique perspectives based on their experience (Sargeant 2012).

A purposive sampling method was used in phase I (paper I) to reach participants (Holloway & Galvin 2017 p. 143–144) who represented different wards and had different experiences of seclusion and restraint. The sampling focused on psychiatric nurses who used seclusion and restraint as part of their work. To understand the unsafe acts and latent conditions in seclusion and restraint, it was vital to understand the perspectives of those who used these as part of their work (de Wet et al. 2018).

The sample consisted of psychiatric nurses (n = 32) from psychiatric inpatient wards. The types of wards were: acute care (n = 1), geropsychiatric (n = 1), psychosis (n = 1), and forensic psychiatric (n = 2). The participants included both females and males, had different educational backgrounds, and their work experiences ranged

from less than one year to over 15 years. The number of focus groups formed (n = 4) was determined to be sufficient, as it has been shown that 90% of new themes are discovered after three to six focus groups (Guest et al. 2016).

Phase II

In phase II, (papers II & III), the study was conducted in six locked wards in one psychiatric hospital in Finland. The hospital provided specialised psychiatric inpatient care for different patient populations, from difficult-to-treat to forensic patients. The six wards included in this study were geropsychiatric (n = 1), forensic (n = 2), acute psychiatric (n = 2), and psychosis rehabilitation (n = 1). The wards were chosen because they all had facilities for seclusion and restraint, and these were used for challenging patients. The different patient populations in these wards also provided the opportunity to gain a comprehensive perspective on the various aspects of how seclusion and restraint were being used. The participants were studied in their natural setting, and no attempt was made to control the conditions (Bhattacharya 2012 p.788). Instead, the aim was to study seclusion and restraint as they naturally occurred.

The chosen sampling method for phase II of this study (papers II & III) was convenience sampling. Convenience sampling was used as a 'first come, first serve' principle (Palinkas et al. 2015). This meant that video recordings were included in the study until the target sample size was reached. The study sample consisted of video recordings of seclusion rooms from six wards. In the video recordings, healthcare staff, mainly psychiatric nurses, and other healthcare staff, such as physicians, laboratory personnel, and patients, were present. The sample size for the study was 36 video recordings. The sample size was determined by expected data saturation, where new data would repeat previous data (Saunders et al. 2018).

Phase III

The study setting in phase III (paper IV) was one psychiatric hospital in Finland where seclusion was being used as part of care. The study also included a systematic literature search in which the setting was adult psychiatric inpatient care. This included forensic, psychogeriatric, and other specialised psychiatric settings. In the literature, settings included different types of wards. The participants from the psychiatric hospital were also recruited form different wards. This was done because falls include multiple risk factors, some of which can be unique to specific patient populations (Stenhagen et al. 2013; Turner et al. 2020).

The sampling strategy used in phase III (paper IV) was purposive. This approach was suitable as the aim was to reach participants with valuable information and

experience of the topic (Patton 2015), psychiatric nurses with information and experience of patient seclusion. The sample size for this study was six psychiatric nurses from different wards, including a substance abuse ward (n = 1), psychosis wards (n = 4), and geropsychiatric wards (n = 2). The sample size was in line with previous studies that have used sociotechnical probabilistic risk assessment (Bish et al. 2017). The sample sizes of the studies included were between 12 to 206,350 patients or incident reports.

4.3.3 Data collection

Phase I

Focus groups were chosen as data collection method in phase I (paper I) to gain knowledge from the sharp end. Nurses' experiences and views regarding occupational safety incidents, risk factors and nursing were explored. Using focus groups was deemed suitable as they are useful for collecting data from participants with experience and perceptions of the topic (Mansell et al. 2004); the discussions and interactions between the participants can provide in-depth knowledge of the topic (Jayasekara 2012).

The interactions and discussions of the topic were guided and facilitated by a facilitator. The role of the facilitator was to stimulate the discussion by encouraging participants to express themselves, their thoughts, perceptions, and experiences (Grønkjær et al. 2011). The facilitator steered the discussion to the topic of the study. However, the discussions were not too strongly moderated so that participants would be heard and interact with each other (Morgan & Hoffman 2018 p. 250–263). In addition, a co-facilitator was present in all the focus groups to take notes and help with the practicalities (Holloway & Galvin 2017 p. 132), such as operating the audio recorder, providing refreshments, and asking additional follow-up questions.

Phase II

The data for phase II (papers II & III) were collected with non-participant video observations. Video observation provided the opportunity to study participants (patients and psychiatric nurses) in their natural setting (Asan & Montauge 2014) and their complex behaviours, actions, and interactions in seclusion and restraint. The strength of non-participant video observation is that the observations made are not dependent on the researcher on site. This allows for less intrusive data collection (Asan & Montauge 2014). This is especially important for seclusion and restraint events, where it would not be possible to have an external observer present.

Furthermore, video observations record raw data that can be viewed repeatedly to reach reliable interpretations of behaviours and actions (Haidet et al. 2009).

The videos were recorded using the study organisation's standard security cameras. The cameras were mounted on the ceiling, providing a view of the whole seclusion room. The video recordings were limited to picture without audio due to the restrictions set by the ethical board. The contents of the video recordings were transcribed into text format.

Phase III

In phase III (paper IV), the study consisted of two separate data collections, a systematic literature search of existing literature and exploration groups of psychiatric nurses. In ST-PRA, a systematic literature search is recommended to identify risk factors (Marx & Slonim 2003). The literature search was conducted in March 2021. The search focused on studies conducted with various designs and methods of inquiry (Pluye & Hong 2014). The search terms were formed using the PICO framework (Miller & Forrest 2001). The literature search was conducted in three databases (PubMed, PsycINFO, CINAHL) and supplemented with manual and ad-hoc searches. A total of 1,906 records were identified. After screening for duplicates, an abstract title screen, and full-text assessments, 31 studies were included in the synthesis. A literature search for different types of studies was chosen because it provided information regarding the previously identified unsafe acts and latent conditions associated with patient falls in seclusion.

Exploration groups were organized to supplement the information gained from the systematic literature search. Exploration groups were organised for psychiatric nurses (n = 6). Exploration groups are an adaptation of traditional focus groups. In exploration groups, the participants have a more active role. They discuss, review, and develop explanations for the topic (Pope et al. 2002). This method was chosen as the literature on falls in seclusion was limited. Therefore, gaining knowledge from those working closely with the phenomenon was vital. In this study, the psychiatric nurses provided insight into unsafe acts and latent conditions for patient falls in seclusion. They later reviewed and provided feedback on the fault tree. The psychiatric nurses also provided probability estimates of those unsafe acts and latent conditions for which a probability estimate was not acquired from the literature (Marx & Slonim 2003).

4.3.4 Data analysis

Phase I

Inductive content analysis was used to analyse the data in phase I (paper I). The inductive approach was appropriate because the existing knowledge from the perspective of psychiatric nurses was limited. Identifying unsafe acts and latent conditions based on the experiences of psychiatric nurses supports the use of an inductive approach (Elo & Kyngäs 2008). The data analysis process was facilitated using Nvivo 12 (QSR International 2017) data analysis software. The analysis focused only on the manifest content expressed by the nurses (Elo & Kyngäs 2008). Open coding was conducted on the transcribed focus group discussions. This meant that the words, sentences, and paragraphs that informed about unsafe acts and latent conditions were highlighted. The meanings and similarities of the codes were then considered. Similar codes were grouped into categories through the interpretation by two researchers (Elo & Kyngäs 2008). The categorisation resulted in main categories and sub-categories, which described unsafe acts and latent conditions and how they contribute to safety incidents in seclusion and restraint in psychiatric inpatient care.

Phase II

Two different analytical approaches and data analysis methods were used in phase II. First, minimal interpretation was used to gain a concise description of unsafe acts and latent conditions in seclusion and restraint (paper II). Then, a more interpretative approach was used to describe the work at the sharp end: nursing interventions during seclusion and restraint (paper III). The analysis was facilitated using Nvivo 12 data analysis software (QSR International 2017).

In analysing the video recordings for unsafe acts and latent conditions (paper II), inductive thematic analysis was used. No previous studies had used video observation to identify unsafe acts and latent conditions in seclusion and restraint. Therefore, an inductive approach was warranted. Furthermore, thematic analysis is a flexible method for various data types (Nowell et al. 2017). It has been previously used for video observations (Beukers et al. 2015; Linderoth et al. 2015). The analysis process included developing a code book to improve the consistency of the coding process (DeCuir-Gunby et al. 2011). Two researchers were involved in developing, testing, refining, and using the codebook. The codebook guided the coding and categorisation of the data. The reliability of the coding process was assessed with interrater reliability with per cent agreement (Miles & Huberman 1994) and Cohen's Kappa (Cohen 1960). After refining the codebook, a per cent agreement of 97.7%, a

Cohen's Kappa of .948 was reached, which indicated the excellent reliability of the coding (Lombard et al. 2002).

Deductive content analysis was used to describe the context and the work performed by psychiatric nurses at the sharp end of seclusion (paper III). A deductive approach was justified because models exist (Elo & Kyngäs 2008) that can describe nursing. The Roper-Logan-Tierney model of nursing (Roper et al. 2001 p.78, 81–85.) was chosen as the analytical framework. The Roper-Logan-Tierney nursing model is a general, needs-based nursing model consisting of 12 activities of living, representing patient needs that can be met with nursing interventions (Roper et al. 2001 p.81). The data was coded and categorised under the 12 activities of living by two researchers using a categorisation matrix. The consistency of the analytical process was assessed using interrater reliability to ensure that the coding and categorisation were conducted similarly (Burla et al. 2008). Cohen's Kappa was used for a portion (10%) of the data because it considers the agreement by chance (Cohen 1960). A Cohen's Kappa of .951 was reached, indicating excellent reliability.

Phase III

The data analysis in ST-PRA methodology is fault tree analysis (paper IV). It analyses how unsafe acts and latent conditions contribute specifically to patient falls (Wreathall & Nemeth 2004). A simple categorisation method was used in phase III to identify unsafe acts and latent conditions from the literature. Information regarding the study, the incidence of falls reported, identified unsafe acts and latent conditions, probabilities, and fall mechanisms were recorded in a spreadsheet.

The exploration group data were analysed with a simple synthesis method, where information regarding fall risk factors, probability or mechanism of falls was added to the matrix generated from the systematic literature search. The matrix was updated with unsafe acts and latent conditions for falls that were not identified in the systematic literature search. The analysis was a part of the modelling process.

