Delirium Reduction via Scripted Family Voice Recordings in Critically Ill Patients Receiving Mechanical Ventilation

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Background Delirium affects many critically ill patients receiving mechanical ventilation and is an independent predictor of death, length of stay, cost of care, and acquired dementia. More evidence is needed for nonpharmacological interventions that reduce delirium in patients receiving mechanical ventilation in intensive care units (ICUs).
Objectives A structured intervention, Family Automated Voice Recording (FAVoR), used recorded voices of family members to provide patients receiving mechanical ventilation with hourly reorientation to the ICU environment during daytime hours.The primary aim was to compare the effect of the FAVoR intervention vs usual care on delirium in adults receiving mechanical ventilation in the ICU.
Methods This prospective, 2-arm, blinded randomized controlled trial included 178 adults receiving mechanical ventilation in 9 ICUs at 2 large hospitals in south Florida. Delirium was measured with the Confusion Assessment Method for the ICU, administered by study personnel twice daily for 7 days or until ICU discharge. Data analyses included descriptive statistics, χ^2 tests, and multivariable modeling analysis following the intent-to-treat principle.
Results Clinical characteristics and demographics were similar between groups. Patients in the FAVoR group (n=89) had more delirium-free days than did those in the usual-care group (n=89) ($P<.001$). Response to the intervention was dose dependent; more doses of intervention were associated with less delirium ($P<.001$).
Conclusions The FAVoR intervention is a nonpharmacological, low-resource-using intervention to reorient ICU patients receiving mechanical ventilation. In this trial, FAVoR was effective in preventing delirium among these patients. ClinicalTrials.gov identifier: NCT03128671
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CE 1.0 Hour

This article has been designated for CE contact hour(s). See more CE information at the end of this article.

This article is followed by an *AJCC* Patient Care Page on page 438.

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Delirium is a sudden, severe, and distressing neuropsychiatric syndrome with profound clinical, social, and economic impact. Delirium affects up to 8 of 10 patients receiving mechanical ventilation,[1] is one of the most frequent complications for patients in the intensive care unit (ICU),[2] and is associated with poor short-term and long-term cognitive outcomes.[1-3]

Longer duration of delirium is an independent predictor of ICU mortality and worse long-term cognitive function.[1-5] Costs associated with delirium present a significant health care burden given the longer duration of mechanical ventilation,[4] longer ICU and hospital stays,[4,5] and higher health care costs.[6] In a recent systematic review, the economic magnitude of inpatient delirium in the United States was estimated to be between $6.6 billion and $82.4 billion.[6]

Although research results suggest that delirium may be preventable in up to 40% of cases,[6] efforts to prevent and reduce the incidence and severity of delirium in patients in the ICU have had mixed results. To date, most efforts have focused on detecting delirium and evaluating the effects of pharmacological interventions. However, pharmacological interventions (eg, analgesic, sedative, and psychotropic medications) are associated with worse outcomes and none have been identified as effective delirium prevention strategies.[7,8] Studies investigating the use of nonpharmacological interventions to prevent delirium typically use strategies such as continuous reorientation, increased family involvement and presence, music and natural sunlight during the day, reduced nighttime stimulation, or early mobilization.[9-11] Although some findings are promising, evidence quality remains low. However, given the low risk and potential for efficacy, the Society of Critical Care Medicine ICU Liberation Bundle (pain assessment, spontaneous awakening and breathing trials, analgesia choice, delirium assessment, early mobility, and family engagement [ABCDEF or A2F] bundle) encourages family involvement to improve ICU-related outcomes.[12] Unfortunately, family involvement in the ICU can be limited by visitation policies; family workplace, childcare, and other social demands; and hospital environmental factors and visitor limitations that were heightened during the COVID-19 pandemic.

