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Sailas EES, Fenton M

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[Intervention Review]

Seclusion and restraint for people with serious mental illnesses

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ABSTRACT

Background

Seclusion and restraint are interventions used in the treatment and management of disruptive and violent behaviours in psychiatry. The use of seclusion varies widely across institutions. The literature does offer numerous suggestions for interventions to reduce or prevent aggression.

Objectives

1. To estimate the effects of seclusion and restraint compared to the alternatives for those with serious mental illnesses.
2. To estimate the effects of strategies to prevent seclusion and restraint in those with serious mental illnesses.

Search methods

Electronic searches of The Cochrane Controlled Trials Register (Issue 1, 1999) and The Cochrane Schizophrenia Group's Register (January 1999) were supplemented with additional searches of Biological Abstracts (1989-1999), CINAHL (1982-1999), EMbase (1980-1999), MEDLINE (1966-1999), MEDIC (1979-1999), PsycLIT (1974-1999), Sociofile (1974-1999), SPRI & SWEMED (1982-1999), Social Sciences Citation Index (1996-1999), and WILP (1983-1999). In addition, trials were sought by hand searching the reference lists of all identified studies and conference abstracts and contacting the first author of each relevant study.

We updated this search 10 May 2012 and added the results to the awaiting classification section of the review.

Selection criteria

Randomised controlled trials were included if they focused on the use (i) of restraint or seclusion; or (ii) of strategies designed to reduce the need for restraint or seclusion in the treatment of serious mental illness.

Data collection and analysis

Studies were reliably selected, quality rated and data extracted. For dichotomous data relative risks (RR) with 95% confidence intervals (CI) were estimated. Normal continuous data were summated using the weighted mean difference (WMD).

Main results

1. Effect of seclusion and restraint
The search strategy yielded 2155 citations. Of these, the full articles for 35 studies were obtained. No studies met minimum inclusion criteria and no data were synthesised. Most of the 24 excluded studies focused upon the restraint of elderly, confused people and preventing them from wandering or falling.

2. Prevention of seclusion and restraint
Work ongoing.

3. Update search 2012: the 2 new citations in the awaiting classification section of the review may alter the results and conclusions of the review once assessed.

Authors' conclusions

No controlled studies exist that evaluate the value of seclusion or restraint in those with serious mental illness. There are reports of serious adverse effects for these techniques in qualitative reviews. Alternative ways of dealing with unwanted or harmful behaviours need to be developed. Continuing use of seclusion or restraint must therefore be questioned from within well-designed and reported randomised trials that are generalisable to routine practice.

PLAIN LANGUAGE SUMMARY

Seclusion and restraint for people with serious mental illnesses

Synopsis pending.

BACKGROUND

Seclusion and restraint are interventions used in the treatment and management of disruptive and violent behaviours in psychiatry (APA 1985). Seclusion is the placement and retention of an inpatient in a bare room for containing a clinical situation that may result in a state of emergency. Restraint involves measures designed to confine a patient's bodily movements (Gutheil 1995). Seclusion and restraint are suggested to prevent injury and reduce agitation, but the use of seclusion and restraint can have substantial deleterious physical and more often psychological effects on both the patient and the staff (Fisher 1994). It is claimed that seclusion and restraint reduce agitation and prevent injury (Gerlock 1983).

The theoretical foundations of seclusion, much debated in the literature, are based on whether it is a valid therapeutic intervention in itself, merely a method of containment of a psychiatric emergency or a form of punishment (Mason 1993). The reviewers know of no literature discussing differences between seclusion and restraint. The effect of these interventions on the frequency of aggressive incidents is not known (Nijman 1997).

The use of seclusion varies widely across institutions from 0 to 66% (Brown 1992). In a single group of state psychiatric hospitals, all operating the same policies and procedures, considerable variation in the rates of seclusion and restraint were found (Way 1990). Hospitals with high use had a rate more than three times greater than hospitals with low usage. The rate of seclusion and restraint in the 23 hospitals ranged from 0.4 to 9.4% of patients. Only some of the differences between hospitals could be explained by patient characteristics and a large 'facility effect' was found (Way 1990). The least restrictive principle is inconsistently used, and creative alternatives to confinement are not always employed (Aschen 1995). There are only very few studies that calculate the relative risk of seclusion and restraint in different populations (Höyer 1994) and the characteristics of secluded or restraint patients also differ widely from one study to another (Swett 1994, Walsh 1995). In addition, there are reports of patients treated effectively with no use or very little use of restraint and seclusion in many psychiatric settings (Ray 1995).

In some follow-up studies, despite political changes and changes in the size and mission of hospitals, rates of seclusion and restraint have not changed (Crenshaw 1997, Salib 1998). This has been used as evidence to show that seclusion of some disturbed patients will inevitably continue to be used. Further it has been suggested that when a patient cannot co-operate and is at a risk of being dangerous to himself or others seclusion may be the safest and most dignified intervention, especially if there are concerns arising from the patient's medical or psychiatric history (Farnham 1997). Yet, few other forms of treatment which are applied to patients with various psychiatric diagnoses are so lacking in basic information about their proper use and efficacy (Angold 1989).

Violent incidents in psychiatric settings are frequent, serious, underreported and may be an increasing problem (Shah 1991). They do not happen at random and warning signs often exist. These signs may, however, be difficult to identify and interpret (Owen 1998). Three means of controlling violence are verbal de-escalation, medication and/or physical restraint (Tardiff 1992). The literature does offer numerous suggestions for aggression-reducing and preventing interventions. These include for instance suggestions for medication, staff training programs, approaches developed to de-escalate threatening situations, behavioral modifications methods and others (Chow 1996, Essock 1996, McDonnell 1996, Whittington 1996, Kalogjera 1989, Phillips 1995). Relatively little is known about the effects of these interventions on the frequency of aggressive incidents (Nijman 1997).