The fault tree modelling utilised knowledge gained from the systematic literature search and the exploration groups. In fault tree analysis, Boolean logic and graphical illustration are used to analyse how unsafe acts and latent conditions contribute to (Slonim et al. 2014) patient falls. AND and OR gates are central to fault tree analysis. They indicate how unsafe acts and latent conditions depend on or relate to each other. An AND gate means that at least two unsafe acts or latent conditions must occur together for a higher-level event to occur. The OR gate means that any unsafe act or latent condition can result in a higher-level event (Slonim et al. 2014). The fault tree was modelled using Relyence (Relyence UK limited) software. Probabilities were assigned to unsafe acts and latent conditions based on the literature and the experience of professionals. The assignment of probabilities resulted in cut sets and

criticality estimates. Cut sets are the minimum combination of unsafe acts and latent conditions required for a patient fall (Marx & Slonim 2003). Criticality assesses the contribution of individual unsafe acts and latent conditions (Slonim et al. 2014). To ensure the conclusions from the model were valid, sensitivity analysis was conducted on the unsafe acts and latent conditions that had considerable variation in the probability estimate (Marx & Slonim 2003).

4.3.5   Research ethics

The study followed good scientific practice and ethically sound procedures (Finnish National Board on Research Integrity [TENK] 2019). Ethical committee approval was acquired for each phase of the study (I–III). A more in-depth description of the ethical considerations is presented in the discussion in Chapter 6.

5 Results

5.1 Nursing practice at the sharp end of seclusion and restraint in psychiatric inpatient care

Nursing practice at the sharp end of seclusion and restraint involved nursing interventions. Based on the video observations of seclusion and restraint events, the interventions that nurses at the sharp end perform depend on the situation. These nursing interventions were categorised (paper III) as 12 activities of living according to the Roper-Logan-Tierney Model of Nursing (Roper et al. 2009). These are further abstracted into three themes: maintaining safety, providing physical care, and interacting. Nursing in the sharp end is influenced by environmental, patient, and team factors. More detailed description can be found in paper I.

Maintaining safety

Nursing interventions for maintaining safety consisted of restrictive interventions and environmental safety interventions. The video observations (paper III) identified the use of restrictive interventions in the seclusion room. Physical restraint was used by nurses when patients were resisting. Physical restraint was also used to cope with patient aggression by physically holding and moving the patient to the ground. In some of the events when physical restraint was used, it was combined with intramuscular chemical restraint. Chemical restraint was also given orally. The use of mechanical restraint in the seclusion room required the nurses to carry an extra metal bed into the seclusion room. The bed was bolted to the floor, and the patient was forcefully restrained to the bed with belts and straps. When using mechanical restraint, a nurse was present most of the time to observe the patient. However, the video observations showed that this was not always the case.

Nursing interventions were also conducted to ensure the safety of the seclusion and restraint environment. Based on the videos (paper III), nurses ensured safety by searching for and removing items that could be hazardous for the patient or nurses. These items were searched for in the seclusion room and among the patient's possessions. Bodily searches were conducted at the beginning of seclusion and restraint events.

Providing physical care

Nursing interventions during seclusion and restraint focused on patients' basic needs, such as elimination, hygiene, sleep, mobility, hydration, and nutrition (paper III). The level of dependence varied in the interventions. Some physical care interventions were conducted in cooperation with the patient, and some were conducted with the patient.

Based on the video recordings (paper III), physical examinations and physical measurements were used to assess patients' physical health. The measurements used were ECG, blood pressure, urine and blood samples, weighing the patient, assessing the patient's hydration status, and assessing the patient's intoxication levels with a breathalyser.

Patients experienced scratches and wounds during seclusion and restraint. The nurses assessed them and provided wound care. In addition, most of the patients received medication during seclusion and restraint. Medication was administrated orally and with intramuscular (chemical restraint) and subcutaneous injections (anti-coagulant medication) for mechanically restrained patients.

During seclusion and restraint, patients were dependent on nursing interventions to meet some of their basic physical needs. The video observations (paper III) identified many interventions focused on patients' basic needs. The responses to these needs varied between the individual patients. For some patients, nurses provided the means for fulfilling those needs, for example, by bringing food to the seclusion room or providing the patient with clean clothes and hygiene products. For other patients unable to fulfil their needs by themselves, the nurses assisted the patients by feeding them, taking care of their hygiene and dressing them. Mechanically restrained patients were the most dependent on nurses.

Interaction

Based on the video observations (paper III), interactions between nurses and patients consisted of communication between them. Forms of communication included talking face-to-face inside the seclusion room or through the seclusion door. In addition, interactions occurred during the delivery of other nursing interventions. There was more interaction between nurses and restrained patients than between nurses and patients who were only secluded. Overall, the most of the interaction and communication during seclusion and restraint was brief and occurred during other nursing interventions. Interactions between the patient and nurses only made up a tiny proportion (<10%) of the duration of seclusion events.

Environment

According to nurses (paper I), nursing at the sharp end of seclusion and restraint is steered and guided by the organisation's guidelines and resources. Nurses have experienced unclear guidelines for seclusion and restraint, especially regarding their role, tasks, and responsibilities during these events.

The allocation of resources influences nurses' work during seclusion and restraint. Based on the nurses' perceptions (paper I), the organisation might not have enough resources allocated for training and educating nurses who work at the sharp end of seclusion and restraint. Therefore, seclusion and restraint practices might not follow the latest practice or technique recommendations. Nurses also noted that there are not always enough nurses available to enter the seclusion room safely. This can result in delayed nursing interventions, especially at night, when fewer nurses are on the ward.

Nurses considered the physical environments of the seclusion rooms (paper I) to be outdated. The rooms are small, which restricts the nurses' ability to work. This results in conducting nursing interventions with less-than-ideal ergonomics. Furthermore, the equipment used for mechanical restraint is regarded to be difficult to use. In the focus groups, many nurses felt they were not given adequate personal equipment such as shoes, clothing, and personal alarm systems.

Patient

Based on their experiences, nurses (paper I) felt that their work was significantly impacted by patients being secluded or restrained. Aggressive or potentially violent patients require more nurses to be present when entering the seclusion room. This means that it might take longer to gather enough nurses to enter the seclusion room or that the patient's challenging behaviour makes it difficult to enter. Therefore, patients with especially challenging behaviour determine when and what nursing interventions can be used during seclusion and restraint.

Team

Nurses experienced (paper I) challenges with teamwork during seclusion and restraint. These challenges were related to the team that was conducting seclusion and restraint; how the team functioned was related to how the work at the sharp end of seclusion and restraint was conducted.

5.2 Safety incidents occurring in seclusion and restraint in psychiatric inpatient care

Safety incidents in seclusion and restraint in psychiatric inpatient care have been identified from the experiences and perceptions of nurses (paper I) and from video observations of seclusion and restraint events (paper II). These safety incidents resulted or could have resulted in harm to either patients or nurses. These safety incidents are categorised here (Table 4) based on the definition of safety incidents in psychiatric inpatient care given by Marcus et al. (2021). More detailed descriptions of these can be found in papers I and II.

Table 4. Safety incidents in seclusion and restraint.

Safety incident	Subject
Assault (verbal & physical)	Healthcare professional
Fall	Patient, healthcare professional
Medication error	Patient
Non-drug error (elopement)	Patient
Other safety incidents	Patient, healthcare professional
Self-harm	Patient

Assaults

Verbal assaults were described by the nurses (paper I). Nurses described experiences of being verbally assaulted during seclusion and restraint and that this can cause emotional distress, especially for individuals with other emotional burdens. Based on the nurses' experiences (paper I) and the video observations (paper II), physical assaults in seclusion and restraint occured mainly when a patient was resisting physical restraints or at the beginning of the seclusion when the patient was being escorted to the seclusion room. Physical assaults took many forms, such as punching, kicking, pushing and biting.

Falls

Based on the video observations of seclusion events (paper II), falls and near-miss situations were identified. The mechanism of falls was slipping or tripping. Furthermore, many situations were identified in which patients were visibly losing balance. Nurses described (paper I) that, in addition to patients, nurses are also at risk of falling during seclusion and restraint events.

Medication errors

Medication errors in the context of seclusion happen when the administration of medication results in a safety incident. Medication errors were identified from the video observations of seclusion and restraint (paper II). Medication was sometimes administered against the organisation's guidelines, and included injection without disinfecting the skin, medication being dropped on the floor, and needle sticks injuries.

Elopement

The non-drug medical error identified in the video observations of seclusion and restraint was the elopement of a patient (paper II). During seclusion and restraint, the patient was able to break free from either physical or mechanical restraints or escape from the seclusion room.

Other safety incidents

Other safety incidents identified in seclusion and restraint were ergonomic injury, noise hazards, and contamination. Based on the video observations (paper II) and the experience of nurses (paper I), seclusion and restraint situations caused strain on the nurses' bodies when restraining a resisting patient. In addition, nurses described that carrying a heavy metal bed to the seclusion room for mechanical restraints has led to ergonomic incidents. Nurses reported (paper I) that during seclusion and restraint, patients could yell or scream when agitated, which exposed nurses to noise hazards that resulted in hearing injuries. Contamination in a seclusion or restraint event refers to an incident in which a patient or the healthcare staff are exposed to a contaminant. The video observations (paper II) and the nurses' experiences (paper I) indicated that contamination in seclusion and restraint included the exposure to excrement that the patient had spread throughout the seclusion room. Furthermore, patients exposed themselves to contaminants when drinking or eating food that had been exposed to contaminants.

Self-harm

Self-harm during seclusion was identified from the video observations of patients in seclusion and restraint (paper II). Patients attempted or self-harmed by strangling, scratching, or punching themselves. More serious self-harm involved patients banging their heads on the wall. Furthermore, mechanically restrained patients attempted to self-harm by shifting to a position in mechanical restraints where their movement or breathing would potentially be restricted.

5.3 Risk factors contributing to safety incidents in seclusion and restraint in psychiatric inpatient care

The following chapter presents risk factors (unsafe acts and latent conditions) identified in phases I, II, and III. A more detailed description of these unsafe acts and latent conditions are described in papers I, II and IV.

5.3.1 Unsafe acts

Nurses' actions

In seclusion and restraint events, nurses may fail to or not be able to recognise or intervene in a change in a patient's behaviour, condition or environment (paper II). It was identified that nurses either failed to or were unable to recognise patient self-harm during seclusion and restraint. This meant that patients were able to self-harm without the nurses intervening. Nurses also did not recognise or intervene when patients were falling, performing precarious and high-risk movements, acting aggressively, or being exposed to contamination when drinking from the toilet or eating food from the floor. Other recognition failures that exposed nurses to occupational safety incidents were identified from the video observations (paper II) and nurses' experiences (paper I). Nurses sometimes did not carry their alarm systems, knelt close to a patient, or interacted closely with a potentially aggressive patient.

