The effectiveness of nursing management on improving health outcomes for hospitalized older adults with delirium: A systematic review protocol

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Review question/objective

The objective of this systematic review is to identify the best available research evidence related to the effectiveness of nursing management on improving health outcomes for hospitalized older adults with delirium.

The specific review questions to be addressed are:

What is the effectiveness of nursing interventions on:

- reducing the duration, severity and incidence of delirium?
- reducing the decline in cognitive status and functional status?
- reducing mortality?
- reducing length of hospital stay in hospitalized older adults?

Specific nursing interventions include: systematic detection/screening of delirium, systematic geriatric or psychiatric consultation or consultation services by a geriatric nurse specialist, follow-up by a nurse, nursing intervention protocol designed for delirious patients, music therapy, and scheduled pain medication protocol.
Background

Delirium, also called acute confusional state, is the most frequent complication affecting hospitalized older people.\textsuperscript{1,2} It is estimated that about 14\%-56\% of hospitalized older patients develop delirium.\textsuperscript{3} With the aged population accounting for approximately 50\% of all days of hospital care, delirium is associated with 17.5 million hospital days a year. That is 2.5 million patients annually in the United States of America.\textsuperscript{1,4,5} As the population ages, the number of hospitalized older adults will rise and so too will the prevalence of delirium.\textsuperscript{6}

The term delirium means “an acutely disturbed state of mind characterized by restlessness, illusions, and incoherence, occurring in intoxication, fever, and other disorders”.\textsuperscript{7} Delirium is a syndrome with many possible causes that results in a group of symptoms but not a disease.\textsuperscript{6} According to the American Psychiatric Association\textsuperscript{8} definition in text revision of the fourth edition in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR), there are four diagnostic criteria for delirium:

1. Disturbance of consciousness with reduced ability to focus, sustain, or shift attention.

2. A change in cognition or the development of a perceptual disturbance that is not better accounted for by a preexisting, established, or evolving dementia.

3. The disturbance develops over a short period of time and tends to fluctuate during the course of the day.

4. There is evidence from the history, physical examination, or laboratory findings that the disturbance is caused by the direct physiological consequences of a general medical condition.\textsuperscript{6}

The clinical features are divided into seven areas of abnormalities are: (a) arousal, (b) language and cognition, (c) perception, (d) orientation, (e) mood, (f) sleeping patterns and (g) neurological functioning.\textsuperscript{9}

Delirium brings detrimental effects to patients and is associated with poor clinical outcomes.\textsuperscript{10} Patients suffering from delirium will have a greater deterioration in walking ability and activities of daily living, thus an increase likelihood of entering a long-term care facility.\textsuperscript{11} Although dementia is a predisposing factor for delirium, delirium is also a risk factor for developing or worsening of dementia.\textsuperscript{12,13} Symptoms of depression and anxiety are also associated with delirium\textsuperscript{14} and length of hospital stay is increased\textsuperscript{15} and the mortality risk is increased by two to five times.\textsuperscript{16} In addition it has been shown\textsuperscript{17} that 35\%-40\% of hospitalized older people with delirium will die per year. In the United States of America, the annual excess expenditures directly related to delirium were US$ 6.9 billion. As for the greater decline in cognition and function in older adults experiencing delirium, additional post-hospitalization treatment costs increase.\textsuperscript{13} It is estimated that the total health care cost related to delirium ranges from US$38 billion to US$152 billion every year.\textsuperscript{18}

Delirium on older adults is usually the only clue for an acute and serious medical problem\textsuperscript{1} and as such should be treated as medical emergency until other underlying problems are ruled out.\textsuperscript{19} Although some of the disposing factors for delirium such as age and pre-existing dementia are uncontrollable, delirium
is considered as preventable in one-third of the patients at-risk. Even if it is not preventable, the prevalence of severe delirium can still be reduced by 50% by nonpharmacological interventions.\textsuperscript{12}

Despite the significant negative impact of delirium, it usually goes undetected in older hospitalized adults\textsuperscript{20} with a typical non-detection rate of 33\%-66\% as cognitive assessment are seldom done on admission.\textsuperscript{21} With acute onset and fluctuating nature of delirium, nonpharmacological approaches should be taken as first line treatment\textsuperscript{1}, nurses are in the best position in early detection and management.\textsuperscript{22}

