

Effect of Flexible Family Visitation on Delirium Among Patients in the Intensive Care Unit

The ICU Visits Randomized Clinical Trial

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IMPORTANCE The effects of intensive care unit (ICU) visiting hours remain uncertain.

OBJECTIVE To determine whether a flexible family visitation policy in the ICU reduces the incidence of delirium.

DESIGN, SETTING AND PARTICIPANTS Cluster-crossover randomized clinical trial involving patients, family members, and clinicians from 36 adult ICUs with restricted visiting hours (<4.5 hours per day) in Brazil. Participants were recruited from April 2017 to June 2018, with follow-up until July 2018.

INTERVENTIONS Flexible visitation (up to 12 hours per day) supported by family education (n = 837 patients, 652 family members, and 435 clinicians) or usual restricted visitation (median, 1.5 hours per day; n = 848 patients, 643 family members, and 391 clinicians). Nineteen ICUs started with flexible visitation, and 17 started with restricted visitation.

MAIN OUTCOMES AND MEASURES Primary outcome was incidence of delirium during ICU stay, assessed using the CAM-ICU. Secondary outcomes included ICU-acquired infections for patients; symptoms of anxiety and depression assessed using the HADS (range, 0 [best] to 21 [worst]) for family members; and burnout for ICU staff (Maslach Burnout Inventory).

RESULTS Among 1685 patients, 1295 family members, and 826 clinicians enrolled, 1685 patients (100%) (mean age, 58.5 years; 47.2% women), 1060 family members (81.8%) (mean age, 45.2 years; 70.3% women), and 737 clinicians (89.2%) (mean age, 35.5 years; 72.9% women) completed the trial. The mean daily duration of visits was significantly higher with flexible visitation (4.8 vs 1.4 hours; adjusted difference, 3.4 hours [95% CI, 2.8 to 3.9]; $P < .001$). The incidence of delirium during ICU stay was not significantly different between flexible and restricted visitation (18.9% vs 20.1%; adjusted difference, -1.7% [95% CI, -6.1% to 2.7%]; $P = .44$). Among 9 pre-specified secondary outcomes, 6 did not differ significantly between flexible and restricted visitation, including ICU-acquired infections (3.7% vs 4.5%; adjusted difference, -0.8% [95% CI, -2.1% to 1.0%]; $P = .38$) and staff burnout (22.0% vs 24.8%; adjusted difference, -3.8% [95% CI, -4.8% to 12.5%]; $P = .36$). For family members, median anxiety (6.0 vs 7.0; adjusted difference, -1.6 [95% CI, -2.3 to -0.9]; $P < .001$) and depression scores (4.0 vs 5.0; adjusted difference, -1.2 [95% CI, -2.0 to -0.4]; $P = .003$) were significantly better with flexible visitation.

CONCLUSIONS AND RELEVANCE Among patients in the ICU, a flexible family visitation policy, vs standard restricted visiting hours, did not significantly reduce the incidence of delirium.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: [NCT02932358](https://clinicaltrials.gov/ct2/show/study/NCT02932358)

JAMA. 2019;322(3):216-228. doi:10.1001/jama.2019.8766

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A flexible visitation policy for family members in intensive care units (ICUs) has been recommended by professional society guidelines as an important step toward patient- and family-centered care.^{1,2} Flexible ICU visiting hours may contribute to delirium prevention³⁻⁵ and stress reduction^{5,6} among patients as well as improvement in family satisfaction.⁵ However, the evidence suggests that most ICUs still adopt restricted visitation models,⁷⁻¹² possibly motivated by risks purportedly associated with unrestricted visiting hours, mainly disorganization of care,^{13,14} infectious complications,⁶ and burnout.¹⁵ To date, no large randomized trials have assessed the effects of a flexible family visitation model on patients, family members, and ICU staff, and this evidence gap may constitute a barrier to understanding the best way to implement ICU visitation policies.

This article reports the results of the ICU Visits Study, a cluster-crossover randomized clinical trial designed to evaluate whether a flexible visitation policy in the ICU, supported by family education, was more effective than the standard restricted visitation model in reducing delirium among patients. Family member and clinician outcomes were also assessed.

Methods

The institutional review boards of all participating centers approved the study. A mixed consent process was used. At the cluster level, the head of the ICU and the hospital director provided written consent for the study protocol. Among patients, the need for written informed consent was waived in 33 ICUs. The waiver was based on the nature of the proposed interventions, which were directed at the organizational aspects of ICUs and did not involve untested clinical procedures. In these 33 ICUs, patients or their proxies received verbal and written information about the trial, including the option to refuse participation or withdraw from participation at any time. In 3 ICUs, written consent was deemed necessary and was thus obtained from patients or their proxies. Written consent was also obtained from all family members and clinicians participating in the study.

Study Design

This study was a cluster-crossover randomized clinical trial comparing patient, family, and clinician outcomes associated with a flexible family visitation model or the usual restricted visitation model in adult ICUs. ICUs were randomly assigned to 1 of 2 sequences of interventions: flexible visitation followed by restricted visitation or restricted visitation followed by flexible visitation. The duration of interventions in each ICU was determined by the patient recruitment rate (25 patients during the first intervention [phase 1] and 25 patients during the second intervention [phase 2]).

Patients and family members admitted to participating ICUs during phase 1 or 2 were assessed. Clinicians were assessed only in phase 1, to avoid a carryover effect. A 30-day period without recruitment was applied between the 2 phases to avoid contamination. All ICUs had a learning period within

Key Points

Question 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?

Findings In this cluster-crossover randomized clinical trial that involved 1685 patients in the intensive care unit, the incidence of delirium was 18.9% in the flexible family visitation group compared with 20.1% in the standard restricted visitation group, a difference that was not statistically significant.

Meaning Flexible family visiting hours did not significantly reduce the incidence of delirium among patients in the intensive care unit.

the first 15 days of flexible visitation and restricted visitation, during which staff could adapt to study interventions before participant recruitment.

The primary hypothesis was that the flexible family visitation model would reduce the incidence of delirium among patients. The trial protocol and statistical analysis plan have been published and are available in [Supplement 1](#).^{16,17}

Participants

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. ICUs not meeting the minimum structural or organizational requirements for the operation of ICUs in Brazil were excluded.¹⁸

Patients 18 years or older admitted to participating ICUs were consecutively included. The exclusion criteria were coma (Richmond Agitation-Sedation Scale¹⁹ score ≤ -4) lasting longer than 96 hours from initial screening assessment or presence of any of the following characteristics at screening assessment: delirium (positive Confusion Assessment Method for the ICU [CAM-ICU] screening),²⁰ brain death, exclusive palliative care, inability to communicate, predicted ICU length of stay less than 48 hours, unlikely to survive longer than 24 hours, prisoner status, unavailability of a family member to participate in ICU visits, and previous enrollment in the study.

