加護單位彈性會客是否可以降低譫妄發生?

報告者: 林楷宸

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背景:

- ICU時常看到患者出現意識混亂、失去定向感、躁動、注意力不集中，警覺度過高，而這些都是譫妄的症狀。
- 患者特徵多數以患有顱內出血、依賴呼吸器合併使用麻醉型止痛藥(Fentanyl)、65歲已上老年人、患有精神病史為主。
- 當病人在意識混亂甚至出現躁動時，除了安撫外，請家屬前來陪伴與共同安撫病患躁動情況似乎可改善。
- 不禁思考，是否有文獻佐證家屬的陪同或延長會客時間可以降低病人譫妄的發生率。

EFFECT OF FLEXIBLE FAMILY VISITATION ON DELIRIUM AMONG PATIENTS IN THE INTENSIVE CARE UNITTHE ICU VISITS RANDOMIZED CLINICAL TRIAL　RANDOMIZED CLINICAL TRIAL

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步驟 1：
研究探討的問題為何？研究族群 / 問題 (Population/ Problem)、介入措施 (Intervention)、比較 (Comparison)、結果 (Outcomes)：

- **問題: Does a policy that permits flexible family visitation in the intensive care unit (up to 12 hours per day), compared with standard restricted visitation defined by each intensive care unit (median, 1.5 hours per day; up to 4.5 hours per day), reduce the incidence of delirium among patients?**

P　I　C　O

- **目的 ：確定ICU中靈活家庭探視時間政策是否可以減少譫妄的發生?**
- **研究設計: 來自巴西的36個成人重症監護病房，家屬和臨床醫生進行了交叉隨機臨床試驗，探視時間受到限制（每天<4.5小時）。時間於2017年4月至2018年7月。**
- **介入措施：**
  靈活探視組（n = 837名患者、652名家庭成員、435名臨床醫生，靈活探訪時間每天最多12小時)
  限制探視組（n = 848名患者、643名家庭成員、391位臨床醫生，每天1.5小時 ）。
  19個加護病房以靈活探視開始，有17個以限制探視開始。
- **主要結果與措施:** 運用CAM-ICU評估ICU住院期間發生譫妄的比率。次要結果包括患者ICU獲得性感染。家庭成員使用HADS評估的焦慮和憂鬱症狀（範圍為0 [最佳]至21 [最嚴重]）；和ICU工作人員的倦怠（Maslach倦怠清單）。

步驟 2：研究的品質有多好(內在效度)？
招募(RECRUITMENT) - 受試者是否具有代表性？

評讀結果：是

- **The trial enrolled medical-surgical adult ICUs with 6 or more beds and restricted visiting hours (<4.5 hours per day) at public and private nonprofit hospitals in Brazil.**
- **納入: Patients 18 years or older admitted to participating ICUs were consecutively included. 排除: coma (GCS ≤−4) 、delirium (positive)、brain death、 palliative care、 ICU length of stay less than 48 hours、存活小於 24 hours、囚犯、無家人探望及陪伴者.**
- **Day-shift physicians, nurses, nurse technicians, and physiotherapists working in the ICU at least 20 hours per week were eligible for participation as clinicians(休假 >15 days的臨床評估者排除).**
- **所有參與中心的機構審查委員會都批准了該研究。ICU負責人和醫院院長對研究方案提供了書面同意。在患者中，有33個ICU放棄了書面知情同意的需要。在這33個ICU中，患者或其代理人收到了有關該試驗的口頭和書面信息，包括可以隨時拒絕參加或退出參加活動的選擇。在3個ICU中，書面同意被認為是必要的，並因此獲得了患者或其代理人的同意。**

步驟 2：分派(ALLOCATION) - 分派方式是否隨機且具隱匿性...？ 評讀結果：是

- The ICUs were consecutively randomized in a 1:1 ratio using computer-generated randomization with random block sizes of 2, 4, and 6 and stratified分層 by number of ICU beds (≤10 or >10). A statistician統計員 blinded to cluster identity performed randomization.