As for the wide range of etiologies and predisposing factors associated with delirium, broad multifactorial and multi-disciplinary approaches are needed to reduce mortality and morbidity.\textsuperscript{23} Interventions also need to be fast and user-friendly. The balance between comprehensiveness and practicability of the intervention must be considered so as to manage the issue of implementation and adherence on the intervention.\textsuperscript{22, 23, 24}

Nurse-led interdisciplinary interventions, multifactorial interventions or music therapy have been used by nurses to manage delirium\textsuperscript{20, 25, 26, 27, 28}, yet the results are inconsistent. There are also two systematic reviews available in determining the most effective nursing intervention in the management of delirium. Only five major databases till 2003 were included in the study by Milisen et al.\textsuperscript{29} and only three databases were included Hempenius et al.\textsuperscript{30}

Cole et al.\textsuperscript{20} conducted a randomized controlled trial to investigate if a systematic detection and multidisciplinary care of delirium would reduce time to improve the cognitive status of older adults admitted to a general medical service. After a systematic detection of delirium, 227 delirious patients were recruited. Participants in the intervention group received a systematic geriatric or psychiatric consultation and follow-up by a study nurse. The study nurse liaised with the consultant, physicians, family and other nurses and ensured the proper implementation of a nursing intervention protocol designed for the delirious patients. The study collected data on the rate and time to improvement of delirium, functional status, length of stay, rate of discharge to the community, and living arrangements. No significant differences were found between the control and intervention group.

McCaffrey and Locsin\textsuperscript{26} also implemented a randomized controlled trial to determine the effect of music on postoperative delirium in older adults undergoing elective hip and knee surgery. A total of 66 patients were recruited. Episodes, signs and symptoms of delirium were determined by comparing nurses’ notes with a checklist. Scores for alertness, vital signs stability, orientation to time, place and person and comprehension on instructions were given postoperatively to indicate the ability to ambulate. A list of selected music was given in the recovery room according to participants’ preference followed by regular sessions in the orthopedic unit. In addition, participants were allowed to play music at any time they desired. The group who listened to music had significantly fewer periods of delirium and higher scores of readiness to ambulate.

Another study was undertaken by Milisen et al.\textsuperscript{27} to test the effect of a nurse-led interdisciplary intervention program on postoperative delirium for older hip-fracture adults. A total of 120 patients were recruited in this controlled clinical trial without randomization. Interventions included a systematic screening using the Confusion Assessment Method (CAM)\textsuperscript{31} and NEECHAM Confusion Scale\textsuperscript{32}, a consultation service by a delirium resource nurse, a geriatric nurse specialist or a psychogeriatrician, and a scheduled pain medication protocol. The functional status, mortality and length of stay between
the two cohorts were similar. There was no significant difference in the incidence of delirium between the two groups, but the duration and severity of delirium was significantly reduced. Significant improvement was also observed in cognitive functioning for the intervention group.

Lundström et al.\textsuperscript{28} conducted a prospective interventional study on 400 patients admitted to an internal medicine hospital. An individualized care system was adopted instead of a task-allocation care system in the study to investigate the effect this would have on the outcomes for older adults with delirium. Significant decreases were observed on duration of delirium and length of stay in the group receiving individualized care. Prevalence of delirium, number of patients returned to their own home and mortality remained the same.

The above studies evaluated the effect of interventions on the prevalence of delirium yet no significant effects were obtained.\textsuperscript{26, 27, 28} Although it seems unpreventable for hospitalized older adults to develop delirium, it shows that outcomes of the delirious patients can be improved by nursing management. A preliminary search of the Joanna Briggs Institute Library of Systematic Review, JBI COnNECT+, The Cochrane Library, MEDLINE, CINAHL, DARE and PROSPERO databases indicate that there are two systematic review reports\textsuperscript{29, 30} on this topic but with limited databases searched. One systematic review protocol\textsuperscript{33} was found in the Cochrane Library on using multidisciplinary team interventions for the management of delirium in hospitalized patients. However no separate analysis was performed on the outcomes of nursing interventions.

The purpose of this review is to identify the best available evidence for nurses to effectively manage delirium in hospitalized older adults. The findings from this review could inform nurses on development of a systematic screening and management protocol for older adults admitted to hospital thus improving patient outcomes.