We investigated recorded scripted messages from family member voices played directly to patients to explore whether this may improve the continuity of family involvement while recognizing the real challenges facing family member participation in the ICU environment. The use of family-recorded voice messages to prevent delirium holds promise as a simple, low-cost, and easy-to-implement nonpharmacological intervention. However, until this trial, the concept had not been tested in a large clinical trial among patients receiving mechanical ventilation in the ICU.

We developed a rigorous method using a structured reorientation intervention based on family members' voices, the Family Automated Voice Recording (FAVoR) intervention, to provide patients receiving mechanical ventilation in the ICU with hourly reorientation to the ICU environment during daytime hours. This approach blended commonly used strategies suspected to decrease delirium. The primary aim of our study was to test the effect of the FAVoR intervention on delirium in adult patients receiving mechanical ventilation in the ICU. We hypothesized that patients who received the FAVoR intervention would have more delirium-free days than did patients assigned to usual care who did not receive the intervention.

Methods

Study Design and Participants

The FAVoR study was a prospective, multisite, 2-arm, blinded randomized controlled trial of adult

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patients receiving mechanical ventilation in 9 ICUs at 2 large hospitals (1 academic medical center and 1 public trust hospital) in south Florida between April 2018 and November 2020. Eligible patients were randomly assigned to 1 of 2 groups, the FAVoR intervention group and the usual-care (control) group. Our comprehensive intent-to-treat study protocol has been published.[13] Inclusion and exclusion criteria are outlined in Table 1.

The study was reviewed and approved by a university institutional review board and registered at ClinicalTrials.gov.[14] Written informed consent in English or Spanish was obtained from patients' legally authorized representatives.

Enrollment was suspended from March 2020 to June 2020 due to COVID-19 pandemic–related restrictions. One hundred fifteen patients were enrolled before March 11, 2020. Enrollment resumed in June 2020 at 1 of the 2 hospital sites until our target was reached. Sixty-seven patients were enrolled from June 2020 through November 2020. We did not enroll patients with a diagnosis of COVID-19 because these patients were in separate inpatient units where data collection was not possible.

Table 1
Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
At least 18 years old	Dementia (because it complicates planned longitudinal cognitive assessments)
Within 48 hours of initial intubation and admission to the intensive care unit	Anticipation by the clinician of imminent patient death
Patient/legally authorized representative able to provide informed consent in English or Spanish	Medical contraindication to the intervention (eg, psychiatric history of auditory hallucinations or profound deafness)
A family member able to speak English or Spanish available and willing to audio record scripted messages	Inability to speak either English or Spanish

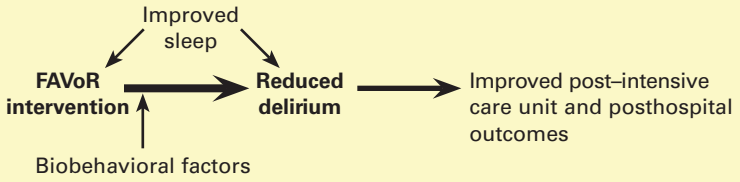

Figure 1 Relationship of Family Automated Voice Recording (FAVoR) study variables. This figure describes the variables of interest in the larger research project; this article focuses on effects of the FAVoR intervention on delirium.

Intervention

The FAVoR intervention is a set of 10 recorded messages, each 2 minutes long, played hourly during usual daytime waking hours (starting at 9:00 AM and ending at 4:00 PM) to promote day-night orientation for a maximum duration of 5 ICU days or until ICU discharge if ICU discharge occurs before 5 days. The FAVoR messages were recorded by a family member chosen by the family. The family member used our standardized script[15] in either English or Spanish, whichever the family member deemed would be most meaningful to the patient. The messages included general information describing the ICU environment, presence of visual and auditory stimuli, and presence of health care professionals and family members. The FAVoR messages were uploaded to a wireless speaker placed near the patient's ear and set to play once an hour for up to 8 doses per day. The total number of messages delivered (dosage) was recorded (dosage range, 0-40). The FAVoR intervention is fully described in our protocol article.[14]