During seclusion and restraint, nurses conducted actions that exposed them to safety incidents. These manifested as rule-based mistakes, for example, when nurses left items in the seclusion room, which can be hazardous. From the video observations (paper II) and based on nurses' experiences (paper I), nurses also tended to go into the seclusion room alone, despite this being against the organisation's safety rules.

From the video observations (II), it was detected that nurses sometimes failed to conduct, or had difficulties conducting, actions required or expected of them. These knowledge-based mistakes manifested as failures to conduct a fall risk assessment for secluded patients, which, as came up in the discussions in the exploration group (paper IV), nurses rarely do for secluded patients. Furthermore, nurses had difficulty conducting some central actions in seclusion and restraint. The video observations (paper II) identified that, when nurses attempted to restrain a patient mechanically, the nurses had challenges in applying the mechanical restraint straps to the patient. The nurses also identified these challenges in the focus groups (paper I). Furthermore, nurses made suboptimal choices (paper II) during seclusion and

restraint, which exposed them to safety incidents. For example, they carried or lifted the patient with poor ergonomics.

Some safety violations regarding seclusion and restraint were identified by nurses (paper I) and from the video observations (paper II). These violations occurred when nurses did not respond to alarms, withdrew from the seclusion room during challenging situations or were not assisting in restraining patients. Furthermore, we identified that nurses gave medication to a patient that had dropped to the floor.

Patient actions

Secluded and restrained patients expose themselves and nurses to safety incidents with unsafe actions. From the video recordings (paper II), we identified that during seclusion and restraint, patients conducted actions that exposed themselves to safety incidents, including precarious movements, exposing themselves to contaminants and preventing the visibility of the surveillance camera. Furthermore, in paper IV it was identified that patient behaviour that is affected by psychological and behaviour disturbances were a fall risk during seclusion. According to the nurses' experiences (paper I), aggression constitutes a significant unsafe act that exposes nurses to safety incidents during seclusion and restraint. Patient aggression was also identified from the video observations (paper II).

5.3.2   Latent conditions

Teamwork

Challenges and difficulties in the teamwork between nurses and other healthcare professionals were regarded by the nurses (paper I) as a significant latent condition during seclusion and restraint. These difficulties in teamwork manifested as breakdowns in communication and in the delivery of information regarding the seclusion and restraint event and the patient's condition. Thus, nurses entering the seclusion and restraint event might not have all the valuable information regarding the patient's behaviour and physical condition. Furthermore, teamwork was impacted by issues in cooperation between healthcare professionals. This can lead to questioning decisions during the seclusion event, which hinders the safe execution of seclusion and restraint.

Environment and equipment design

The design and construction of the seclusion room contained latent conditions that exposed patients and nurses to safety incidents. According to the experiences of nurses (paper I, IV) and from the video observations (paper II), it was identified that the seclusion rooms were too small. They had a narrow doorway and a hard, slippery cement floor. These features in the seclusion room made nursing more challenging, as the environment forced nurses to work with poor ergonomics. Furthermore, nurses were forced to release the patient from a safe holding technique when escorting the patient inside the seclusion room due to the narrow entrance. The material of the floor was slippery, especially when wet, increasing the risk of falls for patients (paper I, IV) and nurses (paper I).

In addition to the environment, the equipment used by the healthcare professionals had undesirable aspects (paper I). The equipment used for mechanical restraints (bed, belts, straps) was heavy and difficult to carry. In addition, the personal equipment, including clothing, shoes, and personal alarm systems, were either old or unsuitable for seclusion and restraint events.

Guidelines and roles

Nurses perceived that the guidelines for seclusion and restraint were unclear (paper I). This means that nurses had not been provided sufficient guidance in using seclusion and restraint safely. Unclear guidelines can result in safety measures being overlooked. For example, in the exploration groups (paper IV), nurses reported that fall risk assessment was rarely conducted for secluded patients. Furthermore, the role of the nurses in seclusion and restraint was undefined, resulting in difficulties in taking appropriate actions and measures regarding their own safety and the safety of the patients.

Training

The training of nurses to use seclusion and restraint was experienced by nurses as inadequate (paper I). The inadequacy of the training is two-fold. First, new nurses working in psychiatric inpatient care units where seclusion and restraint were used had not received adequate initiation and training to use them. Second, nurses who already worked in units where seclusion and restraint were used had not received adequate training to update their skills, techniques, and practices. This resulted in them using outdated practices in seclusion and restraint events, which increased the risk of safety incidents for the healthcare professionals and patients.

Allocation of resources

According to nurses (paper I), especially the lack of nurses on each shift forced nurses to either postpone entering the seclusion room by waiting for assistance from neighbouring wards or to enter the seclusion room with too few staff members. The lack of nurses was significant during night shifts. If nurses cannot enter the seclusion and restraint events on time, the patient's condition might deteriorate, or nurses might not be able to intervene to prevent safety incidents. Furthermore, when nurses enter the seclusion room with too few staff members (papers I, and II), they expose themselves to safety incidents due to either aggression or difficulty applying restraints.

Patient physiological factors

Physiological factors of patients can increase the risk of safety incidents, specifically for falls. In paper IV, most significant risk factors for falls during seclusion were physiological. From the video observations (paper II) it was also identified that patients who had received medication during seclusion had more issues with their balance.

5.3.3   Risk factors for patient falls in seclusion

Risk factors for patient falls in seclusion were analysed in-depth in Paper IV. Falls provide an excellent example of how the risk of a specific safety incident includes both unsafe acts and latent conditions.

For falls in seclusion in paper IV, 88 risk factors were identified. Out of the risk factors, the specific actions were significant. These were typical day-to-day actions, such as getting out of bed or getting up from a seated position. Specific diagnoses increase the fall risk. The most significant diagnoses for fall risk were schizophrenia, bipolar disorder, and Alzheimer's. Furthermore, fall risk was increased due to the patient's physiological factors, such as mobility difficulties, and pre-existing physical illnesses, such as cardiovascular disease. In addition, the side-effects of medication significantly contributed to patient falls in seclusion. The risk factors contribute by themselves or in combination to a patient's fall during seclusion. The more risk factors exist, the higher the risk of falls.

Patient fall in seclusion requires that unsafe acts and latent conditions exist. These form together a critical path that can lead to a fall in seclusion. The critical path requires that the patient has a psychiatric or neurocognitive disorder, either/and psychological or physiological reason for the fall, a specific mechanism of fall, and that the fall prevention methods had failed. Fall prevention methods in seclusion were limited in the findings.

5.4   Summary of results

This study aimed to identify safety incidents and their contributing risk factors in seclusion and restraint events in psychiatric inpatient care by exploring existing nursing practices, safety incidents, and their contributing factors. A summary of these practices, safety incidents and factors are presented in Table 5, based on the study's research questions.

Table 5.   Summary of results.

Research question	Main findings
What is nursing practice at the sharp end (bedside) of seclusion and restraint in psychiatric inpatient care?	• Nurses maintain safety with restrictive interventions and by ensuring the safety of the environment • Nurses' provision of physical care focuses on the patient's basic needs and assessment of the patient's physical condition • Nurses' interaction and communication with patients is brief • The physical and organisational environment guides nurses' actions • Patient aggression is a challenge to the delivery of nursing interventions • Issues in teamwork between nurses hinder their work at the sharp end of seclusion and restraint
What safety incidents occur in seclusion and restraint in psychiatric inpatient care?	• Safety incidents in seclusion and restraint were self-harm, verbal and physical assaults, falls, medication errors, and elopement • Other safety incidents were ergonomic injuries, noise hazards, and contamination
What risk factors (unsafe acts and latent conditions) contribute to safety incidents in seclusion and restraint in psychiatric inpatient care?	• Unsafe acts consist of nurses' actions such as failure to recognise changes in patient condition, actions exposing themselves to incidents, failure to conduct or having difficulties in conducting required actions, attention failures, and violations • Patients' unsafe acts consist of psychological and behavioural disturbances, aggression, precarious movements, and exposure to contaminants • Latent conditions were the system factors: challenges in teamwork, issues in the environment and equipment, unclarity of guidelines and roles, lack of training, scarcity of resources, and patient's physiological factors

6   Discussion

6.1   Discussion of results

This study aimed to identify safety incidents and their contributing risk factors in seclusion and restraint events in psychiatric inpatient care. Existing seclusion and restraint practices and safety incidents were identified in the use of seclusion and restraint. The main results are discussed based on the three research questions.

Nursing practice at the sharp end of seclusion and restraint in psychiatric inpatient care

Nursing practice at the sharp end of seclusion comprises nursing interventions conducted in the seclusion room during seclusion and restraint. Patients who are in a restrictive environment during seclusion and restraint depend on nursing staff to meet their needs (Askew et al. 2019; Askew et al. 2020). The interventions help maintain safety and provide physical care, and involve interaction between nurses and patients.

In this study, the interaction between nurses and patients during seclusion and restraint was brief. The interaction occurred mainly during routine tasks during seclusion and restraint. Previous studies have confirmed this observation. They have reported that patients experience a lack of communication during seclusion and restraint (Brophy et al. 2016). Communication has also been experienced as lacking in warmth and empathy (Brophy et al. 2016; Kontio et al. 2012; Lanthén et al. 2015). Many existing guidelines for seclusion and mechanical restraint do not emphasise therapeutic interaction during seclusion and restraint (National Institute for Health and Care Excellence [NICE] 2017; Tasmanian Government 2021), despite therapeutic interaction being a central element of psychiatric nursing (Moreno-Poyato et al. 2016). It is known that seclusion and restraint cause harm to the therapeutic relationship between nurses and patients (Hawsawi et al. 2020). However, nurses can signal empathy and warmth during seclusion and restraint with verbal communication. Previous studies have indicated that psychiatric nurses have a higher self-reported level of empathy than nurses working in different settings (Ghaedi et al. 2020). Patients have also reported positive experiences regarding

nurses' communication if it was founded on the principles of a patient-centred approach (McCabe 2003). It seems that psychiatric nurses can provide interaction, which is empathetic to patients during seclusion and restraint. The challenge can be that the existing nursing practice guidelines for seclusion and restraint do not emphasise the importance of interaction.

According to the findings of this study, nursing interventions during seclusion and restraint were characterised by task orientation and were conducted briefly. Many interventions were conducted during one visit to the seclusion room. On average, nurses were present for less than 10% of the duration of seclusion and restraint, and the average duration of nurses' visits in seclusion was around 3 minutes. This is similar to the findings of a study by Tucker and Spear (2006), in which the average time for the nursing task was 3.1 minutes for nurses working in hospitals. Nurses have reported that they do not have sufficient time to do their work and that they do not have enough time to spend with their patients (Govasli & Solvoll 2020). This can be reflected in the reality of nursing, where work overload is high in most hospitals (Kowalczuk et al. 2020), including psychiatric inpatient care (Pascoal et al. 2021). In these circumstances, healthcare professionals lack the time to properly conduct nursing interventions. Thus, when considering appropriate nursing interventions during seclusion and restraint, the availability of resources must be considered.