**Keywords**

older adult*; aged; elderly; old age; Hospital*; admi*; Delir*; acute confusion; Nursing assessment; nursing intervention; nursing care; Detect*; screen*; Consult*; refer*; geriatrician; geriatric specialist; psychiatrist; psychi*; Pain; medication; medicine; manage; management; Care system; patient-allocation system; Duration; severity; incidence; prevalence; Cognitive status; functional status; mortality; length of hospital stay

**Inclusion criteria**

**Types of participants**

Older adults aged 65 or above being admitted into acute care hospitals. Those with communication barriers such as aphasia or delirium due to substance abuse will be excluded.

**Types of intervention(s)**

For the purpose of this review, nursing management is defined as any interventions that are coordinated, led or delivered by nursing staff aiming to reduce the duration, severity, incidence, and decline on cognitive and functional status, mortality and length of hospital stay on admitted older patients with delirium. The interventions include:
- a systematic screening of all admitted older adults for delirium
- an intervention protocol on environmental control, patient orientation, familiarity to the environment, communication with patients and patient activities
- a consultation service to geriatric or psychiatric specialist to give advice on individualized care
- an alteration on care system from task-oriented to patient oriented
- a scheduled pain medication protocol
- music therapy according to the patients need throughout their hospitalization.

Studies with multi-components or single intervention will be included in the review and a subgroup analysis will be performed.

The comparator is the usual care that was done in the hospital. For detection of delirium in a usual care setting, detection of delirium relies on diagnosis by a psychiatrist or physician upon referral when agitation and disorientation are sensed by nurses. The consultation service can only be referred by physicians in-charge. No treatment plan or music therapy was designed. No standardized pain medication protocol was established. Pain medication regimen is different according to the preference of physicians.

**Types of outcomes**

The primary outcome for quantifying the effect of the interventions is the duration, severity and incidence of delirious older adults admitted to hospital. Diagnostic criteria according to the DSM-IV-TR will be adopted in evaluating the incidence of delirium. Severity of delirium will be measured by the Delirium index.

The secondary outcome of interest is on the cognition and functional status, mortality and the length of hospital stay of the participants. Cognitive status will be measured by using scales such as Mini-Mental State Examination (MMSE). Functional status will be measured by using tools such as and Katz Index of Independence in Activities of Daily Living (ADL) index.

**Types of studies**

This systematic review will consider all randomized controlled trials (RCTs) to determine the effect of nursing management strategies that are aimed to reduce severity, duration and incidence of delirium on hospitalized older adults. In the absence of RCTs, other experimental study designs including non-randomized controlled trials, quasi-experimental, before and after studies will also be included in the review.

**Search strategy**

The search strategy aims at identifying both published and unpublished studies in English and Chinese. A three-step search strategy will be utilized in this review. First, an initial limited search of MEDLINE and CINAHL will be undertaken. Keywords will be identified with an analysis of the text words contained in the title and abstract, and the index terms used to describe relevant articles. Secondly, all the
keywords and index terms identified will be used in a more extensive search across all the included databases to locate potential articles for inclusion in the review. As index terms may vary across databases, an initial search will be done on each database to develop individual search strategies. The search strategy for MEDLINE was developed and is shown in Appendix I as an example. Thirdly, hand searching of other sources such as relevant postgraduate and doctoral dissertations, conference proceedings and journals will be done to identify additional literature. An online search of databases and websites such as Google Scholar will also be conducted to identify studies relevant to the field of interest but not retrieved through the above search strategies. The reference lists and bibliographies of all articles retrieved will be searched for additional studies. Furthermore, relevant scales used to detect delirium; measure the severity of delirium, cognitive functioning and, activities of daily living will also be searched. For example the CAM, NEECHAM Confusion scale (NEECHAM), Nursing Delirium Screening Scale (Nu-DESC) and, Organic Brain Syndrome Scale for delirium detection. The Delirium index measures the severity of delirium. The Katz ADL index measures functional status and the MMSE measures cognitive functioning.

All articles retrieved from the above search will be assessed on the title and abstract for the relevance to the review according to the inclusion and exclusion criteria. A full report will be elicited for all articles that fulfill the criteria of the review. Full articles will be retrieved when titles and abstracts of the articles are unclear.

