Efficacité des mesures de contrainte en psychiatrie : mythe ou réalité ?

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" Efficacité des mesures de contrainte en psychiatrie : Mythe ou réalité ? "

Thèse
présentée à la Faculté de Médecine
de l'Université de Genève
pour obtenir le grade de Docteur en médecine
par

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Thèse n° 11001

Genève

2020

Référence de l'article de publication originale :

Chieze M., Hurst S., Kaiser S., Sentissi O. (2019), Effects of Seclusion and Restraint in Adult Psychiatry: A Systematic Review. *Front. Psychiatry* 10:491. doi: 10.3389/fpsyt.2019.00491

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Secrétariat des étudiants

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accredited in Switzerland

DOCTORAT EN MEDECINE

Thèse de :

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originaire de France

Intitulée :

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La Faculté de médecine, sur le préavis du Comité directeur des thèses, autorise l'impression de la présente thèse, sans prétendre par-là émettre d'opinion sur les propositions qui y sont énoncées.

Genève, le 13 juillet 2020

Thèse n° **11001**

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Efficacité des mesures de contrainte en psychiatrie : mythe ou réalité ?

CHIEZE, Marie

Résumé :

Déterminer l'efficacité des mesures de contrainte est un défi scientifique. Leur usage courant en psychiatrie malgré des preuves limitées d'efficacité soulève des questionnements éthiques concernant la légitimité de leur utilisation et de la croyance en cette efficacité. Cette revue systématique recherche les effets de l'isolement et de la contention en psychiatrie adulte. Les résultats, hétérogènes, montrent des effets délétères sans bénéfice net pour le patient, même si la relation thérapeutique semble influencer positivement les effets subjectifs. Concernant la méthodologie de recherche, les études prospectives paraissent plus réalisables que celles randomisées contrôlées. Actuellement, il n'y a pas de preuve d'efficacité de la contrainte, mais sans preuve de l'absence d'efficacité. Différentes croyances potentiellement vraies sans preuve existent, allant d'observations empiriques à un récit organisateur d'une société. La légitimité de la contrainte pourrait se baser sur d'autres arguments que des preuves scientifiques. Cette réflexion nécessite d'être approfondie, ouvrant des perspectives de recherche intéressantes.

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Remerciements

Je tiens tout particulièrement à remercier la Prof. Samia Hurst et le Dr Othman Sentissi pour leur accompagnement assidu tout au long de ce travail. Leur enseignement précieux et exigeant a permis l'élaboration et la publication de deux articles rigoureux sur le plan méthodologique et m'a énormément appris sur la démarche de réflexion et d'écriture pour la recherche.

Je tiens également à remercier chaleureusement le Prof. Kaiser, chef de Service de psychiatrie adulte de Genève, dont le soutien a fortement aidé ce projet à voir le jour. Son engagement et son intérêt sur cette thématique inaugurent une poursuite des réflexions au sein d'un groupe de recherche, donnant ainsi un sens à ce travail.

L'aide précieuse de Mmes Gervaise Badet et Mafalda Burri de la Bibliothèque de l'Université de Genève, doit également être soulignée. Leur enseignement sur la méthodologie de la revue systématique et leurs conseils avisés ont été indispensables pour l'apprentissage de la méthode et la réalisation de cette revue.

Abréviations

Art.: Article

BDI-II: Beck Depression Inventory II

BPRS: Brief Psychiatric Rating Scale

CC: Code Civil

CENTRAL: Cochrane Central Register of Controlled Trials

CINAHL: Cumulative Index to Nursing and Allied Health Literature

CNPT: Comité National de Prévention de la Torture

DVT: Deep Vein Thrombosis

EUNOMIA: « European Evaluation of Coercion in Psychiatry and Harmonization of Best Clinical Practice »

HUG: Hôpitaux Universitaires de Genève

PANSS: Positive and Negative Syndrome Scale

PICOS: participants, interventions, comparators, outcomes, study design

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PROSPERO: International prospective register of systematic reviews

PTSD: Post-traumatic Stress Disorder

RCT: Randomized Controlled Trial

USPSTF: U.S. Preventive Services Task Force

I. Résumé

Déterminer les effets cliniques de la contrainte est un défi scientifique et éthique. Les mesures de contrainte sont fréquemment utilisées en médecine, particulièrement en psychiatrie. Toutefois, les preuves de leur efficacité sont limitées, ce qui soulève la question de la légitimité de leur utilisation et du fondement de la croyance en cette efficacité. Cette revue systématique de la littérature recherche les effets de l'isolement et de la contention en psychiatrie adulte de manière élargie. Les résultats, hétérogènes, mettent en évidence des effets délétères sans montrer de bénéfice net pour le patient, même s'il semble que la relation thérapeutique influence positivement ces effets sur le plan subjectif. Concernant la méthodologie de la recherche sur la contrainte, les études prospectives paraissent plus réalisables que celles randomisées contrôlées. A l'heure actuelle, il ne semble pas y avoir de preuve d'efficacité de la contrainte mais cela ne signifie pas la preuve de l'absence d'efficacité. De plus, une croyance en des faits sans preuve à l'appui n'est pas forcément dénuée de vérité et la légitimité pour l'utilisation de la contrainte pourrait également se baser sur des arguments autres que des preuves scientifiques. Différentes catégorisations du mythe existent, allant d'observations empiriques vraies à une croyance sans impact concret en passant par un « mythe » au sens d'un récit organisateur d'une société. Toutefois cette réflexion nécessite d'être approfondie et étayée selon les différentes catégories évoquées, ouvrant ainsi des perspectives de recherche intéressantes.

II. Introduction

1. Contexte

Les mesures de contrainte sont d'utilisation fréquente en médecine, particulièrement visibles en psychiatrie (1). Leur usage est déjà rapporté dans l'Antiquité pour la prise en charge des personnes « psychotiques, dérangées et émotionnellement perturbées » (2). Depuis plus de trois siècles, suite à l'interdiction des chaines dans les asiles de Paris par Pinel au 18^{e} siècle, l'usage de la contrainte est controversé (3). De plus, l'accent progressivement mis depuis plusieurs décennies sur l'autonomie et le respect de la dignité de l'individu d'une part, et sur la demande d'une sécurité communautaire d'autre part, soulèvent de nombreux questionnements concernant l'utilisation de la contrainte (4). Le débat est toujours d'actualité et suscite des réflexions, recherches et propositions de réduction de cet usage dans de nombreux pays (5).

Les mesures de contrainte se définissent par « toute mesure prise contre la volonté d'une personne » (6), et comportent plusieurs dimensions, souvent regroupées en contraintes « formelle », « informelle » et « subjective ». La contrainte formelle comprend l'admission non volontaire, l'isolement, la contention et la médication forcée (7). L'admission non volontaire désigne une hospitalisation décidée contre la volonté du patient (6). L'isolement – souvent appelé « chambre fermée » – correspond à l'enfermement d'une personne seule dans une pièce dont elle ne peut sortir par ses propres moyens (6). La contention est définie par la restriction des mouvements du patient par des soignants (contention physique) ou un artéfact mécanique (contention mécanique) (8). L'isolement et la contention sont aussi appelées « mesures de contrainte limitatives de la liberté de mouvement », dans le sens où ces mesures restreignent les mouvements d'une personne (9). La médication forcée désigne l'administration d'un traitement (oral ou injectable) sans le consentement du patient (6). Les traitements de crise et non urgent peuvent être distingués, et certains pays, dont la Suisse, autorisent ces deux formes de médication forcée (10, Art. 434 Code Civil (CC) (11)). La contrainte informelle regroupe la persuasion, la manipulation ou toute influence sur le patient (12). La contrainte subjective s'intéresse aux ressentis des patients, soignants et proches dans les situations de contrainte. La perception subjective peut différer des évènements objectifs (13). Ces définitions et catégorisations des différentes mesures de contrainte varient largement selon les pays (14).

En psychiatrie, l'indication principale de la contrainte est la gestion des comportements agressifs ou agités (15). Sa fréquence d'utilisation varie de 0.4 à 66% selon les pays, mais aussi entre les différentes institutions d'un même pays (1, 5). L'utilisation de la contrainte semble en effet plus dépendre des habitudes locales que des recommandations juridiques ou éthiques officielles (1), suggérant ainsi une influence culturelle importante (16). Des efforts d'harmonisation des recommandations internationales sont en cours, notamment à travers le projet « European Evaluation of Coercion in Psychiatry and Harmonization of Best Clinical Practice » (EUNOMIA) (17). Toutefois, ces recommandations comme la littérature actuelle sont fortement colorées par la culture occidentale (Amérique du Nord, Europe, Japon, Inde), tandis qu'une autre partie du monde (Afrique, Amérique du Sud, Asie) n'est pas prise en compte (18). Un « vide juridique » semble donc présent (19).

Sur un plan clinique, un trouble psychique décompensé peut nécessiter des soins urgents – notamment en cas de mise en danger – sans que le patient soit apte à prendre une décision adéquate aux circonstances, autrement dit qu'il soit capable de discernement (6). Dans ce contexte où il faut gérer une situation urgente alors que le patient refuse fréquemment les soins tout en se mettant (ou autrui)

en danger, des mesures allant à l'encontre de sa volonté sont souvent appliquées, ce qui porte gravement atteinte aux droits fondamentaux (libertés de choix et de mouvement, autonomie, intégrité physique) (20). Les mesures de contrainte sont donc par principe illicites (21) et ont un enjeu éthique important (4). L'atteinte aux droits fondamentaux comporte un risque d'abus de pouvoir, même non intentionnel – dénoncé dans une dimension plus paternaliste de la médecine (22). Ce risque est d'autant plus important en psychiatrie du fait de la vulnérabilité de la personne souffrant de troubles psychiques (23). Cette vulnérabilité nécessite une protection particulière, notamment juridique (21). En Suisse, la Constitution Fédérale garantit les droits fondamentaux (en particulier l'Art. 10 pour la liberté de mouvement) (24). Le Code Civil délimite le champ d'application de la contrainte, tolérée en dernier recours et en cas d'échec de toute alternative (Art. 377-439 CC (11)). Trois indications exceptionnelles sont définies : « un grave danger menaçant la vie ou l'intégrité corporelle de la personne concernée ou d'un tiers, et une grave perturbation de la vie communautaire » (Art. 383 CC (11)).

L'usage des mesures de contrainte s'inscrit ainsi dans un paysage juridique donné, lui-même représentatif des valeurs de la communauté qui l'érige. La manière dont est utilisée la contrainte dans une société dépend donc de la tolérance de cette dernière envers les personnes souffrant de troubles psychiques et potentiellement dérangeantes en cas de décompensation. Or la perception sociétale du trouble psychique a évolué au cours de l'histoire (25, 26). L'évolution actuelle vers une culture individualiste, valorisant l'autonomie et la liberté de choix d'un côté tout en demandant une sécurité importante au niveau communautaire, accentue la controverse de la contrainte en psychiatrie (27, 28). Ainsi, étudier les mesures de contrainte en psychiatrie demande de prendre en compte la représentation sociale de la personne souffrant de troubles psychiques.

Par ailleurs, la médecine est de plus en plus « basée sur les preuves », selon le concept de l'« evidence-based medicine ». Un acte thérapeutique est légitime lorsqu'une preuve scientifique d'un bénéfice est établie, avec une causalité en principe directe pour le patient (29). Le design d'étude randomisée contrôlée est la méthodologie scientifique optimale pour objectiver une preuve d'efficacité (30). Gutheil rapporte en 1978 que l'isolement pourrait permettre une contenance, une réassurance et une diminution des stimuli sensoriels (31). Depuis, les études parvenant à montrer une efficacité des mesures de contrainte – notamment concernant les hypothèses de Gutheil – semblent extrêmement limitées (18). Les facteurs de risque d'utilisation ont été plus étudiés (32). Il s'agit majoritairement d'études rétrospectives, donc avec un niveau de preuve plus limité (33). La réalisation d'études cliniques sur cette thématique est en effet difficile, pour plusieurs raisons. L'hétérogénéité des

définitions et des pratiques cliniques limite la comparabilité des études (4). L'incapacité de discernement des patients limite le consentement à la recherche. Concernant la réalisation d'études randomisées contrôlées dans ce contexte, le principe de randomisation est d'une part peu applicable pour des personnes en état de crise nécessitant une prise en charge urgente ; et d'autre part peut induire une perte de chances pour l'individu (34). Or, la légitimité des mesures de contrainte, non seulement clinique mais aussi éthique et juridique devrait reposer sur un effet bénéfique direct. Le manque de preuve d'efficacité des mesures de contrainte ainsi que la difficulté à réaliser des études cliniques interrogent ainsi leur légitimité en pratique clinique.

2. Importance clinique de l'étude

La question de cette légitimité des mesures de contrainte est d'une importance primordiale du fait des enjeux éthiques, juridiques et sociaux liés à leur utilisation. Une étude rétrospective (à laquelle participe l'auteur de la thèse) est en cours sur l'utilisation des mesures de contrainte dans le Service de psychiatrie adulte des Hôpitaux Universitaires de Genève (HUG). Selon les résultats préliminaires, 12% des patients hospitalisés en 2017 ont subi au moins une mesure de contrainte au cours de leur séjour. L'isolement est la principale mesure de contrainte utilisée ; et dans 96% des prescriptions, sa durée est supérieure à 24 heures. Il semble qu'actuellement il soit difficile de se passer complètement de la contrainte (15), ce qui motive le Comité National de Prévention de la Torture (CNPT) à recommander une durée maximale de l'isolement à 24 heures (35). L'usage de l'isolement à Genève dépasse donc ces recommandations et appelle à une modification des pratiques, notamment à une réduction de la durée de l'isolement et au développement d'alternatives à ces mesures. Or la recherche sur les mesures de contrainte est actuellement principalement orientée vers l'élaboration de programmes de réduction de la contrainte (15). Pour autant, l'efficacité de ces derniers n'est à ce jour pas démontrée (36). Des données objectives sur les mesures de contrainte – incluant l'efficacité – sont donc nécessaires comme bases de comparaison en amont des interventions de réduction.

La structure hospitalière est également intéressante à considérer dans l'étude de la contrainte, au sens où la diminution d'une forme de contrainte pourrait engendrer la recrudescence d'une autre : l'ouverture des unités – comme dans le Service de psychiatrie adulte de Genève – risque d'augmenter l'usage de l'isolement (7). L'influence de la structure institutionnelle sur l'utilisation de la contrainte est sujet à débat (37). Les données actuelles tendent à observer une diminution de la contrainte lors de l'ouverture des unités, sans que des relations causales aient pu être démontrées (37).

D’autre part, étudier l’efficacité des mesures de contrainte questionne la finalité de leur utilisation (32). Pour Steinert et al., les mesures de contrainte ne sont pas des actes thérapeutiques en soi mais un moyen pour permettre une autre intervention qui, elle, sera thérapeutique (37). Les auteurs ne différencient toutefois pas les différents types de contrainte (37). Intuitivement, une admission non volontaire semble être un moyen pour aider à la mise en place – durant l’hospitalisation – d’une autre mesure qui stabilisera le symptôme du patient. Concernant la médication forcée, un effet thérapeutique direct apparait d’emblée, la molécule administrée nécessitant par définition une preuve d’efficacité pour une autorisation de mise sur le marché. Par contre, pour les mesures limitatives de liberté de mouvement, la présence d’une finalité thérapeutique en soi est moins claire. Cet effet pourrait être protecteur mais la croyance en un bénéfice thérapeutique direct a aussi été observée dans la pratique clinique et décrite dans la littérature (38). Un exemple courant est l’hypostimulation en chambre fermée en cas de décompensation maniaque. Une amélioration clinique est observée empiriquement chez certains patients, sans que des éléments tangibles d’efficacité soient retrouvés dans la littérature (18). Un des buts de ce travail est d’investiguer si cette croyance repose sur des bases scientifiques ou non – autrement dit si elle se fonde sur une réalité ou sur un mythe.

