

Università di Bologna  
Facoltà di Medicina e Chirurgia  
Master in Evidence Based Practice e Metodologia  
della Ricerca Clinico Assistenziale

Use of physical restraints in adult ICU patients to  
prevent patient-initiated device removal:  
a systematic review

Utilizzo della contenzione fisica nei pazienti adulti  
critici per prevenire l'autorimozione dei presidi:  
revisione sistematica della letteratura

Relazione di fine Master di  
Erika Bassi e Marilena Ceresola

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## Abstract

**Review Objective** The aim is to present the best available evidence on the use of physical restraint to prevent patient-initiated device removal in adult ICUs patients.

**Background** The major reason for the use of physical restraints in ICUs is to protect patients from self-removal of therapeutic devices in light of the current sedation trends. Premature discontinuation of technologically complex therapies may result in serious harm. Even if physical restraint is often seen as a "simple" solution, according to many authors the benefits are uncertain as it can heighten agitation and may have devastating physical and psychological effects on patients.

**Search Strategy** A literature search was performed using the following databases MEDLINE, CINAHL, EMBASE, COCHRANE Library. Also unpublished studies were searched. No restrictions were placed on date of publications, no language limits.

**Methods** A critical appraisal of the selected studies was conducted using tool from JBI-MAStARI software. A data extraction and synthesis will follow.

**Main results (before data extraction)** A total of 6 observational studies were included in the present review. Although the area of interest was "patient-initiated device removal" in adult restricted ICU patients with all types of devices, the included publications regards only the unplanned removal of endotracheal tube.

**Final considerations (before data extraction)** Only the primary outcome had been investigated in the six included studies: they all collected the frequency of unplanned extubation in restrained/not restrained patients, but only few of them considered also the complications related to unplanned extubation and none of them the complication related to physical restraints use.

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## Abstract

**Review Question/Objective** L'obiettivo è di presentare le migliori evidenze disponibili sull'uso della contenzione fisica per prevenire l'autorimozione dei presidi nei pazienti adulti critici

**Background** La ragione principale per l'uso della contenzione fisica in terapia intensiva è quello di proteggere i pazienti dall'auto-rimozione dei dispositivi terapeutici. Anche se la contenzione fisica è spesso considerata una soluzione "semplice", secondo molti autori i benefici sono dubbi in quanto può aumentare l'agitazione e ci possono essere devastanti effetti fisici e psicologici sui pazienti.

**Search Strategy** E' stata fatta una ricerca della letteratura utilizzando i seguenti database: MEDLINE, CINAHL, EMBASE, COCHRANE Library. Sono stati cercati anche studi non pubblicati, non sono stati posti limiti temporali né linguistici alla ricerca.

**Methods** E' stata condotta una valutazione critica degli studi non pubblicati usando gli strumenti del software JBI-MAStARI.

**Main results (before data extraction)** Sono stati inclusi in questa revisione 6 studi osservazionali; sebbene l'ambito di interesse fosse l'autorimozione di qualsiasi presidio nei pazienti adulti critici sottoposti a contenzione fisica, gli studi inclusi hanno trattato solo l'estubazione non pianificata.

**Final considerations (before data extraction)** Solo l'outcome primario è stato oggetto di indagine nei sei studi inclusi: hanno tutti preso in esame la frequenza di estubazione sia nei pazienti contenuti che in quelli non contenuti, ma solo alcuni hanno considerato anche le complicanze legate all'estubazione non programmata e nessuno quelle legate all'uso della contenzione fisica.

**Key words:** physical restraints, device removal, unplanned extubation, self-extubation, treatment interference, intensive care unit, critical care .

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## Review title

Use of physical restraints in adult ICU patients to prevent patient-initiated device removal: a systematic review.

## Reviewers

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## 1. Review question/objective

The aim of this systematic review is to present the best available evidence on the use of physical restraint to prevent patient-initiated device removal in adult ICUs patients.

The review question: what is the effectiveness of physical restraints on prevention of patient-initiated device removal in adult ICU patients?

## 2. Background

Restraint in medicine is the use of physical or chemical means to control unwanted behavior, such as agitation, self-extubation, unwilling removal of invasive devices or fall<sup>1</sup>.

Physical restraint has been defined as "any manual method or physical or mechanical device, material or equipment attached or adjacent to a patient's body, that he or she cannot easily remove, that restricts freedom of movement or normal access to one's body"<sup>2</sup>.

The major reason for the use of physical restraints in intensive care units (ICUs)<sup>3,4</sup> is to protect patients from self-removal of therapeutic devices in light of the current sedation trends including daily waking protocols and a shift in clinical patient management from deeper to lighter sedation<sup>1</sup>.

Premature discontinuation of technologically complex therapies (endotracheal tube, intra aortic balloon pump, lung drainage, central venous catheter, arterial catheter, indwelling bladder catheter, feeding tube, ect) may result in serious harm, injury or death<sup>3,4,5</sup>; patient removal of devices other than endotracheal tubes (eg intra aortic balloon pumps) may have similar levels of life-threatening harm; on the other hand, devices as peripheral intravenous catheters may be more likely to cause minor to no harm in patients but can consume significant staff time or costly resources<sup>3,6</sup>.

Although the maintenance of therapeutic devices is a primary reason for the use of physical restraints in ICUs, little is known regarding the rate of patient-initiated device removal other than endotracheal tubes. According to the literature since the 1970s a number of investigators have focused on patient self-extubation from mechanical ventilation<sup>3</sup>. In the past decade, studies from the United States<sup>6,7,8</sup>, Europe<sup>9,10,11,12,13</sup>, and Asia<sup>14,15</sup> have reported incidence rate of self-extubation ranging from 0.3% to 14.3% and prevalence rate of 2.0 to 25.6/1000 ventilator-days<sup>3</sup>; one third or more of the self-extubation events occurred despite use of wrist restraints<sup>3,7,10,13</sup> leaving the effectiveness of physical restraints an unresolved issue.

Even if physical restraint is often seen as a "simple"<sup>16</sup> solution to the problem of the treatment interference in critically ill patients, according to many authors<sup>2, 16, 17, 18, 19</sup> the benefits are uncertain, as it can heighten agitation and may have devastating physical and psychological effects on the patients<sup>20</sup>.

