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Study protocol to assess the effectiveness and safety of a flexible family visitation model for delirium prevention in adult intensive care units: a cluster-randomised, crossover trial (The ICU Visits Study)

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ABSTRACT

Introduction Flexible intensive care unit (ICU) visiting hours have been proposed as a means to improve patient-centred and family-centred care. However, randomised trials evaluating the effects of flexible family visitation models (FFVMs) are scarce. This study aims to compare the effectiveness and safety of an FFVM versus a restrictive family visitation model (RFVM) on delirium prevention among ICU patients, as well as to analyse its potential effects on family members and ICU professionals.

Methods and analysis A cluster-randomised crossover trial involving adult ICU patients, family members and ICU professionals will be conducted. Forty medical-surgical Brazilian ICUs with RFVMs (<4.5 hours/day) will be randomly assigned to either an RFVM (visits according to local policies) or an FFVM (visitation during 12 consecutive hours per day) group at a 1:1 ratio. After enrolment and follow-up of 25 patients, each ICU will be switched over to the other visitation model, until 25 more patients per site are enrolled and followed. The primary outcome will be the cumulative incidence of delirium among ICU patients, measured twice a day using the Confusion Assessment Method for the ICU. Secondary outcome measures will include daily hazard of delirium; ventilator-free days, any ICU-acquired infections, ICU length of stay and hospital mortality among the patients; symptoms of anxiety and depression and satisfaction among the family members; and prevalence of burnout symptoms among the ICU professionals. Tertiary outcomes will include

Strengths and limitations of this study

► The present study is the first large-scale trial aimed to evaluate the effects of different intensive care unit (ICU) visiting policies on relevant outcomes among patients, family members and ICU professionals.

► This study is designed as a cluster-randomised crossover trial, which reduces the risk of contamination and improves covariate balance between the two study arms and statistical efficiency.

► This study uses strategies to enhance the implementation and evaluation of complex interventions such as some degree of adaptability to local circumstances, a learning period to study interventions and assessment of fidelity and quality of the implementations.

► The infeasibility of blinding patients, family members and ICU professionals to the study interventions is a limitation.

► The results of this study will allow healthcare professionals, researchers and policymakers to draw conclusions about the efficacy and safety of a flexible family visitation model for delirium prevention in adult ICUs.

need for antipsychotic agents and/or mechanical restraints, coma-free days, unplanned loss of invasive devices and ICU-acquired pneumonia, urinary tract infection or bloodstream

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infection among the patients; self-perception of involvement in patient care among the family members; and satisfaction among the ICU professionals.
Ethics and dissemination The study protocol has been approved by the research ethics committee of all participant institutions. We aim to disseminate the findings through conferences and peer-reviewed journals.
Trial registration NCT02932358.

INTRODUCTION

Adult intensive care unit (ICU) visitation policies vary worldwide; generally, patients admitted to the ICU are only allowed visitors during certain periods of the day.[1–3] Congruent with this scenario, most Brazilian ICUs have a restrictive policy of family visits in which visiting hours typically last from 30 min to 1 hour, two to three times a day.[4] These restrictive ICU visit policies are rooted mainly in a theoretical increased risk of physiological stress, infectious complications and disorganisation of care.[5] However, these theoretical risks have not been consistently confirmed by the scarce literature on this subject,[6–9] and flexible ICU visiting hours have been proposed as a means to improve outcomes through patient-centred and family-centred care and delirium prevention.[10–12]

Evidence from small observational and before-and-after studies suggests that flexible ICU visitation policies are associated with higher satisfaction among patients and patients' families and with reduction of patient stress.[13 14] Accordingly, one pilot randomised trial showed reduction in cardiocirculatory complications among ICU patients admitted during periods of unrestricted visiting hours, possibly due to reduction of anxiety and establishment of a more favourable hormonal profile.[6] Moreover, some studies suggest the potential role of presence of family members as a strategy to prevent ICU delirium.[15–17] One small prospective single-centre before-and-after study found a reduction of 50% in the cumulative incidence of delirium by changing the visitation policy from a restrictive model (4.5 hours/day) to an extended model (12 hours/day); the length of delirium and ICU stay was also reduced in this study.[12] In this regard, the presence of family in the critical care setting is suggested as a means to achieve better pain control, reduce the use of sedatives and participate in the reorientation and cognitive stimulation of patients. These benefits have been associated with lower incidence of delirium in studies evaluating multicomponent non-pharmacological interventions to prevent delirium and constitute the rationale for the F (Family Engagement and Empowerment) component of the ABCDEF bundle, an evidence-based approach to prevent delirium.[18–21]