S’interroger sur un possible « mythe » de l’efficacité des mesures de contrainte demande de définir ce terme. Au sens commun, un mythe est une croyance sans fondement. A nouveau, la question se pose de ce qu’est une croyance sans fondement – ou sans preuve –, et la part de vérité/légitimité d’une telle croyance. Il existe en effet différentes catégories de croyances sans fondement dont il est important de spécifier les nuances. Certaines croyances basées sur des observations empiriques peuvent être vraies sans preuve scientifique étayée par des études randomisées contrôlées (1^{e} catégorie). Un exemple connu de la littérature est l’absence de preuve de bénéfice de l’utilisation d’un parachute lors de la chute d’un avion du fait de l’absence d’étude randomisée (39) ou de volontaires pour que les résultats de l’étude randomisée contrôlée soient pertinents (40). Pour autant, le bénéfice de l’utilisation du parachute semble vrai et important à considérer pour la pratique, même sans preuve avérée. Un deuxième cas de figure (2^{e} catégorie) est une croyance répandue sur laquelle il peut être prudent de se baser, même sans certitude de sa véracité. Un exemple est l’adage « quand les enfants sont subitement silencieux, ils ont probablement fait des choses dont les parents devraient se soucier ». Il s’agit bien d’une croyance sans fondement mais qu’il est prudent de considérer comme vraie. D’autres croyances n’ont pas d’impact concret et ne sont pas forcément utiles à considérer (3^{e} catégorie), comme par exemple « si une femme enceinte a le ventre haut, ce sera un garçon ». Il existe également des avis d’experts qui sont vrais sans étayage scientifique (« appuyer sur le bouton 3 d’un ascenseur permet

d'aller au 3e étage ») (4e catégorie). Sur le plan sociologique, un mythe est un récit reposant sur les valeurs d'une communauté pour expliquer les phénomènes du monde qui l'entoure (cosmogonie, nature, société, individu) (41) (5e catégorie). Différents types de récits organisateurs peuvent exister, le mariage en est un exemple. En effet, il s'agit d'une construction sociale pour la reconnaissance d'un couple et d'une famille, mais qui ne repose pas sur des données biologiques ou scientifiques. Un mythe peut aussi être un récit allégorique visant une explication des phénomènes métaphysiques, comme par exemple la mythologie grecque qui raconte le monde au travers de la personnification par des dieux. Ce type de récit se rapproche d'une vision psychodynamique du mythe, identifié comme relevant « de processus psychiques » (42), « trouvant son origine dans la perception et l'expérience » (43), contenant ainsi « tout autant de "vérités" que n'importe laquelle des sciences de la nature ; [mais] localisées au niveau psychique » (44) (6e catégorie). Il semble donc qu'un mythe – en fonction des catégories évoquées – puisse avoir une forme de vérité sans preuve scientifique. La question concernant la contrainte est de savoir, dans le cas où on montrerait qu'il n'y a pas de preuves scientifiques d'efficacité, dans quelle catégorie du mythe on se situe. Il serait également important, en fonction de cette catégorisation, d'étudier si certains éléments restent vrais en l'absence de preuve scientifique et les valeurs sur lesquelles reposent ces arguments. Cette analyse permettrait d'étayer une légitimation éthique – ou non – de la contrainte.

3. But de la recherche

Nous avons effectué une revue narrative de la littérature préliminaire sur les preuves d'efficacité des mesures de contrainte limitatives de liberté, sans parvenir à des résultats significatifs (18). Toutefois, « l'absence de preuve n'est pas la preuve de l'absence ». Nous avons montré dans ce premier article une absence de preuve actuelle – mais sans que ce soit de manière exhaustive – et non une preuve de l'absence d'efficacité. Nous avons donc décidé d'approfondir les premiers résultats par une revue systématique de la littérature afin de statuer sur l'existence ou non d'un bénéfice aux mesures de contrainte et ainsi évaluer leur légitimité en pratique clinique. Du fait de la complexité du sujet, la question de recherche nécessite d'être bien définie. Nous avons choisi de limiter cette dernière aux mesures de contrainte limitatives de liberté, dont les effets bénéfiques directs sont moins intuitifs que pour la médication forcée et l'admission non-volontaire. Dans le but d'améliorer l'homogénéité des résultats, nous avons également limité la population cible aux patients hospitalisés en psychiatrie adulte. Par ailleurs, la dernière revue systématique mise à jour en 2012 (45) ne retrouvait que deux études randomisées contrôlées publiées sur l'efficacité de l'isolement et de la contention (46, 47). Dans

ce contexte, pour une approche plus consistante, nous avons choisi d'inclure les études observationnelles prospectives évaluant les effets de l'isolement et de la contention.

Cette revue de la littérature propose d'effectuer un état des lieux exhaustif des effets délétères et bénéfiques au sens large – incluant l'efficacité et le bénéfice thérapeutique – de l'isolement et de la contention en psychiatrie adulte. De plus, par une présentation actualisée de la littérature, elle devrait fournir une base de comparaison en vue de l'implémentation de programmes de réduction de la contrainte. En dernier lieu, nous visons à synthétiser les méthodes de recherche utilisées pour l'étude de la contrainte de manière à améliorer sa faisabilité.

L'article présenté ci-après, élément central de la thèse, est conforme à la méthodologie rigoureuse de la revue systématique. La discussion s'inscrit toutefois dans une réflexion plus large, incluant des dimensions éthiques, juridiques, sociales voire psychodynamiques que nous proposons d'évoquer.

III. Article de publication originale

Effects of Seclusion and Restraint in Adult Psychiatry: A Systematic Review

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Keywords: coercion, restraint, seclusion, psychiatry, inpatient, effect, safety, effectiveness.

Abstract

Background

Determining the clinical effects of coercion is a difficult challenge, raising ethical, legal and methodological questions. Despite limited scientific evidence on effectiveness, coercive measures are frequently used, especially in psychiatry. This systematic review aims to search for effects of seclusion and restraint on psychiatric inpatients with wider inclusion of outcomes and study designs than former reviews.

Methods

A systematic search was conducted following PRISMA guidelines, primarily through Pubmed, Embase, CENTRAL. Interventional and prospective observational studies on effects of seclusion and restraint on psychiatric inpatients were included. Main search keywords were *restraint, seclusion, psychiatry, effect, harm, efficiency*, *efficacy, effectiveness, quality of life*.

Results

Thirty-five articles were included, out of 6854 records. Studies on the effects of seclusion and restraint in adult psychiatry comprise a wide range of outcomes and designs. The identified literature provides some evidence that seclusion and restraint have deleterious physical or psychological consequences. Estimation of Post-traumatic Stress Disorder incidence after intervention varies from 25 to 47%, and thus, is not negligible, especially for patients with past traumatic experiences. Subjective perception has high interindividual variability, mostly associated with negative emotions. Effectiveness and adverse effects of seclusion and restraint seem to be similar. Compared to other coercive measures (notably forced medication), seclusion seems to be better accepted, while restraint seems to be less tolerated, possibly because of the perception of seclusion as “non-invasive”. Therapeutic interaction appears to have a positive influence on coercion perception.

Conclusion

Heterogeneity of the included studies limited drawing clear conclusions, but the main results identified show negative effects of seclusion and restraint. These interventions should be used with caution and as a last resort. Patients’ preferences should be taken into account when deciding to apply these measures. The therapeutic relationship could be a focus for improvement of effects and subjective perception of coercion. In terms of methodology, studying coercive measures remains difficult, but in the context of current research on coercion reduction, is needed to provide workable baseline data and potential targets for interventions. Well-conducted prospective cohort studies could be more feasible than RCTs for interventional studies.

1. Introduction

a. Rationale

Coercion is a theme of worldwide importance in psychiatry and is defined as the use of an intervention against a person's will (6). Coercive measures can also have other dimensions, in particular limitations of freedom of movement (6) that are frequently used in psychiatry, usually for containment of aggressive behaviours, but also in other circumstances and settings, including every medical specialty (48, 15). In the context of overriding a person's will, coercion raises ethics and legal questions. These measures limit several fundamental human rights, such as liberty of choice or movement, autonomy and physical integrity (2) and are therefore subjected to international, European, state and local laws and regulations (21, 49). Discrepancies regarding the use of coercive measures between countries and even regions inside a same country are important (5, 50, 51). They concern clinical practices as well as juridical and ethical application of laws or recommendations. Efforts are made for an international harmonization of guidelines and practices, for example through the "European Evaluation of Coercion in Psychiatry and Harmonization of Best Clinical Practice" (EUNOMIA) project (17, 52).

Various forms of coercion exist that can be differentiated into formal, informal and subjective coercion, but their definitions and interpretations vary between countries (22). Formal coercion usually includes involuntary admission, involuntary treatment, seclusion and restraint. The two latter categories refer to methods limiting freedom of physical movement. Several kinds of physical restraint exist either mechanical when devices are used for immobilization or manual when staff holds the patient. Seclusion is the confinement of the patient in a locked room from which he cannot exit on his own (6). Involuntary admission corresponds to the hospitalization of the patient against his will. Involuntary treatment refers to the administration of a medication against the will of the patient (6). The concept of this coercive measure is however very heterogeneous and can take several forms and definitions depending on the local or state legislations (21). Informal coercion regroups persuasion, manipulation or other types of control or influence (22, 12). Subjective coercion characterizes patients', caregivers' or stakeholders' points of view or feelings in situations of coercion. Subjective perception can differ from objective events (13).

The topic of coercion is particularly relevant in psychiatry as patients suffering from psychiatric disorders can lack decision-making capacity. The latter are thus susceptible to the other's influence or power abuse (22). This susceptibility can lead to disrespect of human rights (20). In this context, use of coercive measures in psychiatry is controversial and needs to be practiced with great care (33).

Importantly, clinical practice should follow the principles of evidence-based medicine. By definition, an intervention is legitimate only if a direct benefit for the patient is scientifically proven (29). However, few data exist on the real benefit of coercive measures, regarding efficiency, efficacy or effectiveness (18, 45). Several problems inherent to the topic limit application of rigorous scientific methodology. These problems include the heterogeneity of definitions (four formal types of coercion, informal and subjective types) and clinical practices (variation between countries, and between hospital of a same country) (2) as well as difficulties in collecting valid and reliable data, with patients not always capable of consenting to research and randomization difficult to implement (34). Despite these scientific limitations in the evidence base, coercive measures are commonly used in adult psychiatric clinical practice. Some multicenter studies reported epidemiological data on the difference of use of coercion between countries or hospitals of a same country. Globally the rate of use of coercive measures in the literature varies from 0.4 to 66% (1). In a multicenter study in 10 German psychiatric hospitals, Steinert et al. reported an exposition to coercion in 9.5% of admissions (53). In Martin et al., 6.6% of admissions in seven Swiss psychiatric hospitals were affected by mechanical restraint compared to 10.4% of admissions in seven German hospitals (54). In the same study, 17.8% and 7.8% of admissions were respectively affected by seclusion. The EUNOMIA 19ospitaliza project conducted at 13 centres in 12 European countries studied the characteristics of the use of coercion and of the patient population submitted to coercive measures (seclusion, restraint and/or forced treatment), and searched for differences between countries (52). The results showed significant variations of frequency of use between countries, from 21 to 59% of involuntary admissions, with higher rates in Poland, Italy and Greece (5, 55). These discrepancies between lack of evidence for efficiency and frequency of use highlight the need for further study of the effects of coercion in adult psychiatry.

In addition, recent research has addressed coercion reduction, mainly through development of programs aiming to reduce coercive measures (15, 56). However, in order to evaluate the effectiveness of coercion reduction, objective data on baseline measures are needed without implementation of specific interventions to reduce coercion. For these reasons, studies on the consequences of coercive measures are of great scientific and clinical importance. Gutheil stated in 1978 that seclusion could in theory permit containment, reassurance and diminution of sensible input (31). Several studies and reviews have since studied risk factors and effects of seclusion and restraint, but the results for effectiveness have been extremely limited (18, 45). Predictors of the use of coercive measures have been studied more extensively (32, 57) but mainly through retrospective databases and analyses (33).

Sailas et Fenton and Nelstrop et al., two systematic reviews (45, 58) and Luciano et al., a critical review (32) found two randomized controlled trials (RCT), but no other studies reporting results on effects or safety of seclusion or restraint with equivalent levels of evidence. Furthermore, the two systematic reviews have not been updated since 2012. The subject is of high importance due to the substantial consequences for patients, especially in case of severe mental disorders. In our view, one condition for legitimacy of coercive measures, not only juridical but also ethical and clinical, should be a beneficial effect for the patient. This could be a protective effect, but we were also concerned about the belief that coercive measures can have therapeutic effects. We have observed this belief in our experience, and it has also been described in the literature (38). We wanted to investigate whether or not this belief has scientific bases. An update of the recent literature on the evidence of efficiency (including efficacy, effectiveness and therapeutic benefit) of coercive measures is thus needed in order to evaluate the legitimacy of their use in clinical practice.

Due to the complexity of the subject, the systematic review needs to be limited to specific, well-defined questions. Efficacy of coercive measures is a fundamental question, as their use implies important clinical, ethical and legal consequences. Concerning involuntary treatment, a direct beneficial and therapeutic effect seems more intuitive than for seclusion or restraint. Involuntary hospitalization is another way of coercion, for which the initial decision is mainly made outside of the hospital context. For these reasons, we chose to limit the present review to the study of seclusion and restraint that represent coercive measures limiting freedom of movement in order to investigate harmful or beneficial effects of these measures. Including involuntary treatment or hospitalization seemed to us to be another research question and would widen the scope of research questions too much for them to be answered in a single review. In addition, these methods directly concern the institutional practices in most countries and searching for their effectiveness and efficacy could provide important information for interventional studies aimed at seclusion and restraint reduction in clinical practice.

b. Objectives and research question

The aim of this study is to conduct a systematic literature review on the negative and potentially beneficial effects of seclusion and restraint on adult psychiatric inpatients, compared to non-exposure or to exposure to other coercive measures. This review should permit establishing the potential harms and benefits of these measures, and therefore, provide an improved evidence base for making decisions in acute psychiatric care. In addition, through systematic synthetization of available baseline data, this review should provide arguments for later implementation of coercion reduction programs. Finally, we

aim to synthesize the methods used to study the topic in order to propose a systematic approach for structuring research and improvement of the evidence basis.

As Sailas and Fenton found already in 2012, there have been only two randomized controlled trials on the effectiveness of seclusion and restraint (45). We chose to widen the search to prospective observational studies with various outcomes measuring benefits and harms of seclusion and restraint. Even though this approach limits the evidence level, it will allow for a broader appreciation of the consequences of interventions limiting liberty of movement.

2. Material and Methods

a. Study design

This systematic review of the literature follows Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, with a search question defined with the participants, interventions, comparators, outcomes, study design (PICOS) method as described in the Cochrane Collaboration Handbook (59). The studied population includes psychiatric inpatients hospitalized in adult psychiatric inpatient units. Interventions are seclusion and/or physical restraint (mechanical or manual). The comparator is either non-exposure to seclusion and/or restraint or exposure to other coercive measures (involuntary admission or treatment, or seclusion and/or restraint (the one that is not the main intervention)). We considered a broad range of potential beneficial and negative effects of seclusion and restraint, including objective effectiveness (symptom intensity, level of needed medication, length of stay), safety, adverse effects, quality of life, incidence of post-traumatic stress disorder (PTSD), and patients' subjective perception of coercion.

b. Eligibility Criteria

i. Inclusion Criteria

Articles studying adult psychiatric inpatients and physically limiting coercive measures (seclusion or restraint) were selected. We included interventional studies (including randomized controlled trials) and prospective observational studies including case-control studies. Articles published in English, French or German were included. Articles investigating of effects of seclusion and restraint on adult psychiatric inpatients were included. After full-text assessment, we synthesized the various studied outcomes and summarized them in different subgroups, which are detailed in Table 1: objective effectiveness (symptom intensity, level of needed medication, length of stay), safety, adverse effects, quality of life, incidence of PTSD, and patients' subjective perception of coercion.

ii. Exclusion Criteria

Studies involving specific populations were excluded: non-psychiatric, geriatric, paediatric, outpatient, or forensic populations, somatic, addictive or eating disorders, and intellectual disabilities. Studies on other coercive measures (involuntary admissions, forced medication or informal coercion) were excluded.

We excluded retrospective studies (including extraction from databases), case series and expert opinions. Qualitative studies restricted to thematic analyses were not included due to lack of objective data. Articles in other than the above-mentioned languages were not included. Studies on the staff's attitude to seclusion or restraint were not included, as in most studies these are considered predictive factors, rather than effects, of coercive measures. Articles focused on risk factors or coercion reduction programs were excluded because they did not meet search question criteria.

c. Search strategies

We searched the following databases: MEDLINE via Pubmed, Embase, Web of Science, PsycINFO, Google Scholar, Cochrane Central Register of Controlled Trials (CENTRAL), Cumulative Index to Nursing and Allied Health Literature (CINAHL) via EBSCO, Cairninfo, PROSPERO, and Clinicaltrials.gov.

Search strategies are detailed in Supplementary Table 1. We designed comprehensive searches for the two main databases (MEDLINE via Pubmed and Embase), described in Supplementary Table 1. For less exhaustive databases, we employed the following keywords: (coercion OR Restraint OR seclusion) AND (psychiatric OR psychiatry OR mental health) AND (effect OR safety OR harm OR efficiency OR efficacy OR beneficence OR risk OR mortality OR quality of life OR effectiveness). References of selected studies and reviews on seclusion and/or restraint were screened and referred to as "other sources" in Figure 1 (32, 45, 56, 57, 58, 60-62).

d. Data sources, study selection and data extraction

i. Data management, including time frame

The systematic literature search was conducted from the first available article to December 8, 2018. Databases searched have been updated since this date. Duplicates were removed before screening titles with EndNote™ X8.2.

ii. Study selection processes

Two authors independently screened titles and abstracts for study selection. Disagreements were resolved by consensus. The eligibility of retrieved full-text articles was discussed with a third author.

iii. Data collection processes

Data were extracted from selected articles using specified fields: author, year of publication, location, design and sample, studied interventions, explored outcomes, results and risk of bias. When available, we reported quantitative results (percentages).

iv. Data analysis

A qualitative analysis of included studies was performed. Due to the heterogeneity of the outcomes reported, a quantitative analysis was not possible. The quality of evidence and risk of bias and were systematically assessed for individual studies using the revised Cochrane Risk of Bias Tool (59) for RCTs and the U.S. Preventive Services Task Force (USPSTF) tool for observational studies (63, 64). Several potential sources of bias were evaluated depending on study design. For RCTs, assessed sources of bias were sequence generation, allocation concealment, blinding of participants, personnel and outcome assessors, selective outcome reporting, and other sources of bias. As described in the Cochrane Collaboration Handbook (59), RCTs can then be assigned to different categories of risk (low, moderate or high). For observational studies, analysed sources of bias were selection bias (assembly and maintenance of comparable groups), quality bias (adequacy of measurements, potential confounders with either restriction or measurement for adjustment in the analysis), information bias (loss to follow-up, definitions of interventions and outcomes), selective outcome reporting. Meta-biases (selection and publication, information and analysis bias) were evaluated following Institute of Medicine guidelines (64).