OBJECTIVES

1. To estimate the effects of seclusion and restraint measured against 'standard care or other alternative interventions for treating people who are violent or a serious danger to themselves or others. It was also proposed to identify any effects of the different techniques for staff.
2. To estimate the effects of strategies used to prevent the use of seclusion and restraint of mentally ill people.

METHODS

Criteria for considering studies for this review

Types of studies

1. Effects of seclusion and restraint
All relevant randomised controlled trials of seclusion and restraint.

2. Prevention of seclusion and restraint
All relevant randomised controlled trials of strategies used to reduce the need for seclusion or restraint.

Types of participants

1. Effects of seclusion and restraint
People with serious or chronic mental illness. People with dementia, or people who were likely to be suffering from dementia or cognitive impairment caused by illness other than psychotic disorders, were, where possible, excluded from this part of the review. Trials primarily focusing on restraining older people to prevent them from wandering were also excluded.

2. Prevention of seclusion and restraint
Anybody who is the focus of a strategy with the primary focus of prevention of seclusion and restraint. As such strategies may not be patient focused, the following participants are included: (i) staff; (ii) organisations; (iii) people with serious or chronic mental illness.
Interventions that aim to reduce the use of seclusion or restraint in the treatment of those whose main problems are learning difficulties, dementia, or drug and alcohol abuse were excluded.

Types of interventions

1. Effects of seclusion and restraint measured against 'standard care' or other alternative interventions
a. Seclusion: containment of the patient alone in a room or other enclosed area from which the patient has no means of freely leaving the area. This does not include the use of locked wards.
b. Restraint: restricting the patient's ability to move by using different devices designed for this purpose or holding the patient down by physical force.
c. Standard care: care delivered under current custom and practice of the unit where the interventions were being compared, not including seclusion or restraint.

2. Prevention of seclusion and restraint
a. Educational strategies;
b. behavioural strategies;

c. any alternative response to seclusion or restraint;
d. changes in policy;
e. medication;
f. administrative measures; or
g. standard care: defined as care delivered under current custom and practice of the unit where the interventions were being compared.

Types of outcome measures

Outcomes were grouped according to time periods: immediate (up to one week), short term (from one week to less than one month), medium term (1-6 months) and long term (more than six months).

Primary outcomes

Effects of seclusion and restraint
The outcome measures used in each trial were all described.

The primary outcomes of interest were:
1. Mental state
1.1 Clinically significant change as defined in individual studies
1.2 Continuous measures of mental state.

2. Behaviour
2.1 Violent or aggressive behaviour

3. Adverse effects
3.1 Physical adverse effects
3.2 Death, suicide or by other causes
3.3 Psychological adverse effects

4. Medication
4.1 Use of antipsychotic medication
4.2 Parental administration
4.3 Use of minor tranquilizers
4.4 Parental administration

5. Hospitalization
5.1 Length of hospital stay
5.2 Changes in hospital status

6. Satisfaction with care
6.1 Patient satisfaction
6.2 Carer satisfaction

7. Economic outcomes

Restraint and seclusion are primarily interventions used in response to an urgent need. Outcomes were grouped according to time periods: short term (less than one hour), medium term (1-12 hours) and long term (more than 12 hours).

Prevention of seclusion and restraint
The outcome measures used in each trial were described.

The primary outcomes of interest were:
1. Changes in levels of seclusion and restraint.

Secondary outcomes

The secondary outcomes of interest were

1. Changes in symptoms
1.1. Violent or aggressive behaviour
1.2. Psychiatric symptoms

2. Adverse effects
2.1. Physical adverse effects
2.1.1. Death, by suicide or other causes
2.2. Psychological adverse effects

3. Medication
3.1. Use of antipsychotic medication
3.1.1. Parental administration
3.2. Use of minor tranquilizers
3.2.1. Parental administration

4. Hospitalization
4.1. Length of hospital stay
4.2. Changes in hospital status

5. Satisfaction with care
5.1. Patient satisfaction
5.2. Carer satisfaction

6. Economic outcomes

Search methods for identification of studies

Electronic searches

1. Electronic searching
In a first phase relevant randomised trials were identified by searching the following two electronic databases:

1.1 The Cochrane Controlled Trials Register (Issue 1, 1999) was searched using the phrase:

COERCION or COERCIVE* or COMPULSOR* or INVOLUNTA* or RESTRAI* or SECLU* or ((IMMOBILI* or ISOLATION) and (PSYCH* or SCHIZO* or AGGRESSI* or MENTAL* or MENTAL-DISORDERS*:ME)) or COERCION*:ME or COMMITMENT-OF-MENTALLY-ILL*:ME or RESTRAINT-PHYSICAL*:ME or (PATIENT-ISOLATION*:ME not BACTERIAL-INFECTIONS-OR-MYCOSES*:ME).

1.2 Cochrane Schizophrenia Group's Register (January 1999) was searched using the phrase:

COERCION or COERCIVE* or COMPULSOR* or IMMOBILI* or INVOLUNTA* or ISOLATION or RESTRAI* or SECLU*

1.3 Biological Abstracts (January 1989 to May 1998) was searched using the Cochrane Schizophrenia Group's phrase for both randomised controlled trials and schizophrenia (see Group search strategy) combined with the phrase:

[and (COERCION or COERCIVE* or COMPULSOR* or INVOLUNTA* or RESTRAI* or SECLU* or (IMMOBILI* or ISOLATION))]

1.4 CINAHL (1982 to August 1998) was searched using the Cochrane Schizophrenia Group's phrase for both randomised controlled trials and schizophrenia (see Group search strategy) combined with the phrase:

