Scoping Review of the literature

Consensus Conference of RECAGE Project (GA No: 779237)

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Elena Berti , MD, PhD
Emilia-Romagna Region, Italy

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Research questions

1.A What kinds of SCU-B are there? With special regard for the "acute" SCU-Bs: what about architectural features, staff compositions, activities, criteria for admission?

1.B What are the main issues related to the SCU-B (informed consent, restraints, "benevolent" coercion …)

Description and technical characteristics of SCU-B (including description of target population, architectural, organizational, legal aspects)

2. What is the evidence of clinical effectiveness of the "acute" SCU-B vs usual care? Effectiveness of SCU-B

3. What is the evidence of cost-effectiveness of the "acute" SCU-B vs usual care? Costs and economic evaluation of SCU-B

4. What are the safety issues of physical restraints and neuroleptic treatments? Safety of SCU-B

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Scoping review: research question 1.a + 2 +3

Special medical Care Unit (SCU-B) for persons with dementia and behavioural disorders: a scoping review of the quantitative and qualitative evidence

Valentina Pecoraro, Silvia Minozzi, Maria Camerlingo, Elena Berti, Andrea Fabbo, Luca Vignatelli, Francesco Nonino, Ron Handels, Sara Fascendini, Carlo Alberto Defanti.

Scoping review purpose: to map the body of literature on a topic area, to include a greater range of study designs and methodologies then SR and to provide a descriptive overview of the reviewed material without critically appraising individual studies or synthesizing evidence from different studies

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SCU-B - definition

Residential medical structure lying outside of a nursing home, in a general hospital or elsewhere, where patients with Behavioral and Psychological Symptoms of Dementia(BPSD) are temporarily admitted when their behavioral disturbances are not amenable to control at home.

The mission of the SCU-B is to improve patient's behavior and its goal is to permit, when possible, her/his coming back home

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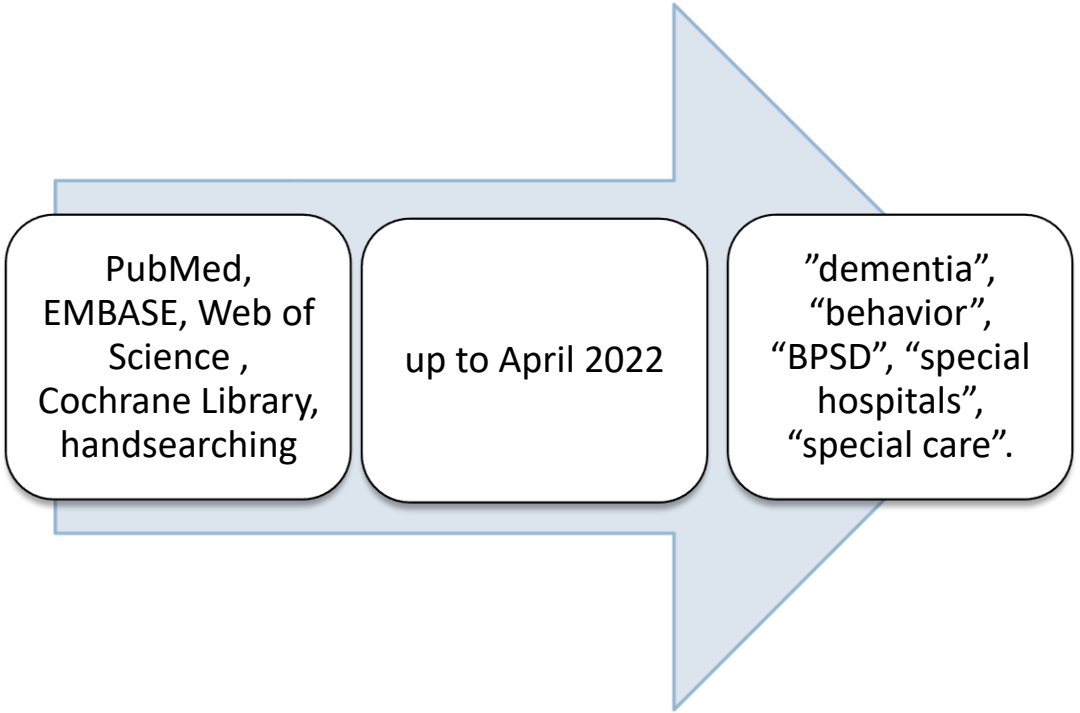
Search Strategy