For each patient, 1 relative was enrolled (identified by the family as the closest relative); those who did not speak Portuguese or had communication difficulties were excluded. Day-shift physicians, nurses, nurse technicians, and physiotherapists working in the ICU at least 20 hours per week were eligible for participation as clinicians; however, those planning to take leaves of absence (>15 days) during phase 1 were excluded.

Randomization and Interventions

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 by number of ICU beds (≤ 10 or >10). A statistician blinded to cluster identity performed randomization.

The flexible visitation model included both flexibility of ICU visiting hours and family education. One or 2 close family members were allowed to visit the patient for up to 12 hours

per day; however, only 1 relative was enrolled in the study. These family members had to attend at least 1 structured meeting in which they received education about the ICU environment, common procedures, multidisciplinary work, infection control, palliative care, and delirium. These structured meetings were conducted by trained clinicians using a face-to-face format at least 3 times per week. Additionally, family members had access to an information brochure and website (<http://www.utivisitas.com.br>) designed to help them understand the various processes and emotions associated with an ICU stay and improve cooperation without increasing ICU staff workload. Patients were also allowed to receive social visits at specific time intervals according to local rules. Social visits were offered to friends or family members who did not qualify for flexible visitation. Implementation of the flexible visitation model is shown in eFigure 1 in Supplement 2.

In the restricted visitation model, visitors were allowed as before randomization, according to local hours (median, 1.5 hours/d [interquartile range {IQR}, 1.0 to 2.0]; up to 4.5 hours/d). Visitors were not required to attend educational meetings.

In both visitation models, visitors received oral and written guidance about minimum requirements to promote a safe and restful environment. Following the standard of care in Brazil, visitors were asked to leave the room during critical care procedures. Participation of family members in multidisciplinary rounds was allowed depending on local rules. Also, in both interventions, visitors were allowed to stay longer than the time limit in any of the following exceptional situations: patient 65 years or older, terminal illness, and conflicts between the ICU staff and the patient or family.

Outcomes and Follow-up

The primary outcome was the incidence of delirium during ICU stay measured by trained evaluators using the CAM-ICU,²⁰ which was administered once during every 12-hour shift. Delirium was defined as at least 1 positive CAM-ICU screening. Interrater agreement between CAM-ICU evaluators before study initiation was good, with a mean Cohen κ of 0.71 (95% CI, 0.64 to 0.78) for 932 measurements (eTable 1 in Supplement 2).

Prespecified secondary outcomes for patients included daily hazard of delirium, any ICU-acquired infections (pneumonia, bloodstream infection, or urinary tract infection) according to Centers for Disease Control and Prevention criteria,²¹⁻²³ 7-day ventilator-free days, length of ICU stay, and hospital mortality. For family members, prespecified secondary outcomes included anxiety and depression, assessed using the Hospital Anxiety and Depression Scale (HADS; score range, 0 [best] to 21 [worst]; cutoff points >7 and >10 indicate, respectively, possible and probable cases of anxiety or depression),²⁴ and satisfaction, assessed using the Critical Care Family Needs Inventory (CCFNI). The CCFNI addresses satisfaction in 5 domains (proximity, information, reassurance, comfort, and support), with total scores ranging from 43 (worst) to 172 (best).²⁵ To our knowledge, no studies have been conducted to establish minimal clinically important differences for the HADS and CCFNI in family members of ICU

patients. For clinicians, the prevalence of burnout was assessed as a prespecified secondary outcome using the Maslach Burnout Inventory (MBI; score range, -48 [best] to 84 [worst], with total scores >-9 indicating burnout).²⁶

The following prespecified tertiary outcomes were assessed: for patients, need for antipsychotic agents or mechanical restraints and unplanned loss of devices (feeding tube, venous catheter, or urinary catheter) during ICU stay, 7-day coma-free days, and analysis of ICU-acquired infections as individual outcomes; for family members, self-perception of involvement in patient care (score range, 0 [no involvement] to 27 [maximum involvement]; Supplement 1); and for clinicians, satisfaction with the visiting policy (score range, 0 [worst] to 4 [best]; Supplement 1). Furthermore, the following post hoc tertiary outcomes were evaluated among clinicians: perception of disorganization of care (score range, 0 [never] to 4 [always]) and conflicts with visitors.

Adherence to implementation of flexible visitation was assessed using semistructured interviews with local staff. Each ICU was rated from 0% [worst] to 100% [best] according to the mean of scores obtained in 4 implementation domains (visiting hours, dissemination, structured meeting, and staff training).

Site investigators followed up patients from study enrollment (baseline) to hospital discharge or death, or for a maximum of 30 days. Family members were evaluated using self-applied questionnaires within the first 48 hours after patient enrollment for baseline data and up to 7 days after patient discharge from ICU, death, or a maximum of 30 days for outcome assessment. Clinicians were evaluated using self-administered questionnaires 2 weeks before study initiation for baseline data and during the last 2 weeks of phase 1 for outcome assessment. Outcome assessors were not blinded to study interventions, except for infectious diseases specialists adjudicating infectious outcomes.

Sample Size

Sample size was calculated based on the results of a before-and-after study³ showing an absolute reduction of 10.9% for delirium with flexible visitation. In that study, the incidence of delirium with restricted visitation was 20.5%. A conservative effect size of 6% was used. A sample of 50 patients per ICU across 33 clusters, for a total of 1650 patients, was estimated to achieve a power of 80% and detect an absolute difference of 6.0% or greater in the incidence of delirium between interventions (considering an outcome incidence of 20.5% with restricted visitation), with a 2-sided α level of .05. This calculation was based on 2 levels of intraclass correlation: 0.05 for patients in the same cluster and period and 0.01 for patients in the same cluster, but in different periods. Forty ICUs were enrolled to compensate for potential losses.

Statistical Analysis

Comparisons were performed at the participant level. Data from participants with a recorded outcome were analyzed according to randomization group. ICUs with incomplete patient recruitment were included in primary outcome analyses considering all participants available in the cluster. Missing data

for the primary outcome were not imputed, except in sensitivity analyses. Multiple imputation was used for missing values in analyses of HADS, CCFNI, and MBI subscales.

