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COERCION, PERCEIVED CARE AND QUALITY OF LIFE AMONG PATIENTS IN PSYCHIATRIC HOSPITALS

by

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Department of Nursing Science, Faculty of Medicine, University of Turku, Finland Annales Universitatis Turkuenis Turku 2013

ABSTRACT

The goals of the study were to describe patients' perceptions of care after experiencing seclusion/ restraint and their quality of life. The goal was moreover to identify methodological challenges related to studies from the perspective of coerced patients. The study was conducted in three phases between September 2008 and April 2012. In the first phase, the instrument Secluded/ Restrained Patients' Perception of their Treatment (SR-PPT) was developed and validated in Japan in cooperation with a Finnish research group (n = 56). Additional data were collected over one year from secluded/restrained patients using the instrument (n = 90). In the second phase, data were collected during the discharge process (n = 264). In the third phase, data were collected from electronic databases. Methodological and ethical issues were reviewed (n = 32) using systematic review method.

Patients perceived that co-operation with the staff was poor; patients' opinions were not taken into account, treatment targets collated and treatment methods were seen in different ways. Patients also felt that their concerns were not well enough understood. However, patients received getting nurses' time. In particular, seclusion/restraint was considered unnecessary. The patients felt that they benefited from the isolation in treating their problems more than they needed it, even if the benefit was seen to be minor. Patients treated on forensic wards rated their treatment and care significantly lower than in general units. During hospitalization secluded/restrained patients evaluated their quality of life, however, better than did non-secluded/restrained patients. However, no conclusion is drawn to the effect that the better quality of life assessment is attributable to the seclusion/restraint because patients' treatment period after the isolation was long and because of many other factors, as rehabilitation, medication, diagnostic differences, and adaptation. According to the systematic mixed studies review variation between study designs was found to be a methodological challenge. This makes comparison of the results more difficult. A research ethical weakness is conceded as regards descriptions of the ethical review process (44 %) and informed consent (32 %).

It can be concluded that patients in psychiatric hospital care and having a voice as an equal expert require special attention to clinical nursing, decision-making and service planning. Patients and their family members will be consulted in plans of preventive and alternative methods for seclusion and restraint. The study supports the theory that in ethical decision-making situations account should be taken of medical indications, in addition to the patients' preferences, the effect of treatment on quality of life, and this depends on other factors. The connection between treatment decisions and a patient's quality of life should be evaluated more structurally in practice. Changing treatment culture towards patients' involvement will support daily life in nursing and service planning taking into account improvements in patients' quality of life.

Keywords: coercion, seclusion, restraint, patients' perception, quality of life, methodology, research ethics, user involvement, empowerment

Päivi Soininen

PAKKO, POTILAIDEN KOKEMA HOITO JA ELÄMÄNLAATU PSYKIATRISESSA SAIRAALASSA

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TIIVISTELMÄ

Tutkimuksen tavoitteena oli kuvata pakkoa kokeneiden potilaiden näkemystä hoidostaan sekä heidän elämänlaatuaan. Lisäksi tavoitteena oli tunnistaa metodologisia haasteita tutkimuksissa koskien potilaiden näkemystä pakosta psykiatriassa. Tutkimus tuotettiin kolmessa vaiheessa syyskuun 2008 ja huhtikuun 2012 välisenä aikana. Ensimmäisessä vaiheessa instrumentti Secluded/Restrained Patients' Perception of Their Treatment (SR-PPT) kehitettiin ja validoitiin Japanissa yhteistyössä suomalaisen tutkimusryhmän kanssa (n = 56). Lisäksi tutkimusaineisto kerättiin edellä mainitulla mittarilla vuoden aikana eristetyiltä/sidotuilta potilailta (n = 90). Toisessa vaiheessa aineisto kerättiin kotiutusvaiheessa olevilta potilaita (n = 264). Kolmannessa vaiheessa tutkimusaineisto kerättiin sähköisistä tietokannoista. Metodologiset ja eettiset aiheet tarkasteltiin systemaattisen kirjallisuuskatsauksen menetelmällä (n = 32).

Potilaat kokivat yhteistyön henkilöstön kanssa heikkona; potilaiden mielipiteitä ei otettu huomioon, hoidon tavoitteita ei asetettu yhdessä ja hoitokeinot nähtiin eri tavoin. Potilaiden mielestä heidän huoliaan ei ymmärretty riittävästi. Kuitenkin potilaat saivat hoitajien aikaa. Erityisesti eristäminen/ sitominen koettiin tarpeettomina. Potilaat kokivat hyötyvänsä eristämisestä ongelmiensa hoidossa enemmän kuin tarvitsevansa sitä, vaikka myös hyöty siitä nähtiin vähäisenä. Oikeuspsykiatrisilla osastoilla hoidetut potilaat arvioivat hoitonsa selkeästi alhaisemmaksi kuin muut. Sairaalahoidon aikana eristetyt/sidotut potilaat arvioivat elämänlaatunsa kuitenkin paremmaksi kuin ei-eristetyt/ sidotut potilaat. Kuitenkaan johtopäätöksenä ei voida todeta, että parempi elämänlaadun arvio olisi seurausta eristämisestä, koska potilaiden hoitoaika eristämiskokemuksen jälkeen oli pitkä ja koska muut tekijät, kuten kuntoutus, lääkitys, diagnostiikka, sopeutuminen, mahdollisesti vaikuttivat tuloksiin. Kirjallisuuskatsauksen pohjalta metodologisena haasteena havaittiin tutkimusasetelmien erilaisuus, mikä vaikeuttaa tutkimusten tulosten vertailua. Tutkimuseettisenä heikkoutena ilmeni puutteellinen kuvaus eettisestä ennakkoarvioinnista (44 %) ja informoidun suostumuksen käsittelystä (32 %).

Voidaan todeta, että psykiatrista sairaalahoitoa vaativan potilaan kohtaaminen ja kuuleminen tasa-arvoisena oman hoitonsa asiantuntijana vaatii erityistä huomiota niin kliinisessä hoitotyössä, päätöksenteossa kuin palveluiden suunnittelussa. Potilaiden ja omaisten tahtoa tulee kuulla kehitettäessä ennaltaehkäiseviä ja vaihtoehtoisia menetelmiä eristämiselle ja sitomiselle. Tutkimus tukee näkökulmaa, että eettisissä päätöksentekotilanteissa tulee tapauskohtaisesti huomioida lääketieteellisten indikaatioiden lisäksi potilaan näkemys, hoidon vaikutus elämänlaatuun ja tilanteeseen vaikuttavat muut tekijät. Hoitopäätösten yhteyttä potilaan elämänlaatuun tulee arvioida strukturoidummin käytännössä. Hoitokulttuurin muutosta kohti potilaan osallisuutta tulee tukea hoitotyön arjessa ja palveluiden suunnittelussa huomioiden yhteys elämänlaadun paranemiseen.

Asiasanat: pakko, eristäminen, sitominen, potilaan näkemys, elämänlaatu, metodologia, tutkimusetiikka, käyttäjänäkökulma, voimaannuttaminen

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ABBREVIATIONS

ANOVA Analysis of variance

CINALH Cumulative Index for Nursing and Allied Health Literature

DF Degrees of Freedom

EBN Evidenced Based Nursing

ECHR European Court of Human Rights

ETENE the National Advisory Board on Health Care Ethics

EU European Union

ICD-10 International Classification of Disease, 10th Revision

PAD Psychiatric Advanced Directives

PE Psychoeducation

PRISMA Preferred Reporting Items for Systematic Reviews and Meta-Analyses

QOL Quality of Life

Q-LES-Q SF Quality of Life Enjoyment and Satisfaction Questionnaire Short Form

(Danovitch & Endicott 2008)

RCT Randomized Controlled Trial

SAS Statistical Analysis Software

SD Standard Deviation

SPSS Statistical Package for the Social Sciences

S/R Seclusion and Restraint

SR-PPT Secluded and Restrained Patients' Perceptions of Their Treatment

TENK The National Advisory Board (Tutkimuseettinen neuvottelukunta)

TUKIJA National Committee on Medical Research Ethics

VAS Visual Analogue Scale

WHO World Health Organization

WMA World Medical Association

LIST OF ORIGINAL PUBLICATIONS

The dissertation is based on the following publications referred to in the text by the Roman numerals I-IV.

- I Noda T., Sugiyama N., Ito H., Soininen P., Putkonen H., Sailas E., Joffe G. 2012. Secluded/restrained patients' perceptions of their treatment: Validity and reliability of a new questionnaire. Psychiatry and Clinical Neurosciences 66, 397-404.
- II Soininen P., Välimäki M., Noda T., Puukka P., Korkeila J., Joffe G., Putkonen H. 2013. Secluded and restrained patients' perceptions of their treatment. International Journal of Mental Health Nursing 22 (1), 47 55.
- III Soininen P., Putkonen H., Joffe G., Korkeila J., Puukka P., Pitkänen A., Välimäki M. 2013. Does experienced seclusion or restraint affect psychiatric patients' subjective quality of life at discharge? International Journal of Mental Health Systems, 7 (28). Open Access, doi: 10.1186/1752-4458-7-28.
- IV Soininen P., Putkonen H., Joffe G., Korkeila J., Välimäki M. 2014. Methodological and ethical challenges in studying patients' perceptions of coercion: a systematic mixed studies review. Resubmitted.

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Introduction 1

1. INTRODUCTION

All patients have a right to high quality treatment, and the care must be arranged so that no person's human dignity is violated or privacy disrespected (Act on the Status and Rights of Patients 785/1992). It is the duty of nursing and medical staff and researchers to protect life, health, dignity, integrity, and the right to self-determination, privacy and the confidentiality of personal information (World Medical Association, WMA 2008, The National Advisory Board on Health Care Ethics, ETENE 2012). People's personal liberty, security, and physical integrity have to be respected in treatment services (United Nations 1948, Finnish Constitutional Act 731/1999). In psychiatric care patients have to be treated as far as is possible in mutual understanding respecting patients' self-determination and dignity. The care plan must be current in the treatment context (Mental Health Act 1423/2001). The definition of patient is a person who has been admitted to observation, referred for examination or treatment, or who uses health care services or is the object of them (Act on the Status and Rights of Patients 785/1992, Mental Health Act 1423/2001).

Coercion in psychiatric treatment still exists, and is legitimated (Mental Health Act 1116/1990). Coercion in the Finnish legislation is defined as involuntary admission to observation and treatment in psychiatric hospitals, treatment against a person's own will, and special limitations, for example, as regards forcible holding, isolation or seclusion, restraint or tying down, and limitations of contacts (Mental Health Act 1423/2001, section 22). The main reasons for coercion use are patient's agitation and aggression, violence toward staff or other patients, visitors or property (Morrison & Leehan 1996, El-Badri & Mellsop 2002, Kaltiala-Heino et al. 2003, Keski-Valkama et al. 2010a, Larue et al 2010). Coercion in psychiatric treatment is ethically challenging due to deep-rooted traditions and attitudes (Huckshorn 2006). In Finland major effort has been invested in reducing the use of coercion in psychiatric treatment, and the goal is to diminish the use of coercion by 40% by 2015 (Ministry of Social Affairs and Health 2009 and 2012, National Institute for Health and Welfare 2011). This is in line with international ethical guidelines (American Psychiatry Association 2003, Australian Government 2008, Janssen et al. 2008, Vruwink et al. 2012). According to the National Advisory Board on Social Welfare and Health Care Ethics there is still a need to develop treatment culture to be more humane, respectful, and cooperative. Any time protective or restrictive measures are undertaken, the possible harm of their use has to be considered (ETENE 2010).

Historically, people with mental disorders or their relatives have not been involved in decision—making in mental health services, and have been at risk of social exclusion and discrimination (World Health Organisation, WHO 2005c). Today there are programmes and efforts to equalize services and achieve full participation of people with any disabilities, and to enhance rehabilitation programmes so that every person has an opportunity to take part in designing and organizing services (United Nations UN 1993,

2 Introduction

WHO 2010). In Helsinki, in 2005 European countries announced the Mental Health Declaration for Europe to give a commitment to develop government policies to enhance mental health services. European development and implementation toward community-based mental health services needs service users and carers in planning services and inspecting mental health facilities (WHO 2005b, WHO 2008). Empowerment is the process of taking control of and responsibility for one's own life incorporating self-reliance, participation in decisions, dignity and respect, and belonging and contributing to the community (WHO 2010). In Finland ETENE (2012) highlights individuality and communality as cornerstones in ethical actions. Service users' expertise should be taken into account more in administration, in planning services and as experts in their own care (Ministry of Social Affairs and Health 2012).

Coerced patients' experiences of their treatment and perceived quality of life (Jonsen et al. 2006) are a central issue when promoting and providing comprehensive and effective mental health services and interventions (WHO 2008, ETENE 2010). Studies concerning patients' perceptions of coercion have been conducted since the 1970's, although most research has been published since 2000. In psychiatric research wide attention has been paid to investigating how disorders are associated with perceived quality of life (e.g. Ristner et al. 2003, Hogdson et al. 2007, Goppoldova et al. 2008, Hope et al. 2009, Pirkola et al. 2009). Studies have shown that people with mental disorders have poorer quality of life than general population (e.g. Gupta et al. 1998, Bengtsson-Tops & Hansson 1999, Tompenaars et al. 2007). In nursing practice nurses undertake many interventions to improve patients' quality of life. Interventions are related to treatment planning, security, activating and social interventions. (Pitkänen et al. 2011) However to the best of our knowledge no studies have been presented on how coercion is associated with quality of life.

The objective of nursing and medical research is to understand, develop and apply means of improving human health. Evidenced-based medicine aims to find the best treatment for patients (National Committee on Medical Research Ethics, TUKIJA 2013) and evidenced based nursing (EBN) aims to provide the highest quality and cost-efficient nursing care possible by utilizing and implementing research findings in practice (Burns & Grove 2007). The WMA (1964, 2008) developed the Declaration of Helsinki as a statement of ethical principles for medical and other research involving human beings. The most important principles in participating in research and giving informed consent are respect for the person, voluntarism, justice, trust and scientific integration (Dane 2011). As in treatment ethics, research ethics should promote respect for all people and protect their health and rights including those who cannot give consent or refuse and those susceptible to coercion (WMA 2008). In psychiatric research the competence of patients with severe mental disorders to consent to treatment and research have been questioned, and many studies have shown that patients with severe mental disorders in a stable state can fully participate in the informed consent process (Carpenter et al. 2000, Moser et al. 2002, Kaminsky et al. 2003, Appelbaum et al. 2006). More research is

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needed on the factors that influence the decision to participate in research among patients with mental disorders (Misra & Dunn 2010).

The aims of the present study were to describe coerced patients' perceptions of their overall care and quality of life and to identify the methodological challenges related to studies of coercion from the patients' point of view. Ethical decision-making theory by Jonsen et al. (2006) was the frame of reference in this study. According to the theory, in ethically controversial care situations patients' medical indications, patients' preferences, consequences for patients' quality of life, and contextual features should be taken into account on a case-by-case basis in treatment decisions. Medical indications to use coercion are determinate in legislation (Mental Health Act 1423/2001) and patients suffering from psychotic disorders, who are allowed to be treated by coercive measures. Patients should always benefit from their care and the treatment decisions should be based on treatment plans. In the present study patients' preferences were investigated by eliciting patients' perceptions of coercion. Their quality of life was also assessed. The study context was general psychiatric hospitals with acute, forensic and emergency units. This study is part of the Research and Development Project on Seclusion and Restraint in Psychiatric Hospitals in Finland and Japan (Sakura). Although Finland and Japan have cultural differences, both countries have used seclusion and restraint extensively and there use is quite similar (Sailas & Wahlbeck 2005, Tateno et al. 2009).