Primary Outcomes and Measures

The primary outcome of this project, as presented in this publication, was the number of delirium-free days. Delirium was measured using the Confusion Assessment Method for the ICU-7 (CAM-ICU-7) twice daily, before the first intervention (at approximately 8:45 AM) and after the last intervention (at approximately 4:15 PM) for both groups.[14] The CAM-ICU is recognized in the clinical practice guidelines for managing pain, agitation, and delirium in adult patients in the ICU[7] as a valid, reliable, and feasible tool to detect delirium in these patients.[12,13,16,17] A meta-analysis demonstrated a pooled sensitivity of 84% and specificity of 95%.[17] Multiple additional validated tools were used to measure other clinical variables in the larger research project and will be described in future analyses.

> The Family Automated Voice Recording (FAVoR) was designed as a reorientation intervention to reduce delirium experienced by ICU patients.

Patient demographics and clinical characteristics were further examined to consider the impact of age, sex, race, ethnicity, Acute Physiology and Chronic Health Evaluation (APACHE) III score, the type of ICU (reflecting the type of critical illness and population: surgical, medical, neurological, cardiovascular, or trauma), reason for intubation, duration of mechanical ventilation, length of ICU stay, and length of hospital stay (Figure 1).

Study Procedures

Detailed study procedures are available in the published protocol article.[14] After the legally authorized representative provided informed consent, the patient was enrolled and baseline data were collected from the electronic medical record. The family member chosen to record was then escorted to a quiet area to complete the scripted FAVoR intervention voice recordings.[15] Patients were randomized to the intervention or control group. Wireless speakers were placed on all patients' bedsides to mask group assignment to outcome assessors. For patients in the intervention group, the wireless speakers were activated and played the 2-minute FAVoR messages once an hour during daytime waking hours over a maximum of 5 days.

Patients in the FAVOR intervention group had a higher rate of delirium-free days than patients in the usual care group.

We conducted CAM-ICU assessments at the same times for 2 additional days after completion of the intervention period, for a total of 7 days of CAM-ICU assessments or until ICU discharge if ICU discharge occurred within 7 days. Each CAM-ICU assessment was completed by outcome assessors who were blinded to the patient's group assignment. Data regarding lengths of mechanical ventilation, ICU stay, and hospital stay were obtained from the electronic medical record.

Sample Size Calculation

The effect size was calculated on the basis of the results of our pilot study[15] using the χ^2 effect size estimator (PASS 2023 Power Analysis and Sample Size, NCSS Statistical Software). A sample size of 127 was identified to achieve 95% power to detect an effect size of $w = 0.35$ with a significance level of .05. To account for early extubation and death related to critical illness, an attrition rate of 40% was used. After adjusting the analysis sample size of 127 by an anticipated 40% attrition rate, the planned recruitment sample size was 178 patients (89 in each group). For more details, please refer to our protocol article.[14]

Statistical Analysis

We followed the data analysis plan as outlined in our protocol article.[14] Following the guidance of the American Statistical Association's statement on statistical significance and *P* values[18] to avoid inference solely on $P < .05$, we performed baseline analysis to examine the sample characteristics of our study participants by group. Between-group comparisons were further performed to check the balance of baseline covariates. Unbalanced baseline covariates were identified and included in the subsequent analysis for effectiveness. Next we performed the planned χ^2 test to compare the primary outcome (delirium-free days) between the 2 groups as an unadjusted analysis. Then we conducted a multivariate modeling analysis to control for covariates including intubation process, ICU length of stay, and the total dosage of the intervention. These covariates were included in the Poisson regression analysis. Reasons for the multivariate modeling analysis include the following: (1) the intubation process was not balanced, according to our baseline analysis, so a multivariate modeling analysis was used to control for the unbalanced baseline variable; (2) patients in our trial had different lengths of ICU stay; and (3) the total amount of intervention (dosage) each patient actually received varied. Given the accepted premise that the dosage in a behavioral intervention study must be taken into account when the effect of the intervention is being evaluated, we controlled for the dosage variable in the intervention group while setting the dosage as 0 for patients in the control group. Last, we conducted an additional analysis based on the most recent guideline on delirium by calculating the effect size (defined as the standardized mean difference) and 95% CI to show the magnitude and direction of the effect. We used the online Shiny calculator[19] to calculate effect size to estimate the standardized mean difference of the Poisson rates of delirium-free days between the 2 groups using Poisson regression analysis. Poisson regression parameters were presented as β coefficients and SEs.