3. Results

a. Study selection and characteristics

Applying the search strategy described above, we retrieved 8590 articles from all databases (Figure 1), and 6854 remained after removing duplicates. There 438 eligible articles for abstract review, and 131 were eligible for full-text reading. Out of these 131, thirty-five studies were included in the qualitative analysis. In all, 96 articles were not related to the research question or did not meet inclusion criteria and were excluded. In terms of PICOS, exclusion criteria addressed the study design: five studies were qualitative, nineteen were retrospective, five were case reports, one was a search protocol and one was a review; the population/setting: one study took place in a forensic ward and four in a non-clinical

setting; the interventions: ten made no differences between types of coercive measures, seven did not study seclusion or restraint; and finally the outcomes: six did not study effects of coercion but other outcomes, thirty-three studied predictive factors, four studied aggression and its management but not the effects of seclusion or restraint (Figure 1). The characteristics of selected studies are arranged by study design, explored outcome and comparator to the main intervention (Table 2). Three studies were randomized controlled trials, and thirty-two had a prospective observational design (thirty cohorts, two cross-sectional studies). Four studies compared secluded versus restrained patients (46, 47, 77, 86). Two studies compared seclusion and restraint (without distinction) versus non-exposure (67, 78) and four studies compared these measures to other coercive measures (65, 66, 87, 88). Nine studies compared secluded versus non-secluded patients. Guzman-Parra et al. compared restraint versus forced medication (79) and Wallsten et al. compared restraint versus non-exposure (91). Two additional studies provided data on secluded or restrained patients (without distinction) (92, 93), two examined only restrained patients (84, 85), and ten studies examined only secluded patients. Diagnoses could differ between studies, but most diagnoses were psychotic disorders (ranging from 26.8 to 82.3%), followed by affective disorders (in particular mania) (varying from 12 to 53.6%), substance uses (ranging from 4.9 to 32%) and personality disorders (varying from 1.9 to 11%) (Table 2). Two articles did not give diagnostic information (68, 90). Two studies selected patients based on the diagnoses of schizophrenic or schizoaffective disorder (74, 81). Symptom intensity was evaluated with the Positive and Negative Syndrome Scale (PANSS) (46, 76); the Brief Psychiatric Rating Scale (BPRS) (66, 85, 87, 91) and/or the Beck Depression Inventory II (BDI-II) (61).

b. Synthesized findings

Overall, evidence for negative effects have consistently been found across studies: PTSD (65, 78, 79, 83), medication need (69), increased length of stay (66, 71-75), Deep Vein Thrombosis (DVT) (84). One study suggested a beneficial effect on quality of life (67). Drawing clear conclusions on beneficial effects of seclusion and restraint were not allowed. Effects of these measures included various outcomes (Table1): two studies explored objective effectiveness of seclusion and restraint (68, 69), four examined beneficial, adverse effects, and subjective perception (46, 47, 65, 76), one examined adverse effects (84), one examined quality of life after seclusion or restraint (without distinction) (67), four examined the influence of seclusion or restraint on length of stay (66, 70-72), three examined length of stay and subjective perception (73-75), one examined the incidence of PTSD after seclusion or restraint (78), four examined incidence of PTSD and subjective perception (77, 79, 83, 85), two examined reported hallucinatory experiences during seclusion and subjective perception (80, 81) and

thirteen examined subjective perception of seclusion or restraint. Fourteen studies reported negative effects of seclusion and restraint, four reported beneficial effects, and seventeen reported negative and beneficial effects. Results for these heterogeneous outcomes strongly diverge across studies. Some of them have struggles in achieving definitive conclusions, namely regarding subjective outcomes. Below, we detail results for each explored outcome by study design and comparator to the main intervention.

i. Objective effectiveness

In Bergk et al. and Huf et al., two RCTs comparing seclusion versus restraint, the two interventions had similar effectiveness in terms of level of needed medication (46, 47), intensity of aggressive symptoms and safety during and after interventions (46). Level of needed medication and aggressive symptoms were significantly lower for the secluded, nonrandomized group compared to the secluded, randomized or restrained (randomized or nonrandomized) groups (46).

Georgieva et al., a prospective study, compared effectiveness (evaluated through global functioning and reduced aggression) between different coercive measures: seclusion or forced medication alone or seclusion combined with forced medication or restraint (65). Seclusion combined with restraint was not more effective than seclusion or forced medication alone or combined (65). In McLaughlin et al, a prospective multi-centre study, length of stay was increased for seclusion, restraint or forced medication compared to non-exposure (to each evaluated coercive measure, but only seclusion remained significant in multivariate analysis) (66). In Soininen et al., secluded or restrained patients (without distinction) reported better subjective quality of life at discharge compared to non-exposed patients (67). The authors concluded that, on the one hand, seclusion and restraint had only little or short-term negative influence on quality of life, and on the other hand, the observed association may not be causal. For them, variations in diagnosis between groups of patients could explain the observed differences (majority of mood disorders in non-exposed versus schizophrenia for exposed patients). Mood disorders are indeed associated with lower subjective quality of life in the literature (67).

In a prospective quasi-experimental study comparing seclusion and non-exposure, Cashin identified no significant differences for level of needed medication or resolution time for emergencies (68). Hafner et al. compared two units prospectively, one using seclusion and the other not using seclusion (69). Seclusion was compared to non-exposure in the same unit on one hand and to the other unit on the other. Secluded patients needed 25% more medication than those agitated but non-secluded in the unit not using seclusion. The authors concluded that seclusion was not sufficient to treat agitation as more medication was needed. On the other hand, in the unit using seclusion, non-secluded patients

needed less medication than those in the unit not using seclusion, suggesting that seclusion could reduce the dangerousness of the ward (69). Several prospective studies found an increased length of stay for secluded versus non-exposed patients (70-75). However, in Mattson et Sacks, this effect was not significant when focusing on patients less than 20 years of age (72).

In Vaaler et al., an RCT comparing seclusion in furnished and unfurnished rooms, no negative influence of furniture was found on effectiveness in terms of length of stay or symptom intensity (76).

ii. Adverse effects

In Bergk et al. and Huf et al., the two RCTs comparing seclusion versus restraint, no significant differences between the two interventions were found for adverse events during or after the intervention in terms of agitation, suicide attempt or self-harm, fracture, revival of previous traumatism, death, hypertension, or physical pain (46, 47). Although 40% of patients were stated to be at risk for PTSD after seclusion or restraint in Bergk et al.'s RCT (46), only one secluded and two restrained patients had symptoms fulfilling PTSD diagnosis at a one-year follow-up (77). These authors concluded that this lower than expected incidence of PTSD may be due to natural resolution of symptoms or to the interviews conducted with the patients, which could have helped prevent PTSD (77).

When comparing seclusion and forced medication alone or combined, or seclusion with restraint, Georgieva et al. reported more adverse events for seclusion combined with restraint than for seclusion or forced medication alone or combined (65). In a prospective study involving involuntarily admitted patients, Steinert et al. found a bidirectional association between history of seclusion or restraint (without distinction) and life-threatening traumatic events (78). Thus, the authors concluded that, on the one hand, exposure to past traumatic events could enhance risk of victimization and revival of previous traumatism during inpatient treatment, and on the other hand, seclusion or restraint may cause re-experienced traumatism.

In Guzman-Parra et al., comparing restraint to forced medication, more traumatic experiences were reported after restraint (79).

In three prospective studies, 31% to 52% of secluded patients reported hallucinatory experiences (80-82). In the Kennedy study, 70% of the 52% reported hallucinations were present before seclusion and the increased intensity during the intervention was not sufficient to conclude that seclusion may cause the hallucinations (81). Hallucinating patients had longer seclusion time and more therapeutic interaction and medication than non-hallucinating patients (81).

In Ishida et al., a prospective study involving mechanically restrained patients receiving prophylaxis, Doppler ultrasound of lower extremities showed 11.6% incidence of asymptomatic deep vein

thrombosis. The authors concluded, therefore, that there was probably underestimation of deep vein thrombosis in routine use of restraint (84). In an observational study, Fugger et al. found a 25% incidence of PTSD after mechanical restraint (29% at hospital discharge and 22% four weeks after discharge) (85), while Whitecross et al. found a 47% incidence of PTSD after seclusion (83).

iii. Subjective outcomes

In Bergk et al. and Huf et al., patients' preferences between seclusion and restraint were not significantly different (46, 47). After one-year follow-up in Bergk et al.'s RCT (46), 58% secluded or restrained patients reported positive emotions, but mechanical restraint was assessed more negatively than seclusion (77). In Sagduyu et al., a prospective study comparing seclusion versus restraint, 40% secluded and 20% restrained patients evaluated the intervention as beneficial (86). Additionally, 71% secluded and 89% restrained patients remembered past experiences (confinement or physical abuse), and 73% secluded and 81% restrained patients reported negative feelings (86).

In Georgieva et al., seclusion combined with restraint was associated with higher perceived coercion than seclusion or forced medication alone or combined (65). In Krieger et al., comparing various coercive measures (involuntary admission combined with seclusion, mechanical or manual restraint, forced medication or video monitoring) to non-exposure (voluntary admission in a closed ward without other coercive measure), more negative emotions were related to seclusion or restraint (87). Patients' understanding of use of seclusion or restraint increased during hospitalization, and seclusion was preferred among all coercive measures, while restraint was less accepted than the other measures (87).

In Gowda et al., another prospective study comparing perceptions of coercion from seclusion, physical (mechanical or manual) or chemical restraint, involuntary treatment and electroconvulsive therapy at admission and discharge, physical restraint was associated with a greater perception of coercion, followed by involuntary treatment, chemical restraint, seclusion and finally electroconvulsive therapy (88).

In Sorgaard, an interventional study, seclusion was the main factor associated with perceived coercion compared to age, sex, forced medication or length of stay (89). In Martinez et al., a cross-sectional study, seclusion was rated as needed in 56.2% of cases, but was mainly associated with negative perception (62% overuse, 76.5% punishment) (90).

In Guzman-Parra et al., restraint was associated with a greater perception of coercion than forced medication (79). In Wallsten et al., a prospective study evaluating adequate patient reports of mechanical restraint, 4 restrained patients reported not having been restrained while 8 non-restrained patients reported having been restrained. The cause of these 8 false positive and 4 false negative reports

was not clear, as it could be due to communication problems, memory failures (false memories for false positive) or emotional traumatic reactivation (91). In this study, the authors raised the question of the subjectivity of patients' self-reports of coercion.

After seclusion or restraint (without distinction), patients reported a feeling of clinical improvement (92), as well as dissatisfaction, denial of necessity or beneficence and insufficiency of dialogue with staff (93).

In Stolker et al., a prospective study evaluating the influence of the ward environment on perceptions of seclusion among secluded patients, perceived coercion was lower in cases of previous stays in multi-bed rooms compared to stays in single rooms (94). The authors concluded that the subjective effect of seclusion on patients could depend on the ward environment. In several prospective studies, seclusion was positively evaluated as safe and secure (73, 82) and slightly necessary (74, 82, 95). In three studies, patients reported feeling better after seclusion (75, 82, 95). In Mann et al., secluded patients reported positive feelings of constant attention and care from staff (73). In Keski-Valkama et al., more therapeutic interaction was demanded by secluded patients (96). Importantly, negative emotions were reported in most studies (82, 95, 97). Patients frequently reported seclusion as not helpful (69, 81, 95) or as punishment, ranging from 54 to 73% (82, 96, 97).

In Fugger et al., an observational study comparing patients' versus physicians' perceptions of mechanical restraint (during and after intervention), patients' ratings showed greater perceived coercion but less memory for the event, and greater feelings of being healthy and more acceptance than physicians expected (85).

c. Quality assessment and Risk of bias

i. RCTs (revised Cochrane Risk of Bias Tool) (59)

The three included RCTs did not use true allocation. Bergk et al. used an optional randomization (46), Huf et al. could re-allocate some patients when stakeholders evaluated seclusion as not efficient (47). In Vaaler et al., allocation depended on patient number in the unit or previous admittance (on equal headcount) (76). Blinding was not possible due to the characteristics of the measures (seclusion, restraint or no coercive measure). Selected studies published significant and non-significant results with beneficial and negative outcomes. Missing data, dropout and reasons for refusing to participate were well-documented in the selected studies. We found no identifiable selective outcome reporting in included studies for outcomes, time-points, subgroups or analyses, but few elements were available for detection of potential selective reporting. Registration of trials before study initiation was indeed performed only for Huf et al. (98). For this RCT, predetermined outcomes were identical to the final

reported outcomes (47). Intention-to-treat analysis was respected in Huf et al. and Vaaler et al. (47, 76). In Bergk et al., statistical analyses were conducted without 6 drop-out patients (46). Intention-to-treat analysis was, therefore, not fully respected. Concerning other potential sources of bias, Huf et al. postulated that restraint is more restrictive than seclusion and concluded by suggesting beginning with seclusion (47). The starting hypothesis seems to be identical to the conclusion and, in our opinion, could be a tautology. In Vaaler et al, the authors compared the influence of interior design on seclusion effectiveness measured as symptom intensity and global functioning during and after intervention (76). However, in our view, the study design seems to be unclear. The aim of the study was to detect differences between patients secluded in furnished or unfurnished rooms. Outlined this way, the design seems to be a superiority study. However, the authors stated in the results and discussion that negative effects of furnished rooms on seclusion effectiveness could not be significantly found due to lack of power. Described this way, the null hypothesis that furnished seclusion rooms have a negative impact on seclusion effectiveness could not be rejected. This formulation would correspond to a non-inferiority design. Thus, there seems to be a discrepancy between predetermined study design and results interpretation. This discrepancy creates questions as to the adequacy of the conclusion stating that furnished rooms seem to have no negative effect on seclusion effectiveness. According to the revised Cochrane Risk of Bias Tool (59), and despite following adequate methodological guidelines, the three included RCTs could be assessed as having a high risk of bias, due most notably to non-exhaustive allocation and no ability to use blinding.

ii. Prospective observational studies (USPSTF tool) (63, 64)

The included prospective studies reported the methods for group constitution and described the group characteristics for assessing comparability. Some studies did not search for confounding factors when an association was found between variables. For example, in several prospective studies, potential confounders were not stated for seclusion or restraint and length of stay (70, 71) or quality of life (67). Some studies had no control group for comparison of results (73, 83, 85, 95, 97). When present, others did not perform subgroup or quantitative analysis for significant differences between groups (86, 90). For some cohort or cross-sectional studies, lack of power and difficulties achieving rejection of the null hypothesis were a problem (68). Selected studies published significant and non-significant results with beneficial and negative outcomes. Missing data, dropout and reasons for refusing to participate were well-documented in the selected studies. We found no identifiable selective outcome reporting in included studies for outcomes, time-points, subgroups or analyses, but few elements were available for detection of potential selective reporting. Registration of trials before study initiation was indeed not

performed for included studies, and we could not compare predetermined outcomes with final reported outcomes. Heterogeneity of seclusion and restraint definitions cause difficulties for assessing comparable outcomes. For some studies, seclusion meant open or locked rooms (70, 90), whereas in most studies, seclusion was defined as a locked room from which the patient cannot get out on his own. For other studies, physical restraint could be either mechanical or manual and sometimes both (79, 84, 85). Gowda et al. described the difference between chemical restraint (used during emergencies) and involuntary medication (in case of leverage) (88), while most studies referred to the two categories as involuntary (or forced) treatment. These authors also distinguished between subjective and perceived coercion, whereas most studies used one or the other without differentiation (88).

4. Discussion

a. Summary of main findings

This review synthesizes a wide range of information into an original overview on coercive measures in adult psychiatric patients. Thirty-five articles addressed the search question on beneficial and negative effects of seclusion and restraint in adult psychiatry. The identified literature strongly suggests that seclusion and restraint have deleterious physical or psychological consequences. The incidence of PTSD after seclusion or restraint ranges from 25 to 47%, which is not negligible (83, 85), especially in patients with past traumatic events (78). The main diagnoses associated with the use of seclusion or restraint in the selected articles are schizophrenic, schizoaffective or bipolar, currently manic disorders. Subjective perception has high interindividual variability and can be positive, with feelings of safety, help (73), clinical improvement (75, 92), or evaluation as necessary (74, 95). However, seclusion and restraint are mostly associated with negative emotions, particularly feelings of punishment and distress (82, 86, 97). Conclusions on protective or therapeutic effects of seclusion and restraint are more difficult to draw. Our results provide little evidence for these outcomes, but further research is clearly necessary. Objective effectiveness of seclusion and restraint seems to be comparable in terms of needed medication, symptom intensity and adverse effects (46, 47, 66). Compared to non-exposure, they have deleterious physical and psychological consequences, like PTSD, revival of previous traumatism, DVT, increased length of stay, hallucinations and negative emotions (65, 79, 89). Seclusion seems to be better accepted than other coercive measures, such as forced medication, while restraint seems to be less tolerated (87, 88). A reason could be that seclusion is perceived as a “non-invasive” method (88). Therapeutic interaction seems to influence perceptions of coercion and could help to avoid negative effects when coercive measures are not avoidable (73, 93, 96).

b. Overall assessment of the quality, completeness and applicability of evidence

We chose to include a broad range of outcomes for effects of seclusion and restraint in adult psychiatry. We found thirty-five relevant articles with significant or exploitable results, but also a high heterogeneity with respect to the study designs and the explored outcomes. There are only three published RCTs, which point out the challenge of obtaining usable data to prove clinical efficiency and to identify benefits or harms of seclusion and restraint on patients with severe mental disorders. In an era of evidence-based medicine, it shows that daily clinical practices can still be traditional habits more than therapeutic methods proven to be effective. This finding does not mean that coercive methods are not necessary in certain cases, but in the context of limiting human rights and potential deleterious consequences, the limitations of the evidence base should invite medical and nursing staff to question their practices and to use them with caution and with hindsight when the decision (as a last resort) to use them is made.