The primary outcome was assessed using generalized estimating equations (GEE) with adjustment for cluster and period effects and for interaction between intervention and period. Prespecified subgroups were defined according to baseline risk of delirium assessed by the Prediction of Delirium in ICU Patients (PRE-DELIRIC)²⁷ score and severity assessed by the Acute Physiology and Chronic Health Evaluation II (APACHE-II)²⁸ score and according to reason for ICU admission (medical vs surgical and neurocritical vs nonneurocritical); consistency of intervention effects on the primary outcome across these subgroups was assessed by means of interaction tests. The daily hazard of delirium was evaluated using a joint model that accounted for the treatment effect on the repeated daily indicator of delirium within each patient and terminating event (death or discharge from the ICU).²⁹ Likelihood ratio testing confirmed that this model satisfied the proportional hazards assumption. The prevalence of burnout was analyzed using GEE with adjustment for cluster effect and baseline MBI total scores. Tertiary clinician outcomes were analyzed using GEE with adjustment for cluster effect. Additional outcomes were assessed using the same model used for the primary outcome.

Prespecified sensitivity analyses for the primary outcome included evaluation of flexible visitation effects on delirium, adjusted for baseline PRE-DELIRIC score and cluster adherence to flexible visitation implementation, and consideration of the potential confounding effect of sedation on delirium diagnosis as well as a best- or worst-plausible-scenario imputation of outcomes among ICUs with incomplete recruitment. Prespecified sensitivity analyses for secondary outcomes were as follows: assessment of flexible visitation effects on family member HADS scores, considering scores as categorical outcomes with relevant cutoff points (>10 points for probable cases of anxiety or depression)²⁴ and adjusting analyses by history of anxiety or depression; assessment of flexible visitation effects on family member CCFNI total and domain scores using the Coen *d* statistic³⁰ to determine effect size of differences (effect sizes ≤ 0.2 were considered small; 0.3-0.7, medium; and ≥ 0.8 , large); and assessment of flexible visitation effects on staff burnout, considering alternative MBI criteria.³¹ Additional post hoc sensitivity and subgroup analyses are described in the eMethods in Supplement 2.

Bonferroni correction was applied to adjust subgroup analyses and secondary outcomes for multiple comparisons. *P* values and 95% CIs of secondary outcomes were adjusted taking into consideration the number of comparisons within each population of interest (patients [5 comparisons], family members [3 comparisons]). ICU-acquired infections and burnout were not adjusted for multiplicity, to increase the power to detect differences in these adverse event outcomes. Tertiary outcomes and secondary analyses that were not corrected for multiplicity should be interpreted as exploratory.

A 2-sided *P* value less than .05, adjusted for multiplicity when appropriate, was established as the level of signifi-

cance for all comparisons. All analyses were performed using R version 3.5.1 (R Development Core Team).

Results

Trial Centers and Participants

A total of 151 ICUs were invited to participate in the trial (Figure 1 and Figure 2). Of these, 40 were enrolled. Four randomized ICUs withdrew consent before study initiation. Therefore, 36 ICUs were analyzed. Because of the slow rate of recruitment, 7 ICUs did not complete the recruitment goal of 50 patients per ICU (3 starting with flexible visitation, 4 starting with restricted visitation). Of these, 2 ICUs did not cross over to phase 2 (1 starting with flexible visitation and 1 starting with restricted visitation).

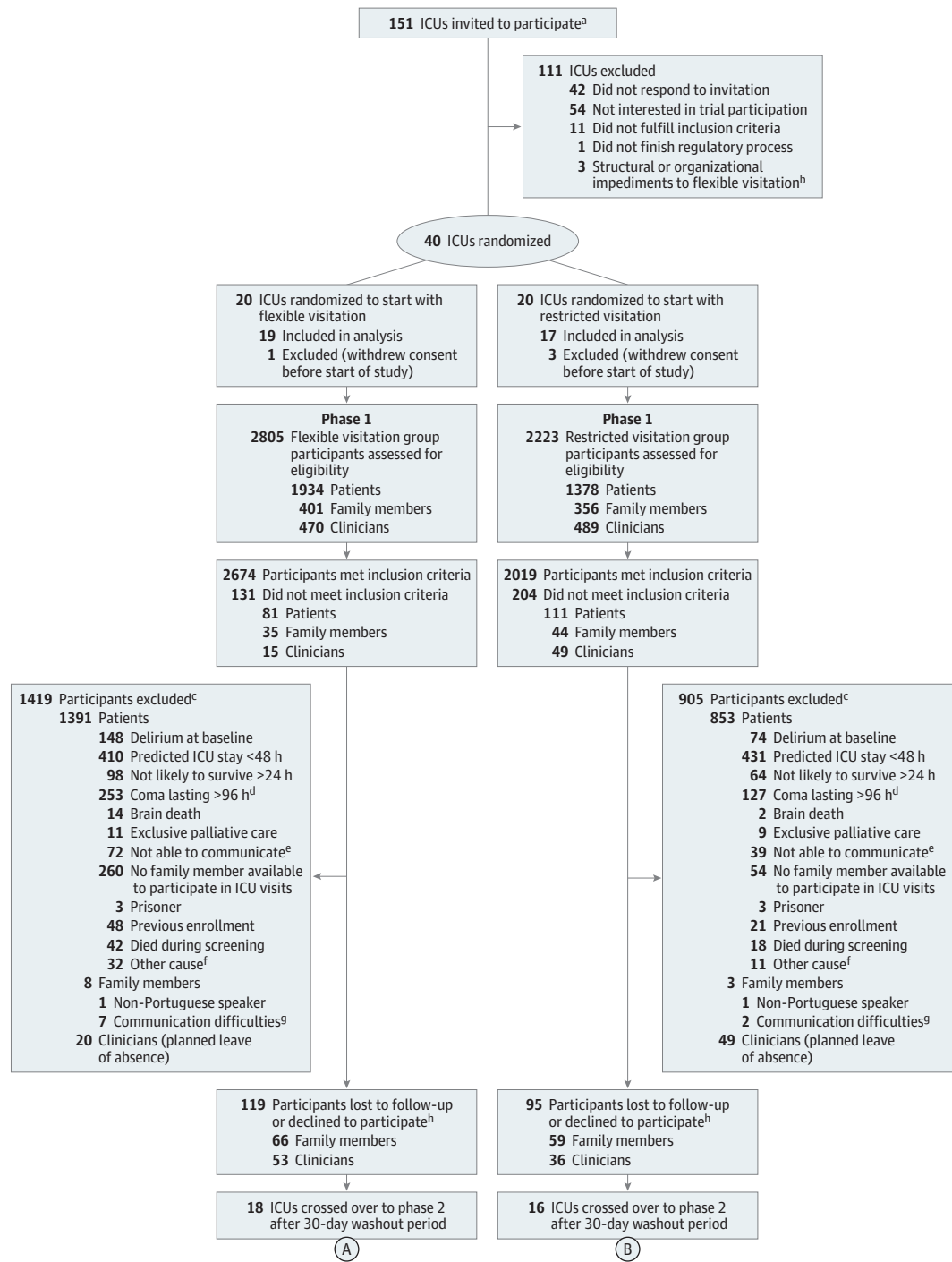
From April 2017 to June 2018, a total of 5837 patients, 1508 family members, and 959 clinicians were screened (Figure 1 and Figure 2; eTable 2 in Supplement 2). The number of patients excluded because of absence of a family member available to participate in ICU visits was higher in the flexible visitation group (15.5% vs 6.8%). There were no other differences between interventions regarding causes of participant exclusion. A total of 1685 patients, 1295 family members, and 826 clinicians were enrolled. No patients were lost to follow-up, although data for the primary outcome were not available for 9 patients (6 in the flexible visitation group, 3 in the restricted visitation group). Among family members, 235 (18.1%) were lost to follow-up or declined to participate (120 in the flexible visitation group, 115 in the restricted visitation group). Among clinicians, 89 (10.7%) were lost to follow-up or declined to participate (53 in the flexible visitation group, 36 in the restricted visitation group). The characteristics of family members and clinicians who were lost to follow-up or declined to participate did not differ significantly between the flexible visitation and restricted visitation groups (eTable 3 in Supplement 2).