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Inclusion criteria

P: adults (≥ 18 years) subjects with dementia and Behavioral and Psychological Symptoms of Dementia (BPSD)
I: SCU-B:
C: if available: usual care, admission in memory clinic, psychiatric unit, neurologic unit, general medicine department, ambulatory management
O: characteristics of SCU-B, quantitative or qualitative data about the effectiveness or health-economic outcomes of admission to a SCU-B.
S: randomised controlled trials (RCTs), prospective and retrospective cohort studies, cross sectional studies, uncontrolled case series, descriptive studies or health-economic evaluation studies

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Methods

Three authors independently screened title and abstracts retrieved via the search. Potentially relevant studies acquired in full text and assessed for final inclusion independently by two authors. Any disagreement discussed with a third author who acted as arbitrator. Two review authors independently extracted data. Two authors independently rated the **methodological quality** of the effectiveness studies and one author of the health-economic evaluation studies

RCTs: criteria developed by Cochrane

Prospective and retrospective cohort studies, cross sectional studies: Newcastle Ottawa Scale (NOS)

Case series: tool developed by the Institute of Health Economics

Health-economic evaluation : CHEC criteria

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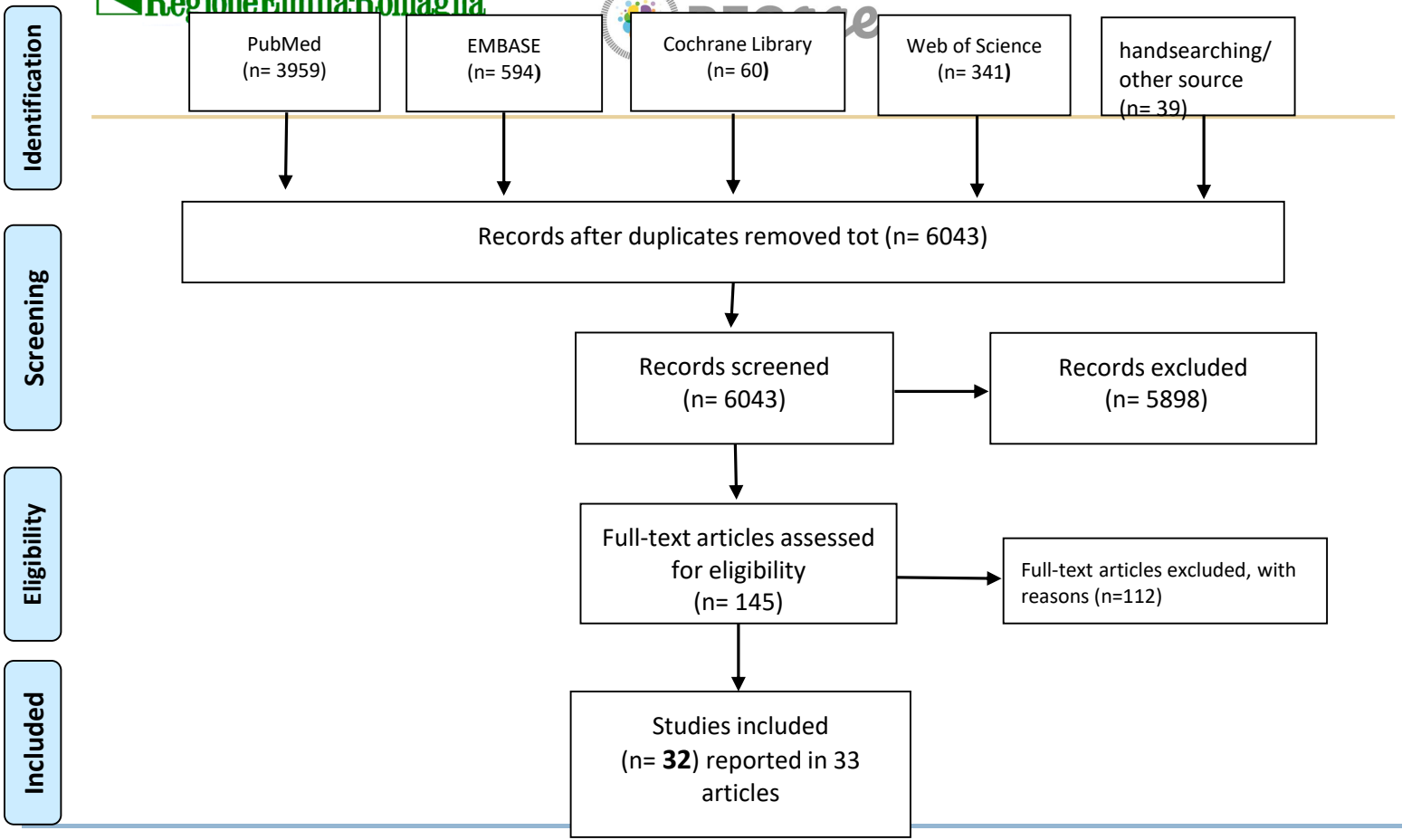