2. OVERVIEW OF THE LITERATURE

The overview of the literature presents a comprehensive picture of psychiatric services in Finland, a description of psychiatric patients treated in hospitals, psychiatric patients' rights and status in hospital care and patients' perceptions of coercive interventions, quality of life s well as methodological issues in nursing research measuring patients' perceptions of coercion.

2.1 Psychiatric services and patient status and rights in Finland

2.1.1 Psychiatric services and patients in Finnish psychiatric hospitals

The Health Care Act (1326/2010) and the Mental Health Act (1116/1990) govern the social and mental health services for people suffering from mental health disorders. Mental health services comprise services provided by the hospital districts, the health centers and social services of municipalities, and the services of the private and third sectors (National Institute for Health and Welfare 2013). The coordination task has been entrusted to the municipalities and services should be customer-oriented (Ministry of Social Affairs and Health 2012). In Finland in recent decades there has been a marked shift from psychiatric hospital care to outpatient clinics (Vieth 2009), yet the aim towards even less institutional psychiatric care has been suggested a reduction, at least 40 % by 2015. This goal means a reduction of psychiatric hospital beds from 4,600 to 3,000 (0.6/1,000 inhabitants), thereby meeting the European level (Tuori 2011, Ministry of Social Affairs and Health 2012, Eurostat 2013).

The Finnish municipalities are advised to draft programmes to develop social welfare and health care services as broader regional entities (Ministry of Social Affairs and Health 2012). For mental health more treatment should be established in primary care by deinstitutionalisation, which means more voluntary based care planned together with patients, families and other caregivers (European Commission 2005, Ministry of Social Affairs and Health 2012). People with mental health problems and those suffering from psychiatric disorders should be treated in outpatient clinics close to their families supporting normal daily living and hospitalisation should be as short as possible (Mental Health Act 1423/2001, WHO 2005a, Ministry of Social Affairs and Health 2009). Mental health services in Finland have improved, but ethical problems persist in providing services that meet the requirements of human rights, dignity, the right to self-determination, and equal and humane treatment. Among others there are problems in accessing treatment despite the high number of mental health professionals compared to the European level. This raises a question whether the problem is in organizing services, and thereby losing resources. (ETENE 2010)

The average duration of a treatment period in psychiatric hospitals has decreased by five days since 2000; in 2011 the average duration was 35 hospital days. Half (45 %)

of the mean treatment period in 2011 remained under 10 days and 74 % under 30 days. One percent of inpatients were treated in hospital for over one year (944 patients). Out of these 717 were forensic patients. The number of treatment periods in inpatient care decreased by 21 % in ten years. At the same time outpatient care increased by 17 %. (National Institute for Health and Welfare 2013)

Patients treated in Finnish psychiatric hospitals in 2011 were men and women in equal numbers. Men were mainly diagnosed with schizophrenia and women with depression. All together 159 000 people were treated in psychiatric specialized care. Most of them were treated in outpatient clinics, yet 14% of them also received hospital care (n = 21 622). The number of patients treated only in hospital care was 6 906 in 2011 (National Institute for Health and Welfare 2013). According to the Mental Health Act (1423/2001) a person can be involuntarily detained for observation and treatment in psychiatric hospital if certain criteria are met. Out of all inpatient days, 31 % (n = 8 376) were treated involuntary in 2011. The number of involuntary treatments decreased by 22 % since 2006 (National Institute of Health and Welfare 2013). Other details are presented in Table 1.

Table 1. Psychiatric patients and coercion in psychiatric hospitals in 2011

Psychiatric services	Number of patients	Percent %
Psychiatric care	159 621	
Outpatient care	152 715	95.6 %
Hospital care (total)	28 528	14.0 %
Hospital and outpatient care	21 622	13.5 %
Hospital care (only)	6 906	4.3 %
Coercion		
Involuntary treatment	8 376	31.0 %
Secluded	1 622	6.2 %
Restrained	766	2.9 %
Forced medicated by injection	570	2.2 %
Forcible holding	436	1.7 %

(National Institute of Health and Welfare 2013)

Wide variation in the volume of use of coercive methods exists among hospital districts in Finland and the reasons for this have been assumed to be local, organizational and administrative factors (Korkeila 2006, Tuohimäki 2007, National Institute for Health and Welfare 2013). The number of involuntary treated patients was highest in North Karelia (255 patients/100 000 inhabitants), while the number of involuntary treated patients in Finland as a whole was 155/100 000, and in HUS 143/100 000 (National Institute for Health and Welfare 2013). In the mental health and social sectors there has been discussion about how to treat or arrange services in cases of ethical dilemmas; e.g. when to restrict a person's self-determination and how to guarantee equal treatment (ETENE 2012).

2.1.2 Psychiatric patients' status and rights in mental health care

Psychiatric patients have the same rights and status as do all citizens according to Finnish legislation (Act on the Status and Rights of Patients 785/1992). According to legislation (Act on the Status and Rights of Patients 785/1992, Mental Health Act 1116/1990) patients have without discrimination a right to high quality care so that his/her dignity is not insulted and his/her religious conviction and privacy are respected. Patients must be treated with their agreement and if a patient is mentally unable to express his or her own will the relatives must be consulted (Act on the Status and Rights of Patients 785/1992, Mental Health Act 1116/1990).

Recommendations in the national Plan for Mental Health and Substance Abuse (Ministry of Social Affairs and Health 2009) and international recommendations, e.g. the Green Paper (European Commission 2005) guide authorities to promote mentally ill people's social inclusion, quality of life, fundamental rights and self-determination e.g. by drafting the patient's will for situations when the patient is unable to express it. Coercive methods used in psychiatric care constitute a risk of infringement of the rights of psychiatric patients (Muir-Cochrane et al. 2001, Meehan et al. 2004, Niveau 2004). Psychiatric patients' rights have been addressed in international recommendations over the years (United Nations 1991, WHO 1996, WHO 2003, The European Court of Human Rights ECHR 2012). Those recommendations highlight the patients' right to receive appropriate care for their health problems, equality of treatment, to be protected against harm and abuse, to be treated in the least restrictive environment, to receive medication only for medical reasons (not administered as a punishment), to adequate information and to express an opinion and to make complaints (Mayers et al. 2010). The ECHR judged that the Finnish Mental Health Act does not sufficiently protect individuals from arbitrary deprivation of liberty and security (Article 5) and noted the omission of an independent examination when involuntary treatment was ordered. The Court also estimated the fulfilment of human rights to protection of private life (Article 8); the decision on involuntary hospitalisation does not give automatic authorisation for other coerced treatments such as forced medication, and was a serious interference with patients' physical integrity (ECHR 283, 2012). This and other judgements drive changes to the Finnish legislation.

Patients' rights should be seen in care and treatment practices. Patient-centred care or person-based rehabilitation strategies have been shown to improve outcomes in severe mental illness and thereby to support the psychiatric services (Priebe et al. 2007, Drucker et al. 2011). Sullivan et al. (2004) investigated how patient-focused care associated with the use of seclusion with a pre and post-intervention design and found that there was no difference in numbers of seclusion but in the length of time in the seclusion room as well as in use of medication (Sullivan et al. 2004). People with severe mental illnesses can be involved in shared decision-making when cognitive impairments are considered (Carpenter et al. 2000, Palmer et al. 2004, Hamann et al. 2009, Duncan et al. 2010). Nevertheless there is a lack of evidence on the effectiveness of patients' participation and shared decision

making for better treatment outcomes and e.g. medication adherence (Mahone 2008, Georgieva et al. 2012). This may be due to persistent paternalism in mental health care (Hoyer et al. 2002). In any case patients' experiences of collaboration are promising and tell about changes in the treatment culture (Mahone 2008). Psychiatric advanced directives (PAD) and their effectiveness in crisis situations have been investigated and strong support found for its use in patients' crisis situations. PAD means that patients give advice on their treatment in writing (Swanson et al. 2003a, Srebnik & Russo 2007).

2.2 Coercion in psychiatric hospital care

Earlier studies on the topics were first searched for in January 2009 from databases (CINALH, MEDLINE and PubMed) and manually. The search terms used were mental* or psych* and seclus* or restraint* and ethics*. Searches were systematically run again in April 2012 and in November 2012 in the Ebsco CINALH, Ovid MEDLINE, PsychINFO databases and the Cochrane Library and the search included the time period 1976-2012. The search regarding QoL with seriously mentally ill patients was first conducted in January 2010 and updated in December 2012. The search terms and search history of Medline are described in Appendix 1.

2.2.1 Definition of coercion

Definition of coercion refers to force and compulsion, and is the practice of compelling a person to behave in an involuntary way, and can be physical or psychological (Webster's online dictionary 2013). The coercive methods on which statistics have been compiled in psychiatric care in Finland are seclusion, restraint, forced medication and physical restraint (National Institute of Mental Health and Welfare 2012). Further, according to the legislation other limitations on patients' self-determination are e.g. limitation of freedom of movement and limitations of contact (Mental Health Act 1423/2001). Seclusion is defined as isolation, placement and retention of an inpatient in a room with minimal furnishing (e.g. Sailas & Wahlbeck 2005, Hyde et al. 2009, Tateno et al. 2009, Bowers et al. 2011). Restraint may be mechanical or physical. Mechanical restraint refers to the use of belts, handcuffs and restricting the patient's movement (Sailas & Wahlbeck 2005), physical or manual restraint refers to manual holding of a physically resistive patient by a team of nurses (Ryan & Bowers 2006). Forced medication (or chemical restraint) refers using any medication (usually intramuscular) to control agitated states against the patient's will in case of an emergency or within involuntary treatment (Sailas & Wahlbeck 2005, Vruwink et al. 2012).

The use of coercive methods, seclusion, restraint, medication, special observation etc. varies across countries (Bowers et al. 2007, Raboch et al. 2010). Mechanical restraint is not in use in the United Kingdom. Although seclusion is used, it is not used on all wards (Bowers et al. 2007, Bowers et al. 2011). In the Netherlands, seclusion is used more often than mechanical restraint and it has been found that multiple seclusion rooms are often occupied (Bowers et al. 2007, Vruwink et al. 2012). In Finland, too, seclusion is used

more than mechanical restraint and regional variations have been reported (Korkeila et al. 2002). Raboch et al. (2010) investigated the use of coercive methods in ten Eastern European countries. Most of these countries used forced medication and the second most common was mechanical restraint. Seclusion was used in six countries out of ten (Raboch et al. 2010).

Coercion is also connected to legal, ethical and human rights questions (Kallert 2008, Sheehan 2009, Prinsen et al. 2009). Traditionally the justification of coercion in psychiatric treatment has been paternalistic. To defend the coercive treatment of patients with mental disorders there are arguments regarding societal interests to protect others, the patients' own health interests, and patient autonomy (Sjöstrand & Helgesson 2008). Involuntary treatment in psychiatric hospital limits patients' autonomy and selfdetermination and includes a feeling of coercion. Yet in involuntary hospital care there is a need to avoid using coercion and power against the patient's will. Yet the conflict between autonomy and beneficence/non-maleficence, human dignity, the experiences of patients and the effects of coercive measures persist. There are arguments that an appeal to respect autonomy and/or human dignity cannot be a sufficient reason to reject coercive measures and the need to use coercive measures has to be justified in the specific circumstances on each case. (O'Brien & Golding 2003, Prinsen & vanDelden 2009). All together, these ethical aspects can be used both to support and to reject a non-seclusion approach (Prinsen & vanDelden 2009). Coercion studies from patients' perspective showed that involuntariness is associated with feelings of being excluded from participation in the treatment (Kallert 2008).

2.2.2 Reducing the use of coercion in psychiatric care

Reducing the use of coercion is the aim in psychiatric care at national and international level (Bowers et al. 2011). Many programmes have been started e.g. to diminish the use of coercion, and service users are involved in these programmes in Finland (National Institute for Health and Welfare 2011), in the United States of America (American Psychiatry Association, APA 2003), in Australia (Australian Government 2008), in the Netherlands (Abma et al. 2005, Jansen et al. 2008, Vruwink et al. 2012), and in Japan, where in 2006 the Mental Health department launched a national project to minimize restraint and seclusion in emergency and acute psychiatric care units (National Institute of Mental Health 2006). Reducing programmes includes state-level support, state-level policy and regulations, leadership and culture, educating and integrating staff, assessment, treatment planning, documentation, management and early intervention, debriefing and guidance on restraint and seclusion (APA 2003, Huckshorn 2004, Smith et al. 2005, Gaskin et al. 2007). In the Netherlands the government provided grants to 34 Dutch psychiatric hospitals in 2006 and finally to 42 hospitals by 2009 to reduce seclusion numbers by 10% per year (Vruwink et al. 2012).

The statistics and use of methods in European countries varies across the countries. Every country has its own legislation, statistics that may be unpublished or published

in the local language have different definitions of the measures and services covered, which makes comparison difficult (Salize et al. 2002, Bowers et al. 2007, Tateno et al. 2009, Keski-Valkama et al. 2010 b), or registers are not found (Bowers et al. 2011). For example in the United Kingdom (UK), the rates of coercive interventions are not available so the use of these measures cannot be compared across different hospitals and partly therefore they do not have reducing programmes (Bowers et al. 2011). Yet at the organizational level rates can be compared and a successful decrease in numbers and length of seclusion and restraint has been achieved by interventions (Hellerstein et al. 2007). Regardless of efforts to reduce coercion, seclusion rates in some countries have risen. The reasons for this have presumably been that due to more admissions of severely ill patients' seclusion rates have increased and some associations have been found (Janssen et al. 2012).

Evidence of which reducing programme is most successful has been questioned mainly due to lack of experimental study designs (Sailas & Wahlbeck 2005, Gaskin et al. 2007, Stewart et al. 2010). Borckardt et al. (2011) conducted a randomized control study to examine the effects of the systematic implementation of behavioural interventions on the rate of seclusion and restraint in psychiatric hospitals and the rates were significantly reduced. Their implementation included trauma-informed care training, changes in ward rules and language, developing a therapeutic environment (physically) and involving patients in treatment planning (Borckardt et al. 2011). Some promising evidence has been found between nurses' therapeutic optimism and lower emotional exhaustion (burnout) and less likely use of seclusion in specific situations (Happell & Koehn 2011). Nevertheless, as long as professionals continue to view seclusion as a necessary intervention reducing its use is limited (Happell & Koehn 2009). However, one solution to motivate nurses to make changes has achieved good results when the reduction programme is developed together (Hyde et al. 2009). In the Netherlands after a reduction programme, professionals perceived that more and ethically sound care should be offered, but the reasons for seclusion did not change, however personell's attitudes changed more critically towards the measure (Mann-Poll et al. 2012). Dutch psychiatric hospitals succeeded in reducing the use of seclusion but instead the use of involuntary medication increased, which they assumed to be a consequence of better registration, an effect of changes in the legislation or then reducing seclusion led to an increase in involuntary treatment (Vruwink et al. 2012).