A total of 1685 patients (1676 for the primary outcome analysis), 1060 family members, and 737 clinicians were analyzed. The characteristics of ICUs are summarized in eFigure 2 and eTable 4 in Supplement 2. The baseline characteristics of the participants enrolled in flexible visitation and of those enrolled in restricted visitation were similar (Table 1).

Interventions

The median duration of intervention was 3.2 months for flexible visitation (IQR, 2.4-4.6) and 3.0 months for restricted visitation (IQR, 2.1-3.8) (adjusted difference, 0.2 months [95% CI, -1.0 to 0.5]; *P* = .85). The mean adherence of ICUs to implementation of flexible visitation was 90% (95% CI, 87% to 92%) (eFigure 3 in Supplement 2). The daily mean duration of visits was significantly higher for flexible visitation than for restricted visitation: 4.8 hours vs 1.4 hours (adjusted difference, 3.4 hours [95% CI, 2.8 to 3.9]; *P* < .001) (Figure 3). There was no significant difference in the mean number of visitors per day between flexible visitation and restricted visitation (1.9 vs 1.9; adjusted difference, -0.06 [95% CI, -0.29 to 0.17]; *P* = .63).

Figure 1. Enrollment, Randomization, and Follow-up in the ICU Visits Study



Continued on Figure 2

ICU indicates intensive care unit.

^a ICUs of public and private nonprofit hospitals from all 5 geopolitical regions of Brazil, all of which have participated in previous studies of the Brazilian Research in Intensive Care Network (BRICNet) or were recommended by the Brazilian Ministry of Health, were invited to participate in the trial.

^b According to the minimum requirements for the operation of ICUs in Brazil, which include multidisciplinary care (intensivist, nurse, nurse technician, and physiotherapist at minimum) and access to monitoring devices, organ support therapies, and specialty care services.

^c Causes of exclusion listed in eTable 2 in Supplement 2.

^d Richmond Agitation Sedation Scale score -4 or -5. Values range from -5 (unarousable) to +4 (combative); eg, a score of -4 indicates no response to voice but movement or eye opening in response to physical stimulation, and a score of -5 indicates no response to voice or physical stimulation.

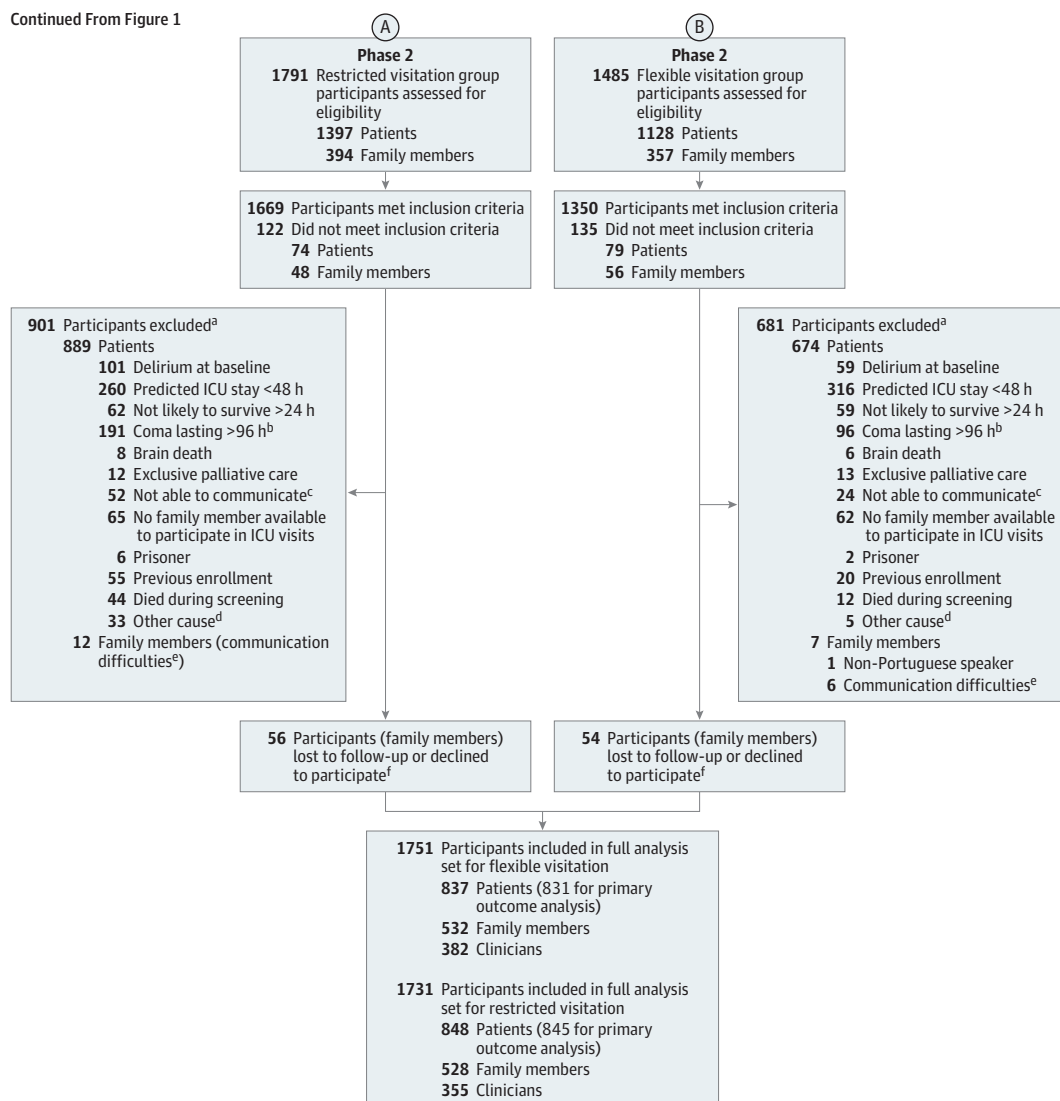
^e Aphasia or severe hearing deficit.