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Characteristics and structure of the SCU-B

29 studies

Rehabilitation service to maintain or stimulate the attentional capacities, to preserve the patients' autonomy, and to stabilize behavioural disorders

Few beds (range from 8 to 50), by wide living spaces such as dining room in which patients could eat together, and lounge or living room with couch, books, TV and games; outdoor spaces

Enclose indoor garden and multisensorial rooms. Therapeutic gardens offering a stimulating space for motor activity to reduce anxiety or agitation, stimulate verbal communication and memory, and support the patients and/or family and nursing team relationship

Multidisciplinary and specialized staff : geriatricians, nurses, psychologists, physical therapists and social workers, but also neurologists, dermatologist, dieticians and ortophonists

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Studies country of origin

Country	Effectiveness	Descriptive	Cost-effectiveness
France	**10**	**8**	**0**
Australia	**4**	**0**	**1**
Italy	**2**		
Germany	**2**		
Singapore	**1**	**1**	**1**
UK	**1**	**1**	**1**
The Netherlands	**1**		
US	**1**		

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Cost-effectiveness outcomes

- **Anderson 2016:**1-year difference in mean cost per person between 5 intervention centres and their matched control centres varied from AU $63,173 lower to AU $-39,567 higher; overall saving of AU$2,526,880 as compared to the control centres
- **Tanajewki 2015:** intervention had a probability of 94% of being cost-effective from a 3-month combined health and social care perspective when usual criteria were applied; the incremental cost-effectiveness ratio (ICER) was dominant. No significant difference in costs and QALYs related to the SCU-B (£-322, 95% CI: -1219 to 621 and 0.008 QALYs, 95% CI: -0.005 to 0.020).
- **Tay 2018:** EQ-5D index score difference between patients of the intervention and usual care was 0.18, and in QALY was 0.045 assuming the difference holds for 3 months. With a total additional cost for the intervention of US$ 10.40 the ICER was US$ 23,111 costs per QALY.

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Methodological quality – risk of bias

RCT (1): low risk of bias for all domains but blinding of participants and personnel, that was not feasible

Comparative non-randomised studies (3): overall at moderate quality. The most relevant limitation was lack of adjustment for confounding factors.

Uncontrolled case series (18): median score: 13 (range 7 to 14) out of maximum score of 16; most relevant limitations: studies conducted in single centres, outcome assessor not blinded, unclear whether the data were prospectively collected

Health-economic evaluation studies (3): from low to moderate due to short follow-up time (all), not representing informal care costs (all), not being randomized (2 studies), and lack of relevant outcomes (1 study)

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Conclusions

No firm conclusions can be drawn as the vast majority of studies were uncontrolled case series and the quality of reporting was often very poor

The only RCT found no difference with standard of care

SCU-B maybe helpful in managing critical exacerbation of BPSD

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Research question 4

What are the safety issues of physical restraints and neuroleptic treatments? Safety of SCU-B

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Scoping review

Safety of physical restraints and neuroleptic treatments (antipsychotic and antidepressant) for the treatments of in people with Behavioral and Psychological Symptoms of Dementia (BPSD): Overview of systematic reviews

- Valentina Pecoraro, Silvia Minozzi, Maria Camerlingo

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Search Strategy

PubMed, EMBASE, Cochrane Library

up to April 2022

”dementia”, “behavior”, “BPSD”, “special hospitals”, “special care”, “physical restraint”, “neuroleptics”, antipsychotics”, “systematic review”