Methods for studying effects of coercion in adult psychiatry can be difficult to design. According to the Cochrane Risk of Bias Tool (59) and despite following adequate methodological guidelines, the three included RCTs could be stated as having a high risk of bias (46, 47, 76). However, due to the nature of the topic, it is very difficult to avoid these biases and the realization and publication of studies are an excellent example how to deal with the inherent methodological constraints. On the other hand, prospective cohort or cross-sectional studies can have difficulties achieving significant results or statements of causal inference. Lack of power, loss to follow-up, presence of confounding factors are frequent faced problems in these studies (67, 68). This overview of evidence assessment outlines the difficulties in realizing clinical trials on this subject. Despite the seethe complexities of the issue and the associated challenges, it seems relevant to give an assessment of the current state of the evidence related to seclusion and restraint in adult psychiatric patients, because of the fundamental aspects and the consequences inherent in these measures.

c. Comparison with other studies and reviews

The previous review most comparable to ours was published by Sailas and Fenton in 2000, with a last update in 2012 (45). The authors found two RCTs awaiting publication meeting their search criteria, with no evidence of efficacy of seclusion and restraint. Our search criteria applied to the literature published until 2018 allowed us to include thirty-five studies, three of which were RCTs. However, even this broader approach could not establish strong evidence of efficacy of seclusion and restraint. Heterogeneity of study designs, studies outcomes and settings did not allow drawing clear conclusions on beneficial effects of these measures. Overall, this overview shows a very limited progress in

establishing efficacy of seclusion and restraint. Thus, it supports the current trend of developing further research, political and juridical regulations as well as reduction programs targeting these coercive measures.

With our search strategies, we included outcomes like staff attitude or effects of seclusion or restraint on staff, but no article seemed to study this outcome as a direct effect of coercion. Studies on staff perception of seclusion or restraint were found (99, 100) but seemed to evaluate opinion on the topic or risk factors for use of coercive measures more than direct effects of seclusion or restraint. In our opinion, they could not help address the search question.

Another source of limitation when studying coercion is the heterogeneity of definitions. We saw some differences when assessing the risk of bias. In the included literature, we found no difference made between coercion as a measure against the patient's will and a limitation of freedom of movement, which are two different elements of a coercive measure (6). To achieve a precise and adequate study of coercive measures, it would be important to specify and clarify the implicit dimensions of coercion.

Some studies are frequently cited in articles or reviews. Of those studies, we chose not to include Soliday 1985 and Wadeson and Carpenter 1976 because of thematic analysis of open interviews (101, 102). From our perspective, results did not address our search question regarding objective effect measures. One of the first articles on the topic is Gutheil 1978 that theoretically conceptualized the effects of seclusion as therapeutic (31). This concept has been quoted as a hypothesis in most studies and reviews (70), including Fisher 1994 (48) and Mason 1992 (103), despite the fact that these studies include few evidence-based results.

Some other studies could have been relevant for our search question but did not meet inclusion criteria. For example, Nawaz et al. 2007 conducted an RCT comparing the effectiveness of standard restraint and safety nets but in a geriatric population (104). Generalization of results to the adult psychiatric population seemed difficult and therefore we did not include the study. Mion et al. 1989 studied physical restraint in a mixed adult, but mainly geriatric, population (105). In our opinion, no conclusion for adult psychiatric patients could be drawn, and we chose not to include the study.

d. Implications for clinical practice

Concerning clinical practice, Vaaler et al. found no influence of a furnished seclusion room on seclusion effectiveness (76). This study suggested that the settled norm (strictly unfurnished room for seclusion) could be reassessed, and habits could change in ways more agreeable to patients. The reported adverse effects should be taken into account in clinical practice, mainly when deciding the accuracy of using coercive measures on a patient. The incidence of PTSD after seclusion and restraint

was not clearly stated and varied widely (from 25 to 47%) (65, 78, 79, 83, 85). Steinert et al. and Georgieva et al. found that seclusion and restraint may cause revivals of previous traumatism (65, 78). Difficulties comparing studies are undeniable, but these results show a trend toward potential traumatic experiences after seclusion or restraint. Palazzolo and Kennedy et al. have also reported hallucinatory experiences during seclusion (80, 81), which occurrence mechanism is not clearly stated. Seclusion and restraint should therefore be used with caution, and staff should closely monitor development of post-traumatic symptoms or hallucinations. Following the hypothesis that the prevalence of DVT is likely to be underestimated under restraint (84), new protocols should be elaborated to prevent these negative effects of restraint when clinical circumstances require its use. Seclusion could be better accepted than restraint (87, 88). Preferred use of seclusion could be a possible change to implement in clinical practice, but it should still be used as a last resort method.

On the other hand, diagnostic variations could be a relevant factor in the use of seclusion or restraint. In the selected studies, patients were more frequently diagnosed with schizophrenic, schizoaffective or bipolar, currently manic disorders. These results are consistent with the recent literature that reports associations between schizophrenic or organic mental disorders and risk of use of seclusion (106) and coercive measures generally (5, 53, 107). Martin et al. and Miodownik et al. found an augmented risk of seclusion and restraint for patients with schizophrenic disorders (108, 109) and Beghi et al. an increased of restraint for the same diagnoses (57). These associations have implications in clinical practice: psychotic disorders are known to often be chronic and associated with recurrent decompensation. The type of diagnosis could be considered as a moderator and risk factor of long-term use of coercion. Management of schizophrenic and psychotic disorders generally (including mania) should maybe be reassessed in the light of an augmented risk for the use of coercion. Therefore, the need for development of alternatives to coercive measures is a priority, as well as structured research to better understand efficiency of coercive measures and in which context they could be applied. In addition, this research should consider the subjective preference of patients (46).

Subjective perception of seclusion and restraint is mainly associated with negative emotions, like loneliness, helplessness, feeling of punishment (87, 90, 96). Therapeutic interaction seems to influence perceptions of coercion and could therefore be of importance to help patients coping with these feelings and enhance the therapeutic effect despite the coercive aspect of the measure (110, 111). In several prospective studies, secluded or restrained (without distinction) patients reported feelings of constant attention and care from staff (73), asked for more interaction (96) or evaluated the latter as insufficient (93). Our hypothesis is that interaction with staff permits elaboration of the therapeutic relationship, which mediates treatment outcomes and particularly efficacy (110, 111). This finding suggests that

possibilities of patient-staff interactions should be reinforced to develop therapeutic relationships and secondarily improve the effects and subjective perceptions of coercion. The place and meaning of the therapeutic relationship during coercion could therefore also be explored in future research. Helping to develop a secure therapeutic relationship for the patient could be an alternative to the use of seclusion or restraint, as relations as well as measures limiting liberty of movement have a containment function.

e. Implications for research

Concerning research, our literature review clearly shows that significant results for effects of seclusion and restraint in adult psychiatry remain difficult to obtain. A reason seems to be the disparity in the topic of comparison as well as the complexity of elaborating study designs for agitated patients. In this review, we focused on prospective studies that allow identification of effects of coercive interventions. However, other approaches have been used in research on coercive measures but may be better suited to assess different outcomes. In the following paragraphs, we propose a brief review of different available methodologies and their appropriateness depending on the outcome of interest (Figure 2). In our opinion, specifying these differences is worthwhile for further clinical research in order to adapt the methodology to specific research questions and therefore obtain reliable and valid results. Further research on coercive measures is indeed needed, concerning epidemiology, efficacy, risk prediction. Its purpose should be the elaboration of seclusion and restraint reduction programs and development of alternatives to their use.

Retrospective methodology is frequently used to determine risk factors and predictors of seclusion and restraint (33, 112). A retrospective methodology may however not be adequate for determining the effects of these measures as it can provide associations among risk factors but does not provide significant and reliable associations among effects of an intervention (Figure 2). It seems to us that methodology can greatly influence the significance of the final results.

Another current tendency emphasizes that coercive measures, particularly seclusion and restraint, are last resort methods, and therefore, should be reduced as much as possible. Accordingly, recent articles and reviews focus on reduction programs that have mainly been evaluated with outcomes directly reflecting coercive events themselves, in particular frequency, duration and other parameters (15, 56). This approach has to be clearly differentiated from our question about the consequences of seclusion and restraint (Figure 2). It does not mean that direct study of coercive measures should be discarded as they are still frequently used and are needed as a last resort for difficult situations in clinical practice when no other alternative remains.

In this review, we focused on prospective studies addressing the consequences of seclusion and restraint (Figure 2). Scientific evidence of benefit or harm should ideally be investigated with randomized controlled studies (29, 30). However, concerning seclusion and restraint, and coercive measures in general, the feasibility of such studies is controversial (34). Despite an adequate method, the three published RCTs show difficulties in achieving easily interpretable results without high risk of bias. This observation raises the question of whether of choosing an RCT design is adequate when studying the effects of coercion. One reason for the lack of data when using an RCT design could be that it is deemed dangerous to conduct a randomized controlled trial of seclusion or restraint. This makes the situation rather similar to that which exists in lethal diseases, for example surrounding the Ebola outbreaks that raised ethical discussion on feasibility and adequacy of using RCT design when studying efficacy for candidate Ebola vaccines (113). In this ethical discussion, the authors were in favor of using RCT despite methodological difficulties and dangerousness, arguing with four often neglected factors (benefits to non-participants and participants once a trial is over, participants' prospects before randomization and the near-inevitable disparity between arms in any randomized controlled trial) (113). When studying seclusion and restraint, the second and third factors seem not to be directly applicable, in particular due to the coercive aspect and implementation against the patient's will of the measure. These elements open a wide range of questions that would require supplementary reflection and discussion in further researches.

Cross-sectional studies are also often used in research on coercive measures, but investigation of benefits and harms is very limited with this study design. In this context, well-conducted prospective cohort studies seem to be more feasible than RCTs and should produce meaningful results for effects of seclusion or restraint, even though the evidence level will be reduced in comparison to RCTs. This design could allow collection of more useful results and therefore have greater impact on clinical practice changes.

f. Strengths and Limitations

The main strength of our review is the broad and systematic search for effects of seclusion and restraint in terms of outcomes and methodology. To our knowledge, this review is the first to synthesize this kind of wide range of information and produce an original overview on the topic, with inclusion of beneficial and negative objective effects and patients' subjective perception of seclusion and restraint. This review also examined the methodology used for studying coercive measures. To our knowledge, this aspect has thus far not been considered in the literature and could clarify future research perspectives.

Synthesizing assessment of evidence from individual studies highlights some general problems in evaluating the effects of seclusion and restraint in adult psychiatry. Due to heterogeneity of study methods and settings through populations, interventions, comparators and explored outcomes, synthesizing results and generalization to global conclusions could be at high risk of analysis bias and lead to inaccurate conclusions. For this reason, we tried to compare analogous studies between them and identify some perceptible trends rather than aggregate observations. These trends concern methodology for studying coercive measures on the one hand and effects of seclusion and restraint in adult psychiatry on the other hand.

The width of the conducted search and the selected outcomes are not only strengths but also limitations of our review, as the heterogeneity of the results clearly limits our capacity to draw definitive conclusions. Including objective and subjective outcomes in the same review is a new approach, but again renders the integration of findings more difficult. Due to this inclusion of a broad range of outcomes, we had to limit the review to coercive measures limiting freedom of movement (seclusion and restraint). The exclusion of other types of coercion like involuntary admission or treatment is another limitation is clearly a limitation of this review, which does not allow us to draw general conclusions about coercive measures. Searching for effects of the two other formal coercive measures should be considered in further research.

Concerning the risks of meta-biases (64), various databases and references of broad reviews on the topic were screened to retrieve any grey literature or unpublished studies that met inclusion criteria. Two conference abstracts were found that presented studies otherwise published and therefore were excluded. Non-English language articles were also included to limit these biases. The risk of selective reporting of outcomes and/or results is certainly elevated as no standard for outcomes exist and registration of trials was not performed except for Huf et al. (47). Overall, these limitations clearly point to the need for more original research on the consequences of coercive measures.

g. Conclusions

Effects of seclusion and restraint in adult psychiatry include a wide range of outcomes, and a broad variety of designs has been used to study them. Despite its clear limitations, the identified literature strongly suggests that seclusion and restraint have deleterious physical or psychological consequences. The incidence estimates of PTSD after seclusion or restraint vary from 25 to 47%, which is clearly not negligible, especially for patients with past traumatic experiences. Subjective perception of seclusion and restraint seems to depend on interindividual variability but is largely negative and distressful. No significant differences between them were found in terms of effectiveness or adverse effects. The main

negative consequences reinforce the notion that seclusion and restraint should be used with caution and as a last resort method. Patients should be given the opportunity to take part in the decision whenever possible, and their preferences should be taken into account. The therapeutic interaction and relationship could be a main focus for the improvement of effects and subjective perception of coercion. In terms of methodology, studying coercive measures remains difficult and applicability of the evidence is still limited. Well-conducted prospective cohort studies could be more feasible than RCTs for achieving meaningful results on the effects of coercion. In the context of current research on coercion reduction, the study of effects of coercion provides workable baseline data and potential targets for interventions, and thus, a strong motivation for the development of coercion reduction programs.

5. Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

6. Author Contributions

MC contributed to development of the search question and strategies, data collection and analysis, and to the main part of manuscript redaction, SH participated in development of the search question and strategies. SK supervised advancement of the project and contributed to data selection. OS supervised advancement of the project and participated in development of the search question and strategies and data extraction. The four authors contributed to manuscript redaction and accepted the present manuscript.

7. Funding

This systematic review is part of a research program investigating seclusion and restraint reduction funded by the University Hospital of Geneva.

8. Appendices

a. Table 1: Explored Outcomes

Outcomes	Subgroups
Objective Effectiveness	Symptoms intensity (including aggressiveness) (evaluated with PANSS (46, 76), BPRS (66, 85, 87, 91) and BDI-II (87)) Need to change intervention

	Levels of needed medication Readmission rate Time to emergency resolution Length of stay Safety Quality of life after intervention Global functioning during and after intervention Ward environment
Adverse Effects	Incidence of Deep Vein Thrombosis during restraint Incidence of PTSD after intervention Influence of history of life-threatening events on traumatic effects of intervention Reported hallucinations during seclusion Occurrence of adverse events: agitation, suicide attempt or self-harm, revival of previous traumatism, death, hypertension, physical pain or fracture
Patients' Subjective Perception	Positive and negative reported feelings during and after intervention Acceptance and comprehension of intervention (helpful, necessary or disapproved) Level of perceived coercion Discrepancy between objective and reported coercion Evaluation of interaction and dialogue with staff Influence of ward environment on perceived coercion Feeling of improvement, safety or security during and after intervention Preferences between different coercive measures

Abbreviations: PANSS: Positive and Negative Syndrome Scale; BPRS: Brief Psychiatric Rating Scale; BDI-II: Beck Depression Inventory II

b. Table 2: Characteristics of included studies

Article	Design and Methods	Intervention vs Comparator	Explored Outcomes	Results and Conclusions
Huf et al. 2012, Brazil (47)	- Unblinded RCT, 14-day follow-up - 105 agitated psychotic patients (54 secluded, 51 restrained) - Dg (restrained vs secluded): 82.3 vs 77.8% psychosis (SD or mania), 5.9 vs 11.1% psychological agitations, 11.8 vs 11.1% SU	Seclusion vs restraint	- Effectiveness - Adverse events - Subjective perception	- Negative effect - 2/3 secluded patients fully managed with seclusion, 1/3 changed to restraint - No significant difference between groups in effects, adverse events or patients' satisfaction - Ccl: Suggestion to begin with seclusion that seems not to harm or prolong coercion
Bergk et al. 2011, Germany (46)	- Unblinded RCT - 102 patients (12 randomized/ 48 nonrandomized secluded, 14 randomized/ 28 nonrandomized restrained Semi-structured interview - Dg (randomized vs nonrandomized secluded/ randomized vs nonrandomized restrained): 50 vs 71/ 86 vs 50% SD, 50 vs 8/ 14 vs 25% AD, 0 vs 21/ 0 vs 25% PD	Seclusion vs restraint	- Symptom intensity - Levels of needed medication - Adverse events - Subjective perception	- Negative effect - No significant differences for adverse events and subjective experience - Levels of medication and aggressive symptoms are only significantly lower for nonrandomized secluded patients - Ccl: Clinical decisions should take patients' preferences into account. RCTs on coercion are feasible
Vaaler et al. 2005, Norway (76)	- Non-inferiority RCT - 25 secluded patients in a traditional manner; 31 in a redecorated room - Dg (new interior vs traditional interior): 51.6 vs 24% SD, 16.1 vs 28% AD, 16.1 vs 24% SU, 6.5 vs 4% OD and 9.7 vs 2% O	Seclusion	- Ward environment - Length of stay - Symptom intensity - Subjective perception	- Negative and beneficial effects - No significant differences between groups - Ccl: No negative effects of a refurnished room on seclusion efficacity
Cashin 1996, Australia (68)	- Prospective quasi-experimental study - 53 involuntary admissions (27 secluded patients, 26 non-secluded) - No diagnostic information but no significative difference between groups	Seclusion vs non-exposure	Time to emergency resolution Levels of needed medication	Beneficial effect No significant differences between groups Ccl: Seclusion may be the most effective choice in some circumstances