^f ICU discharge, transfer, or end of cluster recruitment during the assessment of eligibility criteria.

^g Illiteracy or severe visual or hearing impairments.

^h Data on causes of follow-up losses were not collected.

Figure 2. Enrollment, Randomization, and Follow-up in the ICU Visits Study (Continued)



^a Causes of exclusion listed in eTable 2 in Supplement 2.

^b Richmond Agitation Sedation Scale score -4 or -5. Values range from -5 (unarousable) to +4 (combative); eg, a score of -4 indicates no response to voice but movement or eye opening in response to physical stimulation, and a score of -5 indicates no response to voice or physical stimulation.

^c Aphasia or severe hearing deficit.

^d ICU discharge, transfer, or end of cluster recruitment during the assessment of eligibility criteria.

^e Illiteracy or severe visual or hearing impairments.

^f Data on causes of follow-up losses were not collected.

Primary and Secondary Outcomes

Results for the primary and secondary study outcomes are summarized in Table 2. There was no significant difference in the primary outcome between the interventions: delirium occurred in 157 of 831 patients (18.9%) in the flexible visitation group and in 170 of 845 patients (20.1%) in the restricted visitation group (risk ratio [RR], 0.91 [95% CI, 0.73 to 1.15]; adjusted difference, -1.7% [95% CI, -6.1% to 2.7%]; $P = .44$). The results of sensitivity analyses for the primary outcome were similar to those of the main analysis (eTable 5 in Supplement 2). There was no significant heterogeneity in flexible visitation effect on the primary outcome across subgroups of pa-

tients (eFigure 4 in Supplement 2). A post hoc analysis showed no association between duration of visits and incidence of delirium (eTable 6 in Supplement 2).

Flexible visitation effects were not significantly different from restricted visitation effects for daily hazard of delirium (0.09 vs 0.10; hazard ratio, 0.88 [95% CI, 0.74 to 1.04]; adjusted difference, -0.02 [95% CI, -0.13 to 0.09]; $P = .52$), incidence of ICU-acquired infections (3.7% vs 4.5%; RR, 0.81 [95% CI, 0.51 to 1.29]; adjusted difference, -0.8% [95% CI, -2.1% to 1.0%]; $P = .38$), mean 7-day ventilator-free days (5.9 vs 6.0; adjusted difference, -0.01 days [95% CI, -0.05 to 0.03]; $P = .99$), median days of ICU stay (5.0 vs 5.0; adjusted difference, -0.02

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)

(continued)

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)

Abbreviations: APACHE-II, Acute Physiology and Chronic Health Disease Classification System II; ICU, intensive care unit; IQR, interquartile range; PRE-DELIRIC, Prediction of Delirium in ICU Patients; SOFA, Sequential Organ Failure Assessment.

^a Unless otherwise stated.

^b Scores range from 0 to 33, with higher scores indicating greater comorbidity.

^c Alcohol consumption of 14 units or more per week for women and 21 units or more per week for men.

^d Scores range from 0 to 1.0, with higher scores indicating higher risk of ICU delirium. For example, a score of 0.15 represents 15% risk of delirium during ICU stay.²⁷

^e Within 24 hours of inclusion in the study.

^f Scores range from 0 to 71, with higher scores indicating a more severe condition. For example, a score from 10 to 14 represents a 15% risk of hospital mortality among medical patients and a 6% risk of hospital mortality among surgical patients.²⁸

^g Scores range from 0 to 24, with higher scores indicating greater organ dysfunction. For example, a score of 4 may be observed in a patient with decreased consciousness who requires a vasopressor for hypotension.

^h Morphine, methadone, and remifentanyl.

ⁱ Propofol, midazolam, fentanyl, remifentanyl, dexmedetomidine, and ketamine.

^j Diazepam, midazolam, alprazolam, lorazepam, flunitrazepam, clonazepam, and chlordiazepoxide.

^k Although up to 2 close family members received flexible visitation privileges, only 1 family member per patient was enrolled in the study (identified by family as the closest to the patient).

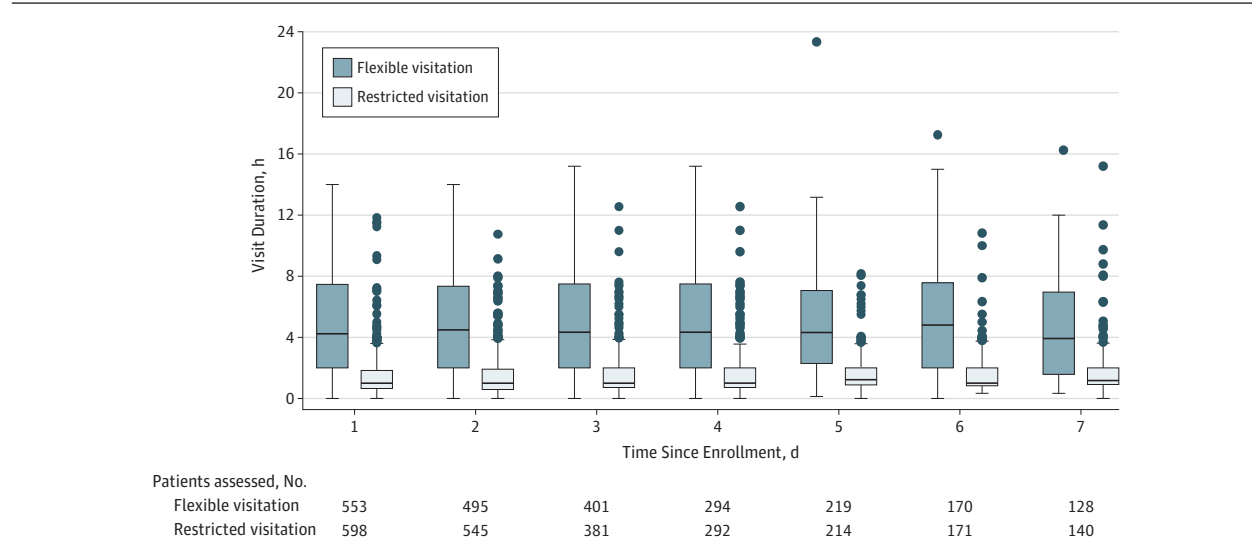
^l Using the 2017 purchasing power parity conversion (US \$1 = R\$2.02).