[and (COERCI* or COMPULS* or INVOLUNTA* or RESTRAI* or SECLU* or ((CONTAIN* or LOCK* or PADDED near1 ROOM) and (PSYCH*)) or (TIME near1 OUT) or ((SOCIAL near1 CONTROL) and (FORMAL or INFORMAL)))]

1.5 EMbase (January 1980 to November 1998) was searched using the Cochrane Schizophrenia Group's phrase for both randomised

controlled trials and schizophrenia (see Group search strategy) combined with the phrase:

[and (COERCI* or COMPULS* or INVOLUNTA* or SECLU* or RESTRAI* or explode "INVOLUNTARY-COMMITMENT"/ all subheadings or ((CONTAIN* or LOCK* or PADDED) near1 ROOM) or (PATIENT near1 ISOLATION) or (PIN near1 DOWN) or (TIME near1 OUT) or ((SOCIAL near1 CONTROL) and (FORMAL or INFORMAL)) or explode "INVOLUNTARY-COMMITMENT"/ all subheadings)]

1.6 MEDLINE (January 1966 to May 1998) was searched using the Cochrane Schizophrenia Group's phrase for both randomised controlled trials and schizophrenia (see Group search strategy) combined with the phrase:

[and (COERCI* or COMPULSOR* or (INVOLUNTA* not MOVEMENT) or SECLU* or (RESTRAI* not ANIMAL) or explode COERCION(MeSH)/all subheadings or explode COMMITMENT-OF-MENTALLY-ILL(MeSH)/ all subheadings or (explode RESTRAINT-PHYSICAL(MeSH)/ all subheadings and HUMAN(MeSH)) or explode PATIENT-ISOLATION(MeSH)/all subheadings or ((CONTAIN* or LOCK* or PADDED) near1 ROOM) or ((SOCIAL near1 CONTROL) and (FORMAL or INFORMAL)) or ((PATIENT near1 ISOLATION) and (MENTAL or PSYCH* or AGGRESSI* or SCHIZO*)))]

1.7 MEDIC, a Finnish medical database (1979 to May 1998) was searched with the phrase:

(CLINICAL TRIALS or RANDOMIS or KONTROLLOI or SATUNNAISTET or VERTAIL or HOITOKO) and (ERIST or PAKKO or LEPOSI or COERCION or COMMITMENT or ISOLATION or RESTRAINT)

1.8 PsycLIT (January 1974 to December 1997) was searched using the Cochrane Schizophrenia Group's phrase for both randomised controlled trials and schizophrenia (see Group search strategy) combined with the phrase:

[and (SECLU* or "PATIENT-SECLUSION" or (RESTRAI* not DIET) or "PHYSICAL-RESTRAINT" or COERCI* or COMPULSOR* or (INVOLUNTA* not MOVEMENT) or "INVOLUNTARY-TREATMENT" or IMMOBILI* or (PATIENT* near1 SECLU*) or "COMMITMENT OF MENTALLY ILL" or PATIENT-ISOLATION)]

1.9 Sociofile (1974 to December 1997) was searched using the Cochrane Schizophrenia Group's phrase for both randomised controlled trials and schizophrenia (see Group search strategy) combined with the phrase:

[and (SECLU* or RESTRAI* or COERCI* or COMPULSO* or INVOLUNTA* or IMMOBILI*or(PATIENT* and ISOLAT*))]

1.10 SPRI (a Swedish database for health technology assessment and
research and development) and SWEMED (a medical database covering Sweden and Norway) (1982 to May 1998).

(CLINICAL TRIALS(MeSH) or RANDOMIS or KONTROLLGRUPP or KONTROLLERAD or BEHANDLINGSSTUDIE) and (TVÅNG or TVANG or RUMSRESTRIKTION or FRIHETSBERÖVANDE or *BÄLTE* or ISOLERING* or COERCION or COMMITMENT or ISOLATION or RESTRAINT)

1.11 Social Sciences Citation Index (SSCI) (January 1996 to July 1998) was searched using the phrase:

(RANDOMI* or ((SINGL* or DOUBL* or TREBL* or TRIPL*) and (BLIND* or MASK*)) or CROSSOVER or TRIAL) and (SECLU* or RESTRAI* or COERCIVE* or COERCION* or COMPULSOR* or INVOLUNTA* or IMMOBILI* or PATIENT-ISOLATION)

1.12 WILP (Wilson Index to Legal Periodicals) (1983 to May 1998) was searched with the phrase:

COERCIVE* or COERCION or COMPULSOR* or INVOLUNTA* or RESTRAI* or SECLU* or (IMMOBILI* and (PSYCH* or SCHIZO* or AGGRESSI* or MENTAL*)) or (PATIENT and ISOLATION)

Prevention of seclusion and restraint

2. Electronic searching
In a first phase relevant randomised trials were identified by searching the following two electronic databases:

2.1 THE COCHRANE LIBRARY CENTRAL Issue 4, 1999, was searched using the phrase:

[explode ("Aggression"/ all subheadings) or (explode "Violence"/ all subheadings) or ("Dangerous-Behavior") or violen* or aggressi* or attack* or assault* or agita* or ((danger* or bizarre) near (behav* or action* or conduct*))]

2.2 COCHRANE SCHIZOPHRENIA GROUP'S REGISTER (October 1999) was searched using the phrase:

[violen* or aggressi* or attack* or assault* or agita* or ((danger* or bizarre) and (behav* or action* or conduct*))]

Conference abstracts were sought from within the Cochrane Schizophrenia Groups Register. After the trials were selected and the review was ongoing, other databases were investigated:

2.3 BIOLOGICAL ABSTRACTS/RRM (January 1989 to August 1999) was searched using the both phrases used to identify randomised controlled trials and articles relating to schizophrenia as published in the Cochrane Schizophrenia Group's search strategy combined with the phrase:

AND [violen* or aggressi* or attack* or assault* or agita* or ((danger* or bizarre) near (behav* or action* or conduct*))]