In this study, many of the nursing interventions identified at the sharp end focused on the physical assessment and physical care of patients. However, from the video recording data, it was impossible to identify how nurses assessed the condition of patients. Psychiatric patients have many physical conditions, especially cardiovascular diseases (Chen et al. 2016) and diabetes (Lindekilde et al. 2021). Patients can also have physical conditions such as mobility difficulties (Kim et al. 2016), obesity, viral infections, musculoskeletal diseases, and others (De Hert et al. 2011). Secluded patients are likely to suffer from various medical and physical conditions. Assessing a patient's physical condition is also crucial from a safety perspective. This study identified significant fall risk factors related to patient physical condition issues. Therefore, assessing the physical condition of secluded and restrained patients is vital for delivering timely and appropriate nursing interventions and detecting patients with an increased risk of falls.

Based on the findings of this study, interventions to maintain safety during seclusion and restraint focused on control, such as using chemical and physical restraints, and interventions to ensure the safety of the environment. From the video observations, workarounds of safety rules were potentially identified when nurses were delivering interventions to meet patients' needs. The demand to provide patients with timely care has been identified in previous studies as one primary reason for workarounds conducted by nurses (Debono et al. 2013). The relationship

between maintaining safety and delivering nursing interventions is essential; previous studies have identified that in psychiatric care, safety is regarded as paramount (Kanerva et al. 2013; Pelto-Piri et al. 2019). Safety is also considered to be the primary justification for the use of seclusion and restraint (Haugom et al. 2019). To improve safety, nurses conduct safety planning and risk assessments (Higgings et al. 2016). Risk management considerations play a significant role in providing nursing care to patients. Therefore, in the context of seclusion and restraint, a critical assessment of the association between the level of control and safety is explicitly needed so that patient and staff safety can be ensured in these events with the least amount of control and the maximum amount of person-centred care.

Safety incidents occurring in seclusion and restraint in psychiatric inpatient care

In this study, we identified several different kinds of safety incidents in seclusion and restraint events. Previous studies have identified similar safety incidents more broadly in psychiatric inpatient care (Marcus et al. 2021; Mills et al. 2018; Nilsson et al. 2020). However, some safety incidents identified in this study have not been previously reported in studies regarding safety incidents in seclusion and restraint (Kersting et al. 2018).

Based on the findings of this study, falls do occur during seclusion and restraint. Previous studies on falls in psychiatric inpatient care have not studied falls in seclusion rooms. However, falls are prevalent in these settings, especially among acute psychotic (Knight & Coakley 2010) and geropsychiatric patients (Oepen et al. 2018)—seclusion and restraint are used predominantly for acutely psychotic and geropsychiatric patients. While most falls do not result in injury, the outcome can be severe injury or death (Blair & Gruman 2005; Turner et al. 2020). Falls have not been identified in previous studies because many studies on falls are based on incident reporting systems, which tend to underreport falls (Toyabe 2015). In this study the falls were identified through video observation. It is possible that relying on incident reporting, they would not have been identified. Therefore, more advanced surveillance technology needs to be adapted to gain a realistic understanding of the incidence of falls in seclusion. A multiple-camera surveillance system using machine learning has shown an accuracy of 89% in detecting different types of falls while differentiating them from non-fall daily activities such as bending and sitting in nursing homes (Shu & Shu 2021). Such technology can also be adopted in seclusion and psychiatric inpatient care to improve the detection of falls.

Assaults during seclusion and restraint were identified. Previous studies have also identified assaults and violence related to the use of seclusion and restraint

(Lancaster et al. 2008; Stubbs et al. 2009; Renwick et al. 2016; Wynn 2003). Assaults and violence are considered significant safety challenges in psychiatric inpatient care. In their systematic review, Weltens et al. (2021) concluded that most nurses working in psychiatric inpatient care are exposed to assaults. Seclusion and restraint are used in response to assaults, especially if a healthcare professional is injured during an assault (Staggs 2021), although seclusion and restraint are recommended as last-resort responses to assaults or threats of violence (Mayor 2005). The occurrence of assaults during seclusion and restraint proposes a challenge, as they are methods used in response to assaults in psychiatric inpatient care. One approach is to develop the practice of these measures needs to improve the safety of nurses. In an intervention study, changes to restraint practices were made based on root cause analysis. Changes were made to shift rosters to have skilled staff working on all shifts. Staff were reminded about and trained in the correct techniques as well as trained in de-escalation. The intervention resulted in a reduction of staff injuries during restraints (Poremski et al. 2019).

Patient aggression is not only targeted at nurses. The findings of this study indicated that self-harm occurs during seclusion and restraint. Previous studies have also linked self-harm and suicides with seclusion and mechanical restraint (Kersting et al. 2019) and have reported that seclusion and restraint are used in response to patient self-harm (Haugom et al. 2019). However, previous studies have not identified as clearly how patients are self-harming during seclusion and restraint. This study identified that despite seclusion and restraint environments are made safe, patients can still self-harm themselves. Furthermore, the appropriateness of seclusion and restraint for self-harming patients must be considered; patients should not be able to continue self-harm during seclusion. Therapeutic interventions are proposed for self-harming patients (Griffiths et al. 2021; Hosie & Dickens 2018; Nawaz et al. 2021). The seclusion and restraint environment provides the possibility to use these interventions for patients who are secluded or restrained due to self-harm. However, for reasons other than self-harm, secluded patients can conduct self-harm during seclusion and restraint because the significant antecedents to self-harm are difficult emotions, psychotic symptoms, and conflict with staff (James et al. 2012). These behaviors and experiences are prevalent in patients who are secluded and restrained. They are also significant risk factors for using seclusion and restraint (Chieze et al. 2021; Ye et al. 2019). In the video observation, such activity was recognised. Nevertheless, caring for and witnessing patients who self-harm can result in experiences of distress for nurses (Babič et al. 2020). After incidents of self-harm, support for nurses should be provided, including staff debriefings (Mangaoil et al. 2020). After serious self-harm events, other support, such as established second victim support programmes, should be considered (Edrees et al. 2016).

Risk factors contributing to safety incidents in seclusion and restraint in psychiatric inpatient care

This study divided the risk factors contributing to safety incidents in seclusion and restraint into unsafe acts and latent conditions. Unsafe acts were identified among nurses as well as patients during seclusion and restraint events. Latent conditions were elements in the system that contributed to safety incidents.

Patient actions were identified to form significant risk factors for safety incidents during seclusion in the video observations (paper II). They were also identified by psychiatric nurses (paper I) as risk factors for falls in paper IV. Many of the patient's unsafe acts, regarded as either aggressive or disruptive behaviour, can be viewed as results of their psychiatric disorders (Fritz et al. 2020; Koekkoek et al. 2006). Challenging patient behaviour can also stem from interpersonal factors, including difficulties in the therapeutic relationship (Koekkoek et al. 2006). Furthermore, patients have reported feeling angry, irritable, and frustrated when being secluded and restrained (Brophy et al. 2016; Ezeobele et al. 2014), which potentially results in further challenging behaviour. Using seclusion and restraint for patients with a history of traumatisation can be especially detrimental. However, a previous study reported that patients with a history of trauma are significantly more likely to be secluded and restrained (Hammer et al. 2011). To cope with challenging patient behaviour, therapeutic interaction during seclusion and restraint can reduce challenging behaviour, as it can provide comfort and compassion during seclusion and restraint (Hawsawi et al. 2020). This can also improve safety (Cutler et al. 2020; Kanerva et al. 2016).

This study identified that nurses acted against the safety rules and guidelines at times. They also had challenges in conducting appropriate actions during seclusion and restraint. Previous studies have reported that nurses act against established safety rules and guidelines if they are unfamiliar (Debono et al. 2013). In psychiatric inpatient care, nurses have also reported more negative attitudes towards safety than nurses working in other healthcare settings (Gallego et al. 2012; Kristensen et al. 2015). Different strategies and interventions have been generated to improve safety culture, most of which have reported significant improvements (Weaver et al. 2013). Interventions that focus on improving leadership, situation monitoring, mutual support, and communication have improved the safety culture in psychiatric inpatient care (Mahoney et al. 2012). Improving safety culture in psychiatric inpatient care can also potentially have a beneficial impact on safety in seclusion and restraint.

Based on the findings of this study, failures to recognise or intervene in unsafe situations during seclusion and restraint were identified. Nurses failed to identify changes in patient conditions and the environment. Previous studies have concluded that, for nurses to identify changes and deterioration in patient condition, they need

to be present and have sufficient time to observe and assess the patient (Kvande et al. 2017). The Finnish Mental Health Act (1116/1990) states that if a patient is secluded or mechanically restrained, a responsible nurse must be appointed to the patient, someone who ensures that they will receive adequate care during seclusion and mechanical restraint. However, what is considered adequate care and how patients are observed during seclusion and restraint is unknown. Reasons for missed observation have included increased workload and frequent interruptions in nurses' work (Tucker & Spear 2006). These can prevent nurses from identifying patient condition changes (Massey et al. 2017). Solving these issues might require legislative changes, as the current Finnish Mental Health Act does not require constant observation for secluded and restrained patients. In the United Kingdom Mental Health Act 1983: Code of Practice (Department of Health 2015), more profound requirements are made regarding observation during seclusion. It states that a skilled professional should be available within sight and sound of seclusion. A sedated patient requires constant observation during seclusion. A record of patient behaviour should be made every 15 minutes. The record's content should provide information on the patient's behaviour, appearance, mood, level of awareness, and any information on decreased health condition. Similar changes to the Finnish Mental Health Act could improve practice and patient safety during seclusion and restraint.

This study found issues and a lack of training for nurses regarding seclusion and restraint. Previous studies have found a disparity in training regarding restraints in psychiatric inpatient care. Not all nurses have the opportunity to receive training before being involved in seclusion and restraint events, and not all nurses who have received training have updated their skills (Stewart et al. 2009). Safety training and education for nurses is regarded by nurses as fundamental for improving safety (Bedgood & Mellot 2021). However, there is currently a lack of emphasis on patient safety in the nursing curriculum (Creswell et al. 2013; Steven et al. 2013; Tella et al. 2014). The existing nursing curriculums should be developed to include more patient and occupational safety education. Furthermore, a significant number of nurses working in clinical settings have insufficient safety knowledge and competence (Vaismoradi et al. 2020). They require education on the principles of patient- and occupational safety and clinical training on the specific safety issues in their working context.