For missing data, we followed the intent-to-treat principle and included all patients who were randomized in the final analysis. To assess the sensitivity of our multivariate analysis toward missing data, we performed a multiple imputation analysis using the R package MICE (Multiple Imputation by Chained Equations, R Foundation for Statistical Computing). Five imputed data sets were generated. One Poisson model was fitted on each of these data sets. The variability of effects and *P* values from the Poisson models on imputed data sets were used to assess the sensitivity of our inferences under the influence of missing data.

Results

Patients (N = 178) were randomized into 2 groups: the FAVoR intervention group (n = 89) and the usual-care (control) group (n = 89). The Consolidated Standards of Reporting Trials (CONSORT)

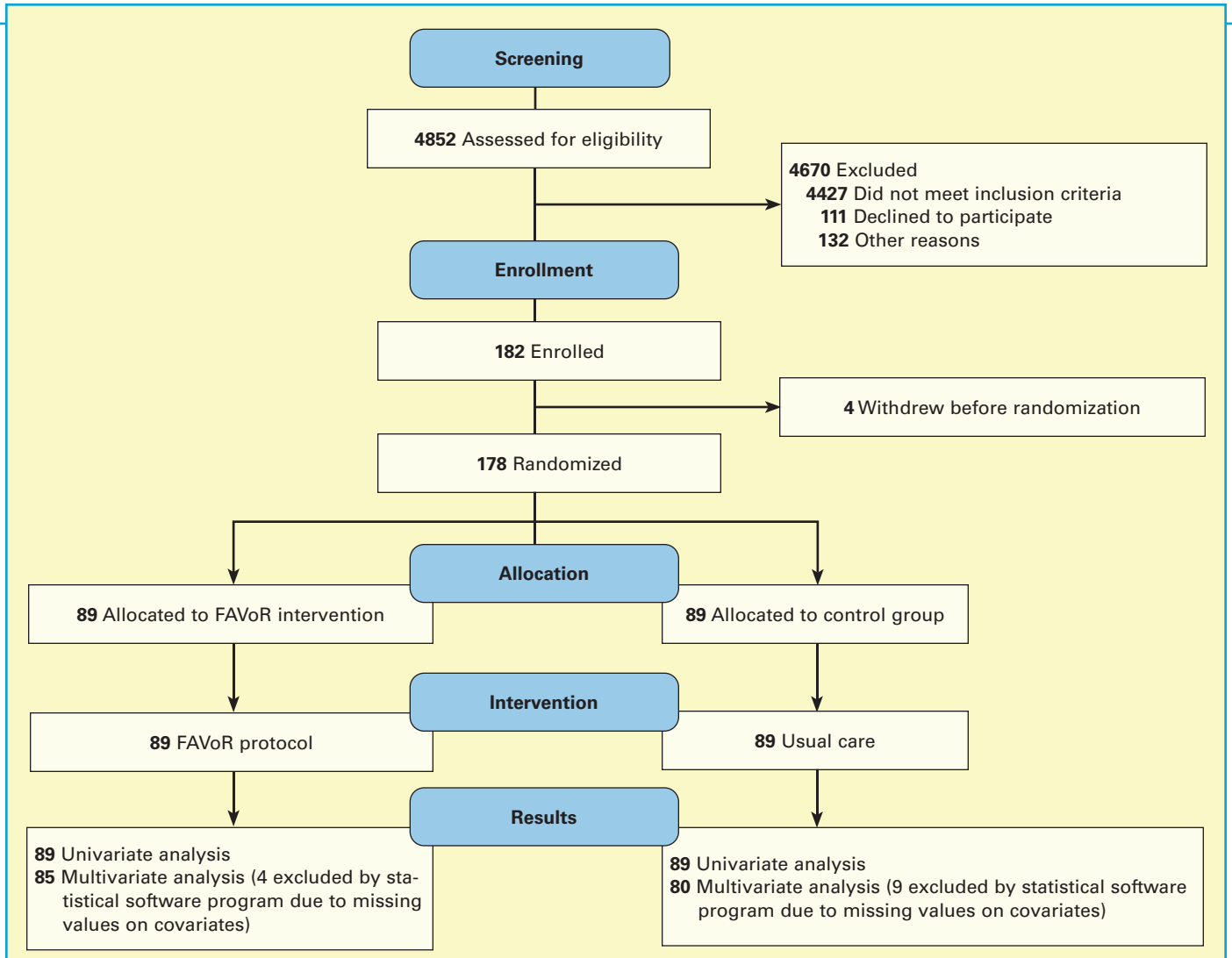

Figure 2 Consolidated Standards of Reporting Trials (CONSORT) diagram. FAVoR indicates Family Automated Voice Recording.

diagram is shown in Figure 2. No major protocol deviations occurred.

Sample Characteristics

Baseline characteristics are presented in Table 2. Of the total sample, 60% were male, 78% were White, and 60% were Hispanic/Latino. The mean (SD) age was 59.3 (17.1) years, and the mean (SD) APACHE III severity of illness score was 66.3 (27.6). The groups were well balanced at baseline.

Study Outcomes

Patients in the FAVoR intervention group overall had a higher percentage of delirium-free days (34.8%) than did patients in the control group (33.7%). Although the initial unadjusted χ^2 analysis result was not significant ($P = .07$), the Poisson regression model using ICU length of stay as an offset and adjusting for the total dosage of the intervention showed a significant