2.4 CINAHL (1982 to August 1999) was searched using the both phrases used to identify randomised controlled trials and articles relating to schizophrenia as published in the Cochrane Schizophrenia Group's search strategy combined with the phrase:

AND [(explode "Aggression"/ all topical subheadings/ all age subheadings) or violen* or aggressi* or attack* or assault* or agita* or ((danger* or bizarre) near (behav* or action* or conduct*))]

2.5 EMBASE (January 1980 to August 1999) was searched using the both phrases used to identify randomised controlled trials and articles relating to schizophrenia as published in the Cochrane Schizophrenia Group's search strategy combined with the phrase:

AND [(explode "Aggression"/ all subheadings) or (explode "Violence"/ all subheadings) or violen* or aggressi* or attack* or assault* or agita* or ((danger* or bizarre) near (behav* or action* or conduct*))]

2.6 MEDLINE (January 1966 to May 1999) was searched using the both phrases used to identify randomised controlled trials and articles relating to schizophrenia as published in the Cochrane Schizophrenia Group's search strategy combined with the phrase:

AND [(explode "Aggression"/ all subheadings) or (explode "Violence"/ all subheadings) or ("Dangerous-Behavior") or violen* or aggressi* or attack* or assault* or agita* or ((danger* or bizarre) near (behav* or action* or conduct*))]

2.7 PSYCLIT (January 1974 to May 1999) was searched using the both phrases used to identify randomised controlled trials and articles relating to schizophrenia as published in the Cochrane Schizophrenia Group's search strategy combined with the phrase:

AND [(explode "Aggression") or (explode "Violence") or ("Dangerousness-in DE") or violen* or aggressi* or attack* or assault* or agita* or ((danger* or bizarre) near (behav* or action* or conduct*))]

2.8 SOCIOFILE (1974 to May 1999) was searched using the phrase used to identify articles relating to schizophrenia as published in the Cochrane Schizophrenia Group's search strategy combined with the phrase:

(RANDOMI* or ((SINGL* or DOUBL* or TREBL* or TRIPL*) and (BLIND* or MASK*)) or CROSSOVER or TRIAL) and (AGGRESSI* or VIOLEN* or AGITA* or ((DANGER* or BIZARRE*) and BEHAV*)

2.9 Social Sciences Citation Index (SSCI) (Jan 1996 to Jul 1999) was searched using the phrase used to identify articles relating to schizophrenia as published in the Cochrane Schizophrenia Group's search strategy combined with the phrase:

(RANDOMI* or ((SINGL* or DOUBL* or TREBL* or TRIPL*) and (BLIND* or MASK*)) or CROSSOVER or TRIAL) and (AGGRESSI* or VIOLEN* or AGITA* or ((DANGER* or BIZARRE*) and BEHAV*)

3. Cochrane Schizophrenia Group’s Trials Register (May 2012)

We updated this search 10 May 2012. The Trials Search Co-ordinator searched the Cochrane Schizophrenia Group’s Trials Register.

The Cochrane Schizophrenia Group’s Trials Register is compiled by systematic searches of major databases, handsearches and conference proceedings (see group module).

Trials identified through the searching activities are each assigned to awaiting classification of relevant review titles.

Searching other resources

1. Reference searching
The references of all identified studies were also inspected for more trials. Science Citation Index (SCI) and Social Sciences Citation Index (SSCI) (1974 to May 1999) was used to trace papers that had cited included trials. These reports were inspected in order to identify further trials. SciSearch and Social SciSearch (1974 to May 1998) were to be used to trace papers that had cited included trials. These reports were to be inspected in order to identify further trials.

2. Personal contact
The first author of each included study was contacted for information regarding unpublished trials.

Data collection and analysis

[For definitions of terms used in this, and other sections, please refer to The Cochrane Library Glossary.]

1. Selection of trials for the review
The title and abstract of each reference identified by the search was inspected independently by both reviewers to assess its relevance. Where disagreement between the two reviewers occurred, the full article was obtained. Relevance was again assessed independently by both reviewers. Again, where disagreement occurred this was resolved by discussion and when this was not possible, further information was sought. These trials were added to the list of those awaiting assessment pending acquisition of further information.

2. Assessment of the methodological quality of the included trials.
The criteria included in the Cochrane Collaboration Handbook (Mulrow 1999) was used to assess the quality of the trials. It is based on the evidence of a strong relationship between the potential for bias in results and the concealment of allocation and is defined as below:
A. Low risk of bias (adequate allocation concealment);
B. Moderate risk of bias (some doubt about the results);
C. High risk of bias (inadequate allocation concealment).
Trials were included if they met the criteria A or B on this quality criteria.
The Jadad Scale (Jadad 1996) was used to give a second quality rating to the relevant trials.

3. Data collection
Data from selected trials were independently extracted by both reviewers. When disputes arose, resolution was attempted by discussion. When this was not possible and further information was necessary to resolve the disagreement, the decisions documented and where necessary, the authors of the studies were contacted for clarification. Justification for excluding references from the review was documented.

4. Data synthesis
4.1 Incomplete data.
With the exception of the outcome of leaving the study early, trial outcomes were not included if more than 40% of people were not reported in the final analysis.

4.2 Dichotomous - yes/no - data.
As long as over 60% of people completed the study, everyone allocated to the intervention was counted, whether they completed the follow up or not. It was assumed that those who dropped out had the negative outcome, with the exception of death.

Relative risk (RR) and 95% confidence interval (CI) were calculated. If outcomes were heterogeneous calculations were based on the random effects model, as it takes into account any differences between studies. If outcomes were homogeneous, a fixed effects model was applied. Data were inspected to see if analysis using a Mantel Haenszel odds ratio made any substantive difference. Where possible, number needed to treat (NNT) was estimated from the weighted pooled relative risk estimate.