According to the findings of this study, current seclusion and restraint environments and equipment are outdated, which can contribute to safety incidents. The materials and the physical design of the room resulted in challenges, especially for the occupational safety of nurses. Nurses regarded the existing seclusion rooms to be too small. British Columbia's Ministry of Health (2012) recommends that seclusion rooms should be at least 50 square feet (4.7 square meters) and that six

nurses should be able to fit in the room. However, the existing seclusion rooms in Finland are already, on average, over 10 square meters (Laukkanen et al. 2021). Perhaps the issue is not the size of the room itself, but the width of the entrance as well as the materials used. The flooring material recommendations are vinyl, never concrete (Ministry of Health 2012), because it is durable and easy to clean. However, in this study, the nurses reported that vinyl floors are slippery, especially when wet, and that some seclusion rooms still had hard concrete floors. Previous studies have not found significant differences in the fall rate between different hospital flooring materials (Warren & Hanger 2013). However, there is some evidence that compliant flooring, a material with shock absorbency, can reduce the number and severity of injuries (Drahota et al. 2022; Lachance et al. 2017; Mackey et al. 2019). When developing and constructing new seclusion rooms, the safety aspects of the design should be considered. This is especially relevant in Finland, as new psychiatric hospitals are being built, which will feature either seclusion rooms or sensory and comfort rooms.

Another important finding of this study was that patients' physiological factors are the most significant risk factors for falls during seclusion and restraint. These physiological factors stem from the multimorbidity of psychiatric patients and the polypharmacy associated with multimorbidity (Masnoon et al. 2017). Psychiatric patients have a high prevalence of medication for cardiovascular and other diseases, which increases the risk of falls (Chen et al. 2016). Furthermore, schizophrenia has significantly been associated with mobility issues (Kim et al. 2020), a significant risk factor for falls in psychiatric inpatients (Aso & Okamura 2019). The prevalence of physiological risk factors is higher among elderly patients (Wynaden et al. 2016). In addition to multimorbidity, psychiatric patients, especially those who are secluded and restrained, generally receive high doses of medication (psychotropic, rapid tranquilisation, antipsychotic, benzodiazepines, mood stabiliser), which increase the risk of falls (Brown et al. 2010; Seppälä et al. 2018). This calls for using routine fall risk assessment developed explicitly for the psychiatric inpatient care population (Shen et al. 2021). Furthermore, the existing medication prescription practices in psychiatric inpatient care should be considered and evaluated on their potential fall risk. Attempts should be made to improve prescription practices to reduce fall risk due to the side effects of medication (Michalowa et al. 2020).

6.2   Ethical considerations

This study followed central ethical principles: respect for autonomy, non-maleficence, beneficence, and justice (Beauchamp & Childress 2009 p. 99–280). This section describes how these central ethical principles were considered in this study.

Respect for autonomy

The autonomy of the study participants in all phases was respected by allowing them to make an informed decision to participate in the study (Beauchamp & Childress 2009 p. 99, 103–105). To ensure that the participants made informed decisions, sufficient, comprehensive, and understandable information was provided (Kadam 2017). The information was provided both orally and in writing. The participants were also encouraged to ask questions regarding the study and their role in it. Informed consent was acquired from patients (phase II) and nurses (phases I, II III).

In phase II, informed consent was acquired from patients who were secluded or restrained. These patients are considered vulnerable based on two perspectives. First, patients suffering from severe mental disorders are often defined as a vulnerable group (Gordon 2020; World Medical Association 2022). Second, a more refined perspective is that patients suffering from severe mental disorders are contextually vulnerable when they have a momentarily diminished capacity to make informed decisions (Bracken-Roche et al. 2016; Gordon 2020). In this study, the patients were considered contextually vulnerable during seclusion and restraint. This influenced how the consent procedure was designed.

Informed consent from psychiatric patients was acquired retrospectively because, during psychiatric inpatient care, patients who will be secluded or restrained cannot be identified beforehand. Therefore, it was not possible to acquire prospective informed consent. Furthermore, their ability to provide informed consent is diminished once a patient is secluded or restrained. In order to acquire informed consent from patients, it needed to be acquired after the seclusion or restraint event. A similar process has been described in previous studies (Bergk et al. 2011; Dib et al. 2021). In this study, informed consent was acquired from the patients during debriefing discussions of seclusion and restraint. Before this, a physician evaluated every patient's capacity to provide informed consent.

Informed consent was acquired from psychiatric nurses in all three phases. In phases I and III, informed consent was acquired before the focus groups and exploration groups. In phase II, it was not possible to identify those psychiatric nurses who would participate in seclusion and restraint events. For this reason, informed consent was acquired from all psychiatric nurses working on the hospital wards before the start of the data collection. This meant that, for psychiatric nurses, the consent process was prospective. To respect nurses' autonomy (Gorup 2020 p. 475–491), the psychiatric nurses had the opportunity to change their minds about participation, even after giving informed consent beforehand. If they decided to decline during the data collection or did not give informed consent before the data collection, to ensure they were not included in the video recordings of seclusion and restraint, they would write down the time and date when they were present in a

seclusion and restraint event. The sections of the video recordings where they were present were not included in the data.

The confidentiality of the participants in this study was valued and protected. This was important as the data was considered sensitive (Kaiser 2009). Data consisting of patients being secluded and restrained, the errors and mistakes of nurses, as well as nurses' perceptions of organisational failures can be regarded as sensitive. The confidentiality of the participants was preserved throughout the study.

In the video observations, protecting the confidentiality of the participants was essential. Therefore, the video observation data was watched and transcribed with computers that were only used for this purpose. The computers did not have any external software or internet connection. They were stored behind locked doors in a locked cabinet. No personal information (gender, age, ethnic background) was recorded when transcribing the video recordings. In the data analysis, transcriptions were used because researchers who did not watch the video recordings were included in the analysis. In reporting results, no personal information of patients or nurses was reported in the papers (II & III).

In phases I and III, the confidentiality of the nurses who participated in the focus groups and exploration groups was protected. In transcribing the data for analysis and reporting the results, pseudonyms to conceal the identity of the participants were used (Saunders et al. 2015). Other background characteristics were reported in these phases, as they provided crucial contextual information. These background characteristics included age, gender, professional background, work experience, and current position.

Beneficence and non-maleficence

The principle of non-maleficence in this study referred to the study itself not causing harm (Beauchamp & Childress 2009 p.149–155, 197–201; Haahr et al. 2014; Varkey 2021) as well as participants not experiencing any harm due to their participation. In this study, the participants were not exposed to any interventions. Harm in this study meant possible psychological distress caused by discussions of sensitive topics or the burden of participating in the study (Townsend et al. 2010). When discussing a sensitive topic, the participants were informed that they could quit the study at anytime. In addition, the facilitators had a psychiatric and mental health nursing background and were sensitive to any distress expressed by the participants. The discussions in the groups of nurses were confidential. Therefore, any expressions regarding failures or shortcomings of the organisation were not reported to the organisation to ensure that participants would not receive any negative consequences from participating in the study.

This study did not result in direct benefits to the participants. Instead, the principle of beneficence is considered in reflection of the study outcomes and their potential benefit to the larger society (Townsend et al. 2010; Varkey 2021). The findings from this study can be used to improve the safety of seclusion and restraint practices in psychiatric inpatient care.

Justice

The principle of justice in this study refers to the fairness and fair treatment of the study participants (Beauchamp & Childress 2009 p. 240–244; Orb et al. 2001), as well as to listening to those who are disadvantaged (Orb et al. 2001). Fairness was emphasised in the recruitment of participants. For example, in the collection of video recordings, the seclusion and restraint events were not cherry-picked. Instead, all participants had an equal chance of be included in the study during the data collection period. In phase III, the goal was to hear the patients' perspectives by recruiting individuals with an experience of seclusion and restraint to provide their expertise and perceptions regarding falls in seclusion. However, despite these efforts, such individuals could not be recruited.

6.3   Trustworthiness

The trustworthiness of this study was ensured using criteria by Lincoln and Guba (1985 p. 290): truth value, applicability, consistency, and neutrality. These criteria were selected because this study leans heavily on a qualitative approach (Lincoln & Guba 1985 p. 294).

Truth Value

Truth value is the adequate and credible representation of the findings based on the interpretations made (Lincon & Guba 1985 p. 294–296). To represent credible findings, the inquiry process needs to be credible (Lincoln & Guba 1985 p.301; Miles & Huberman 1994 p. 278–279).

In phase I (paper III), the credibility was strengthened by presenting the interpretations through prior theory (Miles & Huberman 1994 p. 278–279). In the data analysis, the Roper-Logan-Tierney Model of Nursing was used as the analytical framework in the deductive analysis. This meant that the depiction of nursing at the sharp end of seclusion and restraint is concurrent with nursing in other contexts.

In phase II (papers I and II), some limitations to credibility were present in the data analysis process. Due to the interpretative nature of the inductive analysis, the researchers' characteristics could have influenced the interpretations made

(Graneheim & Lundman 2004). The data were analysed by two researchers, both with experience in psychiatric inpatient care and the use of seclusion. To reduce potential bias, peer debriefing was used. The co-authors assessed the coding, categories, interpretations, and conclusions (Cook 2012; Lincoln & Guba 1985 p. 308–309). They all had experience in the context, seclusion, and restraint in psychiatric inpatient care, but their experiences and perspectives differed. Therefore, their valuable input was used to refine the coding, categories and conclusions.

In phase III (paper IV), credibility was sought using member checks to ensure that the interpretations made were coherent to the study participants (Lincoln & Guba 1985 p. 314–316; Miles & Huberman 1994 p. 278–279). A discussion session was organised where the credibility of the fault tree was assessed by the nurses who participated in the study. The nurses provided feedback regarding the logic and connections made in the fault tree. Changes to the fault tree were made based on the discussions. Presenting the findings to the participants of the other phases (I, II) would have strengthened the credibility. However, the findings were credible to the researchers who conducted the studies and had experience using seclusion and restraint in psychiatric inpatient care.

Applicability

Assessing the applicability of the study findings is to consider whether and how findings are transferable to other contexts (Lincoln & Guba 1985 p. 296–299; Noble & Smith 2015). The transferability of the findings should not be made by the researcher familiar with the studied context. Instead, the transferability of the findings is assessed by those who wish to apply the findings to a different context (Lincoln & Guba 1985 p. 316).

In this study, the transferability of findings was enhanced by detailed descriptions of the study settings in the papers (I–IV). In each of the papers, the legislation on the use of seclusion and restraint was described according to the Mental Health Act (1116/1990) because, as described in previous studies, seclusion and restraint practices differ between countries due to legislation and other factors (Janssen et al. 2008; Lepping et al. 2016). The study settings, including the types of wards included, were described in papers I–III. In phase I (paper I) and phase III (paper IV), the sample was described in detail. In papers II and III (phase II), the sample was not described in detail because the study participants were considered vulnerable, and the possibility to recognise the participants was minimised. Therefore, no details of the participants' background characteristics were provided.