Hafner et al. 1989, Australia (69)	- 38-weeks multi-centre prospective study - 30 secluded and 60 non-secluded patients - Dg (secluded, no difference between groups): 46.3 (vs 23% non-secluded) SD, 12.2% BPD, manic state, 12.2 % MDD, 9.8% OD, 7.3% PD, 9.8% SU, 2.4% BRP	Seclusion vs non-exposure	- Levels of needed medication - Length of stay - Readmission rate	- Negative and beneficial effects - 25% more neuroleptic medication for secluded patients, suggesting that seclusion did not permit to reduce the levels of medication required to manage psychiatric agitation - Less medication for non-secluded patients, suggesting that secluding agitated patients may reduce the unit level of dangerousness - No differences in length of stay or readmission rate, suggesting no adverse effect of seclusion
Georgieva et al. 2012, Netherlands (65)	- 3-year prospective study - 125 coerced patients (62 secluded, 18 forced medicated, 34 secluded and forced medicated, 11 secluded and restrained) - Structured questionnaires - Dg (secluded/ involuntary treated/ secluded and treated/secluded and restrained): 27/39/53/60% SD, 34/33/38/10% AD, 9/33/9/0% PD, 32/28/13/30% SU, 5/0/6/0% PTSD	Seclusion and restraint vs other coercive measures	- Effectiveness - Adverse events - PTSD - Subjective perception	- Negative effect - Combined Seclusion and restraint with higher psychological and physical burden than seclusion alone or seclusion and forced treatment - No significant difference in effectiveness - Ccl: forced medication seems better tolerated. Seclusion and/or restraint could give revival of previous traumatism or PTSD
Soininen et al. 2013b, Finland (67)	- 1-year prospective study - 36 secluded or restrained (no distinction) patients, 228 non-exposed - Structured questionnaire - Dg (secluded vs non-secluded): 54 vs 33% SD, 31 vs 49% AD, 14 vs 18% O	Seclusion and restraint vs non-exposure	Quality of life	- Beneficial effect - Exposed patients reported a better subjective quality of life at discharge compared to non-exposed patients - Ccl: seclusion and restraint had either only short-term negative influence on quality of life, or the observed association may not be causal
McLaughlin et al. 2016, 10 European countries (66)	- Multi-centre prospective study (EUNOMIA project) - 2030 involuntary admissions, 770 with one or more coercive measures (84 secluded, 439 restrained, 556 forced medication). - 1353 interviews - Dg (coerced vs non coerced): 68 vs 60% SD	Seclusion and restraint vs other coercive measures	Length of stay	- Negative and beneficial effects - At 3 months, 843 involuntary admitted patients approved and 506 (37.4%) disapproved their previous admission. Forced medication was the only significant measure associated with admission disapproval - Seclusion and restraint were associated with increased length of stay (in multivariate analysis, only seclusion remains significative). Secluded patients' symptom intensity did not fully explain the observed increase
Soloff et Turner 1981, US (70)	- 8-month prospective study - 59 secluded patients, 159 non-secluded - Structured questionnaire - Dg (secluded vs non-secluded): 42.4 vs 40.9% SD, 5.1 vs 1.9% BPD, 11.9 vs 11.3% other AD, 6.8 vs 4.4% OD, 8.5 vs	Seclusion vs non-exposure	Length of stay	- Beneficial effect - Length of stay associated with incidence of seclusion, but no influence of chronicity and legal status at admission. - Initial postulate: Seclusion as therapeutic and control function for patient and ward milieu

	12.6% PD, 0 vs 11.3% neurosis, 23.7 vs 17.6% O (SU and MR)			
Schwab et Lahmeyer 1979, US (71)	- 6-month prospective study - 52 secluded patients, 90 non-secluded - Dg (secluded vs non secluded): 29 vs 29% SD, 19 vs 7% BPD, manic state, 14 vs 14% psychotic MDD, 14 vs 32% neurosis, 8 vs 3% SU, 6 vs 3% PD, 10 vs 12% O	Seclusion vs non-exposure	Length of stay	Negative effect Increased length of stay for secluded patients
Mattson et Sacks 1978, US (72)	- 1-year prospective study - 63 secluded patients, 160 non-secluded - Dg (secluded vs non secluded): 63 vs 38% SD, 17 vs 4% BPD, manic state, 10 vs 14% PD, 10 vs 44% O	Seclusion vs non-exposure	Length of stay	- Negative effect - Increased length of stay for secluded patients - Effect no longer significant when focusing on patients less than 20 years of age
Hammill et al. 1989, US (74)	- Prospective study - 100 patients (26 secluded, 74 non-secluded) with SD or SAD - Semi-structured interview	Seclusion vs non-exposure	- Length of stay - Subjective perception	- Negative and beneficial effects - Increased length of stay for secluded patients - 13/17 secluded patients evaluated seclusion as necessary
Plutchik et al. 1978, US (75)	- 2 prospective studies - 1st: descriptive (118 secluded patients, 118 randomly assessed non-secluded) - 2nd: qualitative (30 secluded and 25 non-secluded patients) - Structured interview - Dg (secluded vs non secluded): 64 vs 45.8% SD, 2.5 vs 0% BPD, manic state, 3.4 vs 8.5% psychotic MDD, 10.2 vs 13.6% depressive neurosis, 0.8 vs 5.1% SU, 6.8 vs 13.6% PD, 5.9 vs 8.5% adjustment reactions, 3.4 vs 5.1% OD, 2.5 vs 0% MR	Seclusion vs non-exposure	- Length of stay - Subjective perception	- Negative and beneficial effects - 1st study: Increased length of stay for secluded patients - 2nd study: 40% secluded patients rated seclusion as not helpful. 60% reported feeling better after seclusion
Mann et al. 1993, US (73)	- 6-month prospective study - 50 secluded patients - Structured questionnaire - Dg: 24% MDD, 10% dysthymic disorders, 30% BPD, 2% SAD, 16% SD, 6% BRP, 8% SU, 4% none	Seclusion	- Length of stay - Subjective perception	- Negative and beneficial effects - Seclusion safe and secure (67%) - Feelings of constant attention and care from staff (45%) - Increased length of stay for secluded patients (compared to general unit mean)

Ishida et al. 2014, Japan (84)	- Prospective study - 190 restrained patients - Dg: 3.9% OD, 9.9% SU, 63.5% SD, 14.9% AD, 1.1% somatoform disorders, 6.6% PD	Mechanical restraint	Adverse effects	- Negative effect - D-dimer augmentation for 72 restrained patients with prophylaxis. - US Doppler of lower extremities showed asymptomatic DVT in 21 patients (11.6%) - Incidence of DVT associated with excessive sedation, longer duration of restraint, lower antipsychotic dosage - Ccl: Probable underestimation of DVT in routine use of restraint
Steinert et al. 2013, Germany (77)	- Cross-sectional study, 1-year follow-up after Bergk et al. 2011 - 60 of 102 (59%) previous patients (31 secluded, 29 restrained) - Dgs: 63% SD, 23% BPD, 14% O	Seclusion vs restraint	- PTSD - Subjective perception	- Negative and beneficial effects - Seclusion reported as less restrictive - 1 secluded and 2 restrained patients with symptoms fulfilling PTSD diagnosis - Ccl: the lower than expected incidence of PTSD may be due to natural resolution of symptoms or to the interviews conducted with the patients, which could have helped prevent PTSD
Guzmán-Parra et al. 2018, Spain (79)	- 2-year prospective study - 111 coerced patients (32 restrained, 41 forced medicated, 38 forced medicated and restrained) - Dg (restrained vs involuntary treated vs combined): 4.9 vs 9.4 vs 10.5% SU, 58.5 vs 50 vs 68.4% SD, 22 vs 28.1 vs 18.4% AD, 2.4 vs 3.1 vs 0% anxiety disorders, 7.3 vs 6.3 vs 0% PD, 4.9 vs 3.1 vs 2.6% O	Mechanical restraint vs forced medication	- PTSD - Subjective perception	- Negative effect - Higher perceived coercion with restraint (compared to forced medication). - Higher post-traumatic stress with forced medication - Combined forced medication and restraint associated with higher coercion perception and less treatment satisfaction (than restraint or forced medication alone)
Steinert et al. 2007, Germany (78)	- Prospective study - 117 involuntary admissions with history of seclusion or restraint, 18 secluded or restrained (no distinction) patients at present admission - Structured questionnaires - Dg: 79.5% SD 8.5% other psychotic disorders, 12% SAD	Seclusion and restraint vs non-exposure	Influence of history of life-threatening events on traumatic effects of intervention	- Negative effect - Bidirectional association of history of seclusion or restraint with life-threatening traumatic events. - Exposure to past traumatic events enhances the risk of revictimization and revival of previous traumatism during inpatient treatment - Ccl: coercive measures may cause re-experienced traumatism
Wallsten et al. 2008, Sweden (91)	- 2-year prospective study - 115 patients (19 reported mechanically restrained but 8 false positives; 98 reported non-restrained but 4 false negatives); 15 truly restrained - Structured interview - Dg (true positives/ true negatives/false positives/false negatives): 46/52/38/25% SD, 36/9/63/25% AD, 18/19/-/50% O	Mechanical restraint vs non-exposure	- Discrepancy between objective and reported coercion - Subjective perception	- Negative effect - 42% false positive and 4% false negative reports of restraint. - Causes are not clear (communication problem, memories failures (or false memories), or emotional traumatic reactivation) - Ccl: Subjective quality of reports of past traumatic events

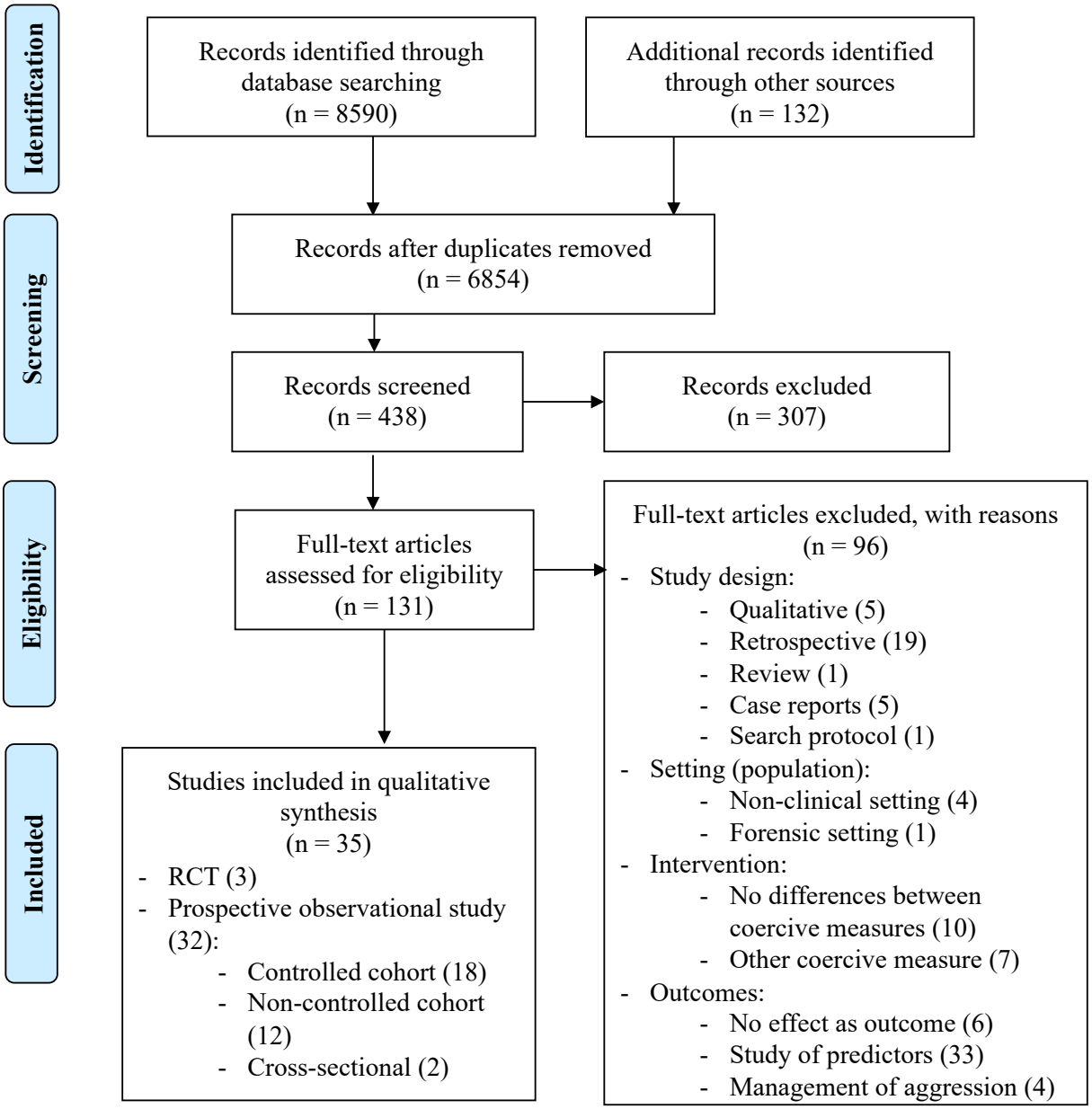
Whitecross et al. 2013, Australia (83)	- 9-month prospective study - 31 secluded patients - Dg: 51.6% SD, 32.3% SAD, 16.1% O	Seclusion	PTSD	Negative effect 47% probable PTSD (IER-S >33) after seclusion
Fugger et al. 2015, Austria (85)	- 18-month prospective study - 47 mechanically restrained patients - Dg: 23.4% OD, 12.8% SU, 19.1% paranoid SD, 8.5% catatonic SD, 4.2% SAD, manic state, 14.9% BPD, manic episode, 2.1% BPD, mixed episode, 2.1% recurrent MDD, 6.4% anorexia, 6.4% PD	Mechanical restraint after intervention	- PTSD - Subjective perception	- Negative and beneficial effects - 50% high perceived coercion and 25% probable PTSD - Less memory event, more feeling of being healthy and more acceptance of restraint than rated by physicians
Palazzolo 2004, France (80)	- 6-month prospective study - 67 secluded patients - Semi-structured interview - Dg: 32.8% SD, 28.4% BPD, 14.9% BRP, 10.4% SAD, 5.9% anorexia, 4.6% somatoform disorders, 3% antisocial PD	Seclusion	- Hallucinations - Subjective perception	- Negative and beneficial effects - Anger was the most frequent reported emotion - 31% reported hallucinatory experience - 67% reported anxiety - 8% reported feeling better, and 8% the necessity of continuing treatment
Kennedy et al. 1994, US (81)	- Prospective study - 25 secluded patients with SD or SAD - Semi-Structured interview	Seclusion	- Hallucinations - Subjective perception	- Negative and beneficial effects - For 48%, seclusion was not helpful - 52% reported hallucinations during seclusion - 70% who experienced hallucinations during seclusion were hallucinating before seclusion but proportional increase of hallucinations during seclusion was not significant - Hallucinating patients had longer (but not significantly) seclusion stay, more therapeutic interaction (nurse-patient relationship) and levels of needed medication
Sagduyu et al. 1995, US (86)	- Prospective study - 25 secluded and 25 restrained patients - Semi-structured interview - 76% restrained and 80% secluded patients had a SD	Seclusion vs Restraint	Subjective perception	- Negative and beneficial effects - 40% secluded and 20% restrained with positive evaluation - 71% secluded and 89% restrained remembered past traumatic experiences - 73% secluded and 81% restrained reported negative feelings
Krieger et al. 2018, Germany (87)	- 18-month prospective study, - 213 involuntary admitted patients (78 mechanically restrained, 32 secluded, 30 forced medicated, 20 video monitored) - 51 voluntarily admitted patients in a closed ward, - Structured interview - Dg (coerced vs control groups): 71.1 vs 51% SD, 10 vs 21.6% SU, 12.8 vs 19.6%	Seclusion and restraint vs other coercive measures	Subjective perception	- Negative and beneficial effects - Negative emotions associated with seclusion or restraint - Increasing understanding of use of seclusion or restraint during hospitalization - Seclusion preferred among all coercive measures, while restraint less accepted than the other measures