4.3 Continuous data.
4.3.1 Rating scales: A wide range of instruments are available to measure mental health outcomes. These instruments vary in quality and many are not valid, or even ad hoc. For outcome instruments minimum standards were set. They were that the

psychometric properties of the instrument should have been described in a peer-reviewed journal.
4.3.2 Normal data: Mental health continuous data is often not 'normally' distributed. To avoid the pitfall of applying parametric tests to non-parametric data the following standards were applied to all data before inclusion:
i. standard deviations and means were reported in the paper or were obtainable from the authors;
ii. if the data were scale-derived, or finite measures from, for example 0-100, the standard deviation was multiplied by two. If the result was less than the mean (as otherwise the mean was unlikely to be an appropriate measure of the centre of the distribution (Altman 1996) data were included in meta-analysis and presented in graphical form.
Data not meeting these standards were reported in the 'Other data types' of the 'Results' section if they had been analysed with appropriate non-parametric tests.

5. Heterogeneity
Heterogeneity in the results of the trials was assessed both by inspection of graphical presentations and by calculating a chi-square test of heterogeneity. If heterogeneity was present any underlying explanation was sought.
The reviewers undertook a sensitivity analysis to the presence or absence of these data. All data from studies that have been selected were presented.

6. Addressing publication bias
Data from all identified and selected trials were entered into a funnel graph (trial effect versus trial size) in an attempt to investigate the likelihood of overt publication bias.

7. Tables and figures
Where possible data were entered into RevMan in such a way that the area to the left of the line of no effect indicates a favourable outcome for the intervention of interest.

RESULTS

Description of studies

1. Effects of seclusion and restraint

Excluded studies
All 24 identified studies were excluded. For the full description of why these studies were not included, please see the Excluded studies table. Most did not meet minimum inclusion criteria for their methods, participants or interventions of interest. Most focused upon the restraint of elderly and confused people and on preventing wandering or falling.

Ten studies focused on restraining elderly people with either organic problems or physical ill health. Another was a preliminary report of a trial of room design to aid confused, physically ill people and a further two, investigating the value of restraining elderly confused people, did not use a control.

Four trials did not focus on interventions of interest - either adequate medication or psychosocial environments. A single randomised experiment focused on staff attitudes to using electric shocks of people before and after watching a video of a violent person and another investigated the value of different restraint techniques on healthy volunteers. One randomised trial of a single person investigated the value of different protective clothing on a 13-year-old adolescent with profound learning difficulties, and finally, four were surveys.

2. Prevention of seclusion and restraint
Work underway.

3. Studies awaiting classification
There are 2 studies awaiting classification (Bergk 2011; ISRCTN49454276).

Risk of bias in included studies

1. Effects of seclusion and restraint
No trials were able to be included.

2. Prevention of seclusion and restraint
Work underway.

Effects of interventions

1. Effects of seclusion and restraint

Search
The search strategy yielded 2155 citations. The Cochrane Controlled Trials Register yielded 1018 citations, the Cochrane Schizophrenia Group's Register 126, Biological Abstracts 207, CINAHL 48, EMbase 360, MEDIC zero, MEDLINE 123, PsycLIT 215, Sociofile 27, SPRI & SWEMED one, SSCI 70 and WILP zero. Of these, the full articles for 35 studies were obtained. These same articles came up in several databases (The Cochrane Library CENTRAL, MEDLINE, CINAHL and PsycLIT). From these citations, 18 studies for potential inclusion were identified. No relevant additional studies were found by searching the references of excluded studies.

Lack of data
No studies using restraint or seclusion as an intervention measure in the treatment of psychiatric emergencies were found, but four studies had seclusion or restraint as an outcome. Not one paper fulfilled the pre-stated criteria of the reviewers. As has been discussed above, most studies focused on restraining elderly people with psycho-organic problems or physical ill health in order to prevent them from falling or wandering. There is a surprising and shocking lack of published trials assessing the effects of secluding or restraining people with schizophrenia or similar psychotic illnesses.

2. Prevention of seclusion and restraint
Work underway.

DISCUSSION

The reviewers acknowledge the very great difficulty of carrying out controlled trials in people with challenging behaviours. Nevertheless, the complete lack of trial-derived evidence regarding the effects of seclusion and restraint is surprising given the invasiveness of the intervention and its continued use over time. This dearth may highlight a belief that they are such effective, satisfactory interventions that there is not the need for evaluation in randomised trials. Counter to this is that certain researchers, not satisfied with the effects or nature of seclusion and restraint, have attempted to find creative alternatives (Nijman 1997).

Randomising different techniques of seclusion and restraint, or comparing the former to alternatives, may be thought to be controversial. Conversely, continuing to use a poorly investigated

set of 'invasive' treatments on very significant numbers of people (Way 1990) may seem equally questionable.

Three studies were found that reported an improvement in control of aggression with adequate medication (Chow 1996, Essock 1996, Sommerness 1957). Another trial used a psychosocial programme to reduce the number of episodes of seclusion (Gudeman 1981). These trials are not included in the review of effects of seclusion and restraint as they were not the primary interventions of interest. These will be included in the amended review, including also interventions aimed at reducing need for seclusion and restraint in those with serious mental illness.

AUTHORS' CONCLUSIONS

Implications for practice

In the absence of any controlled trials in those with serious mental illness, no recommendation can be made about the effectiveness, benefit or harmfulness of seclusion or restraint. In view of data from non-randomised studies, use should be minimised for ethical reasons. The use of seclusion or restraint should only be continued in the context of simple, pragmatic randomised trials given the marked variation between institutions and reports of harm in qualitative reviews.