The use of physical restraints seems to vary within and between countries. In Norwegian ICUs interventions to prevent treatment interference have traditionally not included the use of physical restraints; rather, a norm has prevailed for nurses to remain within a distance that allows direct observation and "eye contact" with intubated patients, both to avoid isolation and to be alert for sudden behavioral changes. Devices commercially available in the United States, such as soft wrist restraints and vest jackets, are not marketed to the critical care community in Norway<sup>20</sup>.

In the British Association of Critical Care Nurses position statement<sup>21</sup> on the use of restraint in adult critical care unit the authors suggested many alternative non-restraint methods to manage agitated patient and to prevent the device removal: minimizing noise and sleep deprivation, promote patient comfort, assess and monitor pain levels, reduce isolation as far as possible and involve the family in the surveillance of the patient.

A systematic review by Evans et al entitled "Physical Restraint in Acute and residential Care"<sup>22</sup> was published in 2002 in The Joanna Briggs Institute Library. The objective of this review was to present the best available information on the use of physical restraint in acute care hospitals and in residential care facilities; the authors investigated a number of areas and tried to answer many questions:

- The use of restraints (What proportion of patients and residents are physically restrained? What is the duration of restraint for patients and residents? What physical restraint devices are used in the acute and residential care setting?)
- Characteristics of restraints (What specific patient or resident characteristics increase the likelihood of the initiation of physical restraint?)
- Reasons for restraint (Why do health care workers restrain people?)
- Injury (What proportion of patients and residents suffer restraint-related injury? What injuries do physical restraint devices cause? What injuries are caused by specific restraint devices?)
- Experience (What is the experience of being restrained in an acute or residential care facility? What is the experience of having a relative physically restrained in an acute or residential care facility?)
- Restraint minimization programs (Do restraint minimization programs reduce the use of physical restraint devices in the acute and residential care setting? Is there an increase in adverse events following restraint minimization?)
- Restraint alternatives

The investigation in the acute care settings included also -but not exclusively- studies carried on in ICUs; the results about the reasons for initiating physical restraint in the acute care hospitals highlight that "treatment-oriented reasons" (to protect patients from preventing devices removal) were cited in 85% of the reports found. The most common cited reasons for using physical restraint devices in both the acute and residential care setting are factors associated with the care of the patient: safety, agitation, behavior control, wandering and support were the five sub-themes identified within the "patient-oriented reasons".

The review showed that there is little information related to the prevalence of restraint-related injury in either the hospital or residential care settings. Death is the most commonly reported adverse event directly related to the use of physical restraints that has been reported in the literature retrieved by

Evans et al. However, the authors noted that because of the seriousness of this event, it is far more likely to be identified during retrospective record reviews than less serious injuries; it is possible that some serious, but non-fatal, injuries may not have been detected by the retrospective studies identified. In terms of the circumstances surrounding the reported deaths, the most common is the asphyxiation caused by vest restraint and the victims were typically elderly residents from nursing homes. However, deaths caused by vest restraints have also been reported in younger people and in the acute care setting. The circumstance of the deaths appear to involve the restrained person being able to partially exit the bed or chair and so become trapped by the restraining device. There is little information concerning minor injuries caused by restraint devices like nerve or ischaemic injury caused by wrist restraint, a device often used in ICUs.

According to the authors there have been only limited rigorous evaluation of restraint minimization programs, particularly in the acute care setting; while there have only been a small number of studies in the acute care setting, it appears that the reduction in restraint use in this setting is not as great as has been achieved in residential care facilities. The effectiveness of restraint minimization programs, and the impact on both minor and serious injury, is an area in need of further investigation.

A vast number of alternatives (for example: quiet single room, familiar staff, physical, occupational and recreational therapies, increased staffing level, additional supervision and observation, active listening, increased visiting, provide companionship using family, friends or volunteers) have been used during physical restraint minimization programs, and many others have been suggested based on expert opinion. However, no individual alternative has been demonstrated to be effective and most have not been subject to any evaluation. While a number of studies have shown that physical restraint can be reduced using a variety of interventions, it has not yet been determined which interventions are effective.

The aim of the present systematic review is to focus on adult ICUs patients and to present the best available evidence to support decision pertaining the controversial use of physical restraint to prevent patient-initiated device removal.

### **3. Inclusion criteria**

#### **3.1 Types of participants**

The quantitative component of this review considered studies that include all adult (>18 years old) ICU patients:

- with all types of devices (for example -but not limited to- endotracheal tube, IABP, lung drainage, CVC, indwelling bladder catheter, arterial catheter, feeding tube, etc)
- with any kind of pathology, at any degree of severity and any kind of co-morbidity.

#### **3.2 Types of intervention(s)/phenomena of interest**

The quantitative component of the review considered studies that evaluate:

##### **INTERVENTION**

Physical restraints intended as any kind of device, material, or equipment that is attached (not only "adjacent": bed rails in ICU cannot be considered physical restraints) to a person's body and deliberately prevents the person's free bodily movement.

- All types of sedation at any dosage are accepted in light of the current sedation trends including daily waking protocols<sup>1</sup> and a patient's activity level scored as calm and cooperative
- Patient treated with neuromuscular blocking agent (NMBAs) are excluded from this systematic review;

neuromuscular blocking drugs block neuromuscular transmission at the neuromuscular junction, causing paralysis of the affected skeletal muscles. Their use in ICUs is usually limited to patients affected by severe acute respiratory distress syndrome (ARDS)<sup>23</sup> because they require a deep sedation and could be implicated in lung atelectasis<sup>24, 25</sup>, ICU-acquired myopathies and prolonged duration of mechanical ventilation<sup>26, 27</sup>. Patients treated with NMBAs can't make any movement -restrained or not- and they are not subjected to self-removal of therapeutic devices.

## COMPARISON

Any other strategy (for example -but not limited to- surveillance by family members/volunteers, direct nurse observation, environmental factor, effective communication)

### 3.3 Types of outcomes

This review considered studies that include the following primary outcome measures:

- Frequency of patient-initiated device removal in restrained/not restrained patients.