Regarding possible risks associated with flexible ICU visit policies, some studies have shown that ICU professionals sometimes perceive visits as a source of increased workload and disorganisation in patient care, instead of considering families as 'one' with the patient and as potential sources of reassurance and comfort.[22 23] In a single-centre study,[23] 59% of ICU staff members stated that the open visitation policy impaired the organisation of patient care, and 72% believed that their work suffered more interruptions due to the extended presence of families in the ICU. Congruent with these data, one before-and-after study with nine ICUs[8] showed a significant increase in burnout levels among ICU professionals after a partial liberalisation of visiting policies. The impact of educational strategies directed to ICU visitors in the context of flexible family visitation policies to prevent disorganisation of patient care and burnout among ICU professionals is not known. In relation to the risk of infection, this topic has been evaluated by few underpowered studies.[7 12 15] Although one study[15] showed greater environmental microbial contamination during an open policy of ICU visitation, published studies[7 12 15] failed to show an association between flexible ICU visiting hours and nosocomial infection. Lastly, the impact of flexible ICU visiting hours on symptoms of anxiety and depression of family members is not well studied: there is plausibility for decreased anxiety and depression with flexible ICU visiting hours as a result of improved access to information and more effective sharing of the decision-making process[24]; conversely, it is also plausible to assume that anxiety and depression will increase as a result of higher exposure of family members to complex situations such as terminality and the patient's emotional and physical suffering.[25 26]

The implementation of a flexible family ICU visitation policy, although promising due to its low cost and potential to improve quality of care, is a complex organisational process, given that multiple populations involved in this context may be affected by the intervention in different ways. Additionally, most evidence regarding this intervention is originated from underpowered observational and before-and-after studies. Specifically, no large-scale randomised trial so far has evaluated the potential impact of different ICU visitation models on patient, family and ICU staff outcomes. We hypothesise that compared with the restrictive family visitation model (RFVM), a flexible family visitation model (FFVM) supported by visitor education will reduce the cumulative incidence of delirium among adult ICU patients, reduce symptoms of anxiety and depression and increase satisfaction with care among family members without increasing burnout levels among ICU professionals.

OBJECTIVES

Primary objective

The aim of the present study is to assess if an FFVM, compared with an RFVM, can prevent delirium in adult ICU patients.

Secondary objectives

Our secondary objective is to compare the efficacy and safety of both ICU visitation models with regard to three sets of variables: ICU/patient-related variables (daily hazard of delirium, ventilator-free days, ICU-acquired infections, ICU length of stay, all-cause hospital mortality, need for
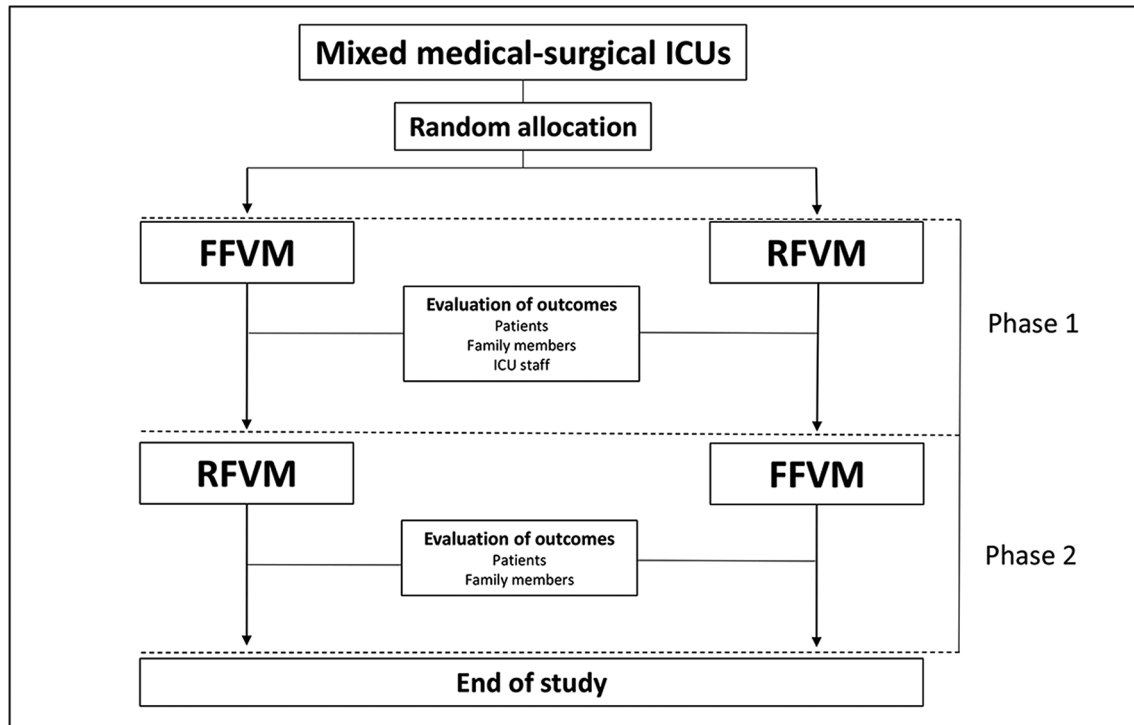
Figure 1 Study design. During the study, the ICU intervention (FFVM or RFVM) will be applied to all admitted patients apart of meeting inclusion criteria for the study. The length of study phases in each ICU will be determined by the patient recruitment rate (25 patients in phase 1 and 25 patients in phase 2). Patients and family members will be recruited during phases 1 and 2. ICU professionals will be evaluated and followed up only during the phase 1. Following the recruitment of the 25th patient, during phase 1, a 30-day period without subject recruitment will occur to allow appropriate conclusion of the follow-up of all recruited patients for the study outcomes and to avoid contamination of the two study arms. FFVM, flexible family visitation model; ICUs, intensive care units; RFVM, restrictive family visitation model.