The databases to be searched for studies in English will include:

Academic Search Premier, British Nursing Index, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Central Register of Controlled Trials, Centre for Reviews and Dissemination, EMBASE, Global Health, Health Sciences: A SAGE, Internurse, MEDLINE, Mosby’s Nursing Consult, ProQuest Health and Medical Complete, PsycArticles, Psychology: A SAGE Full-Text Collection, PsycINFO, ScienceDirect, Scirus, Scopus, Turning Research into Practice. Databases will be searched from inception till present.

The databases to be searched for studies in Chinese will include:

Chinese Academic Journals Full-text Database (CAJ), Chinese Biomedical Literature Database (CBM), China Medical Academic Conference (CMAC), Chinese Medical Current Contents (CMCC), Hong Kong Index to Chinese Periodical (HKInChiP), HyRead, Taiwan Electronic Periodical Services (TEPS), WanFang Data.

The search for unpublished studies or grey literature will include:

The initial search terms will include:

English search terms
-older adult*, older people, aged, elderly, old age
-Hospital*, admi*
-Delir*, acute confusion
-Nursing assessment or nursing intervention or nursing care or intervention nursing
-Detect*, screen*
-Consult*, refer*, geriatrician, geriatric specialist, psychiatrist, psychi*
-Pain, medication, medicine, manage, management
-Care system, patient-allocation system
-Duration, severity, incidence, prevalence
-Cognitive status, functional status, mortality, length of hospital stay

Chinese search terms
-老人, 長者, 年長
-住院
-譫妄 or 妄語
-護理評估, 檢測, 偵查, 護理計畫, 護理措施
-老人專科, 精神科, 諮詢, 會診, 轉介
-疼痛藥物, 疼痛治療, 疼痛處理, 止痛藥, 痛症藥物, 痛症治療
-病人專責護理
-為期, 時期, 嚴重性, 發生率, 病發率
-認知能力, 活動能力, 自理能力, 死亡率, 留院時間, 住院時間

Assessment of methodological quality
Assessment of eligibility
All articles retrieved from the search will be assessed on the title and abstract independently by two reviewers for the relevance to the review according to the inclusion and exclusion criteria. The types of studies, participants, interventions and outcome measures of the articles will be assessed. A full report will be elicited for all articles that fulfilled the criteria for the review. Full articles will be retrieved when titles and abstracts for the articles are unclear. Decisions to include an article in the review will be made by two independent reviewers after appraisal of the full text of all retrieved articles. A study eligibility verification form (Appendix II) will be used to verify the study eligibility. Disagreements between
reviewers will be settled by discussion or consultation with a third reviewer. The references and abstracts identified will be managed using bibliographic software (RefWorks). After comparing the author names, settings, participants, interventions, outcomes, date and duration of the studies, all duplicated articles will be removed.

Assessment of methodological quality

All retrieved papers will be assessed on the methodological validity by two independent reviewers before including in the review. Standardized critical appraisal instruments from the Joanna Briggs Institute will be used according to the study design of the papers. Critical appraisal checklists for either experimental studies (Appendix III) or comparable cohort/case control studies (Appendix IV) will be used. The quality of a study and the extent to which the study has attempted to exclude the possibility of bias in its design, conduct and analysis will be assessed in the critical appraisal process. Disagreements between the reviewers will be settled through discussion, or with a third reviewer.

Data collection

Extraction of data from all the included studies will be done independently by two reviewers using the JBI Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) data extraction form (Appendix V). Disagreements between the reviewers will be resolved through discussion. The data will be extracted and will include specific details about the study designs, settings, populations and participant demographics, inclusion and exclusion criteria of participants, descriptions of interventions, outcome measures, results, and the number and reasons for withdrawals and dropouts. In case of missing or unclear information on the details of the studies, attempts will be made to contact the primary authors of the relevant studies for clarification if feasible.

Data synthesis

Quantitative results of comparable studies will be pooled in statistical meta-analysis using the JBI-MAStARI whenever possible. All results will be subject to double data entry to minimize data entry errors. For dichotomous data, effect size will be measured with relative risk, odds ratio and 95% confidence interval for the included studies. For continuous data, mean difference and 95% confidence intervals will be calculated if outcome measurements in all studies are of the same scale. For continuous data in studies with different scales, standardized mean difference and standard deviation will be calculated. When meta-analysis is not possible, results will be synthesized in words and presented as a narrative summary.