Alternative approaches are needed to reduce the reliance on seclusion and to change seclusion and restraint practices (Happell & Koehn 2009). Alternatives that reduce agitation and aggressive behaviour have been instrumental to reducing medication, working with the patients to find solutions and partnerships with family members (Larue et al. 2010). Time out has been investigated as an alternative to seclusion in UK in 31 hospitals and it was found that it could be used in similar situations for similar patients as an alternative (Bowers et al. 2011). Time out means asking patients to stay in a room, mainly in their bedroom, until they have calmed down (Sailas & Wahlbeck 2005, Bowers

et al. 2011). The other alternative found to the use of seclusion and restraint has been to reduce the use of these measures by introducing a comfort room, meaning a room with comfort furniture, soothing colours, quiet music and other sensory aids (Cummings et al. 2010). There are suggestions for reducing seclusion by strong leadership, a review committee on the use of seclusion and restraint, and analysing the incidence and use of post-incident debriefing (Scanlan 2010).

Staff's attitudes and perceptions affect the treatment culture and thereby the use of coercive methods (Meehan et al. 2004, Bowers et al. 2007, Mann-Poll et al. 2012). Seclusion and restraint creates a complex emotional dilemma for nurses, distress and unpleasant emotions (Moran et al. 2009) as well as anxiety and anger (Sequeira & Halsted 2004). An earlier study of Finnish psychiatric nurses' ethical perceptions of coercive methods showed that the majority of nurses did not perceive coercive methods as ethically problematic at all (Lind et al. 2004). Similar results were found in an international comparative study of staff's attitudes; Finnish personnel's attitude in a forensic setting was significantly more positive towards the use of coercive methods than in other countries (Bowers et al. 2007). Staff's and patients' perceptions of seclusion and restraint differed markedly; staff believed seclusion was necessary for promoting the well-being of the patients, a therapeutic practice to calm patients down (Meehan et al. 2004, Happell & Harrow 2010). Patients perceived seclusion and restraint as punitive, as staff exerting power and control, and patients demanded more explanations for why seclusion and restraint was implemented (Meehan et al. 2004, Mayers et al. 2010). Differences in staff and patients' perceptions of treatment exist regarding treatment goals, options and increasing compliance and trust (Outlaw et al. 1994). A large British attitude study showed that the most approved practices were intermittent observation, time out and medication as needed in the patient group (Whittington et al. 2009).

2.2.3 Patients' perceptions of coercion

Patients' experience of seclusion has been studied since the 1970's (Wadeson et al. 1976, Binder et al. 1983, Soliday et al. 1985, Hamill et al. 1989, Mann et al. 1993) and interest in the theme increased after 2000 (Meehan et al. 2000, Hoekstra et al. 2004, Holmes et al. 2004, Meehan et al. 2004, Sorgaard et al. 2004, Wynn et al. 2004, Chien et al. 2005, Stolker et al. 2006, Steinert et al. 2007, El-Badri et al. 2008, Keski-Valkama et al. 2010a, Kontio et al. 2012). Patients' involuntary treatment is accepted but coercive measures, such as forced medication, seclusion and restraint were regarded by patients as unnecessary (Katsakou & Priebe 2006, Priebe et al. 2009, Sibitz et al. 2011). Satisfaction studies have reported similar findings; patients were quite satisfied with inpatient care but expressed dissatisfaction towards coercion (Kuosmanen et al. 2006, Iversen et al. 2007). Nevertheless experiences of involuntary treatment and of coercive measures are likely to influence the total burden of being coerced (Kjellin & Wallsten 2010). Seclusion and restraint have often been associated with lifetime exposure to life-threatening events and patients are at risk of retraumatization and revictimatization (Frueh et al. 2005, Steinert

et al. 2007). Traumatic events in a patient's history seem to increase the likelihood of being subjected to seclusion and restraint (Steinert et al. 2007). Patients' experiences of coercive methods have been both negative and positive and patients have made some suggestions for practices.

Patients' negative perceptions of coercion were associated with a lack of information on the reason, behaviour and situation which led to the decision to seclude and restraint (Meehan et al. 2004, Sibitz et al. 2011, Kontio et al. 2012). While in seclusion patients had problems maintaining basic needs and a lack of meaningful activities (El-Badri et al. 2008, Keski-Valkama et al. 2010a, Kontio et al. 2012). Patients needed more communication and human presence while undergoing seclusion or restraint (Meehan et al. 2000, Chien et al. 2005, Mayers et al. 2010, Kontio et al. 2012). Coercive methods raised negative feelings such as anger, fear, loneliness, anxiety, hostility, sadness, misery, rejection, betrayal, guilt and embarrassment (Meehan et al. 2000, Holmes et al. 2004, Wynn 2004, El-Badri et al. 2008, Kontio et al. 2012). Patients felt powerless and that they were being subjected more to punishment than to treatment (Gallop et al. 1999, Meehan et al. 2004, El-Badri et al. 2008, Keski-Valkama et al. 2010a, Kontio et al. 2012). Sexually abused women perceived restraint as extremely unnecessary, terrifying, not being heard, believed, human (Gallop et al. 1999). Patients' negative feelings during coercive interventions are likely to affect the therapeutic relationship and patients' self-esteem and may remind them of previous abuse (El-Badri & Mellsop 2008).

Patients' positive perceptions of seclusion and restraint evoked feelings of safety and security, protection, trust, helpful and decreasing stimulation (Binder et al. 1983, Mann et al. 1993, Kennedy et al. 1994, Chien et al. 2005, Kuosmanen et al. 2007, Kontio et al. 2012). Telling the reasons for seclusion and restraint helped patients to understand the restrictions (Meehan et al. 2004, Chien et al. 2005, Kontio 2012). Physical restraint was felt to be therapeutic and protective (Chien et al. 2005), and mechanically restrained patients felt less fear than did secluded patients (Bergk et al. 2011). Caring behaviour and a calm manner on the part of the personnel and an explanation of what is happening as well as the use of the patient's name were positive experiences (Chien et al. 2005). Patients reported being well treated and having specific contact persons from among the staff on the wards (Wallsten et al. 2006). Keski-Valkama et al. (2010) found that patients mostly (82.8%) felt seclusion to be beneficial and gave reasons for this as learning to control one's own behaviour, a positive effect on their condition and their own privacy. A patient–friendly environment was reportedly helpful (Keski-Valkama et al. 2010a, Kontio et al. 2012).

Patients' suggestions for better nursing practices in earlier Finnish studies were external evaluator in the decision-making situation, up-to-date information of how long S/R would last and written agreements on alternative interventions (Keski-Valkama et al. 2010a, Kontio et al. 2012). Alternatives to seclusion such as constant observation, medication, a time-out programme, resting in own room with verbal de-escalation, activities and

opportunity for interaction (Meehan et al. 2000, Keski-Valkama et al. 2010a) were suggested. More interaction and more medication with those hallucinating were also suggested (Binder et al. 1983, Kennedy et al. 1994, Meehan et al. 2000, Meehan et al. 2004). Debriefing is needed to process feelings experienced, to provide psychological and emotional support, to accept the reason for seclusion, and to discuss treatment plans (Mann et al. 1993, Kennedy et al. 1994, Meehan et al. 2000, El-Badri & Mellsop 2008, Ryan & Happell 2009, Keski-Valkama et al. 2010a, Larue et al. 2010, Needham et al. 2010, Kontio et al. 2012). The importance of begin respected as unique, fellow human beings is stressed (Välimäki 1998, Chien et al. 2005). Preventing aggression earlier was called for (Wynn 2004). The environment on the wards needs improvements to isolation rooms and privacy. Patients' views of seclusion seem to be associated with the lack of privacy on the ward. Patients have less negative views of seclusion prior to multi-bed room. (Stolker et al. 2006)

Patients' preferences regarding coercive measures have been investigated in a few studies. Georgieva et al. (2012) found that patients' preferences were mainly defined by earlier experiences; patients having experienced seclusion prefer seclusion if they approved its duration and those without S/R experience or S/R patients with forced medication preferred forced medication. Veltkamp et al. (2008) investigated patients' preferences regarding seclusion and forced medication and the main finding was that an equal number of patients preferred seclusion and forced medication, yet men more often preferred seclusion than did women. Discussion of preferences and explanations of the reason for coercive measures seemed to help patients to accept the measure (Veltkamp et al. 2008, Kontio et al. 2010). Patients' perceived coercion was investigated in an intervention study where patients had an opportunity to take part in planning and decision-making but it was found that this did not reduce patients' coercion (Sorgaard 2004).

The main reasons for using coercive methods seem to be patients' agitation and aggression (Larue et al. 2010), violence towards staff, other patients, visitors or property (Morrison & Lehane 1996, El-Badri & Mellsop 2002, Kaltiala-Heino et al. 2003, Keski-Valkama et al. 2010a), deprivation (Keski-Valkama et al. 2010a), verbal aggression or unexplained reasons (Bowers et al. 2011). Reasons for seclusion named by patients were unclassified reasons, agitation or disorientation and actual violence (Keski-Valkama et al. 2010a). Usually seclusion occurs during the first or second week after admission to hospital (El-Badri & Mellsop 2002, Bowers et al. 2011). Patients secluded after the first week are usually secluded more often during their hospitalization (El-Badri & Mellsop 2002, Larue et al. 2010, Prinsloo & Noonan 2010). Involuntary inpatient stay has been found to be strongly associated with seclusion (Prinsloo & Noonan 2010). Patients with psychotic disorders, male gender, younger age and immigrants tended to be secluded more often than others, followed by patients with bipolar disorders and substance abuse disorders (Outlaw et al. 1994, El-Badri et al. 2002, Steinert et al. 2007, Prinsloo & Noonan 2010, Knutzen et al. 2011, Bowers et

al. 2011). The consequences of coercive intervention for treatment compliance should be considered; those who were restrained during their hospital stay showed lower compliance with outpatient care (Currier et al. 2011).

2.2.4 Psychiatric patients' quality of life

Quality of life (QoL) is one important outcome in psychiatric care (Eack & Newhill 2007, Pirkola et al. 2009, Saarni et al. 2010). It is recommended to pay greater attention to the consequences for QoL when making clinical decisions, especially in ethically complex situations (Jonsen et al. 2006). There is no evidence of how coercive measures are associated with patients' QoL. The QoL of people with mental disorders is a matter for concern in health care (European Commission 2005, WHO 2005) and in nursing care (International Council of Nurses, ICN 2002).

The definition of QoL refers to subjective, and objective well-being, social and emotional functioning and life satisfaction etc. including many descriptions under the same umbrella (Awad & Vorungati 2000, Bobes et al. 2005, Katchnig 2006). Katschnig (2006) has proposed a multi-dimensional definition of QoL, including things that can be beneficial for well-being 1) subjective satisfaction or happiness, 2) ability to function (physical, mental and social) and 3) availability of necessary resources (work, family, environment, property) (Katschnig 2006). Health related QoL (HRQoL) is a narrow point of view on QoL and is associated with mental health, general health perceptions, health care and concentrates more on functional capacity such as physical, social and role functioning (Saarni 2008, Ristner et al. 2011). Measuring HRQoL at population level can be feasible and can provide important and useful information regarding the well-being of the population (Bobes et al. 2005, Pirkola et al. 2009).

Subjective and objective estimates may differ a lot. For example, depressed people tend to perceive their well-being, social functioning, and living condition more negatively than the outside observer due to affective fallacy, and patients with schizophrenia, vice versa (Katschnig 2006, Saarni et al. 2010). Studies on QoL have sought an association between perceived QoL and disorders (e.g. Ristner et al. 2003, Hogdson et al. 2007, Goppoldova et al. 2008, Hope et al. 2009, Pirkola et al. 2009, Saarni et al. 2010, Ristner et al. 2011). To measure QoL in mental disorders both subjective and objective assessment (well-being, satisfaction, functioning and environmental assets) are needed. Psychopathological symptoms and life areas and changes over time are also worth considering (Katschnig 2006, Eack & Newhill 2007).

Despite numerous studies and instruments (Tengs & Wallace 2000, Bobes et al. 2005) it is challenging to measure individuals' QoL. QoL should be measured in a culturally sensitive and comprehensive way (Jenkins et al. 1990, Bullinger et al. 1993). The QoL instruments used in the studies are summarized in Table 2.

Table 2. Examples of QoL instruments used in studies among patients with mental disorders

Author	Instruments	Abbreviation	Year
Heinrich et al.	Quality of Life Scale	QLS	1984
Lehman	The Lehman Quality of Life Interview	QOLI	1988
EuroQol Group Health Policy	EuroQoL,	EQ-5D	1990
Ware & Sherbourne	Medical Outcomes Study-Short Form 36-Item Health Survey	SF-36	1992
Endicott	Quality of Life Enjoyment and Satisfaction Questionnaire	Q-LES-Q	1993
Sintonen	15 Dimension	15D	1994
WHOQOL – group	WHO Quality of Life Assessment Instrument	WHOQOL – 100	1994
Hickey et al.	Schedule for Evaluation of Individual	SEIQoL-DW	1996
Pukrop et al.	Quality of Life—Direct Weighting		2003
Giner et al.	Sevilla Quality of Life Questionnaire	SQLQ	1997
Oliver et al.	Lancashire Quality of Life Profile	Lqo3LP	1997
WHOQOL – group	WHO Quality of Life Assessment Instrument	WHOQOL – BREF	1998
De Jong & van Der Lubbe	Groningen Social Behaviour Questionnaire	100, GSBQ – 100	2001
Vorungati & Avad	Personal Evaluation of Transitions in Treatment	PETiT	2002
Auquier et al.	Quality of Life Questionnaire in Schizophrenia	S-QoL	2003
Danovitch & Endicott	Quality of Life Questionnaire-Short Form	Q-LES-Q SF	2008

Studies have shown that people with mental disorders have poorer QoL than general population (Gupta et al. 1998, Bengtsson-Tops & Hansson 1999, Ponizovsky et al. 2003, Tompenaars et al. 2007, Pirkola et al. 2009, Saarni et al. 2010). Murphy & Murphy (2006) found that people with mental illness had poorer QoL, especially regarding independence and social relationships, and had lower self-esteem and self-efficacy than non-clinically impaired people (Murphy & Murphy 2006). Studies have shown that patients with psychotic disorders estimate their QoL higher than those with depression in psychological domains (Hodgson et al 2007, Goppoldova et al. 2008, Galuppi et al. 2010, Saarni & Pirkola 2010) and schizophrenic patients reported greater life satisfaction than patients with major depression and bipolar disorders (Atkinson et al. 1997, Koivumaa-Honkanen et al. 1999). Tompenaars et al. (2007) investigated Dutch outpatients with a wide range of mental disorders and found severe problems in all aspects measuring social functioning (Tompenaars et al. 2007). Improved QoL of patients with schizophrenia has been found to be associated with reduced depression, anxiety (Norman et al. 2000, Fitzgerald et al. 2001, Malla et al. 2005, Galuppi et al. 2010), paranoid and distress symptoms and increased self-esteem and self-efficacy (Ristner et al. 2003). In particular anxiety disorders appear to be more severe and constituted a greater public health burden than previously thought (Pirkola et al. 2009, Saarni et al. 2010). Changes in QoL with schizoaffective/mood disorders seem to be associated with recovery and changes in depression, sensitivity, expressed emotion and task orienting (Ristner et al. 2003, Kao et al. 2011).