The sampling methods and sample were chosen to gain rich information instead of attempting to reach generalisability through sampling (Vasileou et al. 2018). Purposive and convenience sampling methods were used to form a sample that

would provide rich information (Benoot et al. 2016). However, constraints of time and resources limited the possibility of gathering a more diverse sample, which would have improved the transferability of the findings to different contexts. The limitations to transferability are described in the limitations sections of the papers (I–IV).

Each of the individual studies and their respective reports (papers I–IV) provide conclusions on how the findings can be applied. Furthermore, implications for practice are presented in papers I, II, and III. In the implications for practice, the central findings of the studies that should be considered in other contexts are presented.

Consistency

Consistency is the dependability of findings, and it is assessed by whether the study process was consistent (Lincoln & Guba 1985 p. 298–299; Miles & Huberman 1994 p. 278) and whether quality checks were in place to reduce potential researcher bias (Miles & Huberman 1994 p. 278).

The role and status of the researchers were described in papers (I–III) to allow the reader to assess the potential biases emerging from the researchers' backgrounds (Patton 1999). The researchers had experience using seclusion and restraint in psychiatric inpatient care. However, they were not employed, nor did they have any professional relationship with the organisations where data were collected. This minimised the pressure to report findings favourable to a particular study organisation.

In papers I, II and III, the data analysis was conducted by researchers with experience in seclusion and restraint. Therefore, their experiences and perceptions might have influenced how the data was interpreted (Patton 1999). However, other members and co-authors reviewed the codes and categories generated in the analysis to deflect potential bias. Furthermore, the possibility of potential bias was explicitly stated in the papers (I–III). In paper IV, in the generation of the fault tree model, the conclusions were based on the existing, yet limited, data provided in the literature and by the nurses in the exploration group. Therefore, the fault tree construction relied heavily on the researchers' interpretations. To reduce bias in the interpretations, the nurses validated the fault tree in the exploration. Furthermore, sensitivity analysis was conducted to confirm that the conclusions made in the fault tree analysis were adequate despite the variation in the available literature (Marx & Slonim 2003).

Focus groups were conducted in phase I (paper I) by different researchers. In order to make them consistent, a detailed discussion guide was used (DeJonckheere & Vaughn 2019). In phase II (papers II and III), the video recordings were

transcribed into text format for data analysis. This process required three separate researchers who watched the video recordings and wrote down everything that occurred in the video recordings. To ensure that the transcriptions would be consistent for reliable data analysis, a guide was generated for what information from the video recordings was to be transcribed (Bailey 2008).

In papers II and III, the consistency of the analytical process was assessed using inter-rater reliability. Two coders coded a section of the data (10%). The extent to which they coded the data was similarly assessed using Cohen's Kappa and per cent agreement. Cohen's Kappa was deemed suitable as it considers the agreement by chance (Cohen 1960). The inter-rater reliability was estimated to be excellent in both studies (papers II and III), with Kappa values of .948 and .951, respectively.

The description of the study process, interpretations of the data, description of findings, and conclusions were reviewed by co-authors of the study reports (papers I–IV) in all the phases (I–III). This review by the co-authors strengthened the dependability.

Neutrality

Neutrality refers to confirmability, the degree to which others can confirm findings. It is assessed by considering the conditions of the inquiry (Lincoln & Guba 1985 p. 299–301; Miles & Huberman 1994 p. 278). To ensure the confirmability of the findings, the study methods used were explicitly described in the reports (papers I–IV).

The data collection process was described in detail in all the reports (I–IV) and followed by a description of how the data was transformed into the analytical process. A detailed description was required, especially in phase II (papers II and III), because the data was transformed from video into text. In phase III (paper IV), exploration group data and existing literature were used, which were condensed and transformed to a suitable format (condensed risk factors) for the fault tree analysis. The analytical process was described in detail in all phases (papers I–IV). The findings presented quotations from the focus groups (paper I). In papers II and III, depictions from the transcriptions were included in the results section to allow the reader to assess the interpretations made.

The data was made available to other researchers in paper IV in the Zenodo open data repository with respect to the European Commission's (2023) recommendations for open science in their research and innovation strategy (2020–2024). The data from the other papers (I–III) could not be made available because they are regarded as sensitive data (Kaiser 2009).

6.4   Recommendations

6.4.1   Recommendations to improve the safety of seclusion and restraint in psychiatric inpatient care

Recommendations are made in this chapter based on the synthesis with SCM (Reason 2008 p.101–102) to improve the safety of seclusion and restraint practices. The analogy of Swiss cheese is used (Figure 2). The holes in the slice of cheese are the unsafe acts and latent conditions identified in this study. The placement and order of the holes do not represent priority or importance. They were randomly assigned. The recommendations to improve safety target unsafe acts and latent conditions. These are depicted as pieces of cheese, which block the existing holes. The recommendations are suggestions for improving safety. They are not exhaustive. That is why the red symbol for safety incident exists in the figure 2.

      The slice of cheese in Figure 2 also includes other holes representing unsafe acts and latent conditions that potentially exist but were not identified in this study. Identifying safety incidents and contributing factors is not a one-off event; therefore, it is reasonable to expect that unknown unsafe acts and latent conditions exist (Lele 2012; Lindhout et al. 2020). The following recommendations are not expected to provide a complete solution to the unsafe acts and latent conditions. Instead, they are starting points for developing and improving safer seclusion and restraint practices in psychiatric inpatient care.
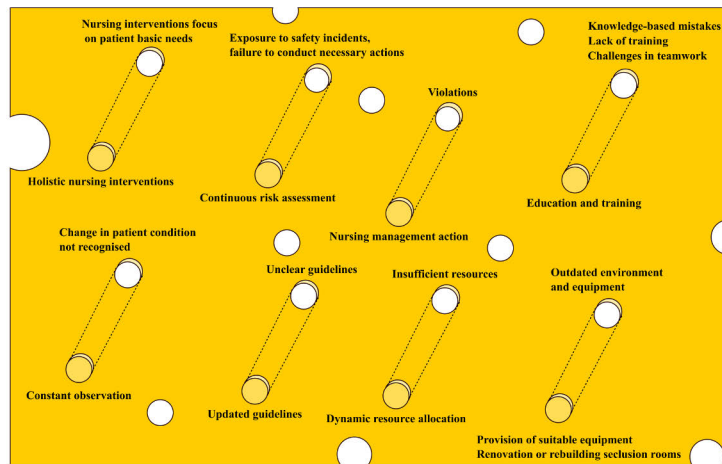
Figure 2. Recommendations to improve safety in seclusion and restraint in psychiatric inpatient care.

Clinical practice

To provide patients with care that meets their needs, it is recommended that nurses conduct a holistic needs assessment for secluded and restrained patients. This needs assessment should consider not only the physical but also the psychosocial needs of the patient. Based on the needs assessment, holistic nursing interventions are needed during seclusion and restraint.

Constant observation is recommended for secluded and restrained patients to recognise changes in the patient's physical condition and behaviour. This requires that a responsible nurse always has an unobstructed visual and voice connection during seclusion and restraint. This can be achieved either by being present in the

seclusion room or with technical applications. Recognising changes in patient condition also requires that the nurses are sufficiently trained to recognise both physical and psychological changes in the patient.

It is recommended that nurses continually assess the risk factors arising from their actions, the seclusion and restraint environment, patients' behaviour and actions, and the task at hand. Continuous risk assessment can reduce the probability that nurses expose themselves to safety incidents. Furthermore, it can reduce the number of attention failures and failures to conduct necessary actions. Based on the risk assessment, nurses can conduct the necessary actions to ensure safety in the clinical practice of seclusion and restraint.

Education and training

Education and training are recommended to minimise knowledge-based mistakes, challenges in teamwork and lack of orientation and continuing education of nurses. It is recommended that all new nurses working on psychiatric inpatient care wards receive the necessary education on seclusion and restraint techniques and techniques to prevent the escalation of violence and aggression. Nurses already working on such wards need to be provided with the opportunity to update their knowledge and techniques regarding the use of seclusion and restraint regularly.

Nursing management

Regarding safety violations in seclusion and restraint, it is recommended that nursing management intervene when violations are identified. Nursing managers must know the existing safety guidelines for seclusion and restraint. They also need to foster a just, no-blame culture where violations can be brought to the managers' attention by nurses who recognise them and commit them. The nursing managers must have a protocol to intervene when violations are reported. This protocol guides the nurse managers in the discussions with the nurses who violate the safety guidelines. Based on the discussions, nurse managers must foremost support the nurse responsible for violations by providing further training, other support, supervision or, if deemed necessary, disciplinary action.

Organisation

The design and equipment for seclusion and restraint were regarded as outdated. It is the organisation's responsibility to provide suitable equipment to nurses for the safe execution of seclusion and restraint. It is recommended that outdated equipment is replaced with new equipment. Organisations need to strongly consider providing

suitable clothing and footwear to nurses in psychiatric inpatient care. The environmental safety elements need to be considered when renovating or rebuilding seclusion rooms. This means that the location, technology, and materials must be evaluated based on their impact on patient and staff safety.

Dynamic resource allocation is recommended as one solution to respond to the challenges in allocating resources available for seclusion and restraint. It means that resources are allocated between the wards based on their needs. The difference to the existing practice is that hospitals should have nurses available to be quickly allocated to different wards. This means that, for each shift, not all nurses should be strictly allocated to specific wards; instead, they can be flexibly allocated where needed most, for example, on wards where seclusion and restraint are used.

It is recommended that the guidelines for seclusion and restraint are updated. In updating the guidelines, safety and care aspects must be emphasised. In developing these guidelines, the experiences and expertise of nurses and patients can be utilised. This will make the guidelines better suited to the needs of patients and nurses.

To improve safety, the focus is not only on the identified latent conditions, instead a non-specified change in the organisation's safety culture can improve safety without being specifically targeted. Change in organisation's safety culture can therefore be considered as a general recommendation to improve safety. However, just as with the other recommendations, it still leaves holes for the latent conditions and unsafe acts to surface. This is illustrated in figure 2. with the holes in the new slice of cheese.

The recommendations focused on identifying unsafe acts and latent conditions. In the system approach to safety, the focus is not on individual recommendations. Instead, it focuses on how all or as many as possible of these recommendations can be implemented. This system approach is essential because it is unreasonable to think that safety can be improved by, for example, updating clinical guidelines if no changes are made to the training of nurses, allocating available resources or improving the physical environment and equipment. Furthermore, the presented recommendations can improve safety only to a certain degree, as nurses can only do so much.