antipsychotic use, coma-free days, need for mechanical restraints and unplanned loss of invasive devices), family-related variables (symptoms of anxiety and depression, satisfaction and self-perception of involvement in patient care) and ICU staff variables (prevalence of symptoms of burnout syndrome and satisfaction).

METHODS
The present study protocol follows the Standard Protocol Items: Recommendations for Interventional Trials statement recommendations.[27] The items from the WHO trial registration data set are described in online supplementary file 1. This study protocol was registered at Clinicaltrials.gov before the randomisation of the first cluster (NCT02932358) .

Study design
The present study was designed to be a cluster-randomised, crossover trial involving mixed medical-surgical ICUs. In this study, the unit of randomisation is the ICU, since the proposed intervention involves components at the organisational level and is intended to be implemented in the whole ICU and not for selected patients. All ICUs will receive both FFVM and RFVM, and the randomisation will determine in which order the visitation models will be evaluated in

each ICU (figure 1). The initial intervention (phase 1) will involve ICU randomisation to either an FFVM or an RFVM. In phase 2, each ICU will be crossed over to the other visitation model. The study analysis will be performed at the subject level according to the intention-to-treat principle and accounts for the cluster-randomised crossover design.

Participants
Cluster eligibility, recruitment and exclusion criteria
Brazilian adult ICUs of public and philanthropic hospitals will be invited to participate in the trial. Mixed medical-surgical ICUs with at least six beds and a restrictive policy of family visitation (<4.5 hours/day) are considered eligible. ICUs with structural or organisational impediments to flexible family visitation, according to the Brazilian resolution of minimal operational requirements for ICUs,[28] will be excluded.

Patient eligibility, recruitment and exclusion criteria
Consecutive patients aged ≥18 years admitted to the ICU during phases 1 and 2 will be enrolled in each cluster. Subjects in a coma (Richmond Agitation Sedation Scale (RASS)[29] −4 or −5) lasting >96 hours from the moment of first evaluation for recruitment and those with delirium at baseline (positive Confusion Assessment Method for ICU (CAM-ICU)[30]) will be excluded. The following exclusion

criteria will also be applied: cerebral death, aphasia, severe hearing deficit, predicted ICU length of stay <48 hours, exclusive palliative treatment at ICU admission, unavailability of a family member to participate in the flexible family visits, unlikelihood to survive >24 hours, prisoner status and, lastly, readmission to the ICU after enrolment in the study.

Family member eligibility, recruitment and exclusion criteria

The sample of family members will include one family member per patient enrolled into the study, with the closest family member being selected. Family members who do not speak Portuguese or have serious impediment in answering the self-applied questionnaires (eg, illiteracy or severe visual or hearing limitations) will be excluded.

ICU professionals' eligibility, recruitment and exclusion criteria

All bedside ICU professionals (physicians, nurses, nursing technicians and physiotherapists) of each cluster who assist patients during the daytime for at least 20 hours per week will be enrolled. ICU professionals who have a

planned leave of absence of >15 days during phase 1 will be excluded.

Interventions

The proposed study interventions may be classified as complex because[31]: (A) there is a large number of interacting components within the experimental and control interventions (eg, changes in ICU processes, education of family members and engagement and training of the ICU multidisciplinary team); (B) there are several groups targeted by the intervention (ICU patients, family members and ICU professionals); (C) there is a large number and high variability of outcomes (evaluation of different outcome domains in three different target populations); (D) a limited degree of flexibility in the intervention is allowed (educational components may be tailored considering the educational level of the target population, visit hours may be customised according to internal processes of the ICU and expected acceptability of the target population).