Association with demographic characteristics (age, gender, partnership, employment status, living etc.) and QoL seems to have some controversy (Tompenaars et al. 2005, Salokangas et al. 2006, Galuppi et al. 2010, Kao et al. 2011). Women, people living in a relationship, working, having higher education and younger people had better QoL (Tompenaars 2005), controversaly other studies have found that older patients' QoL is better than that of younger one's (e.g. Kao et al. 2011). In Finnish research of schizophrenia patients it was found that women with good psychosocial functioning, good physical health, and living arrangements in the community that offer support corresponding to the patient's psychosocial state predicted better QoL (Salokangas et al. 2006). Swanson (2008) found that the more number of hospital care the higher the QoL. Working seems to improve QoL due to findings that employed people perceive their health to be better and estimate their overall QoL more positively than do unemployed people (Sim et al. 2004, Rüesch et al. 2004, Tompenaars et al. 2005, Hodgson et al. 2007). A poor or nonexistent social network contributed to a lack of empowerment and to stigma, which resulted in depression and poor QoL (Sibitz et al. 2011). Longer duration of disease predicts better QoL and might due to adaptation and increased knowledge and greater insight on disease and treatment options (Galuppi et al. 2010, Kao et al. 2011).

Some studies have investigated the impact of interventions such as psychoeducation (PE) and group therapy on perceived QoL in patients diagnosed with bipolar disorder and found that PE improves patients' QoL (Michalak et al. 2005). Eack & Newhill (2007) reviewed QoL studies of patients with schizophrenia and found that psychiatric symptoms had a significant association with QoL in schizophrenia; to improve QoL it is worth paying attention to non-psychotic symptoms and signs, as well to secondary effects such as depression and anxiety. The literature suggests that for improving patients' QoL, especially those suffering schizophrenia, it is worth developing psychosocial approaches and helping people to build broader networks of support and to meet their basic needs (Eack & Newhill 2007). Better consideration of patients' symptoms in treatment, rehabilitation facilities and increased participation of families and communities (Galuppi et al. 2010), improvement of social network, stigma reduction and development of personal strength (empowerment) in the treatment significantly improve the quality of life of people with mental illness (Galuppi et al. 2010, Sibitz et al. 2011).

The outcomes of involuntary treatment have been shown that involuntarily admitted patients' condition improves and treatment could be justified as beneficial (Katsakou & Priebe 2006, Hope et al. 2009). Improvement and outcomes in hospital care predicts better functioning in every day living (Wallsten 2009). Patients treated in an inpatient setting have shown higher positive correlation with QoL than those living in the community (Eack & Newhill 2007). Severely mentally ill patients with poor compliance

with outpatient care has been studied and showed that involuntarily hospitalized patients' outpatient commitment predicted better QoL measured after one year (Swanson et al. 2003). However, studies have shown that early treatment and remission achieved in first episode psychosis and improvement in QoL predict better well-being later and are linked to symptomatic improvement (Lambert et al. 2007, Emsely et al. 2007, Schennach-Wolff et al. 2010).

2.3 Methodological challenges in studies on patients experiencing coercion

The Finnish Medical Research Act (488/1999) includes instructions on the protection and rights of research participants, ethical principles of informed consent and the responsibilities of ethics committees. The Finnish Advisory Board on Research Ethics (TENK) has issued recommendations for good scientific practice, and highlights the responsibility of researchers to follow modes of action endorsed by the research community and principles such as integrity, meticulousness and accuracy in conducting research (TENK 2013). The designs must be clearly described in the research protocol, and the research protocol must be submitted for consideration, comment and approval to a research committee before the study design can be approved (WMA 2008). As treatment ethics, so also research ethics should promote respect for all people and protect their health and rights, including those who cannot give consent or refuse (WMA 2008). Voluntarily based informed consent to participate in research is crucial when studying psychiatric patients (Roberts 2002, Israel & Hay 2006). Informed consent includes information, decisional capacity and voluntarism (Roberts 2002).

Methodologically the study design affects how the rest of the study protocol proceeds; recruitment, selection of participants, data collection and analyses (Burnes & Grove 2007). Experimental research tests the cause-effect hypotheses between independent and dependent variables under highly controlled conditions (Burns & Grove 2007, Dane 2011) and are quite rarely used in studies of psychiatric patients (Sailas & Fenton 2000, Murphy et al. 2007, Bergk et al. 2008). Experimental research uses randomization to select participants and to test hypothesis, e.g. interventions and measures are taken at different points in time (Gillis & Jackson 2002, Murphy 2005, Dane 2011).

In seclusion and restraint studies so far only one randomized controlled trial (RCT) has been conducted (Bergk et al. 2011). To find out the effectiveness of these controversial but widely used measures in psychiatric treatment, more randomized or controlled research is needed (Sailas & Fenton 2000, Murphy et al. 2007, Bergk et al. 2008). The great difficulty of carrying out controlled trials has been found when investigating people with challenging behaviour (Sailas & Fenton 2000). Bergk et al. (2008) state that in emergency situations informed consent can be requested after the intervention (S/R) when the patient is competent (hours or days after). The reason for this is patients' vulnerability in the situation. Informed consent does not affect the randomization but participation in the study; responding to the questionnaire or interviewing (Bergk et

al. 2008). Problems and risks in RCTs should be evaluated and study design should minimize risk. The study should not cause physical risk or loss of individualized care or non-therapeutic components, and psychological impact of research protocol should be assessed in advance, particularly if the research takes place without informed consent in an emergency setting (Morris & Nelson 2007).

Quasi-experimental studies are used to determine the effect of a treatment or outcome variables, but they lack the control of the design, sample, or setting used in the experimental study (Burns & Grove 2007). One type of quasi-experimental study is time-series design, where the dependent variable is measured before and after the intervention of independent variable (Dane 2011). Pure quasi-experimental time-series design with many measurement points including independent and dependent variables is not usual in psychiatric research (Burns & Grove 2007, Dane 2011). In psychiatric coercion studies pre and post measurements have been used (Keski-Valkama et al. 2010, Kjellin & Wallsten 2010).

In quantitative psychiatric coercion studies survey research is the common design (Soliday 1985, Hamill et al. 1989, Mann et al.1993, Kennedy et al.1994, Ray et al. 1996, Meehan et al. 2004, Frueh et al. 2005, Steinert et al. 2007, El-Badri et al. 2008, Whittington et al. 2009). The methods for administering surveys may include face-to-face interviews such as structured conversation used to complete the survey or mail or telephone interview (Polit & Beck 2006, Dane 2011). Quite often participants respond to questions posed by the researcher, and then the data are based on self-report (Polit & Beck 2006). Survey design demands a proper questionnaire (Dane 2011). Instruments used in studies aiming to ascertain psychiatric patients' perceptions of coercion such as seclusion and restraint, are listed in Table 3:

Developer	Name of the Instrument	Abbreviation	Year
Heyman	The Attitude to Seclusion Survey	ASS	1987
Hamill et al.	The Patient View-of-Seclusion	PVS	1989
Gardner et al.	McArthur Perceived Coercion Scale	MPCS	1993
Iversen	Coercion Ladder	CL	2002
Bowers et al.	The Attitudes to Containment Measures	ACMQ	2004
Berøk et al	Coercion Experienced Scale	CES	2010

Table 3. Instruments used in studies of coercion from the patients' point of view

Qualitative studies have been used to explore in-depth knowledge of the phenomena, also in coercion studies from the patients' point of view (Meehan et al. 2000, Hoekstra et al. 2004, Sibitz et al. 2011, Kontio et al. 2012). Methods of collecting data in qualitative studies on patients' perceptions of coercion were observation of art therapy sessions (Wadeson et al. 1976), unstructured interviews (Outlaw & Lowery 1994, Johnson 1998, Homes et al. 2004, Wynn 2004, Ryan & Happell 2009), semi-structured interview with or without questionnaires (Binder et al. 1983, Gallop et al. 1999, Meehan et al. 2000,

Hoekstra et al. 2004, Chien et al. 2005, Sibitz et al. 2011) or focus group interviews (Mayers et al. 2010, Kontio et al. 2012). Credibility (whether the findings hold true) in qualitative studies can be assessed by screening the sampling strategy, relevance of questions, characteristics of the subjects, exclusion criteria and data analyses, for example was more than one researcher interpreting the data, and were negative or discrepant results addressed or just ignored or whether the studies actually address questions under meaning (Polit & Beck 2006, Noyes et al. 2011). Other meaningful questions when estimating the credibility of the qualitative studies could be; how process and context are related to the intervention, and were the conclusions drawn from the results and did researcher explore the alternative results (Mohr 2004).

2.4 Summary of the literature

Policies and statements suggest that mental health services must develop more community-based services. The marked shift to deinstitutionalization continues. The aim by 2015 is a decrease of 1,000 in the number of hospital beds in Finland. More alternatives to outpatient facilities are demanded. At the same time service users and their families are coming to be partners in developing services offering valuable expertise and knowledge. This is a challenge to administrative and personnel to think and act in new ways. At the same time hospital services must develop to be more humane, respectful and achieve a cooperative treatment culture. Human rights, dignity, the right to self-determination, and equal and humane treatment are under debate in the improvement of inpatient care.

Coercive methods used in psychiatric care pose a risk of infringement of the rights of psychiatric patients. Many reduction programmes are on the stocks in many countries, including Finland and Japan. In Finland the use of seclusion, mechanical and physical restraints and forced medication need alternatives for situations when the patient's situation demands interventions. Alternative suggestions are time out, environmental changes such as a comfort room, more space to calm down and single rooms for patients. But the main suggestions involve interaction with and attitudes to patients, which can be seen in better communication, friendliness, calling patients by their names, listening to patients' concerns, giving reasons for interventions, taking patients' opinion into account in treatment planning, and debriefing.

Psychiatric patients' experiences of coercive methods have mainly been negative and more punitive than curative. Yet patients perceive restrictions as safe, secure and therapeutic. In ethical decision-making patients' perceptions should be taken into account and the association of intervention with subjective quality of life estimated. Patients' suggestions for better nursing practices were better communication, up-to-date information and using alternatives to coercive methods. Many studies have shown that patients with severe disorders can be participants in shared decision-making, or if they are temporarily incompetent, their relatives should be consulted. Psychiatric advanced directives have been shown to be effective methods of improving patients' involvement in their own treatment.

Studies of patients' perceptions of coercion are quite a new topic in psychiatric research. Both cross-sectional surveys and interviews have been used to describe and explore the issue. Experimental or quasi-experimental studies are missing. The core issue in research ethics in studying vulnerable populations such as coerced patients is to ensure sufficient information on the research, to ensure patients' understanding of the information to give consent and that such consent is given voluntarily.

3. AIMS OF THE STUDY

The overall aim of this study is to describe with particular reference to quality of life how patients feel about having been secluded/restrained while hospitalized The goals of this study are to describe patients' perceptions after experienced coercion and their quality of life. Methodological, ethical and clinical concerns from the secluded/restraint patients' perspective were also identified in previous research.

PHASE I

Aim: To develop and validate the instrument Secluded/Restrained Patients' Perceptions of their Treatment (SR-PPT) for measuring and describing S/R patients' perceptions of their treatment.

- 1. What is the internal consistency of the SR-PPT? (Paper I)
- 2. What is the validity of the SR-PPT? (Paper I)
- 3. What is the reliability of the instrument SR-PPT? (Paper I)
- 4. What are the S/R patients' perceptions of their care? (Paper II)
- 5. Are there any associations of background variables (age, gender, duration of S/R, diagnoses, choice of S/R (seclusion, restraint or both) with patients' perceptions of their care? (Paper II)

PHASE II

Aim: To describe and compare quality of life among patients who have or have not experienced S/R during their hospital stay (Paper III)

- 1. How did S/R patients assess their QoL compared to non-S/R patients' QoL at the end of the hospitalization?
- 2. Are there any associations between demographic and clinical variables and QoL?

PHASE III

Aim: To explore the methodological and ethical challenges related to previous studies of coercive measures in psychiatric hospital care from the patients' point of view (Paper IV)

- 1. What kind of methodological challenges exist in studies of S/R patients' perceptions?
- 2. What kind of research ethical challenges exist in studies of S/R patients' perceptions?

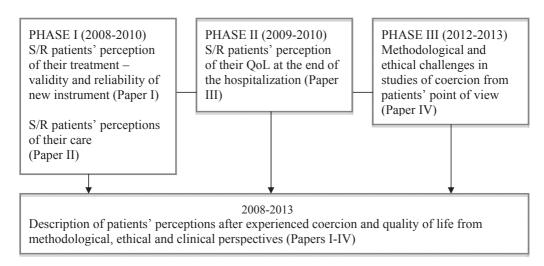


Figure 1. Study phases and overall purpose

4. METHODOLOGY

This study intended to describe patients' perceptions of experienced coercion and quality of life from methodological, ethical and clinical perspective. To obtain a wider picture of patients' points of view on S/R mixed methods were used (Johnson et al. 2007). The study was conducted in three phases between 2008 and 2012. The study was part of an S/R research and development project entitled Sakura in Japan and in Finland. The project started in 2008 with the same interest in both countries. The project had a joint research plan and produced comparative results in five sections. This study focused on patients' perspectives. The first part in Phase I was conducted in Japan and the rest in Finland.

4.1 Design, setting, population and sampling

Phase I was conducted in two parts. In the first part, a cross-sectional survey study was conducted to develop and test a new instrument. Data were collected on two emergency wards and one acute ward in two Japanese psychiatric hospitals in 2008. The population was secluded or restraint patients on the study wards during the study period. Inclusion criteria were patients whose age was 18-65, who had experienced seclusion or restraint and provided written informed consent as well as that of their family members (mandatory in Japan). Exclusion criteria were intravenous infusion due to somatic disease or their clinical condition estimated by the psychiatrist in charge. Out of 86 eligible patients 56 patients completed the questionnaire (65%). The reasons for non-participation were quick discharge, patients' condition, families not reached for informed consent, and physician unwilling to cooperate in the research. (Paper I).

In the second part a cross-sectional study was conducted to describe Finnish S/R patients' perceptions of their treatment in psychiatric hospitals. The study sample was formed in three hospitals and on seven wards in Finland: three acute psychiatric wards, two forensic wards, one difficult-to-treat ward and one emergency ward between January 2009 and July 2010 (expect the emergency ward in 2009). The population was found non-random sampling from all secluded and/or restraint patients on the study wards during the study period. Inclusion criteria were age 18-65, S/R experience, able to speak Finnish and informed signed consent. Exclusion criteria were delirium according to the International Classification of Diseases and Related Health Problems-10 (ICD-10, WHO) or for example mental retardation. Out of 149 eligible patients who were asked to participate in the study, 90 patients (60.4 %) completed the questionnaire and were included. (Paper II).