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Inclusion criteria

P: people with Behavioural and Psychological Symptoms of Dementia (BPSD)

I: physical restraints (abdominal belt/band in the armchair; bed sizes)

neuroleptic treatments (first and second generation antipsychotic; antidepressant)

C: no treatment, placebo

O: number of subjects of at least one adverse events, frequency of different adverse events

S: systematic reviews of randomised controlled trials

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Methods

Two authors (SM, VP) independently screened title and abstracts retrieved via the search. Potentially relevant studies acquired in full text and assessed for final inclusion independently by two authors (SM, VP). Any disagreement discussed with a third author who acted as arbitrator (CAD).

Methodological quality assessed by AMSTAR 2 checklist

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Selection process - methods

1. Selected only the SRs that **reported Adverse Events**
2. Selected the **most recent** SRs (published since 2012)
3. For those most recent, **methodological quality** assessed by AMSTAR 2; excluded SRs of critically low quality
4. grouped the SRs according to the **type of intervention** assessed:
    a. Typical (first generation) antipsychotics
    b. Atypical (second generation) antipsychotics
    c. Antidepressants
    d. Physical restraints
5. Within each group, assessed **overlapping of primary studies**
6. If complete or nearly complete overlapping, data extracted from the review that included the greatest number of primary studies and of higher quality. In case of poor overlapping, data extracted from more than one review for each group

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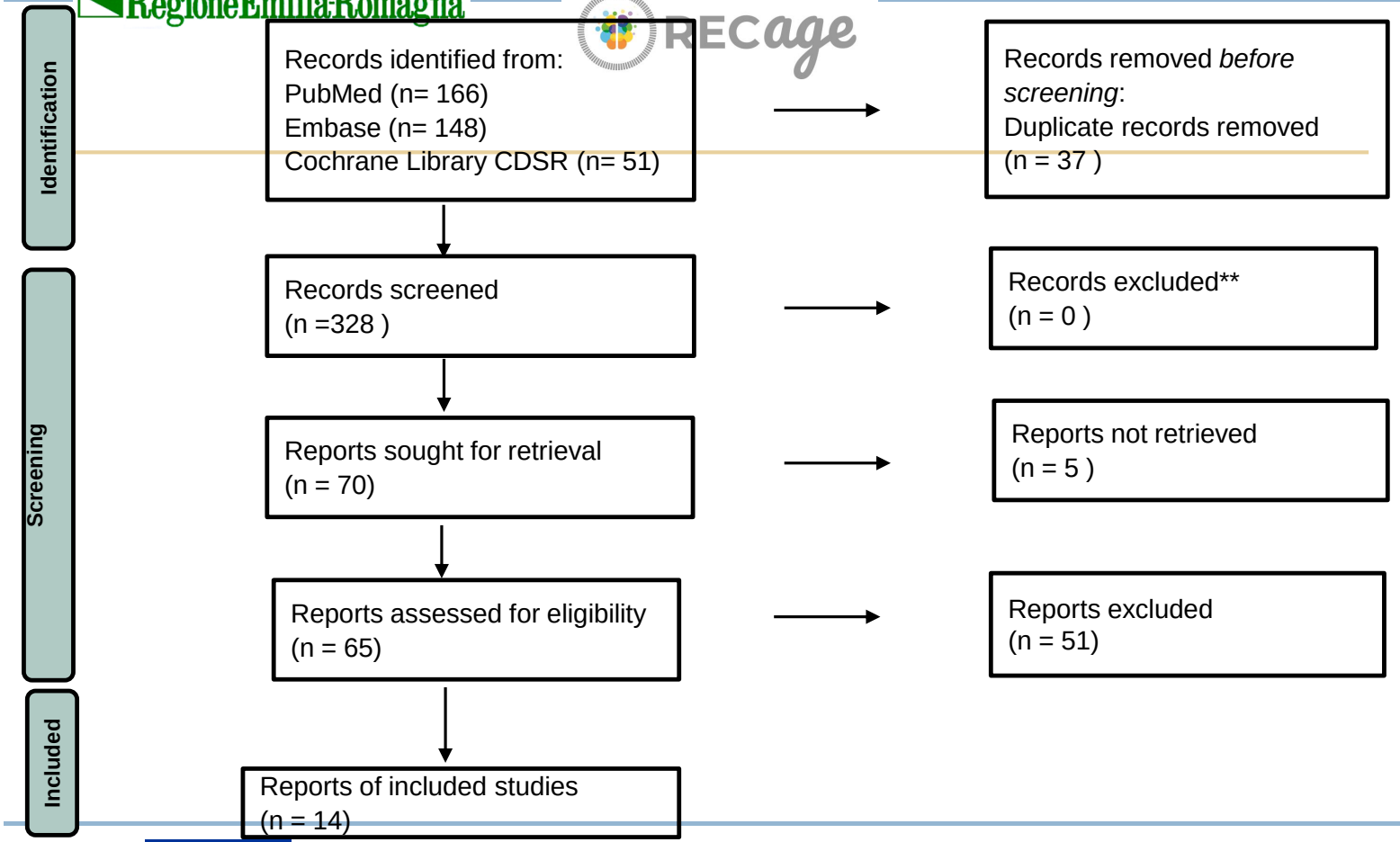