^m Bedside nursing care in Brazil is often delivered by nurse technicians under the supervision of a nurse.

days [95% CI, -0.15 to 0.09]; $P = .99$), and hospital mortality (14.8% vs 14.4%; RR, 1.01 [95% CI, 0.77 to 1.32]; adjusted difference, 0.2% [95% CI, -3.7% to 4.0%]; $P = .99$).

In family members, flexible visitation resulted in significantly better median scores for HADS anxiety (6.0 vs 7.0; adjusted difference, -1.6 points [95% CI, -2.3 to -0.9]; $P < .001$) and HADS depression (4.0 vs 5.0; adjusted difference, -1.2 points [95% CI, -2.0 to -0.4]; $P = .003$) and mean scores for CCFNI satisfaction (146.1 vs 132.6; adjusted difference, 13.5 points [95% CI, 10.4 to 16.7]; $P < .001$), compared with restricted visitation. Sensitivity analyses of the HADS (eTable 7 in Supplement 2) showed that flexible visitation resulted in significantly lower prevalence of probable clinical anxiety (13.4% vs 28.2%; prevalence ratio [PR], 0.48 [95% CI, 0.35 to 0.66]; adjusted difference, -14.6% [95% CI, -20.8% to -8.3%];

Figure 3. Daily Mean Duration of Visits in Each Visitation Model



Daily mean duration of visits per patient is considered the length of stay of all visitors (whether they were family members) at the bedside of an enrolled patient. The box plot inner horizontal lines indicate median; boxes, interquartile

range (25th and 75th percentiles); vertical whiskers, 1.5 interquartile range beyond the 25th and 75th percentiles; and dots, more extreme values.

$P < .001$) and depression (8.1% vs 17.7%; PR, 0.46 [95% CI, 0.28 to 0.76]; adjusted difference, -9.5% [95% CI, -15.3% to -3.7%]; $P = .001$). The adjustment of HADS scores by history of anxiety or depression did not change the results of primary analyses (eTable 7 in Supplement 2).

Sensitivity analyses of CCFNI domains (eTable 8 in Supplement 2) showed significantly better mean scores with flexible visitation than with restricted visitation in proximity (31.5 vs 27.6; adjusted difference, 3.9 points [95% CI, 3.2 to 4.7]; $P < .001$; effect size, 0.83 [95% CI, 0.70 to 0.96]), information (27.8 vs 25.2; adjusted difference, 2.6 points [95% CI, 1.9 to 3.2]; $P < .001$; effect size, 0.59 [95% CI, 0.46 to 0.72]), reassurance (25.3 vs 23.5; adjusted difference, 1.7 points [95% CI, 1.1 to 2.3]; $P < .001$; effect size, 0.50 [95% CI, 0.38 to 0.63]), comfort (19.0 vs 17.4; adjusted difference, 1.5 points [95% CI, 0.9 to 2.1]; $P < .001$; effect size, 0.42 [95% CI, 0.30 to 0.55]), and support (42.4 vs 38.9; adjusted difference, 3.7 points [95% CI, 2.6 to 4.8]; $P < .001$; effect size, 0.49 [95% CI, 0.37 to 0.62]).

Post hoc subgroup analysis showed better HADS and CCFNI scores with flexible visitation, both for family members who accessed the website and for those who did not (eTable 9 in Supplement 2).

For ICU staff, the prevalence of burnout did not differ significantly between the flexible visitation and restricted visitation groups (22.0% vs 24.8%; PR, 0.89 [95% CI, 0.70 to 1.14]; adjusted difference, -3.8% [95% CI, -4.8% to 12.5%]; $P = .36$). Sensitivity analyses considering alternative MBI criteria and incident cases did not change this finding (eTable 10 in Supplement 2). A post hoc subgroup analysis did not find significant differences in the prevalence of burnout between the interventions across subgroups of clinicians (eTable 11 in Supplement 2).

Additional post hoc sensitivity analyses were conducted to assess the consistency of intervention effects on length of

visits and primary and secondary outcomes (eTable 12 and eTable 13 in Supplement 2). Adjustment for number of ICU beds did not change the conclusions of the main analyses. Additionally, there was no evidence of interaction between the ICU intervention sequence and the effects of interventions on length of visits and primary and secondary outcomes.

Tertiary Outcomes

There were no significant differences between the interventions in tertiary patient outcomes (Table 3). The mean score of family self-perception of involvement in patient care was significantly higher with flexible visitation than with restricted visitation (13.8 vs 8.4; adjusted difference, 5.3 points [95% CI, 4.1 to 6.4]; $P < .001$). This result was consistent across multiple domains of patient care, including reorientation, emotional support, helping ICU staff understand patient needs, pain control, and mobilization (eFigure 5 in Supplement 2). For ICU staff, flexible visitation and restricted visitation did not differ significantly regarding the mean score of satisfaction with visiting policy (2.5 vs 2.4; adjusted difference, 0.1 point [95% CI, -0.1 to 0.3]; $P = .27$), the median score of perceptions regarding disorganization of care (1.0 vs 0; adjusted difference, 0.1 point [95% CI, -0.01 to 0.4]; $P = .06$), and conflicts with visitors (3.9% vs 4.8%; RR, 0.83 [95% CI, 0.37 to 1.87]; adjusted difference, -0.7% [95% CI, -4.1% to 2.6%]; $P = .67$).