步驟 2：每個組別，在研究開始時的情況是否相同？ 評讀結果：是

Table 1. Baseline Characteristics of Participants in the ICU Visits Study

Characteristic	No./Total (%)	
	Flexible Visitation	Restricted Visitation
Patients (n = 837 [Flexible Visitation] and 848 [Restricted Visitation])[a]		
Age, mean (SD), y	58.4 (18.3)	58.6 (18.2)
Age ≥65 y	353/837 (42.2)	382/848 (45.0)
Sex		
Men	448/837 (53.5)	442/848 (52.1)
Women	389/837 (46.5)	406/848 (47.9)
Charlson Comorbidity Index, median (IQR)[b]	1.0 (0 to 2.0)	1.0 (0 to 2.0)
History of dementia	9/837 (1.1)	7/846 (0.8)
Hazardous alcohol consumption[c]	63/832 (7.6)	57/844 (6.8)
ICU admission type		
Medical	414/837 (49.5)	438/846 (51.8)
Surgical		
Elective	188/837 (22.5)	177/847 (20.9)
Emergency	181/837 (21.6)	172/846 (20.3)
PRE-DELIRIC, median (IQR)[d,e]	0.15 (0.07-0.29)	0.14 (0.07-0.31)
APACHE-II, mean (SD)[e,f]	13.1 (7.2)	13.3 (7.1)
SOFA, median (IQR)[e,g]	4.0 (2.0-6.0)	4.0 (2.0-7.0)
Mechanical ventilation	222/836 (26.6)	204/848 (24.1)
Medication use[e]		
Vasopressors	224/835 (26.8)	231/845 (27.3)
Opioids[h]	168/831 (20.2)	148/843 (17.6)
Corticosteroids	164/829 (19.8)	152/846 (18.0)
Parenteral sedatives[i]	124/831 (14.9)	116/843 (13.8)
Benzodiazepines[j]	106/831 (12.8)	108/843 (12.8)
Indwelling central venous catheter	530/837 (63.3)	517/848 (61.0)
Urinary catheter	584/837 (69.8)	581/848 (68.5)
Family Members (n = 532 [Flexible Visitation] and 528 [Restricted Visitation])[a,k]		
Age, mean (SD), y	45.7 (13.5)	44.7 (14.1)
Sex		
Men	152/532 (28.6)	163/528 (30.9)
Women	380/532 (71.4)	365/528 (69.1)
Educational attainment, mean (SD), y	11.6 (5.0)	11.3 (4.8)
Monthly household income, median (IQR), US $[l]	1235 (692-1976)	1112 (630-1976)
Unemployed or retired	248/523 (47.4)	244/526 (46.4)
Living with care recipient	291/523 (55.6)	282/521 (54.1)
Surrogate decision maker	481/516 (93.2)	451/518 (87.1)
History of anxiety	76/523 (14.5)	59/525 (11.2)
History of depression	74/521 (14.2)	53/524 (10.1)
ICU Staff (n=382 [Flexible Visitation] and 355 [Restricted Visitation])[a]		
Age, mean (SD), y	35.9 (7.6)	35.0 (7.9)
Sex		
Men	99 (25.9)	101 (28.5)
Women	283 (74.1)	254 (71.5)
Occupation		
Physician	50 (13.1)	49 (13.8)
Nurse	85 (22.3)	75 (21.1)
Nurse technician	191 (50.0)	184 (51.8)
Physiotherapist	56 (14.7)	47 (13.2)

Table 1. Baseline Characteristics of Participants in the ICU Visits Study (continued)

Characteristic	No./Total (%)	
	Flexible Visitation	Restricted Visitation
Years of experience in ICU work, median (IQR)	5.0 (2.0-10.0)	5.0 (1.8-9.0)
Working hours per week, mean (SD)	46.3 (15.0)	45.5 (15.9)
No. of patients per professional, mean (SD)	50 (13.1)	49 (13.8)
Physician	8.8 (3.8)	8.7 (3.6)
Nurse[m]	7.2 (3.5)	7.1 (3.4)
Nurse technician	2.3 (1.7)	2.3 (2.1)
Physiotherapist	10.3 (4.5)	9.7 (3.5)
Burnout at baseline	92/381 (24.1)	92/353 (26.1)

步驟 2：維持(MAINTENANCE) - 各組是否給予相同的治療？ 評讀結果：否

- 靈活探視模式包括ICU探訪時間的靈活性和家庭教育。每天允許一個或兩個親密的家人探望患者長達12個小時(家庭成員必須參加至少1次有組織的會議，在會議中他們接受了有關ICU環境，了解加護常規，感染控制，譫妄教育。)這些結構化會議由訓練有素的臨床醫生以面對面的形式每周至少進行3次。此外，家庭成員還可以訪問信息手冊和網站（http://www.utivisitas.com.br），旨在幫助他們了解與加護病房相關的各種流程，並在不增加加護病房人員工作量的情況下改善合作。

- 根據當地法規，還允許患者在特定時間間隔接受社會訪問。向沒有進行靈活探視的朋友或家人提供了社交探視。

- 受限探訪模式，按照醫院探訪時間（1.5小時/天；最多4.5小時/天）。訪客不需要參加教育會議。

- 這兩種探訪模組中，探訪者皆進行促進安全和寧靜環境的口頭和書面指導。
- (但在以下兩種情況，兩組均允許訪客時間超過時間限制：患者65歲或以上，絕症以及ICU工作人員與患者或家庭之間有衝突)