difference in delirium-free days between groups ($P < .001$) (Table 3). To assess the impact of missing data on the regression model (eg, due to early extubation), we performed a multiple imputation analysis as specified prospectively in the study protocol. In the 5 Poisson models on these imputed data sets, the effect ranged from 0.85 to 1.09 and P values remained less than .001. The congruence of analyses of the raw data set and imputed data sets indicated that missing data did not bias the outcome of the raw data analysis.

Patients in the FAVoR intervention group had a higher rate of delirium-free days ($\beta = 1.094$) than did patients in the control group. The effect size for the FAVoR intervention was significant (standardized mean difference, 0.354; 95% CI, 0.182-0.608). The

Table 2
Baseline characteristics of the study sample

Variable	No. (%) of patients[a]			P[b]
	Intervention group (n=89)	Control group (n=89)	Total (N=178)	
Age, mean (SD), y	58.0 (16.8)	60.6 (17.4)	59.3 (17.1)	.30
Sex				.22
Male	58 (65)	49 (55)	107 (60)	
Female	31 (35)	40 (45)	71 (40)	
Race				.43
White	66 (74)	73 (82)	139 (78)	
Black/African American	22 (25)	15 (17)	37 (21)	
More than 1 race	1 (1)	1 (1)	2 (1)	
Ethnicity				.54
Hispanic/Latino	51 (57)	56 (63)	107 (60)	
Non-Hispanic/Latino	38 (43)	33 (37)	71 (40)	
Intubation				.26
Elective	27 (30)	36 (40)	63 (35)	
Urgent	27 (30)	19 (21)	46 (26)	
Emergency	35 (39)	34 (38)	69 (39)	
Type of intensive care unit				.85
Medical	26 (29)	25 (28)	51 (29)	
Surgical	21 (24)	22 (25)	43 (24)	
Trauma	15 (17)	11 (12)	26 (15)	
Neurologic	9 (10)	8 (9)	17 (10)	
Cardiovascular	18 (20)	23 (26)	41 (23)	
APACHE III score, mean (SD)	66.5 (27.4)	66.2 (27.8)	66.3 (27.6)	.94

Abbreviation: APACHE, Acute Physiology and Chronic Health Evaluation.