Discussion

In this cluster-crossover randomized clinical trial performed in adult ICUs, a flexible family visitation policy supported by family education did not significantly reduce the incidence of delirium among patients compared with standard restricted visitation.

Table 2. Primary and Secondary Study Outcomes

Outcome	Visitation, No./Total (%)		Adjusted Difference (95% CI)	Relative Effect of Flexible Visitation (95% CI) ^{a,b}	P Value ^b
	Flexible	Restricted			
Primary					
Incidence of delirium ^c	157/831 (18.9)	170/845 (20.1)	-1.7 (-6.1 to 2.7)	0.91 (0.73 to 1.15)	.44
Secondary					
Patients					
Daily hazard of delirium ^d			-0.02 (-0.13 to 0.09)	0.88 (0.74 to 1.04)	.52
No.	831	845			
Mean (SD)	0.09 (0.23)	0.10 (0.23)			
ICU-acquired infections	31/836 (3.7)	38/846 (4.5)	-0.8 (-2.1 to 1.0)	0.81 (0.51 to 1.29)	.38
7-d ventilator-free days ^e			-0.01 (-0.05 to 0.03)	NA	.99
No.	837	848			
Mean (SD)	5.9 (2.2)	6.0 (2.1)			
ICU length of stay, d			-0.02 (-0.15 to 0.09)	NA	.99
No.	837	848			
Median (IQR)	5.0 (3.0 to 8.0)	5.0 (3.0 to 8.0)			
Hospital mortality	124/837 (14.8)	121/840 (14.4)	0.2 (-3.7 to 4.0)	1.01 (0.77 to 1.32)	.99
Family members					
HADS anxiety score ^f			-1.6 (-2.3 to -0.9)	NA	<.001
No.	529	525			
Median (IQR)	6.0 (3.0 to 8.2)	7.0 (4.0 to 11.0)			
HADS depression score ^f			-1.2 (-2.0 to -0.4)	NA	.003
No.	529	525			
Median (IQR)	4.0 (2.0 to 8.0)	5.0 (2.0 to 9.0)			
CCFNI satisfaction score ^g			13.5 (10.4 to 16.7)	NA	<.001
No.	493	483			
Mean (SD)	146.1 (18.8)	132.6 (22.9)			
ICU staff					
Burnout	84/382 (22.0)	88/355 (24.8)	-3.8 (-4.8 to 12.5)	0.89 (0.70 to 1.14)	.36

Abbreviations: CCFNI, Critical Care Family Needs Inventory; HADS, Hospital Anxiety and Depression Scale; ICU, intensive care unit; IQR, interquartile range; NA, not applicable.

^a Prevalence ratio for burnout; hazard ratio for daily hazard of delirium; risk ratio for incidence of delirium and other outcomes.

^b The Bonferroni correction was used to adjust 95% confidence intervals and P values of secondary outcomes (except ICU-acquired infections and burnout) for multiple comparisons.

^c The intraclass correlation coefficients found in this trial were 0.04 for participants in the same cluster and period and 0.03 for participants in the same cluster but in different periods.

^d Values range from 0 to 1, with higher values indicating higher daily hazard of delirium. For example, a value of 0.10 represents a daily hazard of delirium of 10%.

^e Values range from 0 to 7, with higher values indicating higher proportion of

days free of mechanical ventilation within the first 7 days. For example, a value of 6.0 means that the patient was free of mechanical ventilation on 6 days during the first 7 days. Ventilator-free days was set to 0 for patients who died.

^f Scores range from 0 to 21, with higher scores indicating worse symptoms. HADS cutoff point greater than 7 indicates possible cases of anxiety and depression. HADS cutoff point greater than 10 indicates probable cases of anxiety and depression. Among patients with chronic pulmonary obstructive disease, a minimal clinically important difference around 1.3 points has been suggested for the anxiety subscale and 1.4 points for the depression subscale; no studies have been conducted to establish a minimal clinically important difference for family members of critically ill patients.³²

^g Score assesses family satisfaction with care in 5 domains (proximity, information, reassurance, comfort, and support). Total scores range from 43 to 172, with higher scores indicating higher satisfaction.

The flexible family visitation model proposed in the present trial was feasible, as reflected by the high adherence of ICUs to implementation. However, although flexible visitation resulted in increased presence of family members at the bedside and in higher perception of involvement in multiple strategies aimed to prevent delirium, such as reorientation, mobilization, and pain control, it was insufficient to prevent delirium.³³ This finding contradicts previous before-and-after studies reporting a lower incidence of delirium with flexible visitation models.^{3,4}

Potential explanations were considered for the lack of effect of flexible visitation on delirium. The relatively short duration of implementation of flexible visitation may have mitigated the potential benefits of this intervention. A longer implementation period might have improved the ability of clinicians to engage family members in multicomponent prevention strategies for delirium. Also, the present eligibility criteria excluded a large portion of patients with increased risk for delirium (eg, patients with prolonged coma),³³ who could have benefited from delirium prevention.³⁴ Therefore, the

Table 3. Tertiary Study Outcomes

Outcome	Visitation, No./Total (%)		Adjusted Difference (95% CI)	Relative Effect of Flexible Visitation, RR (95% CI)	P Value
	Flexible	Restricted			
Patients					
Need for antipsychotic agents	121/833 (14.5)	115/846 (13.6)	0.8 (-1.9 to 3.5)	1.05 (0.87 to 1.28)	.59
Need for mechanical restraints	158/833 (19.0)	156/846 (18.4)	0.1 (-4.2 to 4.4)	1.00 (0.79 to 1.27)	.98
Unplanned loss of devices	65/833 (7.8)	65/846 (7.7)	0.2 (-1.9 to 2.3)	1.02 (0.76 to 1.36)	.89
7-d coma-free days ^a			-0.01 (-0.04 to 0.02)	NA	.66
No.	837	848			
Mean (SD)	6.3 (2.0)	6.3 (1.9)			
ICU-acquired					
Pneumonia	23/836 (2.8)	30/847 (3.5)	-0.9 (-2.6 to 0.7)	0.75 (0.44 to 1.29)	.30
UTI	4/836 (0.4)	4/846 (0.4)	0 (-1.3 to 1.3)	1.00 (0.27 to 3.74)	.99
Bloodstream infection	12/837 (1.4)	10/848 (1.2)	0.4 (-0.4 to 1.3)	1.18 (0.55 to 2.52)	.67
Family members					
Self-perception of involvement in patient care, score ^b			5.3 (4.1 to 6.4)	NA	<.001
No.	454	471			
Mean (SD)	13.8 (7.1)	8.4 (6.3)			
ICU staff					
Satisfaction with visiting policy, score, mean (SD) ^c	2.5 (1.0)	2.4 (0.9)	0.1 (-0.1 to 0.3)	NA	.27
Perception of disorganization of care, score ^d			0.1 (-0.01 to 0.4)	NA	.06
No.	382	354			
Median (IQR)	1.0 (0 to 1.0)	0 (0 to 1.0)			
Conflicts with visitors	15/382 (3.9)	17/354 (4.8)	-0.7 (-4.1 to 2.6)	0.83 (0.37 to 1.87)	.67

Abbreviations: ICU, intensive care unit; IQR, interquartile range; NA, not applicable; RR, risk ratio; UTI, urinary tract infection.