步驟 2：是否有足夠的追蹤(FOLLOW UP)？ 評讀結果：是

- 共邀請151個ICU參加試驗。其中有40名被錄取。
- 四個隨機ICU在研究開始前撤回了同意書後剩 36個ICU。
- 其中，2個ICU沒有進入第2階段（1個以靈活探訪開始，1個以限制探訪開始）。
- 從2017年4月到2018年7月，共篩查了5837位患者，1508位家庭成員和959位臨床醫生。
- 在靈活探訪組中，由於沒有家人可以參加ICU探訪而被排除在外的患者人數更高（15.5%）。
- 最後總共招募1685位患者，1295位家庭成員和826位臨床醫生。其中9位患者無數據（靈活探訪組6例，限制探訪組3例）。在家庭成員中，有235名（18.1%）失訪或拒絕參加（靈活探訪組120名，受限探訪組115名）。在臨床醫生中，有89名（10.7%）失訪或拒絕參加（靈活探訪組53名，限制探訪組36名）。

步驟 2：評估(MEASUREMENT) - 受試者與評估者是否對治療方式及(或)評估目的維持 盲法(BLIND)？

以治療方式無法維持盲法，內文無資料呈現是否維持盲法。

評讀結果：否

步驟 3：研究結果的意義為何？

評讀結果：是

結果:

1. 在1685例患者中，有1295例家庭成員和826名臨床醫生入組，其中1685例患者（100%）（平均年齡58.5歲；女性47.2%），1060例家庭成員（81.8%）（平均年齡45.2歲；女性70.3%）。共有737名臨床醫生（89.2%）（平均年齡35.5歲；女性72.9%）完成了試驗。
2. 靈活探訪組比限制探訪時間的平均時間明顯更長（4.8 vs 1.4小時；*P* <.001）。
3. 靈活探訪組和受限探訪組，其ICU住院期間譫妄的發生率無顯著差異（18.9% vs 20.1%；調整後差異為-1.7%[95%CI，-6.1%至2.7%]；*P* =0 .44）。
4. 另次要結論中，靈活探訪和受限探訪組之間沒有顯著差異如下，包括ICU獲得性感染（3.7%vs 4.5%；調整後差異為-0.8%[95%CI，-2.1%至1.0%]；*P* = 0.38）和員工倦怠（22.0%對24.8%；調整後的差異為-3.8%[95%CI，-4.8%至12.5%]；*P* = 0.36）。對於家庭成員焦慮（6.0 vs 7.0；調整後的差異為-1.6 [95%CI，-2.3至-0.9]；*P* <.001）和抑鬱評分（4.0 vs 5.0；調整後的差異為-1.2 [95%CI ，-2.0至-0.4]；*P* = .003）靈活的訪視效果明顯更好。

Flexible Versus Restrictive Visiting Policies in ICUs: A Systematic Review and Meta-Analysis

Nassar Junior, Antonio Paulo PhD; Besen, Bruno Adler Maccagnan Pinheiro MD; Robinson, Caroline Cabral PhD; Falavigna, Maicon PhD; Teixeira, Cassiano PhD; Rosa, Regis Goulart PhD

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Background

- Most ICUs worldwide adopt restrictive visiting policies大多數ICU都採用限制性訪視政策 . The perception that family presence at the ICU may increase the hazards of infection增加感染的風險, disorganization of care護理混亂, and increased ICU staff burnout 工作人員的倦怠感 seems to be the cornerstone for these restrictive visiting models .

- However, the theoretical risks related to flexible ICU visiting hours have not been consistently confirmed by the literature尚未得到文獻的一致證實 .

- Our objective was to systematically review the literature文獻 and synthesize the differences in outcomes related to patients, family members, and ICU professionals by comparing flexible versus restrictive ICU visiting policies.