[a] Unless otherwise indicated in first column.
[b] From an independent *t* test for continuous variables and from a χ^2 test for categorical variables.

intervention total dosage was also significantly associated with delirium-free days ($P<.001$). The mean (SD) number of doses received in the intervention group was 23.8 (14.2). Within the intervention group, analysis showed a significant positive correlation ($r=0.62$, $P<.001$) between doses of the intervention and the number of delirium-free days, which indicates a potential dose-response relationship.

Discussion

In our randomized controlled trial, we demonstrated that the FAVoR intervention (family members' voice-recorded messages) reduced the risk of delirium in critically ill patients receiving mechanical ventilation. Additionally, the effects were mediated by intervention dosage. The FAVoR intervention is an easy-to-implement, nonpharmacological intervention that can be used in the clinical setting.

Current State

Although the negative outcomes of delirium are widely recognized, delirium prevention interventions remain a gap in research and practice. The 2018 Society of Critical Care Medicine clinical practice guidelines recommend against using pharmacological interventions to prevent or treat delirium in most patients and advocate integration of multicomponent pharmacological and nonpharmacological strategies. However, the guidelines include both pharmacological and nonpharmacological strategies as conditional recommendations in light of low to very low quality of evidence.[7] Recent systematic reviews and meta-analyses of pharmacological and nonpharmacological interventions highlight a heterogeneous body of evidence that fails to offer clear, effective strategies for health care teams.[9-11] For example, a recent Cochrane review of delirium prevention strategies that included 12 randomized controlled trials (3885 participants) noted limitations of small sample sizes and generally low-quality results and did not find significant benefit among pharmacological or nonpharmacological interventions.[9]

Intervention Impact

The FAVoR study tested a robust intervention in a large-scale, rigorous trial and demonstrated more delirium-free days for patients receiving the intervention and a reduced risk of delirium associated with more doses of the intervention. The intervention approach blended a family-oriented strategy with targeted spatial orientation messaging and was developed and enhanced through a pilot study[15] before being deployed

in a large randomized controlled trial. The recruited sample size met the power analysis recommendation and demonstrated efficacy in a large and diverse sample of patients receiving mechanical ventilation who were at high risk for delirium.

The intervention was developed from strong conceptual underpinnings recognizing strengths and limitations in current delirium prevention science. The recordings were developed to reorient patients to the ICU environment and provide an automated option for frequent family involvement. The intervention timing was developed to help reinforce day-night rhythms. Data collected under secondary aims are currently under review to clarify and explore the impact of other factors (eg, sleep) known to influence delirium risk factors.

Implementation of the intervention required minimal institutional resources and was generally perceived to be feasible and easy to adopt in ICU settings. Although nonpharmacological interventions can demand significant staff resources, the FAVoR intervention was designed to be seamlessly incorporated into the existing ICU workflow, drawing on existing clinical assessment protocols and using technology that required minimal if any interaction by staff members. The most significant resource investment was during the initial phase of family message recording, which was managed by the research team staff.

Limitations

Implementing interventions in the ICU is highly complicated and requires coordination of various stakeholders and resources and recognition of implicit limitations when assessing clinical outcomes for patients in this environment. In many circumstances, ICU environments are multifaceted and underresourced, with heterogeneous workflows to meet the critical needs of diverse and medically vulnerable patients. Because of their severe and often life-limiting admitting diagnoses, recruitment and retention of study patients over time can be challenging. Although we were able to exceed our power analysis sample size, implementing and analyzing the results of FAVoR in the context of a high-turnover ICU setting was complex.