^a Values range from 0 to 7, with higher values indicating higher proportion of days free of coma (Richmond Agitation-Sedation Scale score -4 or -5) within the first 7 days. For example, a value of 6.0 means that the patient was free of coma on 6 days during the first 7 days. Coma-free days was set to 0 for patients who died.

^b Score assesses the summarized perception of family members regarding their participation in 9 domains of patient care (hygiene, pain control, mobilization, feeding, improving environment, helping ICU staff understand patient needs, helping patient interpret ICU staff instructions, emotional support, and reorientation) through a 9-question 4-point scale questionnaire. Score ranges

from 0 (no involvement) to 27 (maximum involvement). Results should be interpreted with caution, since score has not been validated.

^c Score assesses ICU staff satisfaction using a 5-point scale question ("Are you satisfied with the current visiting policy of your ICU?"). Scores range from 0 (dissatisfied) to 4 (very satisfied). Results should be interpreted with caution, since score has not been validated.

^d Score assesses ICU staff perception of disorganization of care using a 4-point scale question ("How frequently did the presence of family members result in significant disorganization of patient care in the last 2 weeks?"). Scores range from 0 (never) to 4 (always). Results should be interpreted with caution, since score has not been validated.

study may have missed a smaller difference in delirium than the 6% absolute difference used for sample size calculation.

The findings of this trial concerning infectious outcomes are consistent with those observed in previous studies, which failed to show an association between flexible ICU visiting hours and infectious complications.^{3,6,35} The present results contradict those of a before-and-after study that detected an increased risk of ICU staff burnout after partial liberalization of visiting hours¹⁵ and those of observational studies that showed an increased perception among clinicians of disorganization of care with flexible visitation.^{13,14} In the present study, the use of an educational strategy targeting visitors may have improved visitor understanding of the ICU environment and perhaps lessened any negative effect of increased duration of visits on ICU routines and staff workload.

The consistent effect of flexible visitation on family member anxiety and depression symptoms and satisfaction in this trial draws attention to the important role of ICU organization in the prevention of family dissatisfaction and psycho-

logical distress. The critical care setting may expose family members to a variety of stressors, such as problems with communication, uncertainty about patient survival or rehabilitation, and lack of support for shared decisions.³⁶ Accordingly, the better family outcomes observed with flexible visitation may have been mediated by better communication, proximity to the patient, reassurance, and support, which is suggested by the better results of flexible visitation in these domains of satisfaction.

The strengths of this trial include assessment of flexible visitation effects from the multiple perspectives needed to comprehensively appraise the intervention and use of strategies to enhance the evaluation of complex interventions, such as a learning period, cluster randomization, and assessment of fidelity of implementation.³⁷

Limitations

This study has several limitations. First, although the study recruited a large number of ICUs, the sample was limited to

1 middle-income country. Therefore, flexible visitation may have different effects across distinct sociocultural contexts. Second, data on the characteristics of ICUs not enrolled in the study, and causes of participant losses to follow-up, were not collected. Third, cluster randomization was susceptible to recruitment bias, since participants were aware of the interventions. Some imbalance in number and causes of participant exclusion and follow-up losses might have resulted from this phenomenon. Nevertheless, baseline characteristics of participants were well balanced. Fourth, although this study used a washout period and sensitivity analyses did not show evidence of significant interaction between intervention effects and sequence of ICU interventions (flexible visitation in phase 1 or restricted visitation

in phase 1), the risk of carryover effect still exists. Fifth, the effect of the educational component of the flexible visitation model on family members cannot be isolated from flexible visiting hours. Sixth, this study did not evaluate the effects of flexible visitation on long-term outcomes. The length of clinician follow-up may have been insufficient to properly assess burnout.

Conclusions

Among patients in the ICU, a flexible family visitation policy, vs standard restricted visiting hours, did not significantly reduce the incidence of delirium.

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Accepted for Publication: June 3, 2019.

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Conflict of Interest Disclosures: Dr Falavigna reported receiving grants from Associação Hospitalar Moinhos de Vento and receiving other from HTAnalyze Economia e Gestão em Saúde. Dr Eugênio reported receiving grants from Associação Hospitalar Moinhos de Vento. Dr Barbosa reported grants from Associação Hospitalar Moinhos de Vento. Dr Pellegrini reported receiving grants from Associação Hospitalar Moinhos de Vento. Dr Torelly reported receiving grants from Associação Hospitalar Moinhos de Vento. Dr Ayres reported receiving grants from Hospital Moinhos de Vento. Dr Duarte reported receiving grants from SUS/Sistema Único de Saúde—Brazilian Health Ministry. Dr Lovato reported receiving grants from Associação Hospitalar Moinhos de Vento. Dr de Oliveira Júnior reported receiving grants from Associação Hospitalar Moinhos de Vento. Dr Paranhos reported receiving grants from Associação Hospitalar Moinhos de Vento. Dr Dantas reported receiving grants from Associação Hospitalar Moinhos de Vento. Dr Paulo reported receiving grants from Associação Hospitalar Moinhos de Vento. Dr Pilau reported receiving grants from Associação Hospitalar Moinhos de Vento. Dr Castro reported receiving grants from Associação Hospitalar Moinhos de Vento. No other disclosures were reported.

Funding/Support: This study was funded by the Brazilian Ministry of Health through the Brazilian Unified Health System Institutional Development Program (PROADI-SUS).

Role of the Funder/Sponsor: The Brazilian Ministry of Health had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or

approval of the manuscript; and decision to submit the manuscript for publication.

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Meeting Presentation: Presented in part at the 31st European Society of Intensive Care Medicine Congress; October 24, 2018; Paris, France.

Data Sharing Statement: See Supplement 3.

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