Table 1 Components of study interventions

	RFVM	FFVM
Social visits	X	X
Friends and family members allowed (number of simultaneous visitors allowed in patient's room tailored to ICU preferences)		
Max 4.5 hours per day (according to ICU policies prior to randomisation)		
Family visits		X
Up to two family members allowed (number of simultaneous visitors allowed in patient's room tailored to ICU preferences)		
Maximum of 12 hours per day		
Family members must attend a structured information meeting		
Information meeting		X
For family members who want to participate in the family visits		
Guidance about ICU environment, multidisciplinary work at ICU, common ICU treatments, palliative care, infection control practices, delirium prevention and rehabilitation		
Meeting conducted by a trained healthcare professional that works in the ICU (at least 3x/week)		
Both printed and digital material offered by the study coordinator site (tailored for the specific ICU preferences)		
Printed material focused on patient safety during ICU visits	X	X
Brochure with information about what is allowed and what is not allowed in a social visit		
Printed material focused on education about ICU environment, practices and family engagement on patient care		X
Brochure with information about ICU environment, multidisciplinary work at ICU, common ICU treatments, palliative care, infection control practices, delirium prevention, rehabilitation and family engagement on patient care		
Access to a website focused on education about ICU environment, practices and family engagement on patient care		X
Website with information about ICU environment, multidisciplinary work at ICU, common ICU treatments, palliative care, infection control practices, delirium prevention, rehabilitation and family engagement on patient care		

FFVM, flexible family visitation model; ICU, intensive care unit; RFVM, restrictive family visitation model.

We tested the feasibility and acceptability of implementation of the intervention in a single-centre before-and-after study.[12] Table 1 shows the components to be implemented during FFVM and RFVM. During both FFVM and RFVM, all visitors will be required to perform hand hygiene by washing their hands with antiseptic soap or using alcohol-based hand-rub formulations and to wear disposable vests and/or personal protective equipment when appropriate (eg, contact or droplet precautions). All visitors will receive oral and written guidance about the minimum requirements to promote a safe and restful environment to ICU patients. The visitors will be asked to leave the room during some procedures such as intubation, central venous or urinary catheterisation, bronchoscopy, electrical cardioversion and cardiopulmonary resuscitation. As an exception, some patients, during both study interventions, will be allowed to receive visits longer than the maximum limit of visiting hours. This decision will be allowed in the following situations: patient age ≥65 years, terminal illness and conflicts among patients or family and ICU staff.

Flexible family visitation model

In the FFVM, two or fewer close family members will be allowed to visit the patient for up to 12 consecutive hours each day. Family members who agree to join the family visits will have to attend a structured meeting at the ICU in which they will receive guidance about the ICU environment, common ICU treatments, rehabilitation and basic infection control practices, multidisciplinary work at the ICU and information on palliative care and delirium prevention. Additionally, family members will receive an information brochure and be encouraged to access a website (www.utivisitas.com.br), both of which are designed to explain, in simple terms, what happens during and after an ICU stay to legitimise emotions and improve cooperation with relatives without increasing the ICU staff workload. In addition to family visitation, patients in the FFVM will be allowed to receive social visits at specific time intervals (according to the local ICU policies). Social visits will be offered to patient's friends or other family members who did not qualify for family visitation. The number and duration of social visits will be determined by the patient or proxies. Social visitors will not be required to attend the structured meeting.

Restrictive family visitation model

In the RFVM, patients will be allowed visitors according to routine ICU practices but limited to the maximum of 4.5 hour of visitation per day. Visitors will not be required to attend the structured meeting, because this is the standard of care in Brazil. The length of ICU visiting hours will be similar to that of social visits in the FFVM. The number and duration of visits will be determined by the patient or proxies taking into the account the limits of visiting hours dictated by local policies.

Randomisation

The randomisation unit is the ICU. In hospitals where there is more than one ICU, each ICU will be considered a distinct randomisation units as long as the ICU staff are different. If the staff are the same, all ICUs in the hospital will be considered a single unit of randomisation. The allocation of the initial intervention (ie, FFVM or RFVM) will be performed through blocks of different sizes and stratified by number of ICU beds. A randomisation list will be generated, and ICUs will be consecutively randomised as per the date of approval by the local research ethics committee. In order to guarantee allocation concealment, a statistician will receive an identification code for each unit but will remain blinded to the identity of the ICU. The statistician will then inform the allocation for each unit identification code to the research coordinator. Lastly, the research coordinator will inform the ICUs regarding the group to which they were initially allocated.

Blinding

It is not feasible to blind the researchers, patients, family members or ICU professionals to the study interventions.