No controlled studies to support the continued use of seclusion or restraint in clinical practice were found. As there are reports of serious adverse effects reported in qualitative reviews (Fisher 1994), randomised controlled trials are needed to test the benefits and harms of seclusion and restraint. Attempts must be made to find alternative methods of dealing with unwanted behaviours.

For those with serious mental illness and their relatives
No evidence exists to support or refute the use of these interventions. Although seclusion and restraint techniques are undoubtedly unpleasant, as strategies for preventing assault to others or harm to oneself, these containing treatments may still be both practical and safe. On the other hand, the use of seclusion and restraint could lead to greater morbidity and mortality than alternative drug or non-drug approaches. Those with serious mental illness and their relatives could well pre-specify which technique they would find preferable should their mental state or behaviour seriously deteriorate.

For practitioners
In the absence of any relevant controlled trials, no trial-based recommendations can be made about the effects of seclusion or restraint. In view of data from non-randomised studies, use should be minimised for ethical reasons (Fisher 1994). It is arguable that, except for extreme circumstances, the use of seclusion or restraint should only be continued in the context of simple, pragmatic randomised trials.

Implications for research

Seclusion and restraint are used in the hope of preventing injury and reducing agitation, but qualitative studies have reported substantial deleterious physical, and, more often, psychological effects on both patients and staff (Fisher 1994). Randomised studies are urgently needed. These could compare seclusion and restraint and other interventions such as adequate medication, alternative environments, psychosocial interventions or staff education. Randomised trials should be well planned, executed and reported. Randomising people recognisable in routine practice to generalisable interventions, and measuring simple, clinically relevant outcomes would greatly increase the value of these trials.

ACKNOWLEDGEMENTS

The reviewers would like to thank Kristian Wahlbeck for his editorial comments.

REFERENCES

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Alessi 1995	Alllocation: randomised. Participants: elderly (mean age 85 years), mainly problems of urinary incontinence or physically restrained to prevent wandering or falls. Interventions: physical exercise every two hours versus once a day.
Buckley 1997	Allocation: not randomised. Intervention: risperidone.
Clark 1995	Allocation: randomised. Participants: >65 yrs, confused, diagnosis of acute physical illness. Interventions: Dayroom care versus usual care.
Cole 1994	Allocation: randomised. Participants: aged over 75 with delirium (DSM III). Interventions: consultation with geriatric internist and follow up by liaison nurse versus standard medical care.
Collard 1985	Allocation: randomised. Participants: mean age >77 years, primarily with physical illness. Interventions: care in geriatric intensive care unit versus traditional ward.
Evans 1997	Allocation: randomised elderly care homes. Participants: Age over 80, cognitively impaired. Interventions: restraint education versus restraint education and consultation versus no education or consultation.
Foxx 1996	Allocation: randomised. Participants: staff associated with programs serving persons with developmental disabilities. Intervention: video of a violent person versus no video.
Frank 1996	Allocation: not randomised, review article.
Gaebler 1994	Allocation: not randomised, survey of incidence of restraint in the elderly.
Glazer 1998	Allocation: not randomised, survey of aggressive incidents in trials of clozapine.
Janelli 1997	Allocation: not randomised, case control. Participants: elderly people restrained to prevent falls or wandering Intervention: music through headphones versus no music.
Lewis 1996	Allocation: randomised. Participants: people with severe and profound mental retardation. Interventions: clomipramine versus placebo.
Moretz 1995	Allocation: unclear, preliminary report. Participants: over 70 years old, mentally impaired. Intervention: restraint free room, no obvious control.
Nijman 1997	Allocation: not randomised. Participants: those admitted to a locked unit.

Study	Reason for exclusion
	Interventions: protocol for talking to participants who were displaying aggressive behaviour, discussing treatment goals, explaining why the ward door was locked, providing a shedule of staff mettings, and clarifying the procedure for making an appointment with the psychiatrist. This was the one of the few studies that made a comprehensive attempt to try and find alternative psychosocial treatments to seclusion or restraint.
Phillips 1995	Allocation: randomised. Participants: self-selected male mental health staff. Interventions: didactic training of staff versus didactic training and physical skills versus no training.
Roeggla 1997	Allocation: randomised, cross-over trial. Participants: healthy male volunteers. Interventions: prone versus upright hobble restraint.
Rovner 1996	Allocation: randomised. Participants: mean age > 81 years, dementia. Interventions: a dementia care program versus usual care.
Schnelle 1992	Allocation: randomised. Participants: mean age 84 years, severely impaired physically and cognitively. Interventions: coloured pads used to indicate the patient had been released from restraint every two hours versus no pads.
Schnelle 1996	Allocation: randomised. Participants: mean age 84 years, participants needed to know their own name or be able to name one of two objects (pen or comb) to be included. Intervention: walking or whell-chair movement and rowing exercise versus usual care.
Silverman 1984	Allocation: randomised, crossover, N of 1. Participants: one 13 year old profoudly retarded person. Interventions: padded helmet versus padded helmet and padded slippers versus no protective clothing.
Stoudemire 1996	Allocation: not randomised, review.
Thapa 1996	Allocation: not randomised, prevalence survey of injurious falls, prospective cohort study.
Thomas 1992	Allocation: randomised. Participants: violent patients, admitted to emergency department, physically ill mostly with trauma. Interventions: IM haloperidol or droperidol versus IV haloperidol or droperidol.
Tutunjian 1963	Allocation: not randomised, case series. Participants: psychotic female patients. Intervention: peperacetazine, no control.
Weinrich 1995	Allocation: not randomised, review of managing agitation.

Characteristics of studies awaiting assessment *[ordered by study ID]*

Bergk 2011

Methods

Bergk 2011 *(Continued)*

Participants	
Interventions	
Outcomes	
Notes	To be assessed.