Where possible this review considered also secondary outcome measures:

- Complications related to patient-initiated device removal (for example -but not limited to- bleeding/haemorrhage, respiratory failure/failure, delay in therapy, pneumothorax, urinary retention, aspiration, hypotension, ect)
- Complications related to the use of physical restraints in terms of direct injury (for example -but not limited to- lacerations, bruising, development of pressure sores, ischaemia, nerve compression, etc)

### 3.4 Types of studies

The review took into account any randomised controlled trials and quasi-experimental studies. Because of the adverse nature of the review outcomes, both analytical and descriptive observational study designs were considered for this systematic review.

## 4. Search strategy

The search strategy aimed to find both published and unpublished studies. A three-step search strategy were utilised in each component of this review. An initial limited search of MEDLINE and CINAHL had been undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe article. A second search using all identified keywords and index terms had been undertaken across all included databases. Thirdly, the reference list of all identified reports and articles had been searched for additional studies. No restrictions were placed on date of publications and each database was searched as far back as possible; there weren't also any language limits. The searched databases include:

- PUBMED
- CINAHL
- EMBASE
- COHCRANE Library (just for trial)

The search for unpublished studies included:

- Grey literature report

The types of participants were "all adults" (>18 years old).

The initial key words were: physical restraints, chemical restraint, unplanned extubation, self-extubation, device removal, treatment interference, therapy disruption, agitation, intensive care unit, critical care. The search strategies for identification of the publications are presented in Appendix I.

## 5. Study selection

The title and abstracts identified from the search were stored in a database. Each citation was assessed against the inclusion/ exclusion criteria independently by two reviewers and the full text of studies deemed relevant were obtained; for studies with unclear titles and abstracts, the full text was also obtained. In four cases it wasn't possible to retrieve the full text.

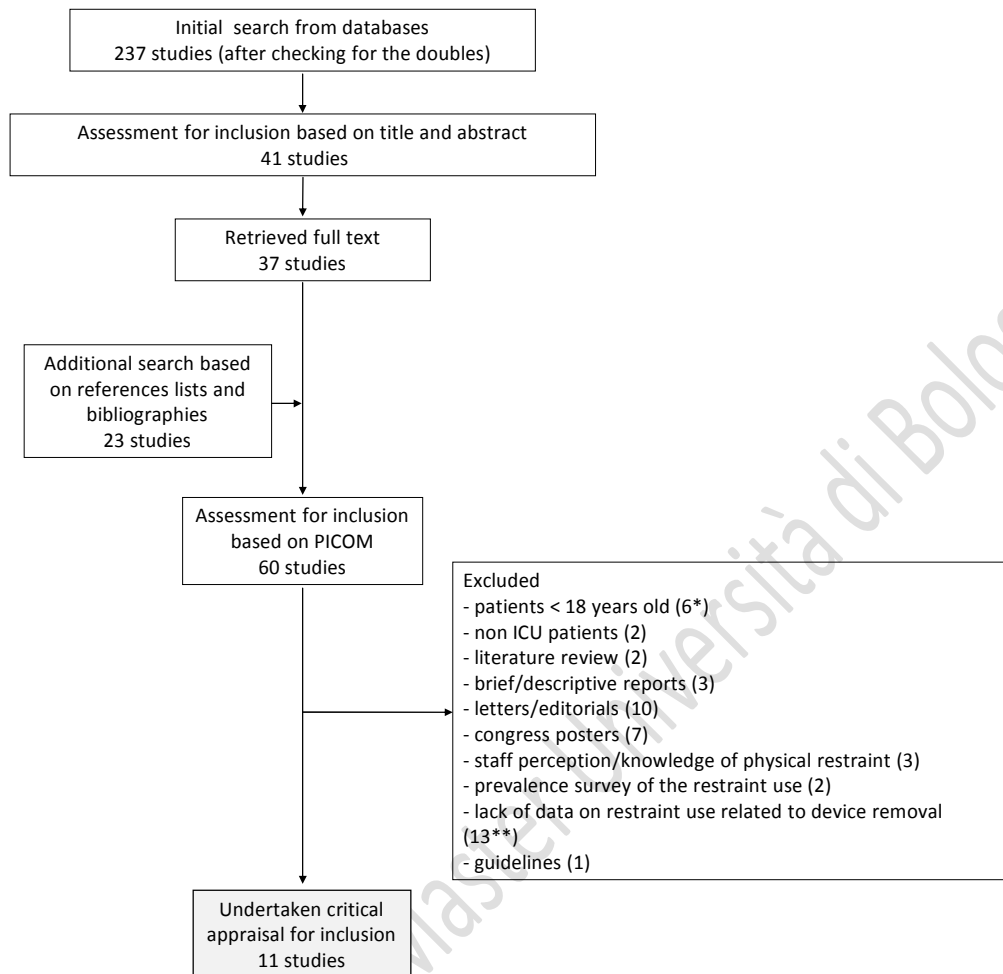
Additional search on references lists and bibliographies of retrieved full text was carried on. The 60 retrieved studies were assessed through PICOM strategy independently by two reviewers: the 11 selected studies reported in table 1 were submitted to JBI-MAStARI critical appraisal criteria.

**Table 1** – Summary of the studies assessed for inclusion in this systematic review.

Authors	Title	Journal	Year	Summary tables
Chang LY, Wang KW, Chao YF	Influence of physical restraint on unplanned extubation of adult intensive care patients: a case-control study.	Am J Crit Care, 17(5):408-15	2008	2
Curry K, Cobb S, Kutash M, Diggs C.	Characteristics associated with unplanned extubations in a surgical intensive care unit.	Am J Crit Care, 17(1):45-51	2008	3
Yeh SH, Lee LN, Ho TH, Chiang MC, Lin LW	Implications of nursing care in the occurrence and consequences of unplanned extubation in adult intensive care units.	J Nurs Stud, 41(3):255-62	2004	4
Chevron V, Ménard JF, Richard JC, Girault C, Leroy J, Bonmarchand G.	Unplanned extubation: risk factors of development and predictive criteria for reintubation.	Crit Care Med., 26(6):1049-53	1998	5
Tindol GA Jr, DiBenedetto RJ, Kosciuk L.	Unplanned extubations.	Chest, 105(6):1804-7	1994	6
Whelan J, Simpson SQ, Levy H.	Unplanned extubation. Predictors of successful termination of mechanical ventilatory support.	Chest, 105(6):1808-12	1994	7
Frezza E.E., Carleton G.L., Valenziano C.P.	A quality improvement and risk management initiative for surgical ICU patients: a study of the effects of physical restraints and sedation on the incidence of self-extubation.	Am J Med Qual., 15(5):221-5	2000	8
Bouza C, Garcia E, Diaz M, Segovia E, Rodriguez I.	Unplanned extubation in orally intubated medical patients in the intensive care unit: a prospective cohort study.	Heart Lung., 36(4):270-6	2007	9
Atkins PM, Mion LC, Mendelson W, Palmer RM, Slomka J, Franko T.	Characteristics and outcomes of patients who self-extubate from ventilator support: a case-control study.	Chest, 112(5):1317-23	1990	10
Coppolo D. P., May J. J.	Self-extubations: a 12-month experience.	Chest, 98(1):165-169	1990	11
Krayem A, Butler R.	Unplanned extubation in the ICU: impact on outcome and nursing workload.	Ann Thorac Med., 1(2):71-75	2006	12