Outcomes
Primary outcome

The primary outcome is the cumulative incidence of delirium during the ICU stay. Diagnosis of delirium will be made using the validated Brazilian translation of the CAM-ICU,[32] which will be applied at least once per 12 hours shift in patients with RASS ≥−3, by trained ICU professionals. The cumulative incidence of delirium is defined as the presence of delirium (at least one positive CAM-ICU) on at least one 12-hour shift during the ICU stay. Before study initiation, all professionals responsible for CAM-ICU assessment will receive training concerning the CAM-ICU. This specific training will be given both during investigator meetings and on-site. Furthermore, inter-rater reliability measurements of the CAM-ICU and RASS will be performed before study initiation to evaluate the quality of assessments and, if necessary, additional training will be provided. A sensitivity analysis of the primary outcome adjusted for the baseline risk of developing delirium determined by the PREdiction of DELIRium in ICU patients (PRE-DELIRIC) score[33] will be conducted to check the consistency of the results. There will be three a priori defined subgroup analyses for the primary endpoint: (1) effectiveness of FFVM versus RFVM in ICUs according to the PRE-DELIRIC score (patients with a predicted risk <25%, 25%–50%, 50%–75% and >75%); (2) effectiveness of FFVM versus RFVM in ICUs according to patient group (medical vs surgical, and neurocritical vs non-neurocritical); and (3) effectiveness of FFVM versus RFVM in ICUs according to Acute Physiology and Chronic Health Evaluation II (APACHE-II) scores (≤15 vs >15 points). Additional exploratory subgroup analysis will be performed based on the level of patient's exposure to sedation, ICU professional's workload and proportion of private ICU beds.

Secondary outcomes

Secondary outcome measures include daily hazard of delirium, ventilator-free days, any ICU-acquired infections (pneumonia or urinary tract infection or bloodstream infection according to Centers for Disease Control and Prevention guidelines[34–36]), ICU length of stay and all-cause hospital mortality among patients; symptoms of anxiety and depression measured by the Hospital Anxiety and Depression Scale (HADS)[37] and satisfaction measured by the Critical Care Family Needs Inventory (CCFNI)[38] among family members; and prevalence of symptoms of burnout syndrome measured by the Maslach Burnout Inventory (MBI)[39] among ICU professionals. The daily hazard of delirium will be evaluated using a joint modelling approach,[40] which is recommended to account for days at risk for delirium (ie, ICU days in a non-comatose state).

All cases of ICU-acquired infections will be adjudicated by an infectious disease physician blinded to the study interventions. Family members and ICU professionals will be evaluated through self-administered questionnaires.

Tertiary outcomes

Tertiary outcomes will include need for antipsychotic agents and/or mechanical restraints, coma-free days, unplanned loss of invasive devices and ICU-acquired pneumonia, urinary tract infection or bloodstream infection among ICU patients; self-perception of involvement in patient care (ie, reorientation activities, pain control, mobilisation, feeding, comfort, emotional support and communication (helping patients to interpret ICU staff orientations and ICU professionals to understand patient needs)) among family members; and satisfaction among ICU workers.

Length of ICU intervention, participant recruitment and timeline, data collection, management and monitoring

The length of study phases will be determined by the patient recruitment rate. During phase 1, 25 patients per ICU will be enrolled. After enrolment of the 25th patient, a 30-day period without subject recruitment (ie, washout period) will occur to allow appropriate conclusion of the follow-up of all recruited patients for the study outcomes and to avoid contamination of the two study arms. After this period, each ICU will be crossed over to the other visitation model (phase 2), with enrolment of an additional 25 ICU patients per ICU.