PICO

- ***研究族群／問題 (Population/ Problem)：***

The patients in ICU

- ***介入措施 (Intervention)：***

Flexible visiting policies

- ***比較 (Comparison)：***

Restrictive visiting policies

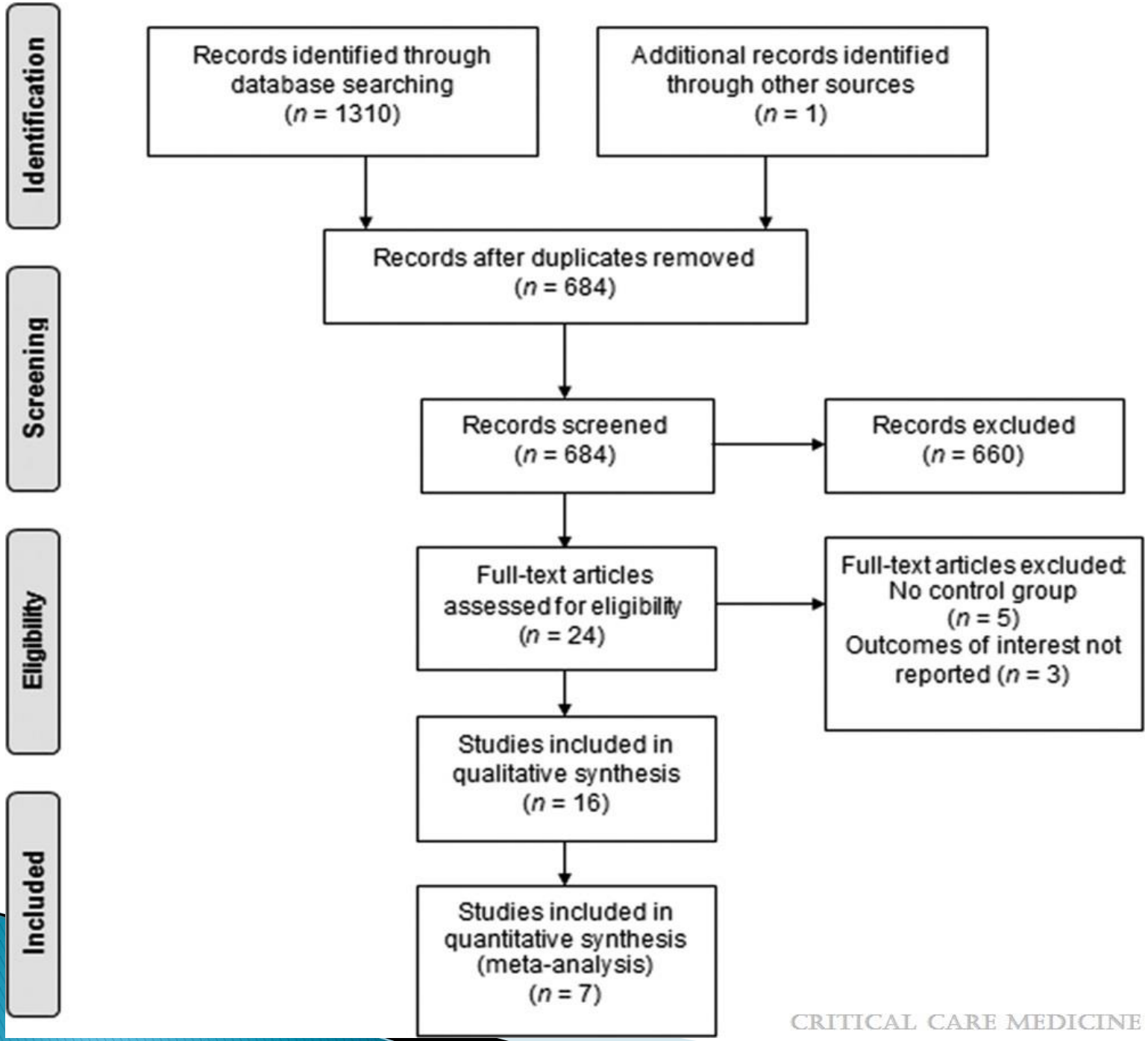
- ***結果 (Outcomes)：***

Patient-Related Outcomes
Family-Related Outcomes
ICU Staff–Related Outcomes

FAITH 快速評讀表

F - 研究是否找到 (Find) 所有的相關證據？ 評讀結果：是

- A literature search was conducted using Medline (via PubMed), Scopus, and Web of Science databases.
- The following search terms were used: ("visitation" OR "visiting") AND ("critical care" OR "intensive care"). The search included observational觀察性 and randomized隨機 studies published until August 03, 2017. The study followed the recommendations of the Preferred Reporting Items for Systematic Review and Meta-Analysis(PRISMA).


Identification
Screening
Eligibility
Included
Records identified through database searching (n = 1310)
Additional records identified through other sources (n = 1)
Records after duplicates removed (n = 684)
Records screened (n = 684)
Records excluded (n = 660)
Full-text articles assessed for eligibility (n = 24)
Full-text articles excluded: No control group (n = 5) Outcomes of interest not reported (n = 3)
Studies included in qualitative synthesis (n = 16)
Studies included in quantitative synthesis (meta-analysis) (n = 7)

FAITH 快速評讀表

A - 文獻是否經過嚴格評讀 (Appraisal)？

評讀結果：是

Assessment of Risk of Bias

The risk of bias in randomized trials was assessed using the Cochrane Collaboration's tool for assessing risk of bias in randomized trials ([13]). The risk of bias was rated as "low," "unclear," or "high" in the following domains: generation of the random allocation sequence; allocation concealment; blinding of participants, health professionals, and outcome assessors; incomplete outcome data; selective outcome reporting; other sources of bias; and overall risk of bias.