	AD, 3.3 vs 7.8% PD, 33.6 vs 45.1% of comorbidities with SU			
Gowda et al. 2018, India (88)	- Prospective study - 200 patients (40 mechanically or manually restrained, 36 secluded, 116 chemical restrained, 64 involuntarily treated, 29 ECT) - Dg: 48% SD, 43.5% AD, 18.5% O, 48.5% comorbidities with SU	Seclusion and restraint vs other coercive measures	Subjective perception at admission and discharge	Negative effect Physical restraint associated with a greater perception of coercion, followed by involuntary treatment, chemical restraint, seclusion and finally ECT
Sorgaard 2004, Norway (89)	- 17-week prospective interventional study - 190 admissions (16% secluded, 160 non-secluded) - Standardized questionnaires - Dg (baseline vs project phase): 26.8 vs 28.6% SD, 53.6 vs 41.2% AD, 3.6 vs 5.0% PD, 8.9 vs 11.8% SU, 7.1 vs 13.6% O	Seclusion vs non-exposure	- Adverse events - Subjective perception	- Negative effect - Seclusion as principal factor associated with perceived coercion (compared to age, sex, forced medication or length of stay)
Martinez et al. 1999 (90)	- Cross-sectional study - 69 patients (53 secluded, 16 non-secluded) - Semi-structured interview - No diagnostic information	Seclusion vs non-exposure	Subjective perception	- Negative and beneficial effects - Negative perception of seclusion (62% overuse, 76.5% punishment) - 56.2% reported seclusion as needed
Larue et al. 2013, Canada (92)	- 1-year prospective study - 50 secluded or restrained (no distinction) patients - Semi-structured interview - Dg: 66% SD, 30% AD, 2% PD, 2% anxious disorders	Seclusion and restraint	Subjective perception	Beneficial effect 52% agreed with improved behavior after seclusion
Soininen et al. 2013a, Finland (93)	- 18-month multi-centre prospective study - 90 secluded or restrained patients (no distinction) - Structured questionnaire - Dg: 12% SU, 60% SD, 20% AD, 6% PD	Seclusion and restraint	Subjective perception after intervention	- Negative effect - Deny of necessity and beneficence of seclusion or restraint - Dissatisfaction - Not enough dialogue
Keski-Valkama et al. 2010, Finland (96)	- 1-year prospective study - 38 secluded patients in general vs 68 in forensic wards - Structured interview - Dg in general wards: 71.1% SD, 10.5% SU, 15.8% AD, 2.6% O	Seclusion	Subjective perception	- Negative and beneficial effects - Mostly negative feelings, loneliness - Need for interaction - Seclusion as necessary - 54% secluded patients perceived seclusion as a punishment
Stolker et al. 2006,	- 18-month prospective study - 78 secluded patients - Structured interview	Seclusion	- Ward environment	- Negative and beneficial effects - Staying in multi-bed rooms prior to seclusion associated with less negative views of seclusion

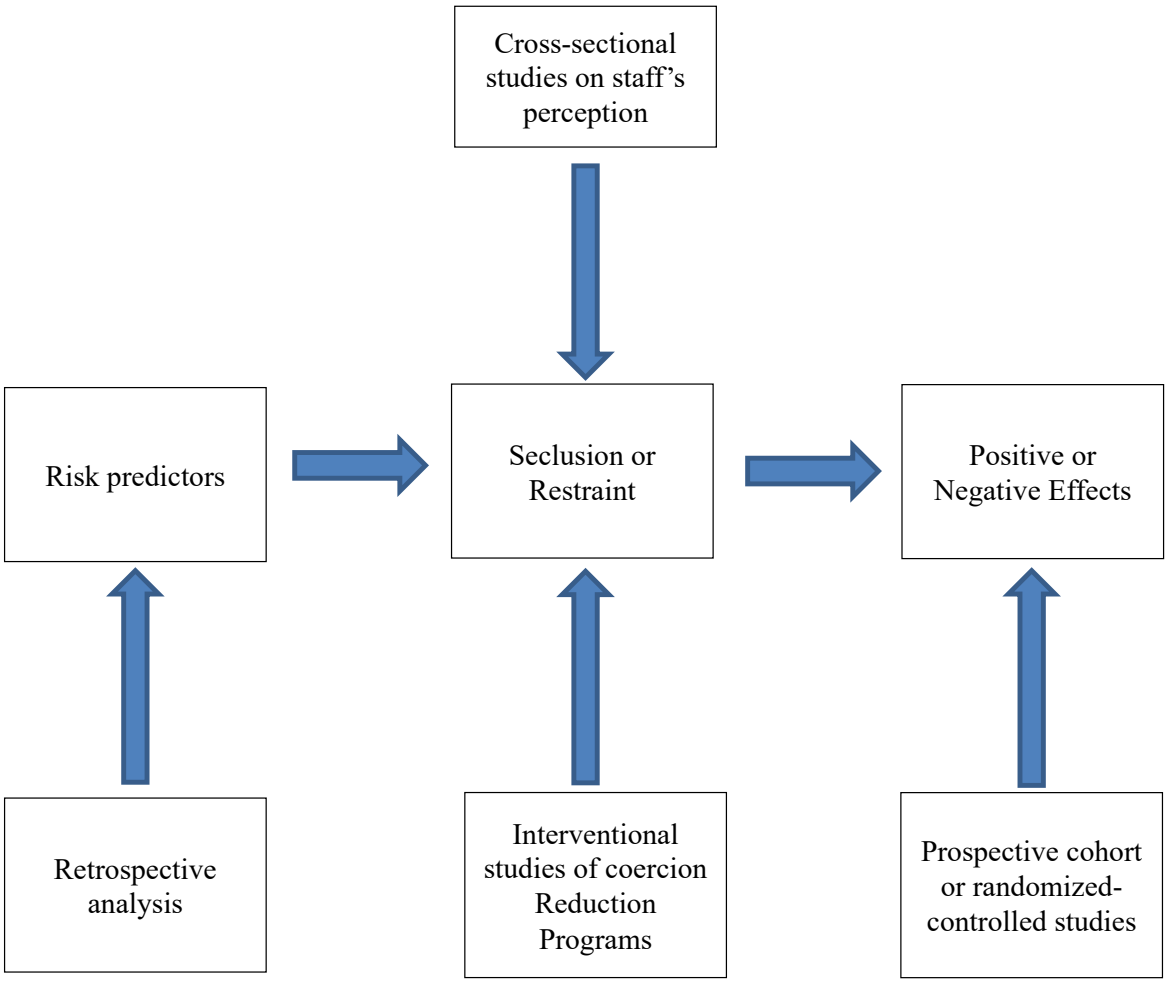
Netherlands (94)	- Dg: 67% SD, 11% BPD, 11% cluster B PD		- Subjective perception	
Richardson et al. 1987, US (82)	- 1-year prospective study - 52 secluded patients - Semi-structured interview - Dg: 36.5% SD, 28.8% SAD, 19.2% AD, 9.6% atypical psychosis, 1.9% borderline PD, 1.9% organic hallucinosis, 1.9% dementia	Seclusion	Subjective perception	- Negative and beneficial effects - 31% patients reported anger, 58% felt punished - 50% reported seclusion as protection, 48% as necessary - 37% reported hallucinatory experience - 20/52 reported improvement after seclusion, 8/52 deterioration
Binder et McCoy 1983, US (95)	- 8-month prospective study - 27 secluded patients - Semi-structured interview - Dg: 45.8% SD, 33.3% AD, 8.3% SAD, 8.3% antisocial PD, 4.2% acute paranoid BRP	Seclusion	Subjective perception	- Negative and beneficial effects - 4 patients rated seclusion as therapeutic, 12 as necessary - 11 rated beneficial aspects (7 hypostimulation) - 18 negative emotions - For 14, seclusion had no effect, 3 beneficial effect, 2 negative effect, 5 first negative effect changed to beneficial effect
Tooke et Brown 1992, US (97)	- 11-week prospective study - 19 secluded patients (11 locked rooms, 8 secluded area) - Structured questionnaire - Dg: 47.3% SD, 26.3% MDD or suicidal ideations	Seclusion	Subjective perception	- Negative effect - 73% secluded patients (in locked rooms) felt punished - Strong negative feelings

Abbreviations: vs: versus; RCT: Randomized controlled Trial; Dg: Diagnoses; Ccl: Conclusions; SD: Schizophrenic Disorders; AD: Affective disorders; PD: Personality Disorders; SAD: Schizoaffective disorder; BRP: Brief Reactive Psychosis; SU: Substance Use; O: others; BPD: Bipolar disorders; MDD: Major depressive disorder; OD: organic disorders; MR: mental retardation; PTSD: Post-Traumatic Stress Disorder; EUNOMIA: European Evaluation of Coercion in Psychiatry and Harmonization of Best Clinical Practice; US: Ultrasound; DVT: Deep Vein Thrombosis; IES-R: Impact of Event Scale-Revised; ECT: Electro-Convulsive Therapy.

c. Figure 1: Prisma-flow Diagram (114)



d. Figure 2: Methodological differences in studying risk predictors and effects of seclusion and restraint



e. Supplementary Table 1: Search strategies

Database	Search
MEDLINE via Pubmed	(((((("Mental Disorders"[Mesh] OR "Psychiatry"[Mesh] OR "Hospitals, Psychiatric"[Mesh] OR "Mental Health"[Mesh] OR mental[tiab] OR mentally[tiab] OR psychiatr*[tiab] OR schizophren*[tiab] OR psychoti*[tiab])) AND ((("Restraint, Physical"[Mesh] OR "Coercion"[Mesh] OR "Patient Isolation"[Mesh] OR "Commitment of Mentally Ill"[Mesh])) OR (((Restraint*[tiab] OR Coerci*[tiab] OR Seclusion[tiab] OR Patient Isolation[tiab] OR Patient Immobili*[tiab] OR Compulsor*[tiab] OR Mentally Ill Commitment[tiab] OR Mentally Ill Commitments[tiab] OR Involuntary Commitment[tiab] OR Involuntary Commitments[tiab] OR (involunta*[tiab] NOT movement*[tiab]))) OR ((lock[tiab] OR locked[tiab] OR locking[tiab] OR contained[tiab] OR containement[tiab] OR containment[tiab] OR containment'[tiab] OR containment's[tiab] OR containments[tiab]) AND (door[tiab] OR doors[tiab] OR ward[tiab] OR wards[tiab] OR room[tiab] OR rooms[tiab])))))) AND ("Outcome Assessment (Health Care)" [Mesh:NoExp] OR "Patient Outcome Assessment" [Mesh:NoExp] OR "Treatment Outcome" [Mesh:NoExp] OR "Beneficence"[Mesh] OR "Risk"[Mesh:NoExp] OR "Risk Assessment"[Mesh:NoExp] OR "Risk Factors"[Mesh] OR "Medical Errors"[Mesh:NoExp] OR "Behavior Control"[Mesh:NoExp] OR "Cooperative Behavior"[Mesh] OR "Patient Acceptance of Health Care"[Mesh:NoExp] OR "Patient Compliance"[Mesh:NoExp] OR "Medication Adherence"[Mesh] OR "Patient Dropouts"[Mesh] OR "Patient Participation"[Mesh] OR "Quality of Life"[Mesh] OR "Clinical Competence"[Mesh] OR "Guideline Adherence"[Mesh] OR "Attitude of Health Personnel"[Mesh:NoExp] OR "Attitude to Health"[Mesh:NoExp] OR "Practice Patterns, Nurses'"[Mesh] OR "Practice Patterns, Physicians'"[Mesh] OR "Professional-Patient Relations"[Mesh:NoExp] OR "Professional Competence"[Mesh:NoExp] OR "Life Style"[Mesh:NoExp] OR "Life Change Events"[Mesh] OR "Dehumanization"[Mesh:NoExp] OR "Prejudice"[Mesh:NoExp] OR "Social Isolation"[Mesh:NoExp] OR "Judgment"[Mesh] OR "Decision Making"[[Mesh:NoExp] OR "Dissent and Disputes"[Mesh:NoExp] OR "Length of Stay"[Mesh] OR ((Outcome [tiab] OR Outcomes [tiab] OR Process [tiab]) AND (Treatment [tiab] OR Assessment [tiab] OR Assessments [tiab] OR Research [tiab] OR Studies [tiab] OR Study [tiab] OR Measures [tiab] OR Measure [tiab] OR Patient-Relevant[tiab] OR Patient Relevant[tiab] OR Rehabilitation[tiab])) OR Effectiveness [tiab] OR Efficiency [tiab] OR Efficacy [tiab] OR Safety [tiab] OR Efficiencies [tiab] OR Commitment Duration [tiab] OR Outpatient Commitment [tiab] OR Beneficence [tiab] OR Benevolence[tiab] OR Nonmaleficence[tiab] OR Risks[tiab] OR Risk Reduction Behavior[tiab] OR Risk Reduction[tiab] OR Harm Reduction[tiab] OR Patient harm[tiab] OR Medical errors[tiab] OR Critical Medical Incidents[tiab] OR Never Events[tiab] OR Behavior control[tiab] OR Cooperative Behavior[tiab] OR

	Health Care Utilization[tiab] OR Patient Acceptance of Healthcare[tiab] OR Health Care Acceptability[tiab] OR Patient Adherence[tiab] OR Patient Cooperation[tiab] OR Treatment Compliance[tiab] OR Medication Compliance[tiab] OR No Show Patients[tiab] OR No-Show Patient[tiab] OR Patient Involvement[tiab] OR Patient Empowerment[tiab] OR Patient Engagement[tiab] OR Quality of life[tiab] OR Clinical Competency[tiab] OR Clinical Skills[tiab] OR Meaningful Use[tiab] OR Health Personnel Attitudes[tiab] OR Staff Attitude[tiab] OR Staff Attitudes[tiab] OR Health Attitudes[tiab] OR Cultural Care[tiab] OR Nurse's Practice Patterns[tiab] OR Nurse Practice Patterns[tiab] OR Clinical Practice Patterns[tiab] OR Professional-Patient Relations[tiab] OR Professional-Patient Relation[tiab] OR Professional Patient Relationship[tiab] OR Professional Patient Relationships[tiab] OR Human Dignity[tiab] OR Burden of Illness[tiab] OR Respect for Life[tiab] OR Right to Life[tiab] OR Treatment Failure[tiab] OR Professional Competence[tiab] OR Satisfaction[tiab] OR Lifestyle[tiab] OR Life Experiences[tiab] OR Life Experience[tiab] OR Self-Management[tiab] OR Self Care[tiab] OR Patient Reported Outcomes[tiab] OR Patient Reported Outcome[tiab] OR Patient Comfort[tiab] OR Involuntary Psychiatric Treatment[tiab] OR Involuntary Psychiatric Commitment[tiab] OR Dehumanisation[tiab] OR Prejudice[tiab] OR Social Isolation[tiab] OR Loneliness[tiab] OR Social Competence[tiab] OR Social Stigma[tiab] OR Decision making[tiab] OR Approach Behavior[tiab] OR Approach Behaviors[tiab] OR Consensus [tiab] OR Patient Participation[tiab] OR Perception[tiab] OR Death[tiab] OR Mortality[tiab] OR Hospitalization duration [tiab] OR Injury[tiab] OR Insight into illness[tiab] OR Hospital Stay [tiab] OR Hospital Stays [tiab] OR Involuntary medication[tiab])))) AND (((((("randomized controlled trial"[pt] OR "controlled clinical trial"[pt] OR "clinical trials as topic"[mesh] OR "random allocation"[mesh] OR "double-blind method"[mesh] OR "single-blind method"[mesh] OR "clinical trial"[pt] OR "research design"[mesh:noexp] OR "comparative study"[pt] OR "evaluation studies"[pt] OR "follow-up studies"[mesh] OR "prospective studies"[mesh] OR "cross-over studies"[mesh] OR "clinical trial"[tiab] OR ((singl*[tiab] OR doubl*[tiab] OR trebl*[tiab]) AND (mask*[tiab] OR blind*[tiab])) OR placebo*[tiab] OR random*[tiab] OR "control"[tiab] OR "controls"[tiab] OR prospectiv*[tiab] OR volunteer*[tiab])) OR ("cohort studies"[mesh] OR "case-control studies"[mesh] OR "comparative study"[pt] OR "risk factors"[mesh] OR "cohort"[tiab] OR "compared"[tiab] OR "groups"[tiab] OR "case control"[tiab] OR "multivariate"[tiab])) OR (Cross-Sectional Studies [mesh] OR Cross-Sectional Studies [tiab] OR Cross Sectional Studies [tiab] OR Cross-Sectional Study [tiab] OR Cross Sectional Analysis [tiab] OR Cross Sectional Analyses [tiab] OR Disease Frequency Surveys [tiab] OR Disease Frequency Survey [tiab] OR Cross-Sectional Analyses [tiab] OR Cross-Sectional Analysis [tiab] OR Cross-Sectional Survey [tiab] OR Cross Sectional Survey [tiab] OR Cross-Sectional Surveys [tiab] OR Prevalence Studies [tiab] OR Prevalence Study [tiab] OR "Research Support, Non-U.S. Gov't"[pt]))))