The flow diagram of the selection process and reasons for exclusion of the publications reason for the exclusion is showed in Figure 1.




**Figure 1** – A flow diagram of the selection process and reasons for exclusion of the publications.  
 \*Mion LC et al in *Patient-initiated device removal in intensive care units: a national prevalence study* declare “adult ICUs” as study setting but in the chapter regarding the patients characteristics the age ranges from 11 to 98 years.  
 \*\*Kept in contact with the authors, no reply.

## 6. Assessment of methodological quality

The 11 studies selected were assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI), see figure 2 and Appendix II. Any disagreements arisen between the reviewers were resolved through discussion in order to reach consensus.

Figure 3 shows the JBI-MAStARI critical appraisal criteria for Comparable Cohort / Case Control Studies: this tool was used to assess the studies reported in summary tables 2-7. Figure 4 shows JBI-MAStARI critical appraisal criteria for Descriptive / Case Series Studies: this tool was used to assess the studies reported in summary tables 8-12.



**MAStARI - Meta Analysis of Statistics Assessment and Review Instrument**

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Select  
Detail  
Assessment  
Extraction  
Results  
Meta-Analysis

**Studies in "Use of physical restraints in adult ICU patients to prevent patient-initiated device removal: a systematic review."**


This page is used to manage the retrieved Studies. From this page, Studies can be selected to perform assessment and extraction and to develop Findings. The drop down box can be used to filter studies as new, included, excluded, extracted or finished.

All filter

# of Citations: 11

Author	Title	Journal	Year	Status	Assessment	Actions
<a href="#">Chevron V, Menard JF, Richard JC et al</a>	Unplanned extubation: risk factors of development and predictive criteria for reintubation	Crit Care Med	1998	New	Awaiting Final	<a href="#">Edit</a> <a href="#">Delete</a>
<a href="#">Frezza EE, Carleton GL, Valenziano CP</a>	A quality improvement and risk management initiative for surgical ICU patients: a study of the effects of physical restraints and sedation on the incidence of self-extubation	Am J Med Qual	2000	New	None	<a href="#">Edit</a> <a href="#">Delete</a>
<a href="#">Atkins PM, Mion LC, Mendelson W, Palmer RM, Slomka J, Franko T</a>	Characteristics and outcomes of patients who self-extubate from ventilator support: a case-control study	Chest	1997	New	None	<a href="#">Edit</a> <a href="#">Delete</a>
<a href="#">Bouza C, Garcia E, Diaz M, Segovia E, Rodriguez I</a>	Unplanned extubation in orally intubated medical patients in the intensive care unit: a prospective cohort study	Heart Lung	2007	New	None	<a href="#">Edit</a> <a href="#">Delete</a>
<a href="#">Chang LY, Wang KW, Chao YF</a>	Influence of physical restraint on unplanned extubation of adult intensive care patients: a case-control study	Am J Crit Care	2008	Included	Complete	<a href="#">Edit</a> <a href="#">Delete</a>
<a href="#">Coppolo DP, May JJ</a>	Self-extubations: a 12-month experience	Chest	1990	New	None	<a href="#">Edit</a> <a href="#">Delete</a>
<a href="#">Curry K, Cobb S, Kutash M, Diggs C</a>	Characteristics associated with unplanned extubations in a surgical intensive care unit	Am J Crit Care	2008	New	None	<a href="#">Edit</a> <a href="#">Delete</a>

Figure 2 – Retrieved studies uploaded in JBI-MAStARI software.



**MAStARI - Meta Analysis of Statistics Assessment and Review Instrument**

Reviews   Study   Logout   About

Select  
Detail  
Assessment  
Extraction  
Results  
Meta-Analysis

**Assessment for : Atkins PM, Mion LC, Mendelson W, Palmer RM, Slomka J, Franko T - Chest (1997)**

Type: Primary  
User: Erika Bassi  
Design: Comparable Cohort / Case Control Studies

Criteria	Yes	No	Unclear	Not Applicable	Comment
1) Is sample representative of patients in the population as a whole?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2) Are the patients at a similar point in the course of their condition/illness?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3) Has bias been minimised in relation to selection of cases and of controls?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
4) Are confounding factors identified and strategies to deal with them stated?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
5) Are outcomes assessed using objective criteria?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
6) Was follow up carried out over a sufficient time period?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
7) Were the outcomes of people who withdrew described and included in the analysis?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
8) Were outcomes measured in a reliable way?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
9) Was appropriate statistical analysis used?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Include: Undefined Reason

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Figure 3 – JBI-MAStARI critical appraisal criteria for Comparable Cohort / Case Control Studies.