In **Phase II**, a cross-sectional study was conducted to describe patients' QoL in the end of hospital care. The study sample was formed in one Finnish psychiatric hospital on five acute wards during one year October 2009 – September 2010. The population

was collected through non-random sampling from all discharged patients aged 18-65. Inclusion criteria were age, discharged home (not to another ward or hospital) and fluent in Finnish and capable of providing informed consent. Exclusion criteria were discharge to another ward or hospital, age below 18 or over 65, not able to understand Finnish. Out of 370 patients asked to participate in the study one hundred refused (18 of these were S/R patients) and 270 patients (73 %) agreed to participate. Six questionnaires were excluded due to inadequate responses. Finally 264 questionnaires were analysed. (Paper III).

In **Phase III**, a systematic mixed studies review (Polit & Beck 2006, Plyue & Hang 2014) was conducted to explore the methodological and research ethical challenges related to studies investigating coercive measures such as seclusion or restraint from the patients' point of view. Peer-reviewed research reports in English, patients' (age 18-65 or adult) experience of coercion in psychiatric care, qualitative, quantitative, mixed method studies and RCTs were included. Reports with only children, adolescent or geriatric participants, patients with mental retardation, dementia or eating disorders, S/R due to somatic disorders and chemical restraint, were excluded. Review articles or studies based on patients' records were also excluded. Out of 846 articles found, 32 articles which fulfilled inclusion criteria were reviewed. (Paper IV).

4.2 Instruments

In **Phase I** in the first part the new instrument Secluded/Restrained Patients' Perceptions of their Treatment (SR-PPT) was developed to measure the overall treatment of patients who had experienced seclusion or restraint during their hospital stay. SR-PPT, a 17-item questionnaire using a visual analogue scale (VAS) of 100 mm was based on the literature (Nguyen et al. 1983, Soliday 1985, Hamill et al. 1989, Horvath et al. 1989, Tracey et al. 1989, Svensson et al. 1994, Kjellin et al. 1997, Meehan et al. 2004, Sorgaard 2004, Frueh et al. 2005, Katsakou et al. 2006, Wallsten et al. 2006). English and Japanese versions of the SR-PPT were prepared. Permission to use the exact wording of the items in the SR-PPT was obtained from all corresponding authors. The items in English were translated into Japanese by the Japanese researcher and back translated into English by two independent native speakers of English. Another native English speaking psychiatry worker checked the back translation. The original items in Japanese were translated into English by two independent native English speakers and then back translated into Japanese. The researcher then checked the back translation. To test the criterionrelated validity of the SR-PPT questionnaire, the other questionnaire Client Satisfaction Questionnaire-8 Japanese version CSQ-8J was used at the same time.

Based on factor analyses, 11 items were selected for the new instrument. Three of the questions were derived from the Working Alliance Inventory (Horvath & Greenberg 1989) and one from Kjellin et al. (1997). A Japanese research group based on the literature developed the remaining seven questions. The SR-PPT (11 items) used a VAS 100 mm line where the left end (0 mm) indicated totally disagrees and the right end (100

mm) totally agree (except for question 2 used in reverse order). The SR-PPT included 11 questions; nine of them were grouped as subscale named Cooperation with Staff and two of them were grouped as a subscale named Perception of SR. The internal consistency for the two subscales measured by Cronbach's alpha for Cooperation with Staff was 0.93 and for Perception of SR was 0.89 in Japan (Noda et al. 2012). (Paper I).

In the second part of Phase I the data were collected with the Finnish version of the SR-PPT. The Finnish research group checked the English version of the 17-item questionnaire and it was decided to use the 11-item version in light of the earlier results of the validation process in Japan. The English version was translated into Finnish using iterative translation and independent back translation according to standard procedures (Jones et al. 2001). Translation to Finnish was done by a member of the research group and back-translated into English by another member of research group. The Japanese researcher and the creator of the questionnaire checked the English version. The internal consistency for the two subscales measured by Cronbach's alpha were for Cooperation with Staff was 0.89 and for Perception of SR 0.77 (Paper II).

In Phase II patients' QoL was elicited at the end of the hospital stay using a structured self-report questionnaire, the Quality of Life and Satisfaction Questionnaire short form (Q-LES-Q SF; Danovitch & Endicott 2008). The instrument includes 16 items and each question is scored on a 5-point Likert scale (1= very poor, 5= very good degree of enjoyment or satisfaction). The 14 items are summed for the global QoL index, which measures patients' general activities and patients' subjective QoL during the past seven days; physical health, feelings, work, household duties, social relationship, family relationship, leisure activities, daily functioning, sexual drive, economic situation, living arrangements, mobility, vision and overall wellbeing. The two remaining items measure overall satisfaction and medication. The Q-LES-Q has been used with psychiatric patients and in clinical trials among patients with schizophrenia and related disorders (Bishop et al. 1999, Ristner et al. 2002, Kingsep et al. 2003, Ristner et al. 2003, Ristner et al. 2011). The Q-LES-Q SF is identical with the General Activities subscale of the longer version. The validity, reliability and feasibility of the Q-LES-Q SF Finnish version were tested earlier. The study on Finnish population showed high internal consistency (Cronbach's alpha 0.89) and this suggests its reliability, validity and feasibility for use with psychiatric patients (Pitkänen et al. 2012). (Paper III).

In **Phase III** published research reports were identified using computerized searches CINALH, (Cumulative Index of Nursing and Allied Health Literature, Ebsco) Ovid Medline (Medical Literature Analysis and Retrieval System Online, National Library of Medicine), PsychINFO (American Psychological Association) and Cochrane Library. Selected articles were analysed on the basis of the methodological literature (Polit & Beck 2006, Burns & Grove 2007, Dane 2011). To evaluate the research ethics in the selected studies, two questions based on the Declaration of Helsinki (2008) were asked. (Paper IV).

4.3 Data collection

In **Phase I** the data were first collected on the study wards by the researcher. The ward physician estimated the patients' condition. Before completing the survey eligible participants were informed of the study and then they signed the consent form. In accordance with the Japanese legislation involuntary patients' relatives consent was also asked. The investigator showed how to fill the visual analogue (VAS) questionnaires. Participants first practised filling in the measures and then completed the questionnaire independently. (Paper I).

In the second part of Phase I nursing staff working on the study wards elicited the patients' willingness to participate and evaluated the right moment to answer the questionnaire based on the patients' condition at least five days after the coercive measure. Patients received written and oral information on the study, completed the questionnaire independently, and returned it in a sealed envelope. (Paper II).

In **Phase II**, nursing staff was informed of the study protocol and delegated to give written and oral information about the survey and ask for consent when the decision on a patient's discharge was made. After signing the consent form patients were given the questionnaire, which they completed independently and returned it together with the signed consent form in a sealed envelope. (Paper III).

In **Phase III** the published research reports were identified using computerized searches of databases. The search terms were mental* or psychiatr* and seclus* and mechanical or physical restraint and hospital* or inpatients* and qualitative* or quantitative* or rct* or empir* or random*or stud*or research* or trial* and adult*. The databases used were CINAHL 1987-2012, Ovid Medline 1976- 2012, and PsychINFO 1982-2012 and Cochrane database. The assistance of a librarian was used in constructing the search strategies. (Paper IV).

4.4 Data analyses

In **Phase I** in the first part differences in characteristics between 86 eligible participants who did not complete the SR-PPT and those 56 respondents who completed the SR-PPT were examined. Student's t-test for continuous variables of normal distribution (Shapiro-Wilk test p > 0.1) and the Mann-Whitney U test for variables of non-normal distribution (Shapiro-Wilk test p < 0.1) were used. For categorical variables Chi-Square test was applied. Factor analysis (main factor method) was used to identify factors and Cronbach's alpha coefficient to examine the internal consistency of the subscales. To estimate the concurrent validity Pearson's correlation coefficient between the SR-PPT score and the CSQ-8J score was used. The correlation of the SR-PPT score with the external criteria was estimated using Pearson's correlation coefficient (for GAF and BPRS) and the partial correlation coefficient (for GAF improvement). Pearson's correlation coefficient for continuous variables of normal distribution, and Spearman's rank correlation coefficient for variables of non-normal distribution were used to test the

relationship between patient characteristics and patient burden induced by answering the SR-PPT. One-way ANOVA was applied to categorical variables. The significance level was set in the study along with two-tailed test. All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) version 15.0.

In the second part of Phase I, descriptive analyses (frequency, percentage, mean, standard deviation SD, and median) were conducted for the individual items of the SR-PPT. For each of the two subscales, mean scores were calculated. Then the items within each subscale were compared using repeated measures ANOVA. To examine the correlations between patients' ages, S/R duration, and score values for the SR-PPT subscales Pearson's or Spearman's correlation coefficients were used. ANOVA or independent samples t-test was used to test for differences between groups and associations among patients' background variables (gender, diagnoses, and S/R) and their perceptions of treatment and the two SR-PPT subscales. Non-parametric Wilcoxon and Kruskal–Wallis tests were used in the case of non-normal variables. A post-hoc Tukey's test was also used to examine pair wise differences among means. P-values 0.05 or less were interpreted as statistically significant. Statistical analyses were performed using SPSS version 17.0 and Statistical Analyses Software (SAS) version 9.1.

In **Phase II** individual items of the Q-LES-Q SF were tested using descriptive analyses (frequency, percentage, mean, SD, median). Then according to the instructions of the developer of the instrument the subscale item-scores 1-14 were summed (Danovitch & Endicott 2008). The normality of the distribution of variables was tested using the Shapiro-Wilk test. Possible differences between S/R patients and non-S/R patients regarding their background information were analysed using cross-tabulations with Chi Square tests. To estimate the statistical significance of differences between S/R patients and non-S/R patients in their evaluations of subjective QoL regarding the total subscale and individual items of the instrument independent samples t-test was used. Interaction between S/R or non-S/R and background variables was evaluated by two-way analysis of variance. Nonparametric methods were used when available to check some skewed distributions of the results of the statistical tests. P-values of 0.05 or less were regarded as statistically significant. Statistical analyses were performed using SPSS version 17.0 and SAS version 9.1. To replicate the findings in comparable samples a matched non-S/R patients sample was chosen for the S/R patients. The matching criteria were age, gender, ward and diagnosis. In case of several matching patients random selection was applied.

In **Phase III** data were extracted to qualitative and quantitative studies. Mixed method studies were classified on qualitative or quantitative based on which method was mainly reported in article. Data were synthesized according to certain criteria based on the literature. Information on authors, country and year were listed according to year of publication from older to more recent. Data on design, data collection methods, recruitment methods used, participants, sampling, ethical approval, patient informed consent, refusal or non-participation as well as time elapsing from coercive episode to

data collection were extracted to reduce the information so that core information was maintained and then the data were synthesized in specific categories. A synthesis was produced on the basis of the data extracted. Synthesis included information on the recruitment and data collection processes (who, when and how), research procedures from an ethical point of view, the representativeness of the participants (refusal and non-participation) and checking possible confounding factors related to study protocols.

4.5 Ethical considerations

An ethical approach guided the selection of the research topic and the process. Psychiatric patients' vulnerability (Gupta & Kharawala 2012) and capability to participate in decision-making on treatment solutions (Carpenter et al. 2000) may have been impaired due to their condition in acute situations in hospital care. Recent research showed that patients diagnosed with severe mental illness can participate in shared decision-making (Hamann et al. 2009). Seclusion and restraint are critical measures used in psychiatric hospital care that raise ethical questions about patients' human rights, self-determination and autonomy (Kontio et al. 2010). Psychiatric care is in line with general medical ethics and is required to produce beneficence, justice and autonomy and avoid harm (Beauchamp & Childress 2001). To study patients' S/R experiences after the measure and the end of their hospital care, the timing in asking informed consent was considered. Staff responsible for the study protocol (in Phases I and II) was informed in oral sessions and with written information and they had an opportunity to ask the researcher for advice.

National ethical guidelines, research ethical principles and the legislation on health care were followed throughout the study process (Medical Research Act 488/1999, the National Advisory Board on Research Ethics 2002, the Declaration of Helsinki 2011). Before the study phases were conducted ethical approval was obtained from the Ethics Committee of the Hospital District of Helsinki and Uusimaa and the Ethics Review Board of the National Center of Neurology and Psychiatry in Japan (Phase I). Authorities of the study organisations approved the permission for data collection. Participants were informed of the purpose of the study and the researchers were introduced in the leaflets given when consent was asked. Participants' consent was asked to use their completed questionnaires and to check background information from their records. Participation was voluntary and participants could withdraw whenever they wanted. Participants could not be identified later from the research reports. The researcher was responsible for archiving the data collected and had access to it. All data were handled in an appropriate way (Archive Act 831/1994, Personal Act 532/1999).

In **Phase I** the Ethics Review Board of the National Center of Neurology and Psychiatry approved the first part of the study protocol in Japan. In Japan informed consent for the research participation of an involuntarily admitted patient with limited comprehension, consent from the patients' relatives was obtained (Ito & Sederer 1999, Tateno et al. 2009). All eligible patients were given a comprehensive description of the study and informed that their participation or refusal would not affect their care. Patients were

informed that the staff would not see their responses and the completed questionnaire would be sealed in an envelope in their presence and that the data would be treated in confidence. Participants and their family members signed consent forms.

In the second part of Phase I the Ethics Committee of the Hospital District of Helsinki and Uusimaa in Finland approved the study and the authorities of the organisations concerned gave research permission. Patients' ability to participate was evaluated by the patients' nurses or physicians. After the complete description of the study had been given by the ward staff according to the instructions of the research group, the participants signed the consent forms. They were informed that participation or refusal would not affect their treatment. Participants responded to the questionnaire independently and the completed questionnaires were put in envelopes together with the consent forms. The sealed envelopes were sent to the researcher.

In **Phase II** the study was approved by the Ethics Committee of the Hospital District of Helsinki and Uusimaa and by the relevant institutional authorities. Patients on study wards who were to be discharged to their own homes were asked by the ward staff to participate according to the instructions of the researcher. After being given written and oral information on the research the patients signed the consent forms and responded to the questionnaires independently. The consent forms and the completed questionnaires were sent to the researcher in sealed envelopes.

In **Phase III** the ethical guidelines and recommendations for review articles were followed. To ensure reliability, another researcher inspected the extraction and synthesis.

5. RESULTS

The results are reported according to the research questions in three phases of the study. Phase I describes the S/R patients' perceptions of their overall treatment experience in two parts. The first part presents the validity and reliability of the new instrument SR-PPT (Paper I) and the second part describes the S/R patients' perceptions of their treatment (Paper II). Phase II describes S/R and non-S/R inpatients' QoL just before discharge (Paper III). The third part describes methodological and research ethical challenges of coercion studies from the perspective of adult inpatients (Paper IV).