The risk of bias in observational studies was assessed using the Risk Of Bias In Non-randomized Studies of Interventions tool ([14]). The risk of bias was rated as "low", "moderate", "serious", "critical", or "no information" in the following domains that have the potential to lead to bias: confounding judgment, selection of participants, classification of interventions, deviations from intended interventions, missing data, measurement of outcomes, selection of the reported results, and overall risk of bias. Disagreements between reviewers were resolved by consensus.

FAITH 快速評讀表

I - 是否只納入 (Included) 具良好效度的文章？

評讀結果：是

Assessment of Risk of Bias

One randomized trial was rated as having a low risk of bias ([19]), whereas another trial was rated as having a high risk of bias ([17]). Most observational studies were rated as having a moderate risk of bias (**Supplemental Table 2**, Supplemental Digital Content 2, http://links.lww.com/CCM/D517). Three studies were published as "Letters to the Editor" ([23,27,28]) and one as a congress abstract ([18]). One of these studies was a secondary analysis ([28]) of a previously published study ([31]), and the assessment of risk of bias was based on the primary research.

FAITH 快速評讀表

T - 作者是否以表格和圖表「總結」(Total up) 試驗結果？

評讀結果：是

H - 試驗的結果是否相近 - 異質性 (Heterogeneity)？

評讀結果：是

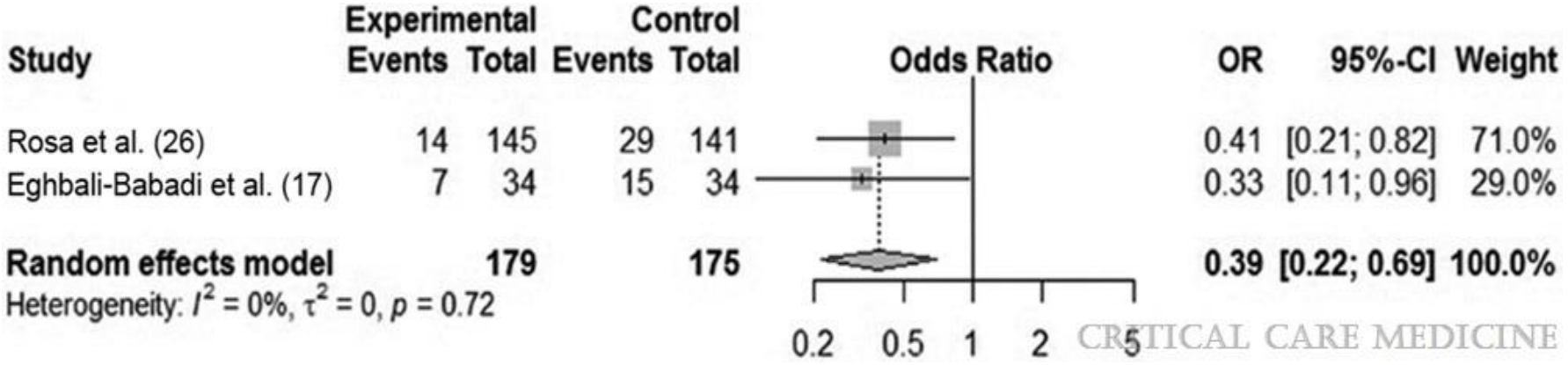
1. Patient-Related Outcomes

2. Family-Related Outcomes

3. ICU Staff–Related Outcomes

Patient-Related Outcomes (評譫妄)

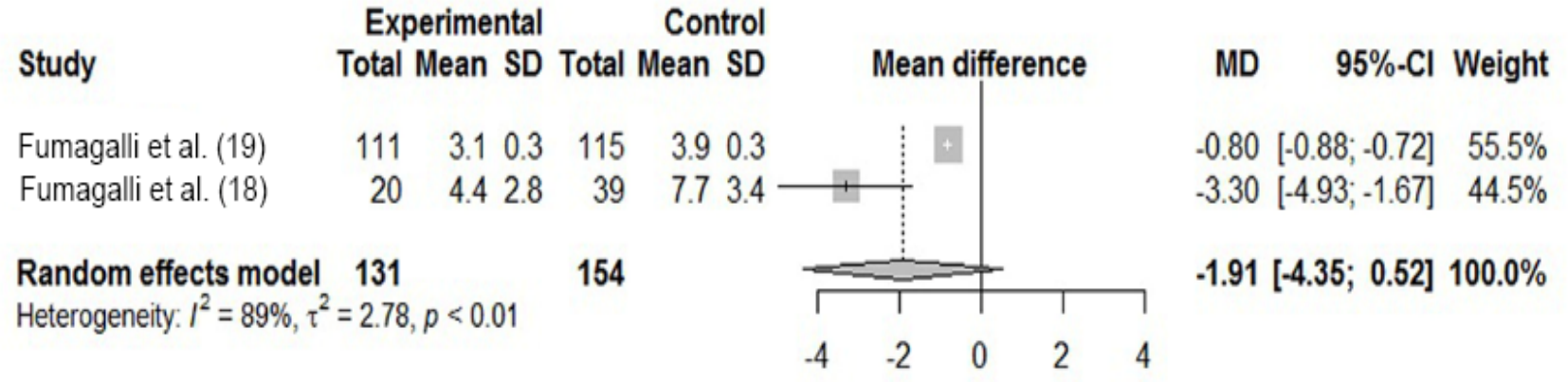
- Two studies evaluated the frequency of delirium in a total of 354 patients . The flexible visiting policy was associated with a reduced frequency of delirium (OR, 0.39; 95% CI, 0.22–0.69; I2 = 0%) .