Evaluation will be done on each study in an effort to avoid bias. Intention-to-treat analysis will be used if the study includes or retains all randomized participants in the original designed group in the analysis.

Clinical heterogeneity of the studies will be evaluated by considering the settings, populations, interventions and outcome measures. Chi-square test and I² will be used to evaluate the extent of statistical heterogeneity between studies. I² delineates the percentage of total variation in effects estimated that is attributable to heterogeneity rather than chance. A fixed effect model will be adopted when clinical or statistical heterogeneity does not exist among studies. A random effects model will be adopted when statistical heterogeneity is present. Sensitivity analysis will be done by excluding results.
from studies with high risk of bias to determine how the results are affected. A Funnel plot and Egger's test will be used to assess potential publication bias. Subgroup analysis will be done to determine the most effective combination of interventions in reducing the duration, severity and incidence of delirium. If statistical pooling of results of the included studies is not appropriate or possible, the findings will be presented in a narrative summary.

**Conflicts of interest**

No conflict of interest.

**Acknowledgements**

We would like to thank Professor Winnie SO and Professor Janita CHAU for their continuous support and valuable advice on the development of this protocol.
References

Appendix I: Search Strategy

MEDLINE (OVID)

1 delirium.mp. or exp Delirium/
2 deliri*.mp.
3 acute delirium.mp.
4 acute confusion.mp.
5 1 or 2 or 3 or 4
6 elderly.mp. or exp Aged/
7 elder*.mp.
8 frail elderly.mp.
9 senior citizen.mp.
10 exp older adult.mp.
11 old age.mp.
12 aged person.mp.
13 geriatric.mp. or exp Geriatrics/
14 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
15 exp Hospitalization/ or hospitalization.mp.
16 inpatient.mp. or exp Inpatients/
17 15 or 16
18 exp Nursing Assessment/ or nursing assessment*.mp.
19 exp Nursing Care/ or nursing intervention*.mp.
20 assessment* nursing.mp.
21 intervention* nursing.mp.
22 18 or 19 or 10 or 21
23 exp Diagnosis/ or diagnos*.mp.
24 recogni*.mp.
25 detect*.mp.
26 screen*.mp.
27 signs.mp.
28 symptoms.mp.
(work up or workup).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
29 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31
30 assess*.mp.
31 evaluat*.mp.
32 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31
33 exp "Referral and Consultation"/ or consult*.mp.
34 referral*.mp.
(consultation* and referral*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
35 33 or 34 or 35 or 36
37 second opinion*.mp.
37 33 or 34 or 35 or 36
38 psychiatr*.mp.
39 exp Psychiatry/ or psychiatrist*.mp.
40 doctor* of psychiatry.mp.
41 exp Geriatrics/ or geriatrician*.mp.
42 gerontologic physician*.mp.
43. gerontologic*.mp.
44. gerontologist*.mp.
45. exp Geriatric Assessment/ or geriatric*.mp.
46. 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45
47. 37 and 46
48. pain management.mp. or exp Pain Management/
49. exp Pain/ or pain control.mp.
50. analgesia*.mp. or exp Analgesia/
51. managing pain.mp.
52. controlling pain.mp.
53. relieving pain.mp.
54. exp Pain, Postoperative/ or giving pain relief.mp.
55. 48 or 49 or 50 or 51 or 52 or 53 or 54
56. music therapy.mp. or exp Music Therapy/
57. therapy music.mp.
58. 56 or 57
59. patient allocation system.mp.
60. patient*.mp. or exp Patient Care/ or exp Nurse-Patient Relations/
61. allocation*.mp.
62. 59 or 60 or 61
63. duration*.mp.
64. severity.mp.
65. severities.mp.
66 63 or 64 or 65
67 exp Incidence/ or incidence*.mp.
68 exp Cognition/ or cogniti*.mp.
69 exp "Activities of Daily Living"/ or functional status.mp.
70 mortalit*.mp. or exp Mortality/
71 death rate*.mp.
72 fatality rate*.mp.
73 mortality statistic*.mp.
74 length of stay.mp. or exp "Length of Stay"/
75 los.mp.
76 74 or 75
75 70 or 71 or 72 or 73 or 76
Appendix II: Study Eligibility Verification Form

The effectiveness of nursing management on delirium in hospitalized older adults

<table>
<thead>
<tr>
<th>Record Number</th>
<th>Reviewer</th>
<th>Date</th>
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<tbody>
<tr>
<td>Article Title</td>
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Tick [ ] as appropriate.