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Selection process – detailed results

Acquired in full text: n. 65

1. Selected only the SRs that **reported Adverse Events** and corresponded to **PICO:** n. 36
2. Selected the **most recent** SRs (published since 2012): n. 21
3. For those most recent, **methodological quality** assessed by AMSTAR 2; excluded SRs of critically low quality; included high, moderate, low quality: n. 14
4. grouped the SRs according to the **type of intervention** assessed:
    a. Typical (first generation) antipsychotics: n. 7
    b. Atypical (second generation) antipsychotics: n. 10
    c. Antidepressants: n. 6
    d. Physical restraint: n. 0
5. Within each group, assessed **overlapping of primary studies**
6. data extracted
    a. Typical (first generation) antipsychotics: n. 2
    b. Atypical (second generation) antipsychotics: n. 3
    c. Antidepressants: n. 2

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Typical (first generation) antipsychotics vs placebo: 2 SRs

Mortality:

Hulsof 2015: 17 RCTs, 2387 participants; RD : 0.1%, 95%CI -1.0% to 1.2%

Mühlbauer 2021: 3 RCTs, 578 participants; RR : 1.46, 95% CI 0.54 to 4.00

Other AEs

Mühlbauer 2021: 6 RCTs, 771 participants;

Serious adverse events: RR 1.32, 95% CI 0.65 to 2.66

Somnolence: RR 2.62, 95% CI 1.51 to 4.56

Extrapyramidal symptoms: RR 2.26, 95%CI 1.58 to 3.23

Worsening of cognitive functioning: (MMSE) MD: -0.25, 95%CI-1.27 to 0.77

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Atypical (second generation) antipsychotics vs placebo: 3 SRs

Mortality:

Yunusa 2019: 17 RCTs, 5373 participants; no significant difference

Yunusa 2021: 39 RCTs, 10 open label, 2 observational, 13.334 participants:

olanzapine and risperidone higher mortality (data not shown);

Mühlbauer 2021: 20 RCTs, 5909 participants; RR : 1.36, 95% CI 0.90 to 2.05

Cerebrovascular AEs:

Yunusa 2019: 17 RCTs, 5373 participants: increase for risperidone:

OR 3.85, 95%CI 1.55 to 9.55; other drugs no difference

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Antidepressants vs placebo

Hsu 2021: 14 RCTs, 1374 participants

Mortality: not assessed

Any adverse events: OR 1.27, 95% CI 0.80 to 2.03

Drop out for any reasons: OR 1.29, 95%CI 0.96 to 1.75

Dudas 2018: 10 RCTs, 1592 participants

Drop out for any reasons: OR 1.51, 95%CI 1.07 to 2.14

Any adverse events: OR 1.55, 95% CI 1.21 to 1.98

SAEs: data not pooled. Overall, it seems that SAEs occurred more often in those participants given antidepressants compared to those on placebo

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Conclusions

The use of antipsychotics is associated with an increased risk of serious adverse effects (death, cerebrovascular complications and cerebrovascular complications and acceleration of cognitive decline) in people with dementia

Antidepressants are better tolerated than antipsychotics but also have adverse effects too

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Thanks for your attention