6.4.2   Recommendations for further research

The findings generated in this study provide recommendations for future research on safety in seclusion and restraint in psychiatric inpatient care.

- The probabilities of the risk factors identified in this study and the safety incidents occurring in seclusion and restraint events need to be assessed. This provides a basis for focusing limited resources on the most significant risk factors.

- Further research is needed to assess the association between organisational factors and safety incidents in seclusion and restraint events.

- More research is needed that utilises patients' unique perspectives, views, and expertise in identifying safety incidents and their risk factors in psychiatric inpatient care.

- Future research needs to explore the patient safety actions and interventions that nurses conduct in seclusion and restraint in psychiatric inpatient care.

7   Conclusions

This study strengthened the knowledge that seclusion and restraint in psychiatric inpatient care are peculiar in the context of safety. They are interventions used in psychiatric inpatient care as a last resort to uphold safety. At the same time, many safety incidents for patients and nurses occur during their use. Nurses have a central role in upholding safety during seclusion and restraint and in providing patients with care that meets their physical and psychosocial needs. However, nurses' actions can also contribute to safety incidents during seclusion and restraint. Many of the risk factors for safety incidents stem from system elements. When attempting to improve safety in seclusion and restraint practices in psychiatric inpatient care, it is important that focusing on individual safety incidents or risk factors might not be enough. There is a need for system-level changes. These changes can improve safety in seclusion and restraint events and, more broadly, in psychiatric inpatient care.

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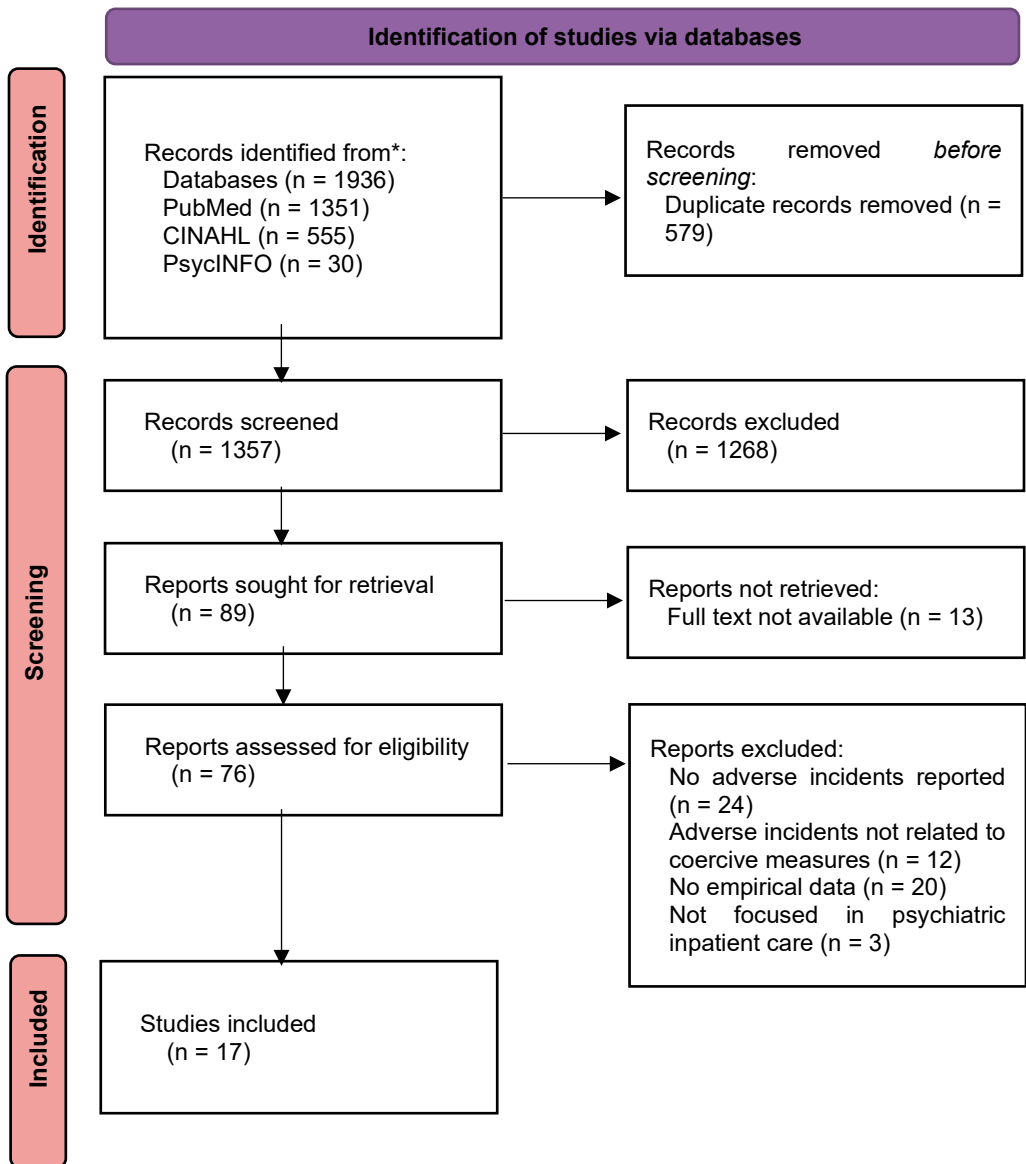
Appendices

APPENDIX 1

Appendix Table 1. Search strings used in electronic databases for the systematic literature search.

Date of search	Database	Search string	Results
28.2.2022	PUBMED	("psychiatric hospital*" OR "psychiatric care*" OR "psychiatric unit*" OR "psychiatric nursing*" OR "psychiatric ward*" OR "psychiatric service*" OR "psychiatric setting*" OR "mental health ward*" OR "mental health setting*" OR "mental health unit*" OR "psychiatric institutional care" OR "forensic psychiatr*" OR "forensic setting*" OR "Hospitals, Psychiatric"[Mesh] OR "Forensic Psychiatry"[Mesh] OR "Psychiatric Nursing"[Mesh]) AND (patient* [tw] OR "Patients"[Mesh] OR inpatient* OR "Inpatients"[Mesh] OR "psychiatric patient*" OR "mental health patient*" OR consumer* OR client* OR "service user*") AND ("behavior control*" OR "behaviour control*" OR "Behavior Control"[Mesh] OR coercion* OR "Coercion"[Mesh] OR "coercive measure*" OR containment* OR "containment method*" OR "control method*" OR "manual restraint*" OR "mechanical restraint*" OR "physical restraint*" OR "Restraint, Physical"[Mesh] OR restraint* OR "restrictive intervention*" OR isolation* OR seclusion* OR "Social Isolation"[Mesh] OR "Social Isolation*" OR "physical immobilisation*" OR "physical immobilization*" OR compulsion* OR "rapid tranquilization*" OR "rapid tranquilisation*" OR "rapid tranquillization*" OR "rapid tranquillisation*" OR "pro re nata" OR "forced injection*" OR "injections"[Mesh] OR injection* OR "time out*" OR time-out* OR timeout* OR "close observation*" OR prn OR "prn medication*" OR "social isolation*" OR "chemical restraint*" OR "intermittent observation*" OR "im medication*" OR PICU* OR "constant observation*" OR "chemical restraint*" OR "net bed*" OR net-bed* OR "intermittent observation*" OR "open area seclusion") AND ("risk of injury" OR "injury risk*" OR "risk for injury" OR wound* OR "Wounds and Injuries"[Mesh] OR "wounds	1351

		and injury" OR "Wounds and Injuries" OR "Self-Injurious Behavior" OR "adverse effects" [Subheading] OR "adverse effect*" OR "Long Term Adverse Effects"[Mesh] OR "adverse impact*" OR "adverse event*" OR "Safety incident*" OR harmful* OR harm OR harms* OR mistake* OR slip* OR laps* OR incident* OR injur* OR "psychological trauma" OR "Psychological Trauma"[Mesh] OR "Trauma and Stressor Related Disorders"[Mesh] OR "Stressor Related Disorders" OR "stressor related disorder" OR "trauma related disorder" OR "trauma related disorders" OR mortalit* OR "Mortality"[Mesh] OR "mortality" [Subheading] OR morbidit* OR "Morbidity"[Mesh] OR death* OR "Death"[Mesh] OR suicid* OR "Suicide"[Mesh] OR "Suicide, Attempted"[Mesh] OR "suicide attempt*" OR fatalit* OR diagnostic error* OR "Diagnostic Errors"[Mesh] OR "Risk"[Mesh] OR "Risk Factors"[Mesh] OR "risk factor*" OR "patient fall*" OR "Accidental Falls"[Mesh] OR "accidental fall*" OR "medication error*" OR "Medication Errors"[Mesh] OR "Adverse Health Care Event" OR "Risk for Trauma" OR "medication error*" OR "Medication Errors"[Mesh])	
28.2.2022	CINAHL	("psychiatric hospital*" OR "psychiatric care*" OR "psychiatric unit*" OR "psychiatric nursing*" OR "psychiatric ward*" OR "psychiatric service*" OR "psychiatric setting*" OR "mental health ward*" OR "mental health setting*" OR "mental health unit*" OR "psychiatric institutional care*" OR "forensic psychiatr*" OR "forensic setting*" OR MH "Hospitals, Psychiatric" OR MH "Forensic Psychiatry+" OR MH "Psychiatric Nursing+" OR sanatorium*) AND (patient* OR MH "Patients+" OR inpatient* OR MH "Inpatients" OR "psychiatric patient*" OR "mental health patient*" OR consumer* OR client* OR "service user*") AND ("behavior control*" OR "behaviour control*" OR coercion* OR MH "Coercion" OR "coercive measure*" OR containment* OR "containment method*" OR "control method*" OR "manual restraint*" OR "mechanical restraint*" OR "physical restraint*" OR restraint* OR "restrictive intervention*" OR isolation* OR seclusion* OR MH "Social Isolation+" OR "social isolation*" OR "physical immobilisation*" OR "physical immobilization*" OR compulsion* OR "rapid tranquilization*" OR "rapid tranquillisation*" OR "rapid tranquillization*" OR "rapid tranquilisation*" OR "pro re nata" OR "forced injection*" OR MH "Injections+" OR injection* OR "time out*" OR time-out* OR timeout* OR "close observation*" OR prn OR "prn medication*" OR "social isolation*" OR MH "Restraint, Chemical" OR "chemical restraint*" OR "intermittent observation*" OR "IM medication*" OR PICU* OR "constant observation*" OR "net bed*" OR netbed* OR net-bed* OR "open area seclusion*") AND ("risk of injur*" OR "risk for injur*" OR "injury risk*" OR wound* OR MH "Wounds and Injuries+" OR "Wounds and Injur*" OR MH "Self-Injurious Behavior" OR "Self-Injurious Behavior*" OR MH "Injuries, Self-Inflicted" OR "adverse effect*" OR "Long Term Adverse Effect*" OR "adverse impact*" OR "adverse event*" OR "serious adverse event*" OR "Safety incident*" OR harm* OR harmful* OR mistake* OR slip* OR laps* OR "patient harm" OR incident* OR injur* OR "psychological trauma" OR MH "Psychological Trauma" OR "Trauma and Stressor Related Disorder" OR MH "Mortality+" OR mortalit* OR MH "Morbidity+" OR morbidit* OR death* OR MH "Death+" OR MH "Suicide OR suicid* OR MH "Suicide, Attempted" OR "suicide attempt*" OR fatalit* OR "diagnostic error*" OR "Diagnostic Errors+" OR risk* OR MH "Risk Factors+" OR "patient fall*" MH "Accidental Falls" OR "Accidental Fall*" OR medication error*" OR MH "Medication Errors+" OR MH "Adverse Health Care Event+" OR "Adverse Health Care Event*" OR "Risk for Trauma*" OR "Medication Error*")	555