Embase	('mental disease'/exp OR 'psychiatry'/exp OR 'mental hospital'/exp OR 'mental health'/exp OR mental:ab,ti OR mentally:ab,ti OR psychiatr*:ab,ti OR schizophren*:ab,ti OR psychoti*:ab,ti) AND ('restraint'/exp OR 'involuntary commitment'/exp OR 'seclusion'/exp OR restraint*:ab,ti OR coerci*:ab,ti OR seclusion*:ab,ti OR compulsor*:ab,ti OR ((patient* NEAR/1 (isolation OR immobili*)):ab,ti) OR (((compulsor* OR involunta* OR legal OR psychiatric OR mental*) NEAR/2 commitment*):ab,ti) OR (((lock OR locked OR locking OR contained OR containement*) NEAR/1 (door* OR ward OR wards OR room OR rooms)):ab,ti) OR (involunta*:ab,ti NOT movement*:ab,ti)) AND ('outcome assessment'/de OR 'treatment outcome'/de OR 'beneficence'/exp OR 'risk'/de OR 'risk assessment'/de OR 'risk factor'/exp OR 'medical error'/de OR 'behavior control'/de OR 'cooperation'/exp OR 'patient attitude'/de OR 'patient compliance'/de OR 'medication compliance'/exp OR 'patient dropout'/exp OR 'patient participation'/exp OR 'quality of life'/exp OR 'clinical competence'/exp OR 'protocol compliance'/exp OR 'health personnel attitude'/de OR 'attitude to health'/de OR 'nursing practice'/exp OR 'clinical practice'/exp OR 'professional-patient relations'/de OR 'professional competence'/de OR 'lifestyle'/de OR 'life event'/exp OR 'dehumanization'/de OR 'prejudice'/de OR 'social isolation'/de OR 'decision making'/exp OR 'conflict'/de OR 'length of stay'/exp OR 'risk factor':ab,ti OR 'patient dropout':ab,ti OR 'conflict':ab,ti OR 'length of stay':ab,ti OR (((outcome* OR process* OR risk* OR harm) NEAR/2 (treatment OR assessment* OR research OR studies OR study OR measure* OR 'patient relevant' OR 'patient relevant' OR rehabilitation OR reduction)):ab,ti) OR effectiveness:ab,ti OR efficienc*:ab,ti OR efficacy:ab,ti OR safety:ab,ti OR ((commitment NEAR/2 (duration OR outpatient)):ab,ti) OR beneficence:ab,ti OR benevolence:ab,ti OR nonmaleficence:ab,ti OR risks:ab,ti OR 'patient harm':ab,ti OR (((medical OR critical) NEAR/2 (error* OR incident*)):ab,ti) OR 'never events':ab,ti OR (((control OR cooperative) NEAR/2 (behavior OR behaviour)):ab,ti) OR ((('health care' OR healthcare) NEAR/2 (utilization OR acceptance OR acceptability)):ab,ti) OR (((patient OR patients OR treatment OR medication OR protocol) NEAR/2 (adherence OR cooperation OR 'no show' OR 'no-show' OR involvement OR empowerment OR engagement OR participation OR compliance OR attitude)):ab,ti) OR 'quality of life':ab,ti OR (((clinical OR professional) NEXT/1 (competency OR competence* OR skill*)):ab,ti) OR 'meaningful use':ab,ti OR (((health OR staff) NEAR/2 attitude*):ab,ti) OR 'cultural care':ab,ti OR (((nurs* OR clinical) NEAR/2 practice NEAR/2 pattern*):ab,ti) OR ((('professional patient*' OR 'professional patient') NEXT/1 relation*):ab,ti) OR 'human dignity':ab,ti OR 'burden of illness':ab,ti OR (((respect OR right) NEAR/2 life):ab,ti) OR (((treatment OR therapy OR medication) NEAR/2 failure):ab,ti) OR satisfaction:ab,ti OR lifestyle:ab,ti OR ((life NEAR/2 (experience* OR event*)):ab,ti) OR 'self management':ab,ti OR ((self NEXT/1 (management OR care)):ab,ti) OR ((patient NEAR/2 reported NEAR/2 outcome*):ab,ti) OR 'patient comfort':ab,ti OR ((involuntary NEAR/2 psychiatric NEAR/2 treatment):ab,ti) OR dehumanisation:ab,ti OR dehumanization:ab,ti OR

	prejudice*:ab,ti OR 'social isolation':ab,ti OR loneliness:ab,ti OR ((social NEAR/2 (competence* OR stigma)):ab,ti) OR 'decision making':ab,ti OR ((approach NEAR/2 (behavior* OR behaviour*)):ab,ti) OR consensus:ab,ti OR perception:ab,ti OR death:ab,ti OR mortality:ab,ti OR (((hospitalization OR hospital) NEAR/2 (duration OR stay*)):ab,ti) OR injury:ab,ti OR ((insight NEAR/2 illness):ab,ti)) AND ('randomized controlled trial'/exp OR 'controlled clinical trial'/exp OR 'clinical trial (topic)'/exp OR 'randomization'/exp OR 'double blind procedure'/exp OR 'single blind procedure'/exp OR 'clinical trial'/exp OR 'methodology'/de OR 'comparative study'/de OR 'evaluation study'/exp OR 'follow up'/exp OR 'prospective study'/exp OR 'crossover procedure'/exp OR 'cohort analysis'/exp OR 'case control study'/exp OR 'cross-sectional study'/exp OR 'risk factor'/exp OR ((('randomized controlled' OR controlled OR clinical OR comparative OR evaluation OR 'follow up' OR prospective OR crossover OR 'case control' OR 'cross-sectional' OR 'cross sectional' OR 'disease frequency' OR prevalence) NEAR/2 (trial OR trials OR procedure OR procedures OR study OR studies OR analysis OR analyses OR surveys OR survey)):ab,ti) OR (((singl* OR doubl* OR trebl*) NEAR/2 (mask* OR blind*)):ab,ti) OR randomization:ab,ti OR methodology:ab,ti OR 'cohort analysis':ab,ti OR 'risk factor':ab,ti OR placebo*:ab,ti OR random*:ab,ti OR control:ab,ti OR controls:ab,ti OR prospectiv*:ab,ti OR volunteer*:ab,ti OR cohort:ab,ti OR compared:ab,ti OR groups:ab,ti OR multivariate:ab,ti)
Google Scholar	(coercion OR Restraint OR seclusion) AND (psychiatric OR psychiatry OR mental health) AND (effect OR safety OR harm OR efficiency OR efficacy OR beneficence OR risk OR mortality OR quality of life OR effectiveness)
Web of Science; PsycINFO	(coercion OR Restraint OR seclusion) AND (psychiatric* OR psychiatry OR mental health) AND (clinical trial)
Cochrane Central Register of Controlled Trials (CENTRAL); Cumulative Index to Nursing and Allied Health Literature (CINAHL) via EBSCO; Cairninfo; PROSPERO. Clinical.trial.org	(coercion OR Restraint OR seclusion) AND (psychiatric* OR psychiatry OR mental health)

IV. Discussion

1. Synthèse des principaux résultats

Cette revue synthétise une vaste étendue de résultats selon une perspective originale. Trente-cinq articles correspondent aux critères de recherche sur les effets bénéfiques et délétères de l'isolement et de la contention en psychiatrie adulte. Ces articles suggèrent fortement la survenue de conséquences néfastes physiques et psychiques tels que stress post-traumatique (PTSD), thrombose veineuse profonde (pour la contention), hallucinations, augmentation de la durée de séjour (79). L'incidence de PTSD après isolement ou contention varie de 25 à 47% (85), avec une majoration en cas d'antécédents de traumatismes (78). L'isolement et la contention semblent comparables en termes d'intensité de symptômes observés, médication nécessaire, survenue d'effets indésirables (46). Les diagnostics principaux retrouvés sont les troubles schizophréniques, schizo-affectifs et bipolaires en phase maniaque. La perception subjective des patients est d'une grande variabilité interindividuelle. Des ressentis positifs peuvent être rapportés, comme une impression de sécurité (73), d'amélioration clinique (92), de nécessité (74). Toutefois, cette perception subjective est principalement associée à des émotions négatives, notamment de punition, solitude, détresse (86). L'isolement – possiblement perçu comme « non invasif » – paraît mieux accepté que les autres mesures de contrainte tandis que la contention semble moins bien tolérée (88). L'interaction thérapeutique pourrait influencer la perception de la contrainte et aider à en diminuer les effets négatifs (96). Les résultats ne montrent donc pas de preuves scientifiques d'un effet thérapeutique direct. Cela ne signifie toutefois toujours pas la preuve de l'absence d'efficacité. Toutefois, au vu des conséquences non négligeables de l'utilisation de la contrainte pour les patients, il semble important d'étudier la légitimité éthique concernant cette utilisation dans l'état actuel des connaissances, à savoir qu'il n'y a pas de preuve formelle d'efficacité. Il convient donc de se demander dans quel type de croyance sans preuve scientifique nous nous trouvons, selon les différentes catégories évoquées dans l'introduction. Nous proposons d'analyser cette question dans un paragraphe suivant.

2. Méthodologie de l'étude de la contrainte

Cette revue de la littérature montre clairement que des résultats significatifs sur les effets de l'isolement et de la contention en psychiatrie adulte restent difficiles à obtenir. Elle met en évidence

la disparité des études cliniques rendant leurs comparaisons difficiles ainsi que la complexité de leur réalisation pour des patients agités et incapables de discernement. Ces observations posent la question du design d'étude adapté pour la recherche sur le sujet. Or cette dernière est nécessaire pour permettre une réduction de la contrainte et le développement d'alternatives. Rechercher les différents designs possibles et leurs indications est donc important pour les études futures afin d'adapter la méthodologie et obtenir des résultats fiables. Malgré une démarche rigoureuse, les trois études randomisées contrôlées publiées sur le sujet rencontrent des difficultés pour parvenir à des résultats interprétables sans un haut risque de biais (46, 47, 76). Dans cette revue, nous avons ciblé les études prospectives pour identifier les effets des mesures de contrainte (Figure 2 p. 45). Un design rétrospectif est souvent utilisé pour déterminer les facteurs de risque de la contrainte (112). Cette méthodologie ne paraît toutefois pas adaptée pour analyser les effets de ces mesures dans le sens où elle ne permet pas d'évaluer les conséquences des interventions (Figure 2). Les études interventionnelles, réalisées principalement dans le cadre des programmes de réduction, étudient les caractéristiques des évènements et non leurs conséquences (Figure 2, 15). Les études transversales (« cross-sectional ») sont souvent utilisées, mais l'investigation des effets est limitée avec cette procédure (Figure 2). Dans ce contexte, les études de cohortes prospectives, bien conduites et de bonnes qualités, semblent plus réalisables que les études randomisées contrôlées et pourraient permettre d'obtenir des résultats satisfaisants sur les effets de la contrainte (37). De manière à diminuer les problèmes fréquemment rencontrés dans ces études (manque de puissance, pertes de vue ou facteurs confondants) (67), réaliser des études de cohortes multicentriques est une option, comme proposé avec le projet EUNOMIA (17). Les comparaisons multicentriques restent toutefois compliquées étant donné les différences observées au niveau des patients, des équipes et des pratiques institutionnelles. L'élaboration de protocoles de recherche communs (voire idéalement, de pratiques de soins) serait une option permettant une meilleure comparabilité et in fine l'obtention de résultats fiables.

3. Implications pour la clinique

a. Prise en charge des patients à risque

L'absence actuelle de preuve d'efficacité renforce l'injonction à une utilisation de dernier recours ainsi que la tendance internationale à réduire cette utilisation et à développer des alternatives.

Dans les études sélectionnées, les diagnostics les plus fréquents sont les troubles schizophréniques, schizo-affectifs et bipolaires en phase maniaque. Ces résultats concordent avec la littérature récente évaluant spécifiquement les facteurs de risque de l'isolement (109), de la contention (57) ou des mesures de contrainte en général (5). Ces associations ont des implications en pratique clinique : les troubles psychotiques sont connus pour être souvent chroniques et avec des décompensations récurrentes. Ces diagnostics peuvent donc être considérés comme un facteur de risque de l'utilisation à long terme de la contrainte. La prise en charge des troubles psychotiques de manière générale (y compris la manie) devrait être réévaluée à la lumière de l'augmentation du risque de contrainte.

De plus, la particularité du Service de psychiatrie adulte de Genève est sa politique d'unité ouverte. La gestion des fugues est particulièrement difficile dans les unités ouvertes et demande une certaine expertise pour éviter le recours à l'isolement, le risque de fugue n'étant pas une indication légale à son utilisation (Art. 383 CC (11)). Des travaux importants à ce sujet avec la mise en place de stratégies codifiées ont été effectués (116) qu'il serait intéressant d'implémenter dans le Service afin d'évaluer s'ils permettent de diminuer l'usage de l'isolement.

b. Perception subjective et relation thérapeutique

La perception subjective de l'isolement et de la contention est principalement associée à des émotions négatives (115) tandis que la préférence des patients paraît être un élément déterminant pour l'efficacité de l'isolement ou de la contention (46). Pendant l'usage de la contrainte, certains patients rapportent ressentir une attention et un soin particuliers de la part des soignants (73) ou demandent plus d'interactions (96). Ces résultats incitent à renforcer les possibilités d'interaction patient-soignant de manière à développer les relations thérapeutiques et par suite, améliorer les perceptions subjectives de la contrainte (111). L'établissement d'une relation sécure pour le patient pourrait ainsi être une alternative à l'isolement ou la contention.

4. Implications pour la recherche

a. <u>Recherche clinique :</u> Programmes de réduction et alternatives

Cette revue met en avant le manque de preuve d'un bénéfice direct de l'isolement et de la contention. Il est donc important de réduire l'usage de ces mesures le plus possible et de développer des alternatives. Au niveau international, des programmes de réduction de la contrainte se

développent (15), comprenant plusieurs axes principaux : développement du leadership, formation et sensibilisation des équipes soignantes, évaluation des situations à risque, développement d'indicateurs qualité pour suivre en temps réel l'usage de la contrainte en pratique clinique (117, 118). Dans le Service de psychiatrie adulte de Genève, un programme de réduction de l'isolement est en cours d'élaboration. Des formations sur la gestion de la violence ont lieu, cette dernière stratégie étant la principale indication de la contrainte. Des outils d'évaluation du risque de violence sont également mis en place. Comme mentionné dans l'introduction, une étude rétrospective analysant l'utilisation des mesures de contrainte en 2017 dans le Service est en progression, dans le but d'identifier les patients à risque d'être contraints. Des indicateurs qualité sont actuellement en développement en collaboration avec le Service Qualité des HUG. De plus, la perception subjective influençant les effets de la contrainte, des études sur le vécu des patients et des soignants seraient intéressantes à mener. A notre connaissance, il n'y a pas d'étude sur l'efficacité des mesures de contrainte ou l'implémentation de programmes de réduction de la contrainte en milieu ouvert. La recherche en vigueur dans le Service pourrait donc apporter un bénéfice scientifique sur un plan international.

b. <u>Recherche éthique :</u>

i. Légitimité éthique et niveau de preuve

La thématique des mesures de contrainte semble dépasser la simple pratique clinique et implique différentes dimensions, notamment éthiques, juridiques, sociales et psychodynamiques (Figure 3 p. 59). Les questionnements sociaux et politiques sont sous-tendus par des représentations et des valeurs dont la discussion et la mise en perspective pour aboutir à une réponse s'inscrivent dans une démarche de réflexion éthique. Il est donc possible de les regrouper sous une seule catégorie « éthique » dans une vision synthétique du sujet (Figure 3).

Au vu des conséquences non négligeables pour les patients, les justifications éthiques légitimant l'usage de la contrainte sont importantes à clarifier. Steinert et al. font le parallèle entre les justifications éthiques des mesures de contrainte et celles concernant l'ouverture des unités (37). Pour les auteurs, la structure institutionnelle – ouverte ou fermée –, au même titre que les mesures de contrainte, sont des moyens pour la mise en place d'une autre intervention qui, elle, sera thérapeutique (37). Dans ce contexte, les légitimités éthiques de la structure ou de la mesure en tant

que telles ne sont pas au premier plan pour eux (37). Toutefois, faire l'impasse de cette réflexion pour la contrainte paraît difficile du fait de l'atteinte aux droits fondamentaux.