5.1 Secluded/restraint patients' perception of their treatment (Phase I)

5.1.1 Validity and reliability of the SR-PPT instrument for measuring secluded and/or restrained patients' perception of their treatment (Paper I)

The number of eligible patients (aged 18-65 and having experienced S/R) was 110. Out of these nine patients had soon after the episode been discharged, five patients had no opportunity to participate due to physician's refusal or due to the physician's assessment of their condition (n = 10). Two patients refused and the families of 27 patients were not reached. Finally the SR-PPT questionnaire was tested on 56 patients. Patients' mean age was 42 years, 55 % were male. Most of the patients (69 %) were diagnosed with schizophrenia according to ICD-10 (WHO). Mean length of days in seclusion was 12 days and in restraint 5 days. Internal consistency was evaluated and the alpha coefficients of two subscales were calculated. Subscales Cooperation with Staff (nine items Cronbach's' alpha 0.93) and Perceptions of SR (two items, Cronbach's' alpha 0.88) showed sufficient internal consistency and concurrent validity. The total score was calculated by summing the means of the 11 items and it was 658.7 (min 0 – max 1100), subscale Cooperation with Staff (max. 900) was 559.3 and for Perceptions of SR (max. 200) was 99.4. Analysing the correlation together with the CSQ-J8 questionnaire tested validity and a strong high correlation was found between them. The burden of completing the SR-PPT was estimated and it was found that the questionnaire was easy to complete and the patients' condition did not deteriorate. After factor analysis the 11item SR-PPT was suggested as the final questionnaire.

5.1.2 Secluded and/or restrained patients' perceptions of their treatment (Paper II)

During the study period 307 patients were submitted to S/R and out of these 149 were eligible patients. Twenty-one refused to participate, 10 questionnaires were excluded because of written responses instead marking the line on VAS-scale or empty questionnaire. Eighteen patients responded more than once, so 90 returned questionnaires were eventually analysed (response rate 60.4 %). Out of 90 patients 61 % were men.

Patients' mean age was 36 years. Mean duration of S/R was 53 hours (from 75 minutes up to 16 days). Seclusion was administered to 45 % of patients, 26 % underwent restraint and 24 % experienced both coercive measures. 56 % responded in acute/emergency units, 12 % in forensic and 32 % in difficult-to-treat units. The main diagnosis was in the schizophrenia disorders group (60 %).

On the subscale Cooperation with Staff there were statistical differences between nine items (p = 0.001, n = 87, mean = 49.00, SD = 21.45). When screening the results of separate items, in the values of three items the mean was over the half point: item two asking if patients felt that staff ignored them (mean = 65.20, SD = 30.90 as a reversed result), item seven on getting enough time from staff (mean = 55.22, SD = 28.16) and item ten on working together with staff toward mutual goals (mean = 50.34, SD=29.68). They can be judged as more positive experiences. On the subscales Cooperation with Staff patients perceived that they were given enough time during their care (mean = 55.22, SD = 28.16), but did not receive understanding for their concerns (mean = 41.70, SD = 29.68), their opinions were not taken into account (mean 41.03, SD = 31.45) and they did not collaborate with staff towards mutual goals for their treatment (mean = 44.78, SD = 31.11).

The subscale Patients' Perceptions (n = 86) of Seclusion and/or Restraint showed the lowest numbers (mean = 37.90, SD = 30.60). On that subscale there were only two items. The difference between these two items measuring perceived necessity and benefit of S/R was statistically significant (p = 0.0029). Item five Patients' Experience of S/R Necessity was the lowest of the whole scale (mean = 33.01, SD = 33.45). Item six on patients receiving benefit of S/R showed higher scores (mean = 43.43, SD = 34.81). This result suggests that patients perceived S/R as unnecessary, yet received some benefit of these measures.

Of the background factors age, gender and hospital were associated with patients' perceptions of their treatment. Age showed negative correlations with two factors on the subscale Patients' Perceptions of S/R (r = -0.23, p = 0.034), meaning that the older the patient was, the more negative was the perception of S/R use. Gender seemed to correlate with age and the S/R necessity and benefit subscale (r = -0.40, p = 0.019). Women considered S/R unnecessary and were dissatisfied with the use of S/R more than were men. Women were more critical than men assessing their treatment on all items, but no statistical significances were found. Statistically significant differences among study hospitals were found. Out of three hospitals, the one treating forensic patients (mean = 10,) differed from the others (means = 39.8 and 46.2) statistically significant in total score of Perception of S/R (p = 0.0011). Also statistically significant among hospitals were item six of patients' perception of benefit of S/R (p = 0.002). In the forensic wards Patients' perceptions of the benefit of S/R were much lower (mean = 6.8) than in the others (mean = 45.7 and 54.5). Diagnosis and coercive method, seclusion, restraint, or both, showed no remarkable association with the responses.

5.2 Secluded/restrained patients' perceptions of their QoL at the end of the hospitalization (Paper III)

Out of 669 discharged patients, participation was asked from 370. Of these 100 refused. The response rate was 73 % (n = 270). Finally 264 questionnaires were analysed (six questionnaires excluded). Inpatients who were secluded or restrained (n = 36, 13.6 %) during their hospital care estimated their quality of life significantly higher (mean = 70.62, SD = 12.64, range 41 - 100) than non-secluded (n = 228, 82.4 %) respondents (mean = 55.29, SD = 19.22, range 5 - 100) on the subscale (t = 6.2, DF = 61.8, p < 0.001). Differences occurred in all items except living arrangements, vision and medication.

The mean age of all inpatients was 38 years. Women were representative in non-S/R patients (n = 135, 59 %) and men in the S/R group were men (n = 19, 51 %). Patients in the non-S/R group were most often (49 %) diagnosed with mood disorders (depression) according to ICD–10 (WHO) or the group other (18 %) than mood disorders or schizophrenia, schizotypal and delusional disorders. Patients in the S/R group were most often (54 %) diagnosed with schizophrenia, schizotypal and delusional disorders, secondly mood disorders (bipolar) (31 %) or others (14 %, n = 5). Patients hospitalized for the first time were 38 % (n = 77) of the non-S/R patients and 17 % (n = 6) of the S/R patients. Most inpatients were single or divorced: 64 % (n = 132) in the non-S/R group and 86 % (n = 30) in the S/R group. A minority of the respondents were working or studying in the non-S/R group (32 %, n = 66) and in the S/R group (26 %, n = 9). The livelihood was mainly obtained from a pension, rehabilitation support, sickness or maternity allowance. Almost half of the non-S/R inpatients were living with their families (49 %, n = 100) and most of the S/R inpatients were living alone, in sheltered accommodation or were homeless (69 %, n = 24).

The analyses of the association of the respondents' characteristics (age, gender, diagnosis, month of hospitalization, marital and socioeconomic status and living arrangements) with QoL ratings in the S/R and non-S/R patients showed that the S/R patients' ratings were significantly better than those of the non-S/R patients in almost all subgroups. Only single (p = 0.16), first time hospitalized patients (p = 0.13) showed no association, like did not the length of hospital care after the S/R episode.

5.3 Methodological challenges in the studies of patients' perception of coercion (Paper IV)

To evaluate the methodology of the studies on patients' perceptions of coercion, 32 peer-reviewed articles of which 14 were qualitative and 18 were quantitative were selected for a more detailed analysis. The studies were mainly conducted in the USA until 2000 and after that in European countries (the Netherlands, Finland, Norway, Sweden, Germany, Austria, and the United Kingdom), Canada, Hong Kong, New Zealand, South Africa and Australia. Over half (65 %) of the articles reviewed were published after 2000. Most studies used descriptive or explorative study designs (n = 27), then cross-sectional

surveys (n = 8), and comparative follow-up (n = 3), intervention, action research and randomized controlled trial one each. In the qualitative studies data collection was by observation (n = 1), unstructured interviews (n = 5), semi-structured interviews with questionnaires (n = 3) or with open-ended questions (n = 3) or focus group interviews (n = 2). In quantitative studies data were collected using self-report questionnaires (n = 13), semi-structured interviews with questionnaire (n = 1) and, structured interviews with questionnaire (n = 4). Sample sizes in the qualitative studies varied from four to 84 participants and in the quantitative studies from 17 to 1,361 participants. Sampling methods used were mainly convenience sampling, but in five studies randomization was used. Patients' refusal was mentioned in 40 % of the studies and non-participation explained in 15 %. In six studies numbers of individuals in every stage were reported and in one study a flow diagram was presented. The recruitment process was explained in 59 % of the studies. The time elapsing between experienced coercion and data collection was mentioned in 47 % of the studies (n = 15) and there was considerable variation (min. while restraint – max. one month), mean seven days after the episode.

Almost half (44 %) of the studies did not mention any ethical review process and 32 % did not report if informed consent was requested. Out of 24 studies where informed consent was requested, 43 % mentioned having obtained informed written consent. Mainly consent was asked by the researcher (59 %, n= 19) and by staff in five studies (16 %). Staff evaluation before the researcher asked for consent was mentioned in five studies (16 %). Voluntarily participants were contacted to researcher in four studies (12 %).

6. DISCUSSION

Our studies on S/R patients' perceptions of their treatment, comparison of S/R and non S/R inpatients QoL and the review of studies of inpatients' perceptions and experiences of coercion, especially S/R, yielded information to improve psychiatric patients' hospital care and involvement in their treatment. This study generates new knowledge which influences nursing research and practice.

6.1 Validity and reliability of the study

Validity and reliability are the most important criteria in evaluating quality of the study. Validity refers to the extent to which a variable measures the theoretical concept it is supposed to measure. It also refers to the extent to which the conclusions can be defended on the basis of logic (Dane 2011). Evaluating quantitative studies both internal (the extent to which the observed effects are true for people in a study and evaluation of the method used) and external validity (generalizability or applicability; the extent to which the effects in a study truly reflect what can be expected in a target population) (Noyes et al. 2011). In quantitative studies construct validity (extent to which a measure represents the concepts it should represent) is important (Dane 2011). Reliability refers to the extent to which an instrument in repeated measures yields similar results. To refer to the reliability consistency, stability and accuracy are often used (Gillis & Jackson 2002). Validity and reliability were examined through the phases of the study.

In **Phase I** first part a new questionnaire was developed; validity and reliability were tested.

Internal validity was achieved because in this study the participants were all S/R patients who met the inclusion criteria on the study wards. Participating patients' characteristics, their symptoms and functioning based on GAF/BPRS (objective evaluation) ratings were compared to those non-participating but eligible individuals, and no significant differences were found. The external validity was not estimated because in this study the results were focused on the instruments' validity and reliability process so patients' responses were not analysed in this part. It is debatable how the instrument testing is affected by cultural factors such as testing the instrument in Japan (Gillis & Jackson 2002). The study was conducted in two hospitals on three wards in Japan and the data collection time was quite short (four months) and resulted in 56 completed responses, which can be deemed a small sample to test the questionnaire (Polit & Beck 2006). The size and the study context were limited to ensure sufficient loadings.

To evaluate the validity of the instrument, four aspects should be considered; face validity, content validity, criterion-related validity and construct validity (Polit & Beck 2006, Ketokivi 2009, Dane 2011) and these were satisfactory. Concurrent validity refers to comparing a new measure to an existing, valid measure. Concurrent validity is a

specific form of criterion-related validity (Polit & Beck 2006, Dane 2011). In this study concurrent validity was estimated using Pearson's correlation coefficient between the SR-PPT score and the CSQ-8J score and the correlation was high. The higher the correlation, the more valid the new instrument is (Dane 2011). To assess the correlation between external criteria (objective evaluation) and the SR-PPT (subjective evaluation) Pearson's correlation coefficient (for SR-PPT score, GAF and BPRS) and the partial correlation coefficient (for GAF improvement) were used. GAF was measured on admission and in the intervention S/R, BPRS were measured once during the intervention. According to the literature a new instrument should be compared with more than one existing instrument (Dane 2011). Construct validity was tested by the research group assessing surveys of perceptions of S/R, involuntarily admitted patients' perceptions of their treatment, questionnaires on patients' satisfaction and the Working Alliance Inventory. The method of construct validation in this case involves an examination of the relationship based on theoretical predictions (Polit & Beck 2006). Mainly construct validity in this study was tested by factor analysis. By using factor analysis it is possible to identify main patterns and factors within a questionnaire. Item reduction in this study was based on factor analysis (Rask et al. 2008, Ketokivi 2009).

The reliability coefficient is an important indicator of the quality of an instrument. Knowledge of an instrument's reliability is critical in interpreting research results (Polit & Beck 2006). When developing a questionnaire it is important to ascertain what the questionnaire measures (Rask et al. 2008). In this study factor analyses were used (main factor method) and two main subscales were found. The internal consistency of the subscales was examined by calculating the alpha coefficient (0.93 for Cooperation with Staff and 0.89 for Perceptions of S/R). The internal consistency reliability of the instrument can be said to have been achieved when all its subparts measure the same characteristics (Polit & Beck 2006).

In **Phase I** second part the SR-PPT 11-item Finnish version was used for the first time. The Finnish research group estimated content validity and it was approved as an instrument in Finnish research based on the earlier results of the factor analysis. Estimating internal consistency tested the reliability of the instrument. The internal consistency of the SR-PPT Finnish version was found to be satisfactory (Cronbach's alpha coefficient 0.89 for Cooperation with Staff and 0.77 for Perceptions of S/R).

External validity refers to the generalizability of the results, the representative sample size and context of the study (Gillis & Jackson 2002, Burnes & Grove 2005). Out of 307 S/R patients on the study wards in the study period, 149 eligible patients were asked to participate. The number of respondents remained quite low (n=90). Out of all secluded/ restrained patients 51% were excluded partly due to exclusion criteria (e.g. diagnosis, age, condition estimated by staff or language). The other reasons for non-participation were quick discharge, or staff forgot to give the patients the questionnaire. In future more attention should be paid to the recruitment process. Although the staff was educated and those in charge of the study protocol on the wards (research assistants and head nurses)

were contacted and educated regularly, there were times when substitute personnel were in charge of treatment and a knowledge gap in the study protocol occurred. Quite many of the secluded/restrained patients were subjected to S/R more than once, and the first completed questionnaire was analysed, so 18 responses were excluded due to that. Other reasons were empty or questionnaires where respondents had written the experiences. This may indicate that the patients were pleased to respond and wanted to express their feelings and experiences to the unknown researcher. The study was conducted in three hospitals, in seven units (emergency, acute and forensic units) in southern Finland and the context can be considered representative of psychiatric care in Finland and the results from this point of view can be generalized to national level.

In **Phase II** data were collected using the Q-LES-Q SF questionnaire validated and reliability tested in Finland. The Finnish validation process was conducted with schizophrenia patients in the most acute state of their illness, a few days after admission or after the observation period prescribed by the Mental Heath Act 1116/1990 (Pitkänen et al. 2012). In our study data were collected at the end of hospitalization from all patients on the five acute study wards. Patients' diagnoses in the S/R group were ca. half schizophrenia and in the non-S/R group mood disorders (depression). Although in earlier studies the Q-LES-Q SF has shown high internal consistency and criterion validity among patients with severe mental illness (Bishop et al. 1999, Ristner et al. 2005, Stavinovic 2011, Pitkänen et al. 2012), the validity of the instrument can be considered through face and content validities and generalisation of results.

The content (Ketokivi 2009), face (Dane 2011) validities were supported by comparing content, results and patients' characteristics. Face validity was evaluated through the results that one item of living arrangement had the largest number of missing responses probably due to some technical problem, the location at the top of page two in the questionnaire. Content validity was evaluated through the results and earlier quality of life studies. Validity and reliability were not tested in this study. In any case this was the first time that S/R patients' QoL was measured. The timing of responses and the questions in that time are crucial (Polit & Beck 2006, Ketokivi 2009). The results showed that the S/R episode mainly occurred at the beginning of the treatment and the S/R patients' hospitalization thereafter was extremely long. This may produce bias and confounding of the results thereby compromising validity. Asking about household duties or satisfaction in working during the preceding seven days when patient has been hospitalized may produce biased responses.