| 28.2.2022 | PSYCINFO | ("psychiatric hospital*" OR DE "Psychiatric Hospitals" OR "psychiatric care*" OR "psychiatric unit*" OR DE "Psychiatric Units" OR "psychiatric nursing*" OR "psychiatric ward*" OR "psychiatric service*" OR "psychiatric setting*" OR "mental health ward*" OR "mental health setting*" OR "mental health unit*" OR "psychiatric institutional care*" OR "forensic psychiatr*" OR "forensic setting*" OR DE "Forensic Psychiatry") AND (patient* OR DE "Patients" OR inpatient* OR "psychiatric patient*" OR "mental health patient*" OR consumer* OR client* OR "service user*") AND ("behavior control*" OR "behaviour control*" OR coercion* OR DE "Coercion" OR "coercive measure*" OR containment* OR "containment method*" OR "control method*" OR "manual restraint*" OR "mechanical restraint*" OR "physical restraint*" OR DE "Physical Restraint" OR restraint* OR "restrictive intervention*" OR isolation* OR seclusion* OR DE "Patient Seclusion" OR DE "Social Isolation" OR "social isolation*" OR "physical immobilisation*" OR "physical immobilization*" OR "physical immobilization*" OR "rapid tranquillisation*" OR "rapid tranquilization*" OR "rapid tranquillization*" OR "rapid tranquillization*" OR "pro re nata" OR "forced injection*" OR injection* OR "time out*" OR time-out* OR timeout* OR "close observation*" OR prn OR "prn medication*" OR "social isolation*" OR "chemical restraint*" OR "intermittent observation*" OR "IM medication*" OR PICU* OR "constant observation*" OR "net bed*" OR netbed* OR net-bed* OR "open area seclusion*") AND ("risk of injur*" OR "risk for injur*" OR "injury risk*" OR wound* OR DE "Wounds and Injur*" OR DE "Self-Inflicted Wounds" OR "self-inflicted wound*" OR DE "Self-Injurious Behavior" OR "Self-Injurious Behavior*" OR "adverse effect*" OR "Long Term Adverse Effect*" OR "adverse impact*" OR "adverse event*" OR "serious adverse event*" OR "Safety incident*" OR harm* OR harmful* OR mistake* OR slip* OR laps* OR "patient harm" OR incident* OR injur* OR "psychological trauma*" OR "Trauma and Stressor Related Disorder*" OR DE "Mortality Rate" OR mortalit* OR morbidit* OR DE "Morbidity" OR death* OR DE "Death and Dying" OR DE "Suicide" OR suicid* OR DE "Attempted Suicide" OR DE "Suicidality" OR suicidality* OR "suicide attempt*" OR fatalit* OR "diagnostic error*" OR risk* OR "risk factor*" OR "patient fall*" OR "Accidental Fall*" OR "medication error*" OR "Adverse Health Care Event*" OR "Risk for Trauma*") | 30 |

APPENDIX 2

Appendix Figure 1. Flow chart of the systematic literature search modified from Page et al. (2021).

APPENDIX 3

Appendix Table 2. Details of previous studies on safety incidents from coercive measures.

Author, year, country	Aim	Methods	Results
Bauer et al 2016. Denmark	To examine the efficacy of intramuscular pharmacological treatment of agitation in psychiatric population	Observational study. The effects of IM injections were assessed. Patients (n = 55) and injections (n = 72).	Side-effects reported included pain at injection site, headache, extra pyramidal symptoms (EPS), dizziness, nausea, sedation. Serious side-effects (n = 2) were dystonia after haloperidol.
Daniels et al. 2007. USA	To describe the case of a head-banging psychiatric patient	Case report of a patient (n = 1). Consultant responses (n = 4).	Violent thrashing of torso to bang head and forcible pull of limbs in mechanical restraint causing subdural hematomas.
Dickson & Pollanen. 2009. Canada	To contribute to understanding the pathophysiology of sudden death under physical restraint	Retrospective review of records (n = 3) of fatal pulmonary thromboembolism.	Death due to pulmonary thromboembolism caused immobility due to mechanical restraint. (three-to-five point, and waist belt).
Fujita et al. 1999. Japan	To report a cause of suspected death due to psychiatric care	A case report of a patient (n = 1).	Death due to pulmonary thromboembolism resulting from immobilisation due to physical restraint and excessive medication.
Funayama & Takata. 2020. Japan	To investigate whether physical restraint itself may cause certain medical conditions	Retrospective cohort study of patients in two groups physical restraint (n = 110), control (n = 1198).	Two aafety incidents were associated with mechanical restraint; deep vein thrombosis (9%, p = 0.01, OR 6) and aspiration pneumonia (15%, p = 0.01, OR 4.1). One participant also suffered burns due to rubbing of restraint straps.
Gildberg et al. 2015. Denmark	To investigate the reason for and characteristic of prolonged episodes of mechanical restraints in forensic psychiatry	Document analysis of medical records of prolonged mechanical restraints (n = 23).	During mechanical restraint, patients protested with violence towards staff. Total of 17 (74%) somatic complaints were identified during mechanical restraints.
Haj Salem et al. 2013. Tunisia	To describe an unusual case of smothering by a medical nebuliser of a psychiatric in-patient	A case report of a patient (n = 1).	A patient was found dead in a seclusion room due to suicide caused by ingesting a medical nebuliser.

Hirose et al. 2021. Japan	To test the hypothesis whether the use of mechanical restraint is associated with risk of pulmonary embolism	Retrospective nested case-control study of patients (N = 223,681), case controls (n = 660), cases (n = 132).	Mechanical restraint for duration of over 15 days was associated with pulmonary embolism (p = 0.02, OR 3.24).
Ishida et al. 2014. Japan	To compare the incidence of deep vein thrombosis in restrained patients who received UFH prophylaxis to those who did not	Chart review of patients who received UFH (n = 93) and those who did not (n = 117).	Sedation (p = 0.008, OR 3.78), presence of physical comorbidities (p = 0.006, OR 6.29) and a longer duration of restraint (p = 0.003, OR 1.22 per day) were significantly associated with increased deep vein thrombosis. The use of UFH did not reduce the incidence of deep vein thrombosis.
Lancaster et al. 2008. United Kingdom	To identify whether restraint position was associated with increased risk of non-fatal injury to either staff or patients	Retrospective review of violence and aggression database records of physical restraint (n = 680).	Injury rate in physical restraint was 17% for staff and 4% for patients. Main predictor for staff injury during restraint was assault from patient (p = <0.001, OR 4.22). For patient injuries the predictors were self-harm (p = 0.002, OR 4.5), substance abuse (p = 0.008, OR 5.46), and possession of a weapon p = 0.005, OR 4.25). Position of restraint was not associated with risk of injury to patients or staff.
Lee et al. 2019. Hong Kong	To report four cases of fatal pulmonary embolism in a psychiatric hospital	Case study. Autopsies (n = 4) of pulmonary embolism.	All four patients were mechanically restrained prior to their death.
Moyo & Robinson 2012. Australia	To describe patterns of injuries sustained by nurses during restraining of aggressive patients and to identify factors that can be modified to improve safety	Quantitative, within-method triangulation study of incident reports (n = 22) of nurse injuries, and questionnaire (n = 30).	Physical assault by patient caused majority of injuries (n = 21), one injury had unspecified cause. The injuries were sustained in the holding stage (55%), initiation stage (27%), and exist stage 18%). From questionnaire half (56%) of staff reported to be injured during restraint due to physical assault (n = 11), falls (n = 7), and due to unspecified cause (n = 2).
Nielssen et al. 1997. Australia	To review the practice of intravenous sedation of involuntary patients admitted to psychiatric hospitals	Medical record review of patients (n = 495) of which 132 (27%) were intravenously sedated.	49 (37%) suffered dystonic reactions, hypotension (n = 11, 8%), confusion or delirium (n = 7, 5%), phlebitis (n = 3, 2%).

Renwick et al. 2016. United Kingdom	To describe the precursors to incidents leading injury to staff	Retrospective review of incident reports (n = 552, injuries, n = 544) from a national database.	Injuries during physical restraint (n = 43, 25%) in hospitals with high security, (n = 104, 28%) without high security. 60 fractures (11% occurred during physical restraint. Injuries during physical restraint were attributed to patients assaulting, and resisting restraints.
Saint-Martin et al. 2006. France	To present a case of suicide during seclusion in psychiatric inpatient care	A case report of patient (n = 1).	A patient was found dead in the seclusion room. The cause of death was smothering due to ingestion of pellets of toilet paper.
Vedana et al. 2018. Brazil	To understand the experiences and perceptions of nursing staff about physical and mechanical restraint in psychiatric units	Qualitative descriptive study. Data collected with individual interviews (n = 29).	Participants experienced on average two restraint related accidents. Restraints were regarded to cause damage to patients and staff. Injuries to staff were considered frequent. Risk of injury is heightened when insufficient number of staff is involved.
Visaggio et al. 2018. USA	To determine if a restraint chair resulted in shorter duration and fewer patient and staff injuries than mechanical restraint and seclusion	Retrospective chart review of restraint cases (n = 743).	The proportion of injury were same for all types of restraints for patients. For staff the use of mechanical restraint were more likely to cause injury than restraint chair (p = 0.0048, OR 4.32) and seclusion (p = 0.0007, OR 8.1). Total injuries for staff in seclusion (n = 6, 2%), mechanical restraint (n = 9, 9%) and restraint chair (n = 13, 4%). Total injuries for patients in seclusion (n = 11, 4%), mechanical restraint (n = 3, 3%), and restraint chair (n = 5, 2%).

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