Certains éléments sont importants à considérer dans la réflexion sur la légitimité de la contrainte en présence ou absence de preuve scientifique d'efficacité. Il se peut que nous parvenions à montrer des preuves formelles d'efficacité de la contrainte. Mais cela ne signifierait pas automatiquement qu'il faudrait l'utiliser : toute intervention prouvée efficace n'est pas utilisée, par exemple si elle présente de trop grand risque par rapport aux bénéfices attendus pour le patient, si la situation clinique ne semble pas pertinente, si le patient n'est pas d'accord. Cela pose la question des valeurs qui doivent être présentes pour permettre cette utilisation. Plusieurs formes de légitimation existent sur un plan éthique, en fonction des éléments qui caractérisent une décision (la conséquence d'un acte, l'adéquation à une maxime) (16). Ces arguments sur lesquels repose l'utilisation de la contrainte mériteraient d'être explicités et développés. Il se peut également que nous ne parvenions pas à montrer de preuves d'efficacité par des études randomisées contrôlées. Il convient alors de savoir quel type d'énoncé reste vrai en l'absence de preuve scientifique, selon les différentes catégories du mythe vues en introduction. Deux situations importantes doivent être différenciées, selon si un effet des mesures de contrainte est observé ou non. Dans le cas où il n'y a pas d'effet (3^{e} catégorie), il n'y a pas de conflit de valeur, il suffit d'arrêter d'utiliser la contrainte, de la même manière que l'on arrêterait une intervention chirurgicale prouvée inefficace. Mais cela ne parait pas si simple concernant les mesures de contrainte : envisager simplement d'arrêter de les utiliser semble compliqué au vu du risque concernant le patient, les autres patients de l'unité, les soignants, les proches, la communauté. Le manque d'alternatives semble aussi être un facteur de la poursuite de l'usage de la contrainte (4). En effet, renoncer à une prise en charge rapide des patients agressifs ou désorganisés – même si le seul recours est une mesure de contrainte – équivaudrait à une « non-assistance à personne en danger » (3). Il semble donc qu'il y ait des effets malgré tout, mais la distinction entre les 1^{e}, 2^{e} et 4^{e} catégories nécessiterait d'être étayée dans un futur travail. Ces réflexions questionnent la place des données empiriques pour une légitimation sur un plan éthique, autrement dit le lien entre les faits observés et les valeurs prescriptives sur lesquelles on peut s'appuyer pour agir (sur un plan moral). Le sujet, abordé dans la littérature (119), serait intéressant à développer spécifiquement pour la contrainte.

ii. Place de la contrainte et de la psychiatrie entre soins, justice et société

Nous avons vu d'une part que l'utilisation de la contrainte est influencée par la culture et une certaine représentation sociale du trouble psychique ; et d'autre part qu'un système législatif est sous-tendu par les valeurs de la société qui l'érige. Or la justice ou la communauté peuvent être à l'origine de la demande de soins d'un patient décompensé, voire même d'une demande d'utilisation de la contrainte (hospitalisation non volontaire et/ou chambre fermée pour éviter des fugues et mises en danger). Ces exigences peuvent amener à utiliser la contrainte pour répondre aux instances sociales et juridiques (120), soulevant la question de la place de la contrainte dans une démarche de soin. Lorsque les demandes de soin et sociale/juridique se mélangent, le psychiatre se retrouve dans une position difficile comportant des conflits de valeurs et demandant une conciliation. La psychiatrie se situe donc à la jonction entre mandat thérapeutique et protection de la communauté (3). D'un point de vue normatif, le rôle du psychiatre devrait rester avant tout thérapeutique, et la relation interpersonnelle permettre de garantir la dignité du patient en le plaçant au cœur des soins (121). Toutefois, dans la réalité clinique, cette prescription n'est pas toujours évidente à respecter, surtout lorsque les soins et les demandes officielles (juridique ou sociale) d'utilisation de la contrainte se mélangent. Cette réflexion sur la contrainte dans la démarche de soin pose la question de la place et du rôle de la psychiatrie, et mériterait d'être approfondie.

iii. Incidence de la contrainte comme indicateur qualité d'une institution

Sur un autre plan, l'incidence de la contrainte est de plus en plus utilisée comme indicateur qualité d'une institution (108, 122). Or le lien entre la qualité des soins d'une institution et l'utilisation de la contrainte n'est pas forcément évident et mériterait d'être étudié. En effet, les usages sont très différents selon les habitudes de soins, indépendamment des recommandations scientifiques et de la législation en place (1). Ces disparités sont telles que comparer l'usage de la contrainte entre les différents hôpitaux est difficile, même au sein d'une même pays (4). Évaluer la qualité des institutions à travers l'incidence de la contrainte semble donc comporter des biais qu'il importe de clarifier.

c. <u>Recherche psychodynamique :</u> contenance et autonomie relationnelles

L'intensification de la prise en charge des personnes à risque de violence semble diminuer le risque de passage à l'acte (22). Le lien interpersonnel avec les soignants – développé au cours de ce

processus – pourrait apporter la contenance habituellement recherchée par la contrainte, qui passe alors d'une forme « physique » à une forme « relationnelle ». Ces notions se fondent sur les théories psychanalytiques du développement infantile : une mère « suffisamment bonne » (123) absorbe les projections non élaborées « béta » de l'enfant, les métabolise et les restitue en éléments « alpha » acceptables pour ce dernier (124). La fonction maternelle « alpha » permet ainsi à l'enfant d'intégrer progressivement de nouveaux éléments dans un environnement sécure et de moindre intensité (124). Les rôles de l'institution et du soignant, à travers l'accompagnement progressif du patient vers un recouvrement de son autonomie, semblent proches de cette fonction maternelle, introduisant ainsi la notion d'« autonomie relationnelle » (22). Toutefois, dans cette conception, une confiance réciproque et donc une certaine coopération du patient sont nécessaires. Or l'utilisation de la contrainte implique une incapacité de discernement. Ce paradoxe soulève la question de la possibilité de soigner une personne contre son gré et de l'amener à désirer être soignée. La contrainte permet de stabiliser la situation de crise mais généralement pas de conduire à un changement existentiel fondamental. La contenance et l'autonomie relationnelles – à travers le lien interpersonnel et l'accompagnement – pourraient permettre d'instaurer une dynamique d'autonomisation progressive et ainsi servir d'alternative à la contrainte (22). Ces perspectives demandent à être explorées.

5. Mythe ou réalité ?

L'efficacité des mesures de contrainte ne paraît actuellement pas reposer sur des preuves conformes à l'« evidence-based medicine ». Cette efficacité pourrait donc être qualifiée de « mythe » au sens commun d'une croyance sans fondement. Comme abordé plus haut, il semble qu'il y ait des effets à la contrainte sur un plan empirique, ce qui laisse supposer une part de vérité la concernant, même sans preuve scientifique (1e, 2e et 4e catégories). Nous avons vu par ailleurs que l'utilisation des mesures de contrainte dépend d'une représentation sociale de la personne souffrant de troubles psychiques et que cette perception évolue au cours du temps (25, 26). Or une « représentation sociale » fait évoquer un récit organisateur d'une communauté, ce qui pourrait rejoindre la définition sociologique du mythe. De plus, il existe une conception évolutive du mythe au sens psychodynamique, en fonction de l'avancée des valeurs de la société qui le porte (125), ce qui rejoint également la précédente observation. Mais si les mesures de contrainte s'inscrivent bien dans un mythe véhiculé par la société, il conviendrait de rechercher la nature de ce dernier ainsi

que le sens et les phénomènes qu'il cherche à expliquer. Il peut être également intéressant de s'interroger sur les raisons de l'existence et de la persistance d'un tel mythe au cours du temps. La tendance internationale à développer des alternatives pour réduire l'usage de la contrainte (15) parle en faveur d'une évolution et d'un changement des perceptions dont il serait important d'explorer les tenants et aboutissants. Comme énoncé plus haut à travers les concepts de contenance et autonomie relationnelles, la finalité de l'instauration d'une mesure de contrainte semble être le recouvrement de l'autonomie et la croissance personnelle du patient, ce qui n'est pas sans rappeler le « mythe de l'individuation » appelant chacun à devenir « un "individu" psychologique, c'est-à-dire une unité autonome et indivisible » (126). Certains éléments en lien avec l'utilisation de la contrainte semblent ainsi évoquer une perspective sociologique et psychodynamique du mythe (5e et 6e catégories), parlant de nouveau en faveur d'une certaine vérité sans preuve scientifique. La contrainte semble donc se rapprocher des catégories du mythe contenant une part de vérité, sans que leurs distinctions soient encore claires ni dans quelle mesure cette vérité est suffisante pour légitimer une utilisation de la contrainte. Ces réflexions demandent à être approfondies et développées dans un futur travail.

6. Forces et Limites

La force principale du travail présenté est la recherche systématique des effets bénéfiques et délétères de l'isolement et de la contention, y compris les perspectives subjectives des patients. A notre connaissance, cette revue est la première à inclure des résultats aussi étendus, permettant ainsi une vue d'ensemble originale sur le sujet. Par la synthèse des différentes méthodes utilisées dans la recherche sur la contrainte – un aspect non encore abordé dans la littérature –, cette revue propose une approche structurée pour aborder cette thématique complexe.

Toutefois, l'étendue des résultats sélectionnés est en même temps une limite. Inclure des résultats objectifs et subjectifs dans une même revue en rend la synthèse plus difficile, diminuant ainsi la force des conclusions. L'exclusion de la médication forcée et de l'admission non volontaire représente une autre limite. Suite à ce travail, la réponse apportée ne peut en effet pas s'appliquer aux mesures de contrainte de manière générale. Il serait donc intéressant d'étudier l'ensemble des mesures de contrainte, y compris informelles et subjectives.

Par ailleurs, la discussion proposée alliant différents niveaux de discours – scientifiques, juridiques, éthiques, sociologiques et psychodynamiques – ouvre des champs de réflexions nouveaux, chacun pouvant faire l'objet d'un travail à part entière (Figure 4 p. 60). Faute de place, nous n'avons fait que les évoquer. Aborder le sujet sous un angle aussi vaste en montre la richesse, la profondeur et la complexité mais comporte un risque de confusion des différents niveaux de langage, illustrant par la même occasion la difficulté à étudier cette thématique.

L'originalité de cette thèse repose sur la mise en perspective de l'article central – basé sur une méthodologie scientifique rigoureuse – au sein d'une réflexion incluant différents angles d'approche. Cette manière peu commune d'étudier le sujet engendre une réponse sur plusieurs niveaux : la croyance en une efficacité des mesures de contrainte est questionnée sur un plan rationnel, mais n'est pas pour autant invalidée sur un plan empirique, sociologique voire psychodynamique. Cette mise en abyme offre des pistes de changement sans forcément disqualifier le réel déjà présent.

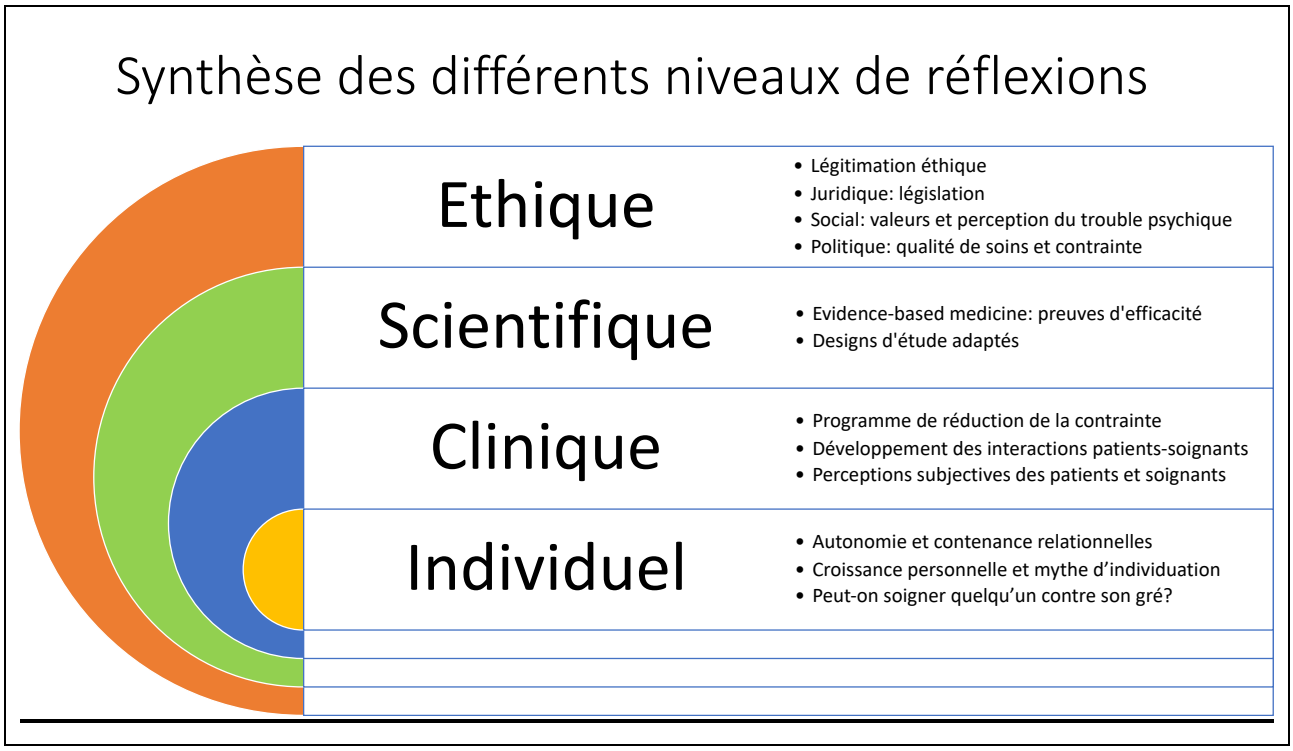
7. Conclusions

Les effets de l'isolement et de la contention en psychiatrie adulte incluent une grande variété de résultats, avec des designs d'études très différents. Malgré des limitations claires, la littérature identifiée suggère fortement des conséquences néfastes physiques et psychiques à l'isolement et à la contention. L'incidence estimée de PTSD après isolement ou contention varie de 25 à 47%, avec une majoration en cas d'anciens traumatismes. La perception subjective des patients, d'une grande variabilité interindividuelle, est principalement négative. Il n'y a pas de différence significative entre l'isolement et la contention en termes d'efficacité ou d'effets indésirables. Les effets délétères objectivés renforcent la recommandation d'utiliser ces mesures avec précaution et en dernier recours. Il semble important que les patients puissent prendre part aux décisions quand les circonstances le permettent et que leurs préférences soient prises en considération. Les interactions patients-soignants sont un point central à développer pour améliorer la perception subjective de la contrainte. En termes méthodologiques, étudier les mesures de contrainte reste complexe, ce qui limite le niveau de preuve disponible. Des études de cohortes prospectives bien conduites semblent plus réalisables que des études randomisées contrôlées pour parvenir à des résultats significatifs et exploitables. Dans le contexte des recherches actuelles, l'étude des effets de la contrainte fournit une base de comparaison pour les interventions visant sa réduction.

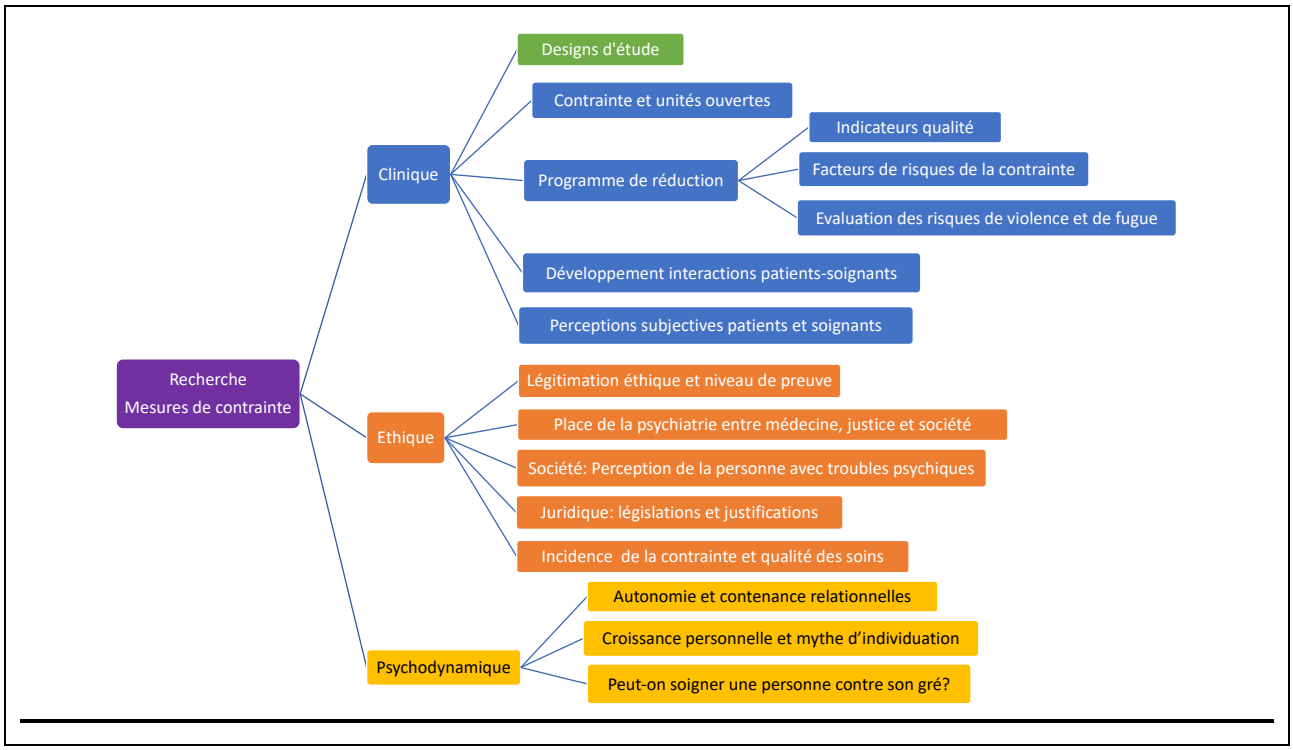
Actuellement, il n'y a pas de preuve scientifique d'efficacité des mesures de contrainte. Pour autant, la preuve de l'absence d'efficacité n'est pas claire. En l'état actuel de l'absence de preuve, l'efficacité de la contrainte semble rejoindre différentes catégories du mythe contenant chacune une certaine vérité, même sans preuve scientifique. Des données empiriques semblent parler en faveur d'un certain effet (1e, 2e et 4e catégories), ce qui rend difficile l'éviction totale de l'usage de la contrainte. Certains aspects ne sont pas sans évoquer un récit organisateur et porteur d'un système de valeur explicatif du monde, notamment au travers d'une recherche de croissance personnelle, ce qui se rapprocherait d'une perspective sociologique et psychodynamique du mythe (5e et 6e catégories). Toutefois, la distinction entre ces différentes catégories et la mesure dans laquelle cette part de vérité serait suffisante pour légitimer l'utilisation de la contrainte ne sont pas encore claires et demandent à être approfondies. La contenance relationnelle semble une piste intéressante de changement, grâce au développement d'un lien interpersonnel et d'un accompagnement individualisé visant une autonomisation progressive du patient. Malgré tout, les questions du libre-arbitre et de la possibilité de soigner une personne contre son gré restent ouvertes. Chaque axe de réflexion soulevé peut faire l'objet d'un travail à part entière et inaugure des perspectives de recherche intéressantes.

V. Annexes

1. Figure 3 : Synthèse des différents niveaux de réflexions



2. Figure 4 : Perspectives de recherches cliniques, éthiques, psychodynamiques



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