Impact of COVID-19 Pandemic–Related Changes in ICU Care

The FAVoR study was disrupted in March 2020 as health systems pivoted to rapidly address the COVID-19 pandemic. Systemwide changes affected study recruitment, retention, and analysis. Patients infected with SARS-CoV-2 were excluded from the study and located in separate units from study patients. However, visitor restrictions affected all patients irrespective of SARS-CoV-2 infection status. Although this period presented uniquely intensifying demands on ICU clinical teams to respond to a global crisis, the FAVoR intervention offered a high-impact solution without further straining ICU resources. Further analysis is underway to clarify whether the impact of the pandemic, with accompanying limitations on family visitation, had a moderating effect on patients' responses to the recordings.

> The FAVoR intervention was designed to be seamlessly incorporated into existing ICU workflows.

Future Directions

The FAVoR study provides high-quality evidence supporting this nonpharmacological, low-resource-using intervention for preventing delirium among patients receiving mechanical ventilation in the ICU. These results offer several potential directions to clarify and deepen our understanding of best practices for delirium prevention. Although the data

Table 3
Poisson regression analysis of primary outcome: delirium-free days[a]

Model	β	SE (β)
Raw data set		
I		
Intercept	–3.430	0.070
Group	1.090	0.180
Dose	–0.030	0.005
Imputed data sets		
I		
Intercept	–3.460	0.065
Group	1.140	0.166
Dose	–0.030	0.004
II		
Intercept	–3.430	0.066
Group	1.150	0.175
Dose	–0.030	0.005
III		
Intercept	–3.440	0.066
Group	1.210	0.173
Dose	–0.030	0.005
IV		
Intercept	–3.430	0.065
Group	0.900	0.164
Dose	–0.026	0.004
V		
Intercept	–3.420	0.064
Group	0.950	0.160
Dose	–0.028	0.004

[a] All results were significant at $P<.001$.

showed clear clinical improvements among patients who heard the messages recorded by a family member, it is not clear whether the content of the scripted messages or the regular sound of a familiar voice had a higher impact on delirium risk. Future work could include intervention groups using unscripted or family-scripted messages addressing similar content areas. Furthermore, a better understanding of the impact of intervention participation on the experience of family members could elucidate whether the intervention improves family members' well-being, especially when they cannot be physically present. One strength of the FAVoR study was inclusion of Spanish-speaking patients, but further work is needed to understand the impact of culture and language preference on delirium prevention. Future work should engage patient and family representatives from more diverse communities to better address this unique and critical health equity issue facing patients with low English proficiency receiving mechanical ventilation in the ICU. We hypothesize that patients with low English proficiency have particularly elevated risks for delirium when receiving care in a language-discordant ICU. Better serving this cohort of patients may address a critical and poorly understood phenomenon.

Conclusions

Delirium prevention science needs significant investment of time and resources to impact this incompletely understood medical state. Scripted family-recorded voice messages are potentially high-impact, low-cost nonpharmacological interventions that can prevent delirium in patients receiving mechanical ventilation in the ICU. The FAVoR study offers a robust and well-studied intervention that may reduce risks for delirium, potentially impacting other concerns, including nursing burden and implementation strategies for the Society of Critical Care Medicine ABCDEF bundle. More research and investment are needed to expand our understanding of the clinical, cultural, and operational implications to further develop effective nonpharmacological delirium prevention interventions.

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FINANCIAL DISCLOSURES

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SEE ALSO

For more about delirium management, visit the *AACN Advanced Critical Care* website, **www.aacnacconline.org**, and read the article by Dayton et al, "Stopping Delirium Using the Awake-and-Walking Intensive Care Unit Approach: True Mastery of Critical Thinking and the ABCDEF Bundle" (Winter 2023).

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CE 1.0 Hour Category A

Notice to CE enrollees:

This article has been designated for CE contact hour(s). Increasing knowledge on the following objectives is the desired outcome of this activity:

1. Describe negative outcomes associated with delirium in the intensive care unit.
2. Explain why listening to a scripted recorded message from a family member might reduce a patient's risk of delirium.
3. Compare the delirium results of the intervention group with the results for the group who received usual care.

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