ISRCTN49454276

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

APPENDICES

Appendix 1. Previous searches

1. Electronic searching
In a first phase relevant randomised trials were identified by searching the following two electronic databases:

1.1 The Cochrane Controlled Trials Register (Issue 1, 1999) was searched using the phrase:

COERCION or COERCIVE* or COMPULSOR* or INVOLUNTA* or RESTRAI* or SECLU* or ((IMMOBILI* or ISOLATION) and (PSYCH* or SCHIZO* or AGGRESSI* or MENTAL* or MENTAL-DISORDERS*:ME)) or COERCION*:ME or COMMITMENT-OF-MENTALLY-ILL*:ME or RESTRAINT-PHYSICAL*:ME or (PATIENT-ISOLATION*:ME not BACTERIAL-INFECTIONS-OR-MYCOSES*:ME).

1.2 Cochrane Schizophrenia Group's Register (January 1999) was searched using the phrase:

COERCION or COERCIVE* or COMPULSOR* or IMMOBILI* or INVOLUNTA* or ISOLATION or RESTRAI* or SECLU*

1.3 Biological Abstracts (January 1989 to May 1998) was searched using the Cochrane Schizophrenia Group's phrase for both randomised controlled trials and schizophrenia (see Group search strategy) combined with the phrase:

[and (COERCION or COERCIVE* or COMPULSOR* or INVOLUNTA* or RESTRAI* or SECLU* or (IMMOBILI* or ISOLATION))]

1.4 CINAHL (1982 to August 1998) was searched using the Cochrane Schizophrenia Group's phrase for both randomised controlled trials and schizophrenia (see Group search strategy) combined with the phrase:

[and (COERCI* or COMPULS* or INVOLUNTA* or RESTRAI* or SECLU* or ((CONTAIN* or LOCK* or PADDED near1 ROOM) and (PSYCH*)) or (TIME near1 OUT) or ((SOCIAL near1 CONTROL) and (FORMAL or INFORMAL)))]

1.5 EMbase (January 1980 to November 1998) was searched using the Cochrane Schizophrenia Group's phrase for both randomised controlled trials and schizophrenia (see Group search strategy) combined with the phrase:

[and (COERCI* or COMPULS* or INVOLUNTA* or SECLU* or RESTRAI* or explode "INVOLUNTARY-COMMITMENT"/ all subheadings or ((CONTAIN* or LOCK* or PADDED) near1 ROOM) or (PATIENT near1 ISOLATION) or (PIN near1 DOWN) or (TIME near1 OUT) or ((SOCIAL near1 CONTROL) and (FORMAL or INFORMAL)) or explode "INVOLUNTARY-COMMITMENT"/ all subheadings)]

1.6 MEDLINE (January 1966 to May 1998) was searched using the Cochrane Schizophrenia Group's phrase for both randomised controlled trials and schizophrenia (see Group search strategy) combined with the phrase:

[and (COERCI* or COMPULSOR* or (INVOLUNTA* not MOVEMENT) or SECLU* or (RESTRAI* not ANIMAL) or explode COERCION(MeSH)/all subheadings or explode COMMITMENT-OF-MENTALLY-ILL(MeSH)/all subheadings or (explode RESTRAINT-PHYSICAL(MeSH)/all subheadings and HUMAN(MeSH)) or explode PATIENT-ISOLATION(MeSH)/all subheadings or ((CONTAIN* or LOCK* or PADDED) near1 ROOM) or ((SOCIAL near1 CONTROL) and (FORMAL or INFORMAL)) or ((PATIENT near1 ISOLATION) and (MENTAL or PSYCH* or AGGRESSI* or SCHIZO*)))]

1.7 MEDIC, a Finnish medical database (1979 to May 1998) was searched with the phrase:

(CLINICAL TRIALS or RANDOMIS or KONTROLLOI or SATUNNAISTET or VERTAIL or HOITOKO) and (ERIST or PAKKO or LEPOSI or COERCION or COMMITMENT or ISOLATION or RESTRAINT)

1.8 PsycLIT (January 1974 to December 1997) was searched using the Cochrane Schizophrenia Group's phrase for both randomised controlled trials and schizophrenia (see Group search strategy) combined with the phrase:

[and (SECLU* or "PATIENT-SECLUSION" or (RESTRAI* not DIET) or "PHYSICAL-RESTRAINT" or COERCI* or COMPULSOR* or (INVOLUNTA* not MOVEMENT) or "INVOLUNTARY-TREATMENT" or IMMOBILI* or (PATIENT* near1 SECLU*) or "COMMITMENT OF MENTALLY ILL" or PATIENT-ISOLATION)]

1.9 Sociofile (1974 to December 1997) was searched using the Cochrane Schizophrenia Group's phrase for both randomised controlled trials and schizophrenia (see Group search strategy) combined with the phrase:

[and (SECLU* or RESTRAI* or COERCI* or COMPULSO* or INVOLUNTA* or IMMOBILI*or(PATIENT* and ISOLAT*))]

1.10 SPRI (a Swedish database for health technology assessment and
research and development) and SWEMED (a medical database covering Sweden and Norway) (1982 to May 1998).