Table 2

<b>Bouza C, Garcia E, Diaz M, Segovia E, Rodriguez I. Unplanned extubation in orally intubated medical patients in the intensive care unit: a prospective cohort study. Heart Lung. 2007 Jul-Aug;36(4):270-6</b>					
<b>Study type:</b> prospective cohort study (without comparable cohort)					
<b>Criteria</b>	<b>1<sup>st</sup> Reviewer</b>	<b>Comments</b>	<b>2<sup>nd</sup> Reviewer</b>	<b>Comments</b>	<b>Final assessment</b>
1	YES	The authors declare that the sample is only representative of medical ICU patients (not surgical)	Unclear	The sample is big enough but doesn't include surgical patients	YES
2	Not Applicable	There's no comparable cohort	Not Applicable	Cohort study without concurrent cohort	Not Applicable
3	Not Applicable		Not Applicable		Not Applicable
4	YES		YES	Use of logistic regression analysis	YES
5	YES		YES		YES
6	YES		YES		YES
7	YES	patients lost to follow-up(died) were included in the analysis	YES		YES
8	YES		YES		YES
9	YES		YES		YES
Included: YES  Reason: scored YES > 4			Included: YES  Reason: scored YES = 6, Unclear = 1, Not Applicable = 2		Included: YES  Reason: scored YES > 4

Table 3

<b>Coppolo DP, May JJ. Self-extubation: a 12-month experience. Chest. 1990; 98(1): 165-169</b>					
<b>Study type:</b> prospective cohort study (without comparable cohort)					
<b>Crite ria</b>	<b>1st Reviewer</b>	<b>Comments</b>	<b>2nd Reviewer</b>	<b>Comments</b>	<b>Final assessment</b>
1	Unclear	The authors collected data from general ICU intubated patients, the sample is big enough but only self-extubated group characteristics are showed in tables	Unclear	The study presents only the characteristics of self-extubated group	Unclear
2	Not Applicable	There's no comparable cohort	Not Applicable	Cohort study without concurrent cohort	Not Applicable
3	Not Applicable		Not Applicable		Not Applicable
4	Unclear	The authors presents the possible confounders only for self-extubated group	NO	Data about level of sedation, use of physical restraint and mental status are collected only for self-extubated group	NO
5	YES		YES		YES
6	YES		YES		YES
7	Unclear		Unclear		Unclear
8	Unclear		Unclear	No information about data collectors	Unclear
9	Unclear		Unclear		Unclear
Included: NO  Reason: scored YES < 4			Included: NO  Reason: scored YES = 2, NO = 1, Unclear = 6		Included: NO  Reason: scored YES < 4

Table 4

<b>Chang LY, Wang KW, Chao YF. Influence of physical restraint on unplanned extubation of adult intensive care patients: a case-control study. Am J Crit Care. 2008 Sep;17(5):408-15</b>					
<b>Study type:</b> retrospective case-control study					
<b>Criteria</b>	<b>1st Reviewer</b>	<b>Comments</b>	<b>2nd Reviewer</b>	<b>Comments</b>	<b>Final assessment</b>
1	YES	sample big enough, not clearly stated the diagnosis-type in the controls group	YES		YES
2	YES		YES		YES
3	YES		YES		YES
4	Unclear	Not measured the sedation level with a score. The authors only say "sedation yes or no" and it could be a confounder	YES		Unclear
5	YES		YES		YES
6	YES		YES		YES
7	Not Applicable		Not Applicable	Retrospective study based on medical chart and incident report	Not Applicable
8	Unclear		Unclear		Unclear
9	YES		YES		YES
Included: YES  Reason: scored > 4 YES			Included: YES  Reason: scored YES = 7, Unclear=1, Not Applicable=1		Included: YES  Reason: scored = 6 YES, 0 NO

Table 5

Atkins PM, Mion LC, Mendelson W, Palmer RM, Slomka J, Franko T. Characteristics and outcomes of patients who self-extubate from ventilator support: a case-control study. Chest. 1997 Nov 5;112(5):1317-23					
Study type: retrospective case-control study					
Criteria	1st Reviewer	Comments	2nd Reviewer	Comments	Final assessment
1	YES		YES		YES
2	YES	More surgical patients in the control group, but the authors considered it in the analysis	YES	No diagnosis-type of the sample, anyway the two groups are similar for severity of illness. The authors considered in the analysis that surgical and medical patients are not equally distributed in the case and the control group	YES
3	YES		YES	The authors use case matching, logistic regression analysis and use subgroup analysis for surgical and medical patients	YES
4	NO	Not measured the sedation level with a score. The authors included patients receiving neuromuscular blocking agents	NO	The sedation level is a possible confounder. Patients treated with neuromuscular blocking agents are included. The authors should tell us how many restrained patients were treated with NMBA both in case and control group	NO
5	YES		YES		YES
6	YES		YES		YES
7	Not Applicable		Not Applicable	Retrospective study based on medical chart and incident report	Not Applicable
8	YES		YES		YES
9	YES		YES		YES
Included: NO		Included: NO		Included: NO	
Reason: The authors included patients receiving neuromuscular blocking agents		Reason: Patients treated with neuromuscular blocking agents are included.		Reason: The authors included patients receiving neuromuscular blocking agents without declaring how many physically restrained patients were also treated with NMBA *	

\* Kept in contact with the authors in order to know how many restrained patients were also treated with NMBA in both case and control groups. The authors kindly replied to the reviewers that they don't have the requested data. The present SR is about patient-initiated device removal in physically restrained but not "chemically paralyzed" patients.


Table 6

<b>Krayem A, Butler R. Unplanned extubation in the ICU: impact on outcome and nursing workload. Ann Thorac Med. 2006, 1(2):71-75</b>					
<b>Study type:</b> retrospective case-control study					
<b>Criteria</b>	<b>1st Reviewer</b>	<b>Comments</b>	<b>2nd Reviewer</b>	<b>Comments</b>	<b>Final assessment</b>
1	Unclear	Little sample, only one control for each case	YES	General ICU (surgical + medical) patients	YES
2	YES	Non statistically significant difference about clinical characteristics between groups	YES	Similar APACHE III score and diagnosis across groups	YES
3	YES	Use of case-matching	YES	Use of case-matching	YES
4	Unclear	Not measured the sedation/agitation level with a score.	Unclear		Unclear
5	YES		YES		YES
6	YES		YES		YES
7	Not Applicable		Not Applicable	Retrospective study based on medical chart and incident report	Not Applicable
8	Unclear	The authors don't declare who was involved in the data-collecting and if they have been trained	NO	No information about data collectors	NO
9	Unclear		NO	The method section is not enough detailed	Unclear
Included: YES  Reason: scored > 4 YES			Included: YES  Reason: scored YES = 5, NO = 2, Unclear = 1		Included: YES  Reason: scored > 4 YES