The study flow diagram is shown in figure 2, and the schedule of enrolment, interventions and assessments is shown in online supplementary file 2. Patients and
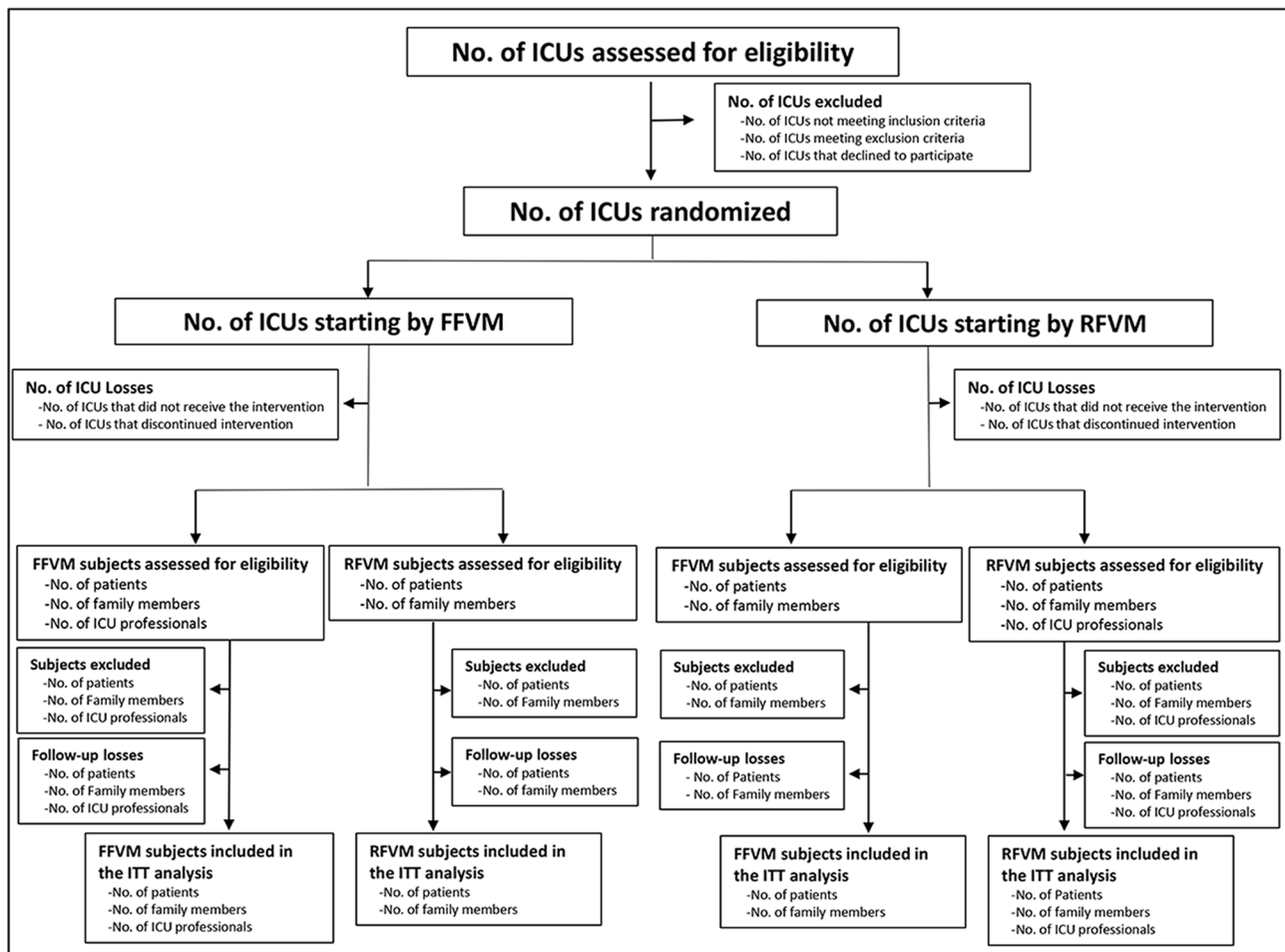
Figure 2 Study flow diagram. FFVM, flexible family visitation model; ICUs, intensive care units; ITT, intention-to-treat; RFVM, restrictive family visitation model.

family members will be recruited during phases 1 and 2. ICU professionals will be evaluated and followed up only during the phase 1 in order to avoid the carryover effect. Patients will be followed up from study enrolment to hospital discharge or death, or a maximum of 30 days. Family members will be evaluated at two time points: within the first 48 hours of patient inclusion into the study (for baseline data) and within 7 days from patient discharge from ICU or death, or a maximum of 30 days (for outcomes assessment). ICU professionals will be evaluated at two time points: 2 weeks before initiation of the first randomised ICU intervention (for baseline data) and during phase 1 (for outcome assessment).

Trained research personnel at the local sites will prospectively collect data on printed case report forms that will be entered into an electronic data capture system (REDCap, Vanderbilt University, Tennessee, USA).[41] In order to allow intention-to-treat analyses, data will be collected and analysed independent of adherence to study interventions. We will deploy the following procedures to enhance the implementation of study interventions and ensure data quality:

1. All local principal investigators and subinvestigators will attend an on-site training session before the beginning of the study to standardise procedures including data collection.
2. All ICUs will have a learning period within the first 15 days of phases 1 and 2. During this period, ICUs will receive the intervention (FFVM or RFVM) but will not recruit subjects. Local investigators will use this period to adapt the ICU staff to the organisational aspects of study intervention, including rules about visiting hours (for both FFVM and RFVM periods), guidance to visitors about the minimum requirements to promote a safe and restful environment to ICU patients (for both FFVM and RFVM periods), role of ICU professionals during family visiting hours (for FFVM period) and conduction of family members-directed structured meetings (for FFVM period). Furthermore, local investigators will use this period to test the study measurements (CAM-ICU, HADS, CCF-NI and MBI) and address concerns regarding case report filling.
3. The investigators will be able to contact the coordinating centre to solve any potential issues or problems.
4. Data cleaning will be applied continuously to identify inconsistencies and missing data. The centres will be notified of any inconsistencies and missing data and prompted to solve them.
5. The coordinating centre will review detailed reports on screening, inclusion, follow-up and data consistency and completeness on a weekly basis. The coordinating centre will take immediate action to solve any problems.
6. Centres will be monitored throughout the study. On-site monitoring visits will occur during phases 1 and 2. A trained professional appointed by the coordinating centre will perform the monitoring visit. During the

monitoring visits, all information will be considered strictly confidential.