The study must have at least one “Yes” in items 1 to 5 to be considered as eligible for inclusion.

<table>
<thead>
<tr>
<th></th>
<th>Study design</th>
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<tr>
<td></td>
<td>(a) Randomized controlled trial</td>
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<td>(b) Controlled clinical trial without randomization</td>
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<td>(c) Observational study</td>
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<td>Participants</td>
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<td></td>
<td>(a) Hospitalized adults aged 65 or above with delirium</td>
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<td>Experimental Intervention</td>
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<td></td>
<td>(a) Systematic screening on all admitted older adults for delirium</td>
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<td>(b) Intervention protocol on environmental control, patient orientation, familiarity to the environment, communication with patients and patient activities</td>
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<td>(c) Consultation service to geriatric or psychiatric specialist to give advice on individualized care</td>
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<td>(d) Patient-allocation care system</td>
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<td>(e) Scheduled pain medication protocol</td>
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<td>(f) music therapy that setting up compact disc player for individual patients and playing music intermittently according to their need through</td>
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<td>(g) any intervention that coordinated / led / delivered by nurses other than the above.</td>
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<tr>
<th></th>
<th>Control Intervention</th>
<th>Yes</th>
<th>No</th>
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<td>(a) Usual care (no specific intervention designed on detection and management.</td>
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<td>Outcome Measures</td>
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<tr>
<td>(a)</td>
<td>Duration of delirium</td>
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<td>(b)</td>
<td>Severity of delirium</td>
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<td>(c)</td>
<td>Incidence of delirium</td>
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<td>(d)</td>
<td>Cognitive status</td>
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<td>(e)</td>
<td>Functional status</td>
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<td>(f)</td>
<td>Mortality</td>
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<td>(g)</td>
<td>Length of hospital stay</td>
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<tr>
<th>6</th>
<th>Language</th>
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<tbody>
<tr>
<td>(a)</td>
<td>Written in English or Chinese</td>
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If you have not ticked at least one box in each category, please do not proceed with the rest of the MASTARI Appraisal Instrument and MASTARI Data Extraction Instrument.

The study is eligible for inclusion:  

Yes
Appendix III: JBI Critical Appraisal Checklist for Experimental Studies

**JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
<th>Not Applicable</th>
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<tbody>
<tr>
<td>1. Was the assignment to treatment groups truly random?</td>
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<td>2. Were participants blinded to treatment allocation?</td>
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<td>3. Was allocation to treatment groups concealed from the allocator?</td>
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<td>4. Were the outcomes of people who withdrew described and included in the analysis?</td>
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<td>5. Were those assessing outcomes blind to the treatment allocation?</td>
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<td>6. Were the control and treatment groups comparable at entry?</td>
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<td>7. Were groups treated identically other than for the named interventions</td>
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<td>8. Were outcomes measured in the same way for all groups?</td>
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<td>9. Were outcomes measured in a reliable way?</td>
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<td>10. Was appropriate statistical analysis used?</td>
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Overall appraisal: Include [ ] Exclude [ ] Seek further info. [ ]

Comments (Including reason for exclusion)

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________________________________________________________________________

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## Appendix IV: JBI Critical Appraisal Checklist for Comparable Cohort/ Case Control Studies

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

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

Comments (Including reason for exclusion)

____________________________________________________________

____________________________________________________________

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Appendix V: JBI Data Extraction Form for Experimental / Observational studies

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

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention ( ) number / total number</th>
<th>Intervention ( ) number / total number</th>
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</thead>
<tbody>
<tr>
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</table>

Continuous data

<table>
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<th>Outcome</th>
<th>Intervention ( ) number / total number</th>
<th>Intervention ( ) number / total number</th>
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<tbody>
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