Table 7

<b>Chevron V, Ménard JF, Richard JC, Girault C, Leroy J, Bonmarchand G. Unplanned extubation: risk factors of development and predictive criteria for reintubation. Crit Care Med. 1998 Jun;26(6): 1049-53</b>					
<b>Study type:</b> prospective case-control study					
<b>Criteria</b>	<b>1st Reviewer</b>	<b>Comments</b>	<b>2nd Reviewer</b>	<b>Comments</b>	<b>Final assessment</b>
1	Unclear	Medical ICU intubated patients. Only few clinical characteristics are showed in tables	Unclear	There is not a table with all the characteristics of the sample.	Unclear
2	Unclear	The authors declare they collected patients' data for cases and controls (age, sex, main reason for admission, ect.) but there isn't any table about it. Cases and controls were similar?	Unclear	The authors declare that control and case groups were similar, but in the article there is not a table with the comparison of control and case group.	Unclear
3	YES		Unclear	The authors randomized the patients in the control group	Unclear
4	YES		YES		YES
5	YES		YES		YES
6	YES		YES		YES
7	YES	One patient died before being re-intubated. It's not clear if he was included in the analysis or not, but anyway it doesn't change the characteristics of the studied patients	Unclear	One patient died before being re-intubated after unplanned extubation, but it is unclear if the authors included this patient in the analysis	YES - One patient died before being re-intubated. It's not clear if he was included in the analysis or not, but anyway it doesn't change the characteristics of the studied patients
8	Unclear	The authors don't declare who was involved in the data-collecting and if they have been trained	NO	No information about data collectors	NO
9	YES		YES		YES
Included: YES  Reason: scored > 4 YES			Included: Unclear  Reason: scored YES = 4, NO = 1, Unclear = 4		Included: YES  Reason: scored > 4 YES





MAStARI - Meta Analysis of Statistics Assessment and Review Instrument

ReviewsStudyLogoutAbout

Select  
Detail  
Assessment  
Extraction  
Results  
Meta-Analysis

Assessment for : Tindol GA Jr, DiBenedetto RJ, Kosciuk L - Chest (1994)

Type: Primary  
User: Erika Bassi  
Design: Descriptive / Case Series Studies

Criteria	Yes	No	Unclear	Not Applicable	Comment
1) Was study based on a random or pseudo-random sample?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2) Were the criteria for inclusion in the sample clearly defined?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3) Were confounding factors identified and strategies to deal with them stated?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
4) Were outcomes assessed using objective criteria?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
5) If comparisons are being made, was there sufficient descriptions of the groups?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
6) Was follow up carried out over a sufficient time period?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
7) Were the outcomes of people who withdrew described and included in the analysis?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
8) Were outcomes measured in a reliable way?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
9) Was appropriate statistical analysis used?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Include Undefined  
Reason   

UpdateUndoCancel

**Figure 4** – JBI-MAStARI critical appraisal criteria for Descriptive / Case Series Studies.

Table 8

Tindol GA Jr, DiBenedetto RJ, Kosciuk L. Unplanned extubations. Chest. 1994 Jun;105(6):1804-7					
Study type: prospective case-series study					
Criteria	1st Reviewer	Comments	2nd Reviewer	Comments	Final assessment
1	Not Applicable		Not Applicable		Not Applicable
2	YES		YES		YES
3	Unclear	Few data about type of and level of sedation .	NO		NO
4	YES		YES		YES
5	Not Applicable		Not Applicable		Not Applicable
6	YES		YES		YES
7	Not Applicable		Not Applicable		Not Applicable
8	Unclear	The authors declare who was involved in the data-collecting but not if they have been trained	Unclear	Probably there are more than one data collectors but is unclear if they were trained	Unclear
9	Unclear	Only few info about statistical analysis	Unclear		Unclear
Included: NO  Reason: scored < 4 YES			Included: NO  Reason: scored YES = 3, NO = 1, Unclear = 2		Included: NO  Reason: scored < 4 YES

Table 9

<b>Whelan J, Simpson SQ, Levy H. Unplanned extubation. Predictors of successful termination of mechanical ventilatory support. Chest. 1994 Jun;105(6):1808-12</b>					
<b>Study type:</b> retrospective case-series study					
<b>Criter ia</b>	<b>1st Reviewer</b>	<b>Comments</b>	<b>2nd Reviewer</b>	<b>Comments</b>	<b>Final assessment</b>
1	Not Applicable		Not Applicable		Not Applicable
2	YES		YES		YES
3	Unclear	The authors identified some possible confounding factors, but they didn't measure them with a score. The authors only say "sedation yes or no"	NO	Not measured the sedation level with a score	Unclear
4	YES		YES		YES
5	YES	The authors compared reintubated and not reintubated patients after unplanned extubation	YES		YES
6	YES		YES		YES
7	Not Applicable		Not Applicable	Retrospective study based on medical chart	Not Applicable
8	Unclear	The authors don't declare who was involved in the data-collecting and if they have been trained	NO	No information about data collectors	NO
9	Unclear		YES	The authors provided a statistical analysis of the two subgroups (re-intubated/non reintubated)	YES
Included: YES  Reason: scored > 4 YES			Included: YES  Reason: scored YES = 5, NO = 2		Included: YES  Reason: scored > 4 YES

Table 10

<b>Curry K, Cobb S, Kutash M, Diggs C. Characteristics associated with unplanned extubations in a surgical intensive care unit. Am J Crit Care. 2008 Jan;17(1):45-51</b>					
<b>Study type:</b> retrospective case-series study					
<b>Criteria</b>	<b>1st Reviewer</b>	<b>Comments</b>	<b>2nd Reviewer</b>	<b>Comments</b>	<b>Final assessment</b>
1	Not Applicable	It's a case series study. The sample consisted of all adult patients in the trauma surgical ICU who had experienced an unplanned extubation	Not Applicable		Not Applicable
2	YES		YES		YES
3	YES		YES		YES
4	YES		YES		YES
5	Not Applicable		Not Applicable		Not Applicable
6	YES		YES		YES
7	Not Applicable		Not Applicable	Retrospective study based on medical chart  The authors declare lack of data about ramsay level in 5/31 patients. They don't consider these patients in the analysis, but they cannot do it...have we to consider it not applicable ?	Not Applicable
8	Unclear	The authors don't declare who was involved in the data-collecting and if they have been trained	NO	No info about data collectors	NO
9	YES		YES		YES
Included: YES  Reason: scored > 4 YES			Included: YES  Reason: scored YES = 5, NO = 1		Included: YES  Reason: scored > 4 YES