異質性低，靈活會客其譫妄發生率降低

Patient-Related Outcomes (評憂鬱)

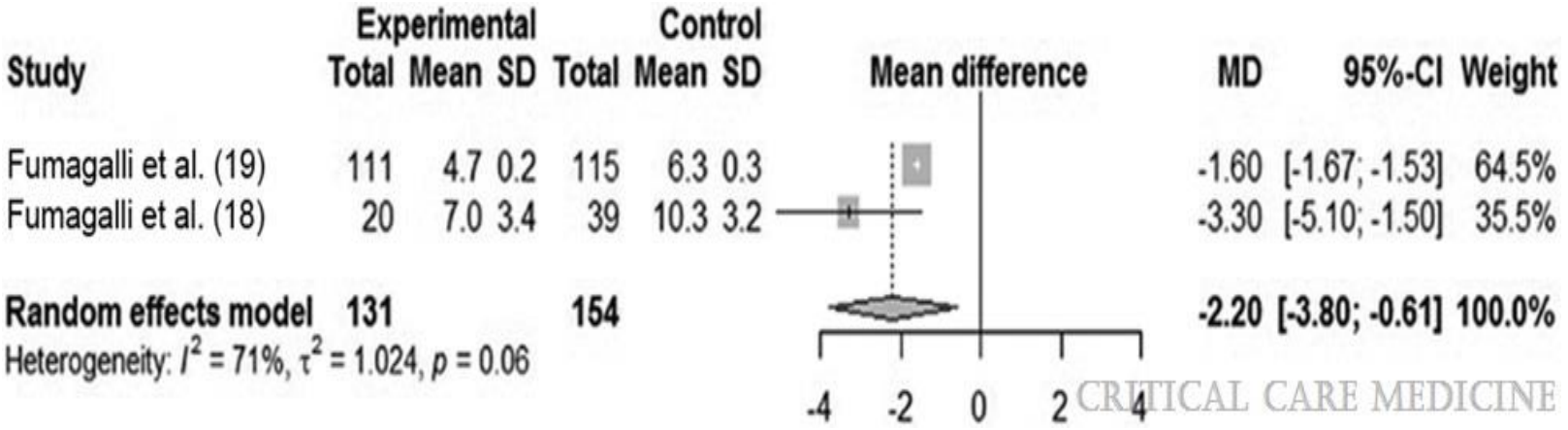
- Symptoms of depression and anxiety were assessed in two studies, conducted by the same research group, using the Hospital Anxiety and Depression Scale in 285 patients . Although no difference was observed in depressive symptoms (MD, –1.91; 95% CI, –4.35 to 0.52; I2 = 89%)



異質性高，靈活會客其憂鬱程度無改變

Patient-Related Outcomes (評焦慮)

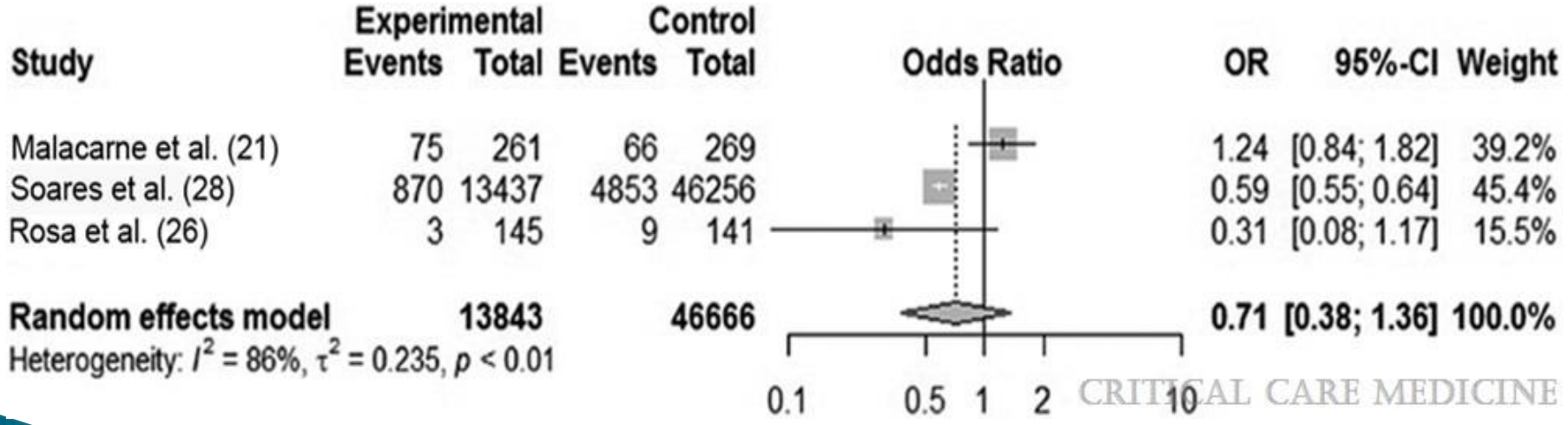
- anxiety symptoms were less severe in patients exposed to the flexible visiting policy (MD, –2.20; 95% CI, –3.80 to –0.61; I^2 = 71%)