External validity (generalizability) can be evaluated by the representativeness of sample and study context. Out of patients discharged from the study wards 55 % were asked to participate in the research. Out of those invited 73 % agreed to participate. Unfortunately 45 % were excluded due to exclusion criteria, quick discharge or were not invited to participate or staff had insufficient information on the study protocol despite information at intervals by the researcher. The small proportion of S/R patients threatens external validity even if the difference in results comparing the responses of the two groups

was remarkable. The study context was quite representative at national level. The study hospital is one of the biggest psychiatric hospitals in Finland treating psychiatric patients in an area with 1.5 million inhabitants. The study wards represented acute wards treating patients with severe mental illnesses.

In **Phase III** the review of the studies on patients' experiences of coercion (S/R) was carried out. The reliability of a review must be evaluated critically at every step of the process (Pudas-Tähkä & Axelin 2007). Questions, search terms, sources, inclusion and exclusion criteria and finally analysis and synthesis are critical. This study was mixed studies systematic review, aiming to review methodology and ethics in both qualitative and quantitative studies. One researcher conducted the review, but the results were checked together with another researcher. To guarantee the value and quality of the review the recommendation is that at least two raters should review the articles (Polit & Beck 2006). In this study we didn't use any critical appraisal tools to find out the quality of selected studies but only looked certain criterias raised from the literature. No tools were specifically designed to appraise the methodological quality (Pluye & Hong 2014).

6.2 Discussion of results

6.2.1 Secluded/restrained patients' perceptions of their treatment

In phase I no instrument was found to measure how S/R patients perceive their overall treatment and this need was filled by developing the SR-PPT questionnaire. Seclusion and restraint are controversial measures which are still widely used, although many studies have shown that patients' experience these measures negatively; they perceive them as punitive rather than curative (Meehan et al. 2004, Keski-Valkama et al. 2010) and proof of their effectiveness is lacking (Sailas & Fenton 2000, Nellstrop et al. 2006). Knowing about patients' perceptions is important in order to improve ethical decisionmaking in treatment and in nursing care. There are also numerous qualitative studies on seclusion and restraint and some of these have reported patients' perceptions (Binder et al. 1983, Norris et al. 1992, Johnson 1998, Meehan et al. 2000, Hoekstra et al. 2004, Kontio et al. 2010). Fewer quantitative studies of S/R patients' perception were found (Hamill et al. 1989, Mann et al. 1993, Meehan et al. 2004) and only one RCT (Bergk et al. 2011), partly due to the lack of a proper instrument, or due to the ethical difficulties of measuring coercive psychiatric care. The S/R PPT instrument, which used a visual analogue scale, was easy for patients to complete even if their state of health was impaired after the containment measures or due to their illness. It is preferable to measure patients' perceptions quite soon after an S/R episode to avoid response bias due to other factors. Follow-up studies using the same instrument could be used longitudinally to show how patients' point of view changes over time.

In Phase I (second part) S/R patients' perceptions of their overall treatment were measured and it was found that patients' perceptions of cooperation with staff and especially their perceptions of seclusion and restraint were negative. Patients' perceptions of the benefit

of these measures were more positive than their perceptions of the necessity of S/R. This difference between perceived necessity and benefit was statistically significant, although both were very low. This result appears contradictory. According to other studies on this theme, patients felt they derived some benefit for their condition and some even wanted to spend time in the seclusion room (Keski-Valkama et al. 2010). There is a lack of comparative studies on which measure is best for de-escalating aggressive behaviour and patients prefer measures that they have encountered in care (Georgieva et al. 2012). Yet according to the findings of this study, seclusion and restraint are not measures that patients perceive to be necessary. As far as these measures are used in Finnish psychiatry, the way these measures have been decided on, and how patients' opinions have been taken into account is likely to be crucial. Patients did find it positive that they were not ignored, and they felt they got attention from the staff.

We found that age is associated with how patients perceive their treatment. Older people were more critical of the use of coercive methods. Maybe they were more familiar with the treatment culture and so more critical. More research is needed to ascertain why older patients perceive S/R more negatively than younger ones. Other studies (Whittington et al. 2009) have found that older patients are more accepting of coercive methods, so our finding differed from this. We can assume that one reason for the differences from other studies could be differences in samples. In our study participants were both acute and forensic patients, whereas the study by Whittington et al. 2009 only examined the views of acute patients. Another reason could the use of coercive measures. Mechanical restraint or both seclusion and restraint were used more frequently in our study settings. However, in the UK mechanical restraint is not in use at all (Bowers et al. 2005). Another potentially important reason for the differences between the results of the studies is in the different instruments used, which makes comparison difficult.

Women were more critical of the degree of cooperation with staff and the use of coercive methods, although the difference was not statistically significant. Earlier studies have reported that gender makes a difference and that women are less satisfied with staff than men (Kuosmanen et al. 2006). In other studies gender has been reported to be associated with patients' preferences as to whether they want to be secluded or medicated when it is needed. Women prefer medication and men seclusion (Veltkamp et al. 2008). In our study women respondents were in the minority (39 %). The reasons for women's dissatisfaction with treatment and the use of coercive measures could be explained by general gender differences. Women more often prefer interpersonal interventions and seek help earlier (Seeman 2006). Men more often suffer from schizophrenia and bipolar disorders than women, whereas women suffer more often from depression (Andreasen 2005). In our study most of secluded/restrained patients were men suffering from schizophrenia.

Patients' felt that collaboration with staff in setting goals for their treatment functioned poorly, and that their opinions were not taken into account and their opportunity to voice their opinions was inadequate. They also reported that staff members' understanding of

their concerns was poor. This concurs with earlier studies where patients suffered from lack of proper communication with personnel (Meehan et al. 2004, Keski-Valkama et al. 2010, Kontio et al. 2010, Mayers et al. 2010). Patients' opinions should be taken into account when making treatment decisions even those concerning restrictions (Bergk et al. 2011, Georgieva et al. 2012). According to these findings patient-centred care, meaning co-working with patients and their relatives is much needed. Basic skills in psychiatric nursing such as communication, dialogue and empathy should be used in nursing. Situations when a patient behaves aggressively, has psychotic ideations and when his/her competence is occasionally impaired or when a patient has cognitive deficit are demanding if the nursing staff tries to negotiate with the patient. The situation may demand quick decisions to ensure safety for all patients and staff and from the patients' point of view it is understandable that they feel that their voice has not been heard. Therefore it is important to prevent such situations by respecting, understanding cooperation aiming to find alternative interventions. Yet even more important than making quick decisions is to concentrate on dialogue with patients and to observe their symptoms, for example, anxiety. Building a therapeutic alliance in every situation has shown some promising evidence in reducing the use of seclusion and the emotional exhaustion of nurses (Happell & Koehn 2011).

In preventing violence risk assessment is one widely used method; hence in risk assessment tools the predictive accuracy varies depending on how they are used. Their use as sole determinants on detention, punitive measures and release is not supported by the current evidence according to a systematic review and meta-analyses (Fazel S et al. 2012). Many assessment tools have been developed to help identify aggressive behaviour (e.g. Steadman et al. 2000, Ogloff et al. 2006, Douglas et al. 2008). A less restrictive intervention is time-out, asking patients to calm down in their own room, a comfort room or similar (Bowers et al. 2011). One can argue which one of the following restrictive methods is less coercive; forced medication, physical restraint (holding and restricting movement), and seclusion in a locked room with minimal furnishing or mechanical restraint by belts, hand-cuffs (Mental Health Act 1423/2001). These are the most restrictive and have been considered to be an infringement of the human rights and self-determination of inpatients. Nurses most often evaluate the need for these interventions and monitor patients during S/R and although starting or ending S/R is at a physician's discretion, nurses make recommendations (Kontio et al. 2010). The main objective is to reduce the use of coercive measures and at least shorten the time in the seclusion room and under mechanical restraint and find alternatives for these measures. We have given up the straitjacket (still used only in some hospitals) what if we give up mechanical restraint or seclusion room. This means other changes will be necessary.

Culture and attitudes of psychiatric staff have been shown to be associated with the use of coercive measures (Meehan et al. 2004, Bowers et al. 2007, Mann-Poll et al. 2007). In psychiatric hospital care the aim is to ensure a safe environment for all patients by preventing violent behaviour and by offering the best treatment to help patients to deal with

their psychotic symptoms. To develop treatment culture toward less restrictive patients' individual choices should lead care more than organizational structures and routines. According to the Finnish legislation, patients have the right to know their treatment plan and they have to be treated in cooperation and with respect for their self-determination. Patients and their relatives have demanded more information on treatment alternatives and to be participants in the care as informants. There seems to be strong evidence for psychiatric advanced directives (PAD), which among other things means patients' written instructions to the medical personal on their treatment preferences in a situation when they themselves are incapable and leads to a better treatment alliance (Swanson et al. 2006). The Finnish guidelines also suggest asking how patients want to be treated when their condition deteriorates and coercive measures are considered (Ministry of Social Affairs and Health 2009). Patients' preferences and suggestions should be elicited when their condition is in balance, mainly in outpatient care and this information should be transferred to the treating hospital (Swanson et al. 2003, Srebnik & Russo 2007). There is still a need to study how PAD reduces the use of seclusion and restraint.

Patients who were treated on forensic wards were distinctly more dissatisfied with S/R measures than patients on general psychiatric wards. This is in line with other Finnish studies, where patients in a forensic setting felt S/R to be much more punitive than in a general setting (Keski-Valkama et al. 2010). Earlier studies have shown that a forensic setting is a more stressful environment than a non-forensic setting and in risk factor research forensic nurses perceive the patients placed in seclusion to be more often at risk of causing harm to themselves or others (Whitehead & Mason 2004). This may be the reason for patients' critical experience in the forensic setting. Nurses are alert and feel stressed under the threat of violence and this may affect the relationship with patients. Tenkanen et al. (2011) found that in a forensic setting nurses need more specific education and training, even in basic clinical knowledge and skills; basic life-support skills, patients' need-adapted treatment, the therapeutic relationship and among others skills to de-escalate violent situations, conduct risk assessments and discuss with patients after a violent episode.

Coercion is an ethical dilemma in itself, and the decision to use coercion is difficult and stressful for both staff and patients. This study confirms that patients' opinions should be taken into account when making decisions and planning care. Treatment should be respectful and cooperative even during the S/R intervention (Chien et al. 2005). This objective is no doubt difficult when the patient is not cooperative because of his/her illness. Patients' backgrounds, gender issues and age should be considered. For example, sexually abused women perceive restraint as unnecessary and terrifying (Gallop et al 1999). This also emerged in our study in the written answers which were excluded. Right from the start of the treatment period empowering issues should be given priority. In psychiatric nursing there is a danger of exercising power over patients and this danger should be recognized when building the relationship with the patients (Cutcliffe et al. 2009). Psychiatric nurses in acute units have also been criticized for focusing on safety

and medication rather than more therapeutic relationships, which the patients have called for (Thomas et al. 2002, Kontio et al. 2010, Keski-Valkama et al. 2010). Patients' demands to know the reasons for interventions (especially for S/R) are justified as well as discussion of alternative treatment methods before using coercive measures and debriefing after the interventions. Debriefing discussion after a coercive measure gives an opportunity to learn about the situation and to deal with feelings and so alleviate the distress (Meehan et al. 2004, Chien et al. 2005, Kontio et al. 2010). Patients also seem to need space and privacy and alternatives in their treatment environment such as private rooms and comfort rooms (Stolker et al. 2006, Cummings et al. 2010).

Our study found differences between Japanese and Finnish in total sum scores. Japanese patients' evaluations of sum scores for "cooperation with staff" and "perceptions of SR" were much higher than Finnish those of patients, which can be interpreted as greater satisfaction with overall care in Japan than in Finland, especially as regards perceptions of S/R. Finnish patients' perceptions of S/R were lowest on the scale, while Japanese estimations were highest. Differences in the duration of seclusion and restraint may be one explanation and therefore that patients' condition when they responded. Japanese patients' condition was estimated by objective scales after S/R in addition on a patients' subjective scale. In the Finnish arm of the research no objective estimation was made, so it is impossible to compare patients' condition and seek any explanation from it. Anyhow not only objective estimation is enough to identify patients' needs, but adequate assessment needs both dialog and subjective estimation independently to articulate perceptions of care and treatment. One reason for differences could be cultural. In Japan harmony is the fundamental value and the main virtue for nursing care is politeness and respect for other people (Konishi 2009).

6.2.2 Secluded/restrained patients' perceptions of their QoL at the end of their hospitalization

Patients' QoL has become an important outcome in psychiatric treatment due to the fact that mental disorders are often long-lasting and multi-symptomatic with a widespread effect on functioning and patients' ability to picture the world. Jonsen et al. (2006) highlighted that the most fundamental goal of care is the improvement of QoL for all those who need and seek care. Ethical questions about the risks and benefits of accepting or refusing recommended medical interventions are among others: is there notable divergence in QoL assessed by staff (objective) or patients (subjective) or what intervention is decided on if the patient is incapable of articulating his/her own wishes on how to improve QoL (who justifies the assessment of QoL). (Jonsen et al. 2006) To the best of our knowledge none of the earlier studies have investigated how seclusion or restraint was associated with psychiatric patients' QoL.

In the present study S/R patients' QoL was compared with that of their non-S/R counterparts and it was found that S/R patients' QoL was better in almost all categories of the questionnaire. This was a surprising result due to the results of Phase I and other

studies where patients' view on S/R was negative. This study also suggests that seclusion and restraint are somehow associated with perceived QoL. We can assume that patients' condition has improved, patients have adapted to their situation, to the treatment culture, care and to their illness, or earlier coerced patients were satisfied about discharge decision. The result may also be due to fairly lengthy hospitalization, while the coercion episode occurred at the beginning of the treatment period.

In our study S/R patients were most often diagnosed with schizophrenia and secondly with bipolar disorder and non-S/R with mood disorders (depression), which can mainly explain the result. Quite many QoL studies have shown that diagnosis is associated with the patients' subjective and objective QoL. Patients' suffering from schizophrenia estimate their QoL higher than when this is estimated objectively (Ristner et al. 2003, Saarni et al. 2010, Ristner et al. 2011). Improved QoL of schizophrenia patients was associated with a reduction in paranoid symptoms and distress. Increased self-efficacy and self-esteem increased the QoL of schizophrenia patients. Patients suffering from depression estimated their QoL lower than did schizophrenia patients. Changes in the QoL index of patients with schizoaffective/mood disorder are associated with depression. (Ristner et al. 2003, Hope et al. 2009). Comparing non s/r patients mainly diagnosed with depression and s/r patients diagnosed with schizophrenia is problematic, because they represent different groups. In future studies to ensure reliability comparisons should be made between s/r and non-s/r patients both diagnosed in schizophrenia. That is why we replicated the findings in comparable samples a matched non- S/R patients sample was chosen for the S/R patients. The same difference in the QoL in favour of S/R patients remained after comparison of samples matched for background factors including diagnosis.