Table 11

Yeh SH, Lee LN, Ho TH, Chiang MC, Lin LW. Implications of nursing care in the occurrence and consequences of unplanned extubation in adult intensive care units. J Nurs Stud. 2004 Mar; 41(3):255-62					
Study type: prospective descriptive study					
Criteria	1st Reviewer	Comments	2nd Reviewer	Comments	Final assessment
1	Not Applicable		Not Applicable		Not Applicable
2	YES		Unclear	Not clear whether responders have potential to differ in some way to non-responders	Unclear
3	Unclear		NO	Not measured the sedation level with a score, not clear the way they assess the state of mind	Unclear
4	Unclear	Objectivity compromised?	Unclear	Even if the outcome "unplanned extubation" is an objective one, data were not collected from medical chart but through a questionnaire filled in by nurses	Unclear
5	NO	The comparison is not clear at all	NO		NO
6	YES		YES		YES
7	Unclear		Unclear	The authors don't declare any loss at follow up even if the numerical data are confused	Unclear
8	Unclear	The authors declare who was involved in the data-collecting but not if they have been trained	Unclear	All ICU nurses were in charge to collect data double-checked by head nurses, but were they trained?	Unclear
9	YES		YES		YES
Included: NO Reason: scored < 4 YES			Included: NO Reason: scored YES = 2, NO = 2, Unclear = 4		Included: NO Reason: scored < 4 YES

Table 12

<b>Frezza EE, Carleton GL, Valenziano CP. A quality improvement and risk management initiative for surgical ICU patients: a study of the effects of physical restraints and sedation on the incidence of self-extubation. Am J Med Qual. 2000 Sep-Oct; 15(5):221-5</b>					
<b>Study type:</b> retrospective descriptive study					
<b>Criter ia</b>	<b>1st Reviewer</b>	<b>Comments</b>	<b>2nd Reviewer</b>	<b>Comments</b>	<b>Final assessment</b>
1	Not Applicable	Retrospective longitudinal study in a 18-bed ICU	Not Applicable		Not Applicable
2	YES		YES		YES
3	Unclear	The authors identified some possible confounding factors, but they didn't measure them with a score	Unclear		Unclear
4	YES		YES		YES
5	Unclear		Unclear	The authors compared only few characteristics across 4 patients groups	Unclear
6	YES		YES		YES
7	Not Applicable		Not Applicable		Not Applicable
8	Unclear	The authors declare who was involved in the data- collecting but not if they have been trained	Unclear		Unclear
9	NO		Unclear	Few info about statistical analysis	NO
Included: NO  Reason: scored < 4 YES			Included: NO  Reason: scored = 3 YES, 1 NO, 3 Unclear		Included: NO  Reason: scored < 4 YES

## 7. Results

### 7.1 Studies included in the review

- Bouza C, Garcia E, Diaz M, Segovia E, Rodriguez I. Unplanned extubation in orally intubated medical patients in the intensive care unit: a prospective cohort study. *Heart Lung*. 2007 Jul-Aug;36(4):270-6.
- Chang LY, Wang KW, Chao YF. Influence of physical restraint on unplanned extubation of adult intensive care patients: a case-control study. *Am J Crit Care*. 2008 Sep;17(5):408-15.
- Krayem A, Butler R. Unplanned extubation in the ICU: impact on outcome and nursing workload. *Ann Thorac Med*. 2006, 1(2):71-75.
- Chevron V, Ménard JF, Richard JC, Girault C, Leroy J, Bonmarchand G. Unplanned extubation: risk factors of development and predictive criteria for reintubation. *Crit Care Med*. 1998 Jun;26(6):1049-53.
- Curry K, Cobb S, Kutash M, Diggs C. Characteristics associated with unplanned extubations in a surgical intensive care unit. *Am J Crit Care*. 2008 Jan;17(1):45-51.
- Whelan J, Simpson SQ, Levy H. Unplanned extubation. Predictors of successful termination of mechanical ventilatory support. *Chest*. 1994 Jun;105(6):1808-12.

### 7.2 Description of studies

Of the 11 studies submitted to JBI-MAStARI critical appraisal criteria a total of 6 publications were included in the present review: one prospective cohort study, two retrospective case-control, one prospective case-control and two retrospective case-series. Two of them were carried on in Nineties and the remaining from 2006 and 2008.

Two studies were conducted in the USA, two in Europe (France-Spain), one in Canada and one in Asia. The settings of the included studies were three medical ICUs, one surgical ICUs and two general ICUs.

The samples studied were not big: they ranged from 23 patients in the smallest case-series to 300 in the biggest case-control study. This is due to the type of the included studies that are all observational.

Although the area of interest of the present SR was "patient-initiated device removal" in adult restricted ICU patients with all types of devices (for example -but not limited to- endotracheal tube, IABP, lung drainage, CVC, indwelling bladder catheter, arterial catheter, feeding tube, etc) the included publications regarded only the unplanned removal of endotracheal tube. The only three studies about other type of devices were excluded either because lack of data<sup>11,73</sup> or because paediatric patients were involved<sup>3</sup>.

Considering that all the included studies were about unplanned extubation, the type of restraints utilized were almost always soft wrist/hand restraints; in fact it is the most common device to prevent ICU intubated patients from self-extubation. Only in two studies<sup>28,36</sup> it was not clearly stated and another one<sup>29</sup> reported that in three instances patients had more than one type of restraint in place at the time of the self-extubation.

## 8. Data collection

Quantitative data will be extracted from papers included in the review using the standardised data extraction tool from JBI-MAStARI (Appendix III). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.

## 9. Data synthesis

Quantitative papers will, where possible, be pooled in statistical meta-analysis using the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI). Where statistical pooling is not possible the findings will be presented in narrative form.