異質性高，靈活會客其焦慮程度降低

Patient-Related Outcomes (評死亡率)

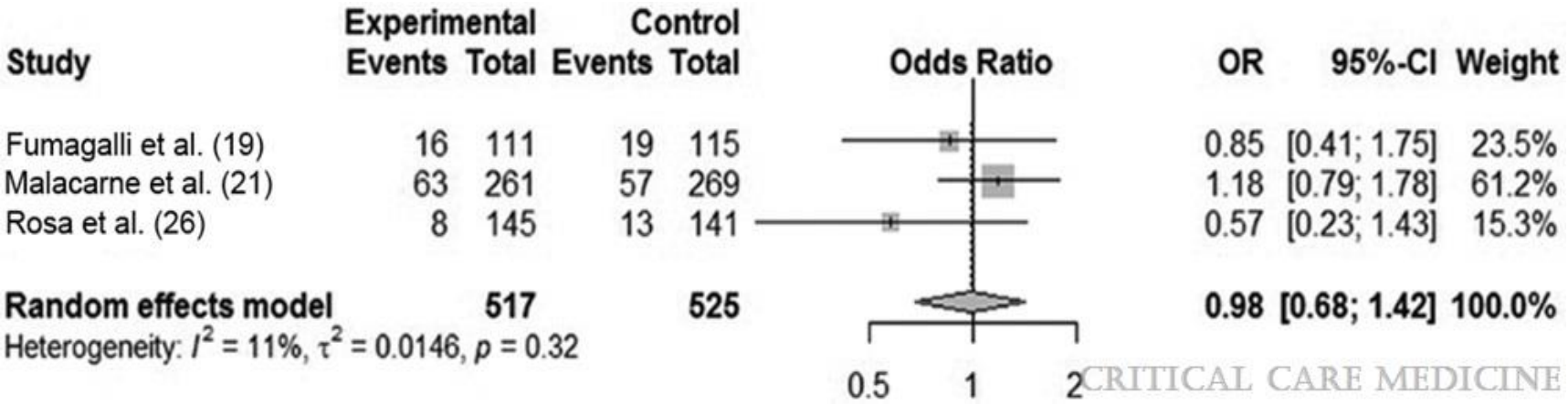
- Three studies evaluated ICU mortality in a total of 60,509 patients . There was no difference in mortality related to visiting policies (OR, 0.71; 95% CI, 0.38–1.36; I2 = 86%)



異質性高，靈活會客其死亡率無改變

Patient-Related Outcomes (評ICU院內感染)