To assess the fidelity and quality of the proposed interventions, we will perform on-site monitoring visits, with a standardised checklist, in order to evaluate if the processes are consistent with the intended intervention or if there are important deviation from the proposed protocol; perception of effectiveness and barriers for implementation will be assessed qualitatively, through semistructured interviews with healthcare professionals involved in the study.[42] In addition, we will collect data related to the length of visits for included patients, study website access and family members characteristics. A data monitoring committee is not required as the risk of study interventions causing significant harms is low.

Sample size and sampling

A minimum of 33 ICUs with recruitment rate of 50 patients per ICU (25 patients per study phase) will be needed (total of 1650 patients) to detect an absolute difference >6.0% in the cumulative incidence of delirium between the two study arms (considering an outcome incidence rate of 20.5% in the RFVM), with 80% power, and two-tailed 0.05 alfa. Two levels of intraclass correlation coefficient (ICC) were considered to calculate the sample size: 0.05 for subjects in the same cluster/time period and 0.01 for subjects in the same cluster/different time periods. Estimates of sample size for the primary outcome were made on the basis of the cumulative incidence of delirium found in a single centre before-and-after study that evaluated the effect of different policies of family visitation on the incidence of delirium.[12] In order to compensate for potential ICU and patient losses, the present study plans to recruit 40 ICUs.

Statistical analysis

A detailed statistical analysis plan will be prepared before data analysis and is intended to be published or made available online. All analyses will be conducted with the intention-to-treat principle. The comparison of cumulative incidence of delirium will be performed using models for correlated data considering the ICU as a cluster and presented as risk ratios and 95% CIs. The same models will be used for analysis of secondary and tertiary outcomes, that is, considering the ICU as a cluster and each outcome with its adequate probability distribution. A statistical significance level of 0.05 will be adopted for all statistical comparisons. The R-Development Core Team will be used for analysis.

DISCUSSION AND TRIAL STATUS

Flexible ICU visiting policy is a complex intervention, with multiple components, targeting different populations with specific outcomes. Figure 3 describes the logic model for the FFVM. Although several outcomes are expected to have a positive impact, we chose incidence of delirium as primary outcome because it combines a strong potential for causal
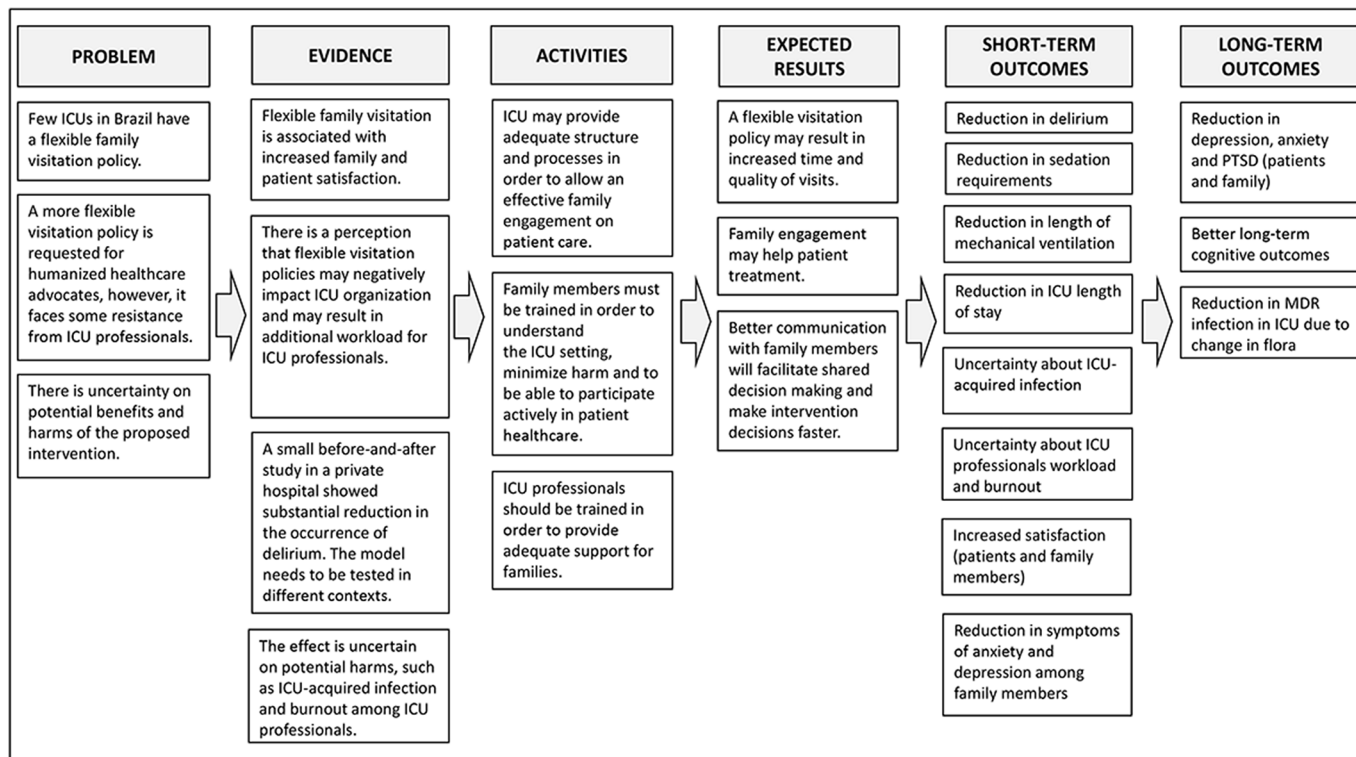
Figure 3 Logic model for flexible ICU visiting hours. FFVM, flexible family visitation model; ICUs, intensive care units; MDR, multidrug-resistant; PTSD, posttraumatic stress disorder; RFVM, restrictive family visitation model.