Timing in asking people to respond to a questionnaire affects the interpretations of the results. Surprisingly patients were treated quite a long time after the S/R episode (ca 2.5 months), so it is impossible to conclude if the better QoL estimation is a consequence of seclusion and restraint, or if it is a consequence of the treatment and care on the ward. According to other studies seclusion usually occurs during the first or second week after admission to hospital (El-Badri & Mellsop 2002, Bowers et al. 2011). It can be assumed that patients' condition on admission was poor and recovery in outpatient care was slow. Unfortunately patients' condition was not measured with any instrument, e.g. any symptom measure. Measuring the condition on admission and at discharge could be informative on the effectiveness of care in any case. The QoL measure is one method to evaluate the change in a patient's condition.

The results of the study on the patients' QoL can be argued by estimating the validation and suitability of the questionnaire in this study. The Q-LES-Q questionnaire elicits satisfaction with activities such as household duties, sex drive etc. in the preceding seven days, which can be estimated in other settings than hospitals. The questionnaire is among the most frequently used outcome measures in psychiatric research (Ristner et al. 2003, Hope et al. 2009, Stevanovic 2011). The validity was tested in Finland in quite a similar context on acute wards and high satisfaction was reported (Pitkänen et al. 2012).

Secluded or restrained patients' better QoL could be explained as adaptation to the illness and nursing practices. Earlier experiences of coercive measures seem to affect patients' preferences. In the study by Georgieva et al. (2012) patients who had experienced seclusion preferred it to medication. Hoekstra et al. (2004) also concluded that patients' earlier experiences had an association with their perceptions. Patients adapted and learned to live with their experiences, finding active coping and controlling methods (Hoekstra et al. 2004). The finding is important when considering what kind of treatment is offered in psychiatric hospital care. The question is a cultural issue. Mechanical restraint is forbidden in many countries and instead isolation and forced medication are preferred to calm patients down. Staff attitudes in Finland expressed the highest approval of containment, when e.g. in Britain much less approval was reported (Bowers et al. 2007).

The results of the present study can be representative hospital care on acute wards, where this study was conducted. In this study S/R episodes most often occurred on the admission ward, where the duration of stay was short. Often treatment continued on the other study wards offering more rehabilitation, therapeutic and psychosocial treatment, which may affect to the patients' responses. Interpersonal relationship has long been seen as crucial in psychiatric nursing care (Barker et al. 2011). In acute inpatients' units nursing has been seen to include an assessment of mental health problems, management and care coordination, ensuring safety, meeting basic health needs and providing effective treatment (Bowers et al. 2006). Still there is a demand to offer psychosocial treatment such as stress management, self-coping skills, relapse prevention, and psychoeducation (Mullen 2009). One conclusion for S/R patients' responses is that they received nurses' attention and their needs was perceived during the quite long hospital care. Future challenge is to ensure patients' empowerment and quality of life for patients more treated in outpatient clinics.

There seems to be a less restrictive and more successful way to treat acute patients; Hamilton & Manias (2008) investigated the power of routine on an acute ward in Australia, where patients were admitted to this ward in an acute state. The ward was 44-bed and unlocked, but had a high dependency unit (corresponding to a psychiatric intensive unit in UK). The nursing culture was based on confidence, where nurses were highly skilled in surveillance, circulated on the ward, assessed and worked with patients. It was concluded that nurses exercised social control over patients, but by surveillance and regulating the distance between themselves and patients, they promoted in patients a greater exercise of self-discipline. They also observed and deduced that by displaying a civil and socially warm manner, nurses were exemplary. (Hamilton & Manias 2008)

6.2.3 Methodological and ethical challenges in the studies on patients' perceptions of coercive measures (S/R)

A systematic mixed studies review was conducted to describe methodological and research ethical concerns related to studies on patients' perceptions of coercive methods. The interest in coercion research from the patients' point of view has grown in recent

years. The outcomes of earlier studies have described how psychiatric patients perceived or experienced coercion. Not many studies have been interested in the methodological and research ethical concerns related to these studies. Both qualitative and quantitative studies were included in the review (Creswell 2009).

The main finding of this study was that study designs were disintegrative, which makes comparison of the results difficult. Most of the studies were descriptive or explorative, examining a phenomenon to characterize it more fully, yet one experimental study was found. The result shows that phenomenon of coercion from the patients' perspective is quite a new research area. In spite of numerous studies on coercion there persists lack of effectiveness of coercive measures (Nelstrop et al. 2006, Bergk et al. 2008). There are difficulties in designing experimental design to ascertain the effectiveness of coercive measures for psychiatric patients by comparing alternative interventions, for example, to seclusion and restraint and patients' perceptions of these interventions. One RCT was found but it included no comparison of an alternative intervention, but randomly selected secluded/restrained patients (Bergk et al. 2010). Issues of validity, reliability and generalizability are used when evaluating quantitative studies and are proof of evidence (Tobin & Begley 2004). To develop ethical and evidence-based guidelines for coercive interventions, more experimental studies are needed (Bergk et al. 2008). In controlled studies alternative methods to seclusion and restraint, such as time out and comfort rooms should be investigated from the patients' point of view. For example Bowers et al. (2010) compared seclusion and time out based on patients records and found that time out can indeed be used in place of seclusion.

In our study only in five studies the sample was selected randomly. Smaller sample sizes in qualitative studies do not impair the value of the studies. The questions (for qualitative and quantitative studies) concern how the process of the studies leads to the findings, and if the findings are applicable to another setting, whether replication of the study with the same population in same context could produce the same results, and whether results reflect the subject or are a product of the researcher's prejudices, were crucial in our minds when making the synthesis (Gillis & Jackson 2002). The study samples or number of participants depend on the study design; a qualitative ethnographic study can be conducted with only a few participants, but a quantitative randomized controlled trial (RCT) study needs a bigger sample. Validity or credibility may be achieved by many methods, but sample size and the representativeness of the study population affect the generalizability or transferability of the findings (Gillis & Jackson, Polit & Beck 2006). Randomization can better guarantee the representativeness of the population than selection. A randomly selected sample can be statistically estimated thereby evaluating the sample size that predicts sample error and probability (Dane 2011).

Findings of the review of methodological challenges emerged the idea to improve the quality and comparativeness of the studies could be the use of guidelines to report study findings as STROBE (Strengthening the Reporting of Observational Studies in Epidemiology), which provide a checklists and tables that authors can use to ensure the

relevant information in empirical studies. Participants' recruitment is an important phase in the study procedure to recruit a representative sample and to achieve the required sample size. The information of who recruited secluded or restrained patients is crucial when evaluating if patients' participation was voluntary and if patients' autonomy was respected. The information in the study reports of how patients were recruited and how many patients had no opportunity to take part in the research and the reasons for non-participation is important when evaluating results of the studies.

Confounding factors in interpreting results should also be considered. In the studies of patients' perceptions of coercion some researchers had paid attention to this issue; the influence of the time elapsing between the S/R episode and responding, adaptation to the coercive methods (Sequeira & Halsted 2002, Hoekstra et al. 2004), or relationship between the researcher and the respondent (Meehan et al. 2000, Bergk et al. 2010). Non-participants could have produced different results, so bias in the results should be estimated. In small samples a few missing informants or respondents can change the results, which affect the transferability of the results. In qualitative studies researchers' attitudes may affect the interpretation of the results (Sequeira & Halsted 2002, Hoekstra et al. 2004). The timing in asking patients' to respond is important and patients' condition and feelings of experienced coercion may affect the responses. More attention should be paid to confounding factors and bias when interpreting results.

The other main finding of this study was that information on the ethical review process and informed consent process was found to be lacking. The importance of these topics in studies is evidential, guided internationally and by national legislations, and due to this must be explained. Coerced patients are in a vulnerable state and it highlights the issue more over.

6.3 Conclusions

The use of coercion in psychiatric care is ethically controversial. Decisions in a situation when none of the possible solutions is satisfactory are challenging in psychiatric nursing care and treatment. Such situations occur when a patient is threatening and aggressive. In ethical decision-making on coercive measures patients' preferences, perceptions and their association with QoL should be taken into account together with medical indications and contextual features. The legislation set limits on the decisions on the treatment of mentally ill people. Then there also should be guidance for practices based on legislation. When making treatment decisions the possibility of therapeutic failure should be taken into account. The patient's safety is one of the most important values in health care and therapeutic failure should be avoided. When considering patients' perceptions or preferences one should take into account their earlier wishes and experiences, patients' advanced directives (PAD) so that patients' rights and self-determination are respected. Patients need an opportunity to be involved in planning their treatment and care.

Patients' involvement in their own care is required and the findings of this study are proof of its importance. In future health and mental health services more resources are needed and the best resource is the patients themselves and their families. Empowering patients to take responsibility for their own lives as much they can is ethically and economically valuable. In every care situation, from the very first contact, patients' cooperation should be sought, with respect for their own objectives in care. To empower the patients sufficient information and guidance have to be given in a formula that patients can understand. After an incident debriefing with the patient is essential. Openness increases confidence, which is important in improving cooperation. Patients feel positive when staff calls them by their name, asks their opinion and ensures that that opinion is considered. Hospital care should be short and the aim of hospital care should be to ensure that patients can cope as outpatients. Outpatient care should be possible around the clock, and should ensure patients' compliance with treatment, thereby avoiding new hospital referrals.

In studies on psychiatric patients' care research ethics and ethical preliminary estimates are legitimated and guided and are important to the planning, doing and reporting of research. The recruitment of participants is important to ensure representative results. If staff recruits participants, regular information from the researcher is required. If changing staff forget or otherwise fail to disseminate information the outcome may be non-participation in long-lasting data collection periods. The most effective remedy here could be research assistance. Non-participation of eligible participants produces bias. To create national guidelines for treating psychotic, aggressive and threatening patients, more experimental studies on the issue are needed. The knowledge that patients prefer the interventions they have received suggests that patients' treatment culture, hospital structure and environment should be built up so that alternatives to seclusion and restraint are really available. Patients need safety and care at some time during their illness. Alternative interventions and their effectiveness should be compared with those of conventional S/R interventions by asking patients' perceptions afterwards and measuring patients' condition, occupational capability and QoL.

6.4 Implications of the study

The study investigated coercion in psychiatric hospitals from the patients' point of view. It is based on the theory of ethical decision-making (Jonsen et al. 2006) focusing on patients' perceptions and on the consequences of decisions for patients' quality of life. To find out how coerced patients perceived their overall treatment, the SR-PPT instrument was developed, validated and used with Finnish study population as well. To the best our knowledge this was the first time the patients' quality of life was measured after S/R and the results compared to those of patients not submitted to S/R. Although numerous studies have been conducted on coercion, not many have addressed the patient's perspective. To find out how to improve research in that area, reviewing studies from coerced patients' points of view identified methodological challenges. The present studies produced implications for clinical nursing, management and nursing science.

1. Clinical Nursing

Secluded/restrained patients' negative perceptions of their treatment and care demand improvements in cooperation and communication with patients. Patients' involvement in decision-making and in the planning of their treatment and care is important. Patients should be treated, as individuals, listened and account should be taken of their personal wishes and history. More planning should be done in cooperation with patients and their relatives. Patients' advanced directives (PAD) are worth developing as an instrument to ascertain patients' wishes in situations when patients are unable to articulate their wishes.

Although patients' perceptions of S/R were really low, they felt they derived some benefit from these measures. The result can be interpreted as patients' need for care, calming and help. More alternatives to the use of seclusion and restraint should be used, such as time out, the use of a single room, more staff presence in the wards to ensure safety, and more activities. The length of seclusion and restraint should be reduced, which means active surveillance and ending the episode as soon as possible. Discussion of the reasons and duration should be held with patients and afterwards there should an opportunity for debriefing afterwards to express feelings.

Secluded and restrained patients' significantly better quality of life than that of their non-secluded/restrained counterparts at the end of a lengthy hospitalization is a challenge to nursing practices. When the goal is to reduce the use of S/R and the length of hospitalizations, managers have to ensure patients' empowerment, rehabilitation and daily activities in outpatient care and to prevent situations that lead to restrictions and involuntary treatment in hospitals. This requires seamless cooperation with patients' relatives and caregivers, and measuring patients' quality of life in clinical practice. Part of patients' in planning practices and measuring quality of life is one possibility to ensure effective and empowering intervention to nursing practices.

2. Management

The study showed that the treatment culture has to be improved to be more ethically sound, humane and cooperative. Patients' involvement and expertise are needed in planning care and services. This is a challenge to vocational education and improving care practices. A personnel needs to know more about nursing research to improve evidenced based practices in inpatient care toward patients' empowerment. At the same time staff need an opportunity for discussion, support and debriefing, knowing that patients' aggression, and decisions to deprive others of their liberty often by use of force is distressing and traumatic not only for the patient but also for the staff. Novel policies of deinstitutionalization demand shortening of hospital stays, which is a challenge to managers to develop outpatient facilities. Challenge is to plan services that improve patients' quality of life in their own environment and to avoid hospital care. Hospital care needs to be improved to be a more ethically sound culture, where patients and their relatives are equal partners in care. In planning ward structure more alternatives should

be taken into account. More space, single rooms and support for improving treatment culture are needed

3. Nursing science

This study produced new knowledge about research of coercive methods from the patients' point of view. The methodological and ethical challenges of the studies were highlighted in the review. Based on this review guidelines such as STROBE were suggested to ensure the methodological quality of the study protocol and to improve research ethical concerns in studies focusing on vulnerable population such as coerced patients. Better descriptions of participants' recruitment and eligible non-participants by describing the process with flow charts would improve the evaluations of results. Attention to confounding factors and possible bias should be better reported and taken into account. The importance of informed consent and ethical review process is highlighted.

6.5 Suggestions for future research

The following future ideas arose from this study:

- 1. Perceptions of restrained and non-restrained patients' treatment should be compared in the same context to identify factors associated with the perception.
- 2. Cultural comparison of Japanese and Finnish of the SR-PPT results should be produced.
- 3. Patients' quality of life should be measured at the beginning and the end of the hospital care and then the results of secluded/restrained patients should be compared to those of non-secluded/restrained patients'. At the same time measuring objective for example occupational competence with another instrument could spread the view of other factors related to patients' QoL.
- 4. The usefulness of psychiatric advanced directives in hospital care in reducing the use of coercive methods is worth investigating. The study design for this could be longitudinal.
- 5. Randomized controlled trials or other controlled studies or cohort-studies with large population are obviously needed to ensure evidence based nursing. Alternatives to the use of seclusion or restraint should be developed in psychiatric hospitals and tested in similar context.

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APPENDIX

The search results of patients' perceptions of coercion and psychiatric patients' quality of life

Ovid MEDLINE(R)

1946 to November Week 3 2012

#	Search History	Results
1	mental* or psychiat*.mp.	505990
2	seclus*.mp.	893
3	((mechanical* or Physical*) adj3 restraint*).mp.	10226
4	(qualitative* or quantitative* or rct* or empir* or random* or	11714334
	stud* or research* or trial*).mp.	
5	adult*.mp.	4216385
6	(hospital* or inpatient*).mp.	1042885
7	2 or 3	10738
8	1 and 4 and 7	977
9	6 and 8	600
10	5 and 9	291

Ovid MEDLINE(R)

1946 to November Week 3 2012

#		
1	quality of life.ti	35161
2	psychiatr*.ti.	77459
3	1 and 2	225