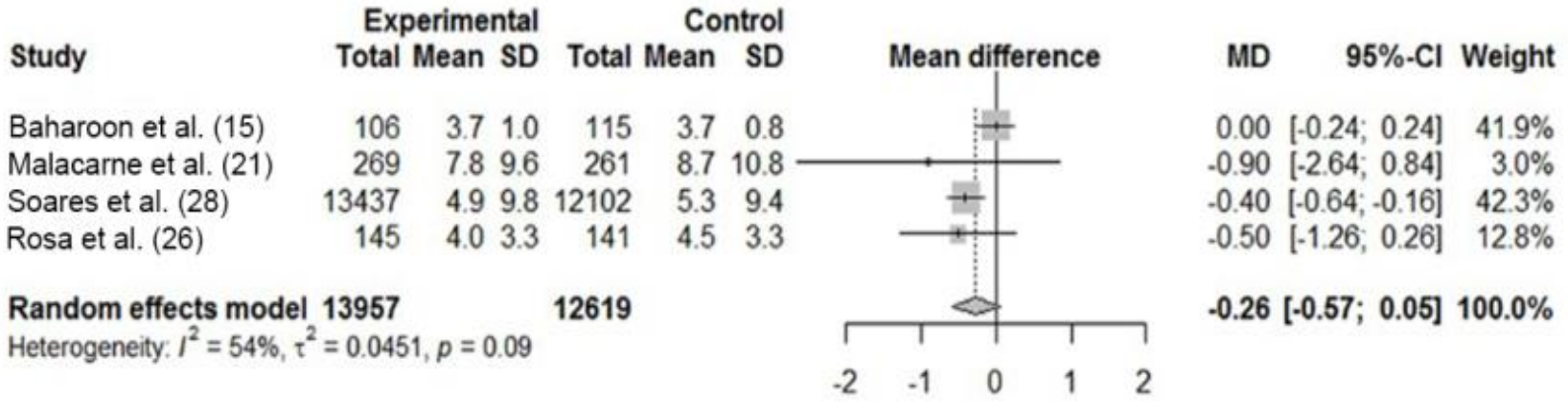
- Three studies, with a total of 1,042 patients, evaluated the frequency of ICU-acquired infections . Likewise, there was no difference in the frequency of ICU-acquired infections related to visiting policies (OR, 0.98; 95% CI, 0.68–1.42; I2 = 11%)



異質性低，靈活會客其感染率無改變

Patient-Related Outcomes (評ICU住院時間)

- ICU length of stay was assessed in four studies, with no difference between visiting policies (MD, –0.26 d; 95% CI, –0.57 to 0.05; I2 = 54%)



異質性高，靈活會客其加護病房住院天數無改變

Patient-Related Outcomes (評病患滿意度)

- Only one study evaluated patient satisfaction with flexible versus restrictive visiting policies. A five-point Likert scale was used to interview 20 patients during the restrictive visiting period and 12 patients during the flexible visiting period. The level of satisfaction increased from 3.15 to 4.42 ($p < 0.005$).

Patient-Related Outcomes (評病患及家屬滿意度)

- In two studies, satisfaction assessment included patients and family members .

- In one study, of 86 patients and family members interviewed, 51% reported being very satisfied with the restrictive visiting policy. After the introduction of the flexible visiting policy, 91% of 36 patients and family members interviewed reported being very satisfied.

Family-Related Outcomes (評家屬滿意度)

Family-Related Outcomes.

Family satisfaction was evaluated in nine studies, but the use of very different assessment tools across studies precluded a combined data analysis. In eight of these studies, family satisfaction increased with flexible visiting policies ([16][22–25][27][29][30]). The following assessment tools were used: the Questionnaires Measuring Satisfaction with Old and New Visitation Policies in two studies, but with different data reporting formats ([16][24]); the Family Satisfaction in the ICU survey in one study ([22]); the Critical Care Family Needs Inventory in one study ([27]); a specifically designed questionnaire in one study ([30]); a four-point Likert scale in one study ([29]); a five-point Likert scale in one study ([25]); and, in one study, participants were directly asked if they were satisfied ([23]). One study showed no improvement in family satisfaction using the Critical Care Family Satisfaction Survey ([15]). As described previously, in two studies, satisfaction assessment included both patients and family members ([23][29]). We found no studies assessing depression, anxiety, or PTSD in family members.

ICU Staff–Related Outcomes (評工作者倦怠程度)

- Only one study assessed burnout syndrome symptoms among ICU professionals ICU專業人士的倦怠綜合症狀. The study showed that higher burnout levels, measured by the Maslach-Jackson Burnout Inventory, increased from 34.5% to 42.6% (p = 0.001) after flexible visiting hours were introduced in the ICU.

- We found no studies assessing depression in ICU professionals.

ICU Staff–Related Outcomes (評工作量)

- One study evaluated the workload perception of ICU professionals with the different visiting policies. Ten of 29 ICU professionals (35%) perceived the workload to be increased in the restrictive family visitation model, whereas 20 of 42 ICU professionals (48%) reported that workload increased in the flexible family visitation model ($p = 0.33$) .

DISCUSSION

- 此篇meta-analysis表明，延長會客時間與ICU患者譫妄發生率降低和焦慮症狀嚴重程度降低有關。

- 延長會客時間與ICU死亡，ICU獲得性感染或ICU住院時間延長的風險增加無關。且大多數研究表明，患者和家屬對延長會客都更加滿意。然而，唯一一項研究表明延長會客對ICU工作人員的倦怠症狀有所增加。

- 然而，對於是否能延長本院會客、如何延長、延長後如何管制和教育家屬、延長後如何降低護理同仁工作量、如何訓練護理同仁的會客技巧...等，這些還有待我們探討。

是否同意加護單位採彈性會客來降低譫妄的發生?

同意(綠牌)：8位
需更多文獻支持(黃牌)：16位
不同意(紅牌)：0位