## 10. Final considerations before data extraction and synthesis

Only six studies met the criteria to be included in the present systematic review. They were all observational studies: cohort, case-control and case-series studies. This is due to the type of review-question and its ethical impact: it is almost impossible to find RCTs about the effectiveness of physical restraints to prevent patient-initiated device removal. As it is well known the strength of inference from a cohort or a case-control study will always be less than that of a rigorously conducted RCT because randomization is the best way to ensure that groups are balance at baseline with respect to determinants of outcome. The reviewers will take it into account in the data extraction and synthesis.

About the outcomes of the present systematic review only the primary one had been investigated in the six included studies: they all collected the frequency of patient-initiated device removal in restrained/not restrained patients, but only few of them considered also the complications related to patient-initiated device removal and none of them the complications related to the use of physical restraints in terms of direct injury.

Last consideration about all the studies included (apart from one<sup>28</sup>) is that their first objective wasn't to investigate the effectiveness of physical restraints to prevent patient-initiated device removal but mostly to understand the reasons for unplanned extubation. The data about physical restraints had been collected as part of patients characteristics in unplanned extubation events. In addition four out of six studies were retrospective and the data had been collected using medical chart: in such designed studies could it be that the data about physical restraints were underestimated? This is a question that reviewers will take into account together with the lack of strength of observational study design.

## 11. Conflicts of interest

None



## References

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## **Appendix I: Search strategy**

### **Search Strategy For MEDLINE (till May 2011)**

- #1. "Restraint, Physical"[Mesh] OR "physical restraint"[TW]
- #2. "Device Removal"[Mesh] OR "device removal"[TW] OR "tube removal"[TW]
- #3. "treatment interference"[TW] OR "therapy disruption"[TW] OR "device disruption"[TW]
- #4. "self-extubation"[TW] OR "self extubation"[TW] OR "accidental extubation"[TW] OR "unplanned extubation"[TW]
- #5. "Intensive Care Units"[Mesh] OR "intensive care unit"[TW] OR "Critical Care"[Mesh] OR "critical care"[TW]
- #6. "restraining therapy"[TW] OR "restraining therapies"[TW]
- #7. "chemical restraint"[TW]
- #8. (#1) AND #5
- #9. (#1) AND #2
- #10. (#1) AND #3
- #11. (#1) AND #4
- #12. (#4) AND #5
- #13. (#8) AND #2
- #14. (#8) AND #3
- #15. (#8) AND #4#
- #16. (#8) AND #7

### **Search Strategy For CINAHL (till May 2011)**

- S1. (MH "Restraint, Physical")
- S2. physical restraint
- S3. (MH "Restraint, Chemical")
- S4. chemical restraint OR restraining therapies
- S5. S1 OR S2 OR S3 OR S4
- S6. (MH "Device Removal")
- S7. device removal

S8. unplanned extubation OR self extubation OR accidental extubation OR treatment interference OR therapy disruption OR device disruption

S9. S6 OR S7 OR S8

S10. S5 AND S9

S11. (MH "Critical Care")

S12. (MH "Intensive Care Units")

S13. critical care OR intensive care units

S14. S11 OR S12 OR S13

S15. S10 AND S14

### **Search Strategy For EMBASE (till May 2011)**

#1. "physical restraint" OR "chemical restraint" OR "restraining therapies"

#2. "device removal"/exp

#3. "unplanned extubation" OR "self extubation" OR "accidental extubation" OR "treatment interference" OR "therapy disruption" OR "device disruption"

#4. #2 OR #3

#5. #1 AND #4

### **Search Strategy For COCHRANE (till May 2011)**

#1. MeSH descriptor **Device Removal** explode all trees

#2. MeSH descriptor **Intensive Care Units** explode all trees

#3. device removal

#4. MeSH descriptor **Restraint, Physical** explode all trees

#5. accidental extubation OR unplanned extubation

#6. treatment interference

#7. physical restraint

#8. intensive care unit

#9. (#1 OR #3)

#10. (#2 OR #8)

#11. (#4 OR #7)

#12. (#9 AND #10 AND #11)

#13. (#10 AND #11 AND #5)

#14. (#10 AND #11 AND #6)

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## Appendix II: MASTARI Appraisal Instrument

### JBI Critical Appraisal Checklist for Comparable Cohort/ Case Control

Reviewer ..... Date .....

Author ..... Year ..... Record Number .....

	Yes	No	Unclear	Not Applicable
1. Is sample representative of patients in the population as a whole?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are the patients at a similar point in the course of their condition/illness?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Has bias been minimised in relation to selection of cases and of controls?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Are confounding factors identified and strategies to deal with them stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Are outcomes assessed using objective criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was follow up carried out over a sufficient time period?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal:      Include ☐      Exclude ☐      Seek further info. ☐

Comments (Including reason for exclusion)

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## JBI Critical Appraisal Checklist for Descriptive / Case Series

Reviewer \_\_\_\_\_ Date \_\_\_\_\_

Author \_\_\_\_\_ Year \_\_\_\_\_ Record Number \_\_\_\_\_

	Yes	No	Unclear	Not Applicable
1. Was study based on a random or pseudo-random sample?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were the criteria for inclusion in the sample clearly defined?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Were confounding factors identified and strategies to deal with them stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were outcomes assessed using objective criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. If comparisons are being made, was there sufficient descriptions of the groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was follow up carried out over a sufficient time period?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal:      Include ☐      Exclude ☐      Seek further info ☐

Comments (Including reason for exclusion)

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Appendix III: MASTARI Data Extraction Instrument

**JBI Data Extraction Form for  
Experimental / Observational Studies**

Reviewer \_\_\_\_\_ Date \_\_\_\_\_  
Author \_\_\_\_\_ Year \_\_\_\_\_  
Journal \_\_\_\_\_ Record Number \_\_\_\_\_

**Study Method**

RCT ☐                      Quasi-RCT ☐                      Longitudinal ☐  
Retrospective ☐                      Observational ☐                      Other ☐

**Participants**

Setting \_\_\_\_\_  
Population \_\_\_\_\_

**Sample size**

Group A \_\_\_\_\_ Group B \_\_\_\_\_

**Interventions**

Intervention A \_\_\_\_\_  
Intervention B \_\_\_\_\_

Authors Conclusions: \_\_\_\_\_  
\_\_\_\_\_

Reviewers Conclusions: \_\_\_\_\_  
\_\_\_\_\_

## Study results

### Dichotomous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number

### Continuous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number

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