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Delirium prevention in critically ill adults through an automated reorientation intervention – A pilot randomized controlled trial

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ABSTRACT

Objectives: Explore the effect of an automated reorientation intervention on ICU delirium in a prospective randomized controlled trial.
Background: Delirium is common in ICU patients, and negatively affects outcomes. Few prevention strategies have been tested.
Methods: Thirty ICU patients were randomized to 3 groups. Ten received hourly recorded messages in a family member's voice during waking hours over 3 ICU days, 10 received the same messages in a non-family voice, and 10 (control) did not receive any automated reorientation messages. The primary outcome was delirium free days during the intervention period (evaluated by CAM-ICU). Groups were compared by Fisher's Exact Test.
Results: The family voice group had more delirium free days than the non-family voice group, and significantly more delirium free days ($p = 0.0437$) than the control group.
Conclusions: Reorientation through automated, scripted messages reduced incidence of delirium. Using identical scripted messages, family voice was more effective than non-family voice.

Introduction

Delirium is an acute disturbance in attention and awareness, with additional change in cognition from the person's baseline.[1] Delirium develops over a short period of time and may fluctuate over the course of the day. Critically ill patients are at high risk for delirium, with 50% of ICU patients and as many as 80% of mechanically ventilated patients experiencing delirium.[2] Meta-analyses indicate that patients with delirium have greater incidence of complications including nosocomial pneumonia, longer duration of mechanical ventilation, longer hospital length of stay, and higher hospital mortality than patients without delirium.[3] Number of days of delirium has been identified as an independent predictor of mortality in ICU patients.[4–6] Delirium in critical illness is estimated to cost $4 to $16 billion annually.[2]

Importantly, delirium in the ICU not only complicates the hospital course, but it is also associated with lasting sequelae.[7–10] Data suggest that 25%–78% of patients who have delirium in the ICU suffer clinically significant declines in cognitive function following their ICU stay.[11,12] Cognitive dysfunction may persist for months or be permanent,[9,11,13] and is associated with impairments in daily function.[14] In recent studies, increasing duration of delirium was an independent predictor of worse cognition 3 months and 12 months after ICU discharge,[11,13] and this remained true even after adjusting for risk factors such as age, severity of illness, severe sepsis, and exposure to sedative medications in the ICU.[11]

To date, the focus of delirium research has been on detection of existing delirium and on its pharmacologic treatment.[15] Prevention of delirium using a non-pharmacologic intervention has not been well examined. Interventions that assist critically ill patients to integrate information more appropriately may decrease delirium and improve outcomes,[16] but have not been rigorously tested. We reasoned that providing ongoing orientation to the ICU environment through recorded messages might enable the patient to more accurately interpret the environment and thus reduce risk of delirium, and that cuing patients only during daytime hours might also improve day/night orientation, further reducing risk of delirium.

We developed a cognitive reorientation intervention which uses automated recorded audio messages, played at hourly intervals during daytime hours, to provide information about the ICU

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