and direct association and an important clinical impact. Delirium is a highly prevalent ICU complication and is associated with increased mortality, longer ICU and hospital stay, higher cost of care and long-term cognitive impairment.[43–45] Therefore, identifying interventions that may reduce the risk and burden of delirium in ICU patients is of paramount importance to improve healthcare quality. Other important outcomes, such as ICU-acquired infections and length of stay, levels of burnout among ICU professionals and symptoms of anxiety and depression and satisfaction among family members may have both a direct and indirect relation with the proposed intervention and, therefore, may represent important markers of effectiveness and safety of the proposed intervention. An FFVM rooted in education of family members may reduce the theoretical risk of increase in ICU staff workload, disorganisation of care and ICU-acquired infections. The higher access to information may have a positive effect on family members' satisfaction and interactions with the patients and ICU professionals. Moreover, an FFVM may result in shorter ICU stay, mediated, for instance, by a lower incidence of delirium; additionally, a better understanding of the condition by the family may avoid delays in ICU discharge.

To the best of our knowledge, this will be the first large-scale, multicentre randomised trial evaluating the effects of different policies of ICU visitation on patients, family members and ICU professionals. Results of this study will allow healthcare professionals, researchers and police makers to draw conclusions about the efficacy and safety of a FFVM in adult ICUs.

Our study has some limitations. First, high variability across institutions is expected; although the chosen ICCs may be considered conservative, there are no estimates in the literature for the proposed intervention, which may result in lack of power if the actual ICC is larger than the estimate. Also, no masking of outcome assessors may result in measurement bias for delirium specially with the use of an instrument with some degree of subjectivity[46]; although blinding is not feasible for the proposed intervention, in order to minimise risk of bias, we chose validated methods for delirium evaluation and will make efforts in order to standardise data collection through continuing education of outcome evaluators. As the number of patients is small for each cluster, the estimate time for data collection for each study phase is from 2 months to 3 months; this length of time may not be enough to properly assess burnout in healthcare professionals. Finally, our trial is not designed to evaluate long-term outcomes, such as posttraumatic stress disorder in patients and family members, as well as microbiological changes in ICU flora due to a higher circulation of individuals from the community. These issues should be assessed in future studies.

The study design and protocol were finalised in March 2016. All site investigators were required to participate in at least one of two investigator meetings (November 2016 and April 2017). Currently, this study is recruiting subjects in 34 ICUs representative of the Brazilian geopolitical territory (figure 4). Another six ICUs are in the process of preparation for study initiation. We expect that this study will be completed in June 2018.

Figure 4 Geographical distribution of participating intensive care units.

ETHICS AND DISSEMINATION
Ethics approval and consent to participate

The research ethics committees of all participant institutions approved the study protocol (online supplementary file 3). The need for patients' written informed consent was waived in 37 of 40 participating ICUs, because the standard of care encompasses both study interventions. In 3 of 40 ICUs informed, consent will be required for patients or proxies. Informed consent will be required for family members and ICU professionals in all ICUs. Site investigators will be responsible for obtaining informed consent from study participants. Subject confidentiality will be assured through data anonymisation and controlled access to case report forms, electronic data capture system and datasets. Any breaches of confidentiality, study protocol or adverse events attributable to this study will be reported to the above research ethics committees.

Dissemination

We hope to make the study findings widely available and plan to disseminate our results in international conferences and peer-reviewed journals. Authors and collaborators will be involved in reviewing drafts of the manuscripts, press releases and any other publication format arising from this study.

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