(CLINICAL TRIALS(MeSH) or RANDOMIS or KONTROLLGRUPP or KONTROLLERAD or BEHANDLINGSSTUDIE) and (TVÅNG or TVANG or RUMSRESTRIKTION or FRIHETSBERÖVANDE or *BÄLTE* or ISOLERING* or COERCION or COMMITMENT or ISOLATION or RESTRAINT)

1.11 Social Sciences Citation Index (SSCI) (January 1996 to July 1998) was searched using the phrase:

(RANDOMI* or ((SINGL* or DOUBL* or TREBL* or TRIPL*) and (BLIND* or MASK*)) or CROSSOVER or TRIAL) and (SECLU* or RESTRAI* or COERCIVE* or COERCION* or COMPULSOR* or INVOLUNTA* or IMMOBILI* or PATIENT-ISOLATION)

1.12 WILP (Wilson Index to Legal Periodicals) (1983 to May 1998) was searched with the phrase:

COERCIVE* or COERCION or COMPULSOR* or INVOLUNTA* or RESTRAI* or SECLU* or (IMMOBILI* and (PSYCH* or SCHIZO* or AGGRESSI* or MENTAL*)) or (PATIENT and ISOLATION)

Prevention of seclusion and restraint

2. Electronic searching
In a first phase relevant randomised trials were identified by searching the following two electronic databases:

2.1 THE COCHRANE LIBRARY CENTRAL Issue 4, 1999, was searched using the phrase:

[explode ("Aggression"/ all subheadings) or (explode "Violence"/ all subheadings) or ("Dangerous-Behavior") or violen* or aggressi* or attack* or assault* or agita* or ((danger* or bizarre) near (behav* or action* or conduct*))]

2.2 COCHRANE SCHIZOPHRENIA GROUP'S REGISTER (October 1999) was searched using the phrase:

[violen* or aggressi* or attack* or assault* or agita* or ((danger* or bizarre) and (behav* or action* or conduct*))]

Conference abstracts were sought from within the Cochrane Schizophrenia Groups Register. After the trials were selected and the review was ongoing, other databases were investigated:

2.3 BIOLOGICAL ABSTRACTS/RRM (January 1989 to August 1999) was searched using the both phrases used to identify randomised controlled trials and articles relating to schizophrenia as published in the Cochrane Schizophrenia Group's search strategy combined with the phrase:

AND [violen* or aggressi* or attack* or assault* or agita* or ((danger* or bizarre) near (behav* or action* or conduct*))]

2.4 CINAHL (1982 to August 1999) was searched using the both phrases used to identify randomised controlled trials and articles relating to schizophrenia as published in the Cochrane Schizophrenia Group's search strategy combined with the phrase:

AND [(explode "Aggression"/ all topical subheadings/ all age subheadings) or violen* or aggressi* or attack* or assault* or agita* or ((danger* or bizarre) near (behav* or action* or conduct*))]

2.5 EMBASE (January 1980 to August 1999) was searched using the both phrases used to identify randomised controlled trials and articles relating to schizophrenia as published in the Cochrane Schizophrenia Group's search strategy combined with the phrase:

AND [(explode "Aggression"/ all subheadings) or (explode "Violence"/ all subheadings) or violen* or aggressi* or attack* or assault* or agita* or ((danger* or bizarre) near (behav* or action* or conduct*))]

2.6 MEDLINE (January 1966 to May 1999) was searched using the both phrases used to identify randomised controlled trials and articles relating to schizophrenia as published in the Cochrane Schizophrenia Group's search strategy combined with the phrase:

AND [(explode "Aggression"/ all subheadings) or (explode "Violence"/ all subheadings) or ("Dangerous-Behavior") or violen* or aggressi* or attack* or assault* or agita* or ((danger* or bizarre) near (behav* or action* or conduct*))]

2.7 PSYCLIT (January 1974 to May 1999) was searched using the both phrases used to identify randomised controlled trials and articles relating to schizophrenia as published in the Cochrane Schizophrenia Group's search strategy combined with the phrase:

AND [(explode "Aggression") or (explode "Violence") or ("Dangerousness-in DE") or violen* or aggressi* or attack* or assault* or agita* or ((danger* or bizarre) near (behav* or action* or conduct*))]

2.8 SOCIOFILE (1974 to May 1999) was searched using the phrase used to identify articles relating to schizophrenia as published in the Cochrane Schizophrenia Group's search strategy combined with the phrase:

(RANDOMI* or ((SINGL* or DOUBL* or TREBL* or TRIPL*) and (BLIND* or MASK*)) or CROSSOVER or TRIAL) and (AGGRESSI* or VIOLEN* or AGITA* or ((DANGER* or BIZARRE*) and BEHAV*)

2.9 Social Sciences Citation Index (SSCI) (Jan 1996 to Jul 1999) was searched using the phrase used to identify articles relating to schizophrenia as published in the Cochrane Schizophrenia Group's search strategy combined with the phrase:

(RANDOMI* or ((SINGL* or DOUBL* or TREBL* or TRIPL*) and (BLIND* or MASK*)) or CROSSOVER or TRIAL) and (AGGRESSI* or VIOLEN* or AGITA* or ((DANGER* or BIZARRE*) and BEHAV*)

WHAT'S NEW

Date	Event	Description
10 May 2012	Amended	Update search of Cochrane Schizophrenia Group's Trial Register (see Search methods for identification of studies), 2 studies (Bergk 2011; ISRCTN49454276) added to awaiting classifciation.

HISTORY

Protocol first published: Issue 3, 1998
Review first published: Issue 2, 1999

Date	Event	Description
31 October 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Eila Sailas - initiated the review, prepared protocol, undertook searches, selected and acquired studies, produced report.

Mark Fenton - prepared protocol, undertook searches, selected and acquired studies, produced report.

DECLARATIONS OF INTEREST

The reviewers believe that seclusion and restraint can be used to excess and that the least restrictive principle is often not sought.

SOURCES OF SUPPORT

Internal sources

- Department of Psychiatry, University of Helsinki, Finland.
- Cochrane Schizophrneia Group, UK.

External sources

- Wilhelm and Else Stockmann Foundation, Finland.
- STAKES/FinOHTA, Finland.

NOTES

Cochrane Schizophrenia Group internal peer review complete (see Module).
External peer review scheduled.

INDEX TERMS

Medical Subject Headings (MeSH)

*Patient Isolation; *Restraint, Physical; Antipsychotic Agents [therapeutic use]; Mental Disorders [drug therapy] [*therapy]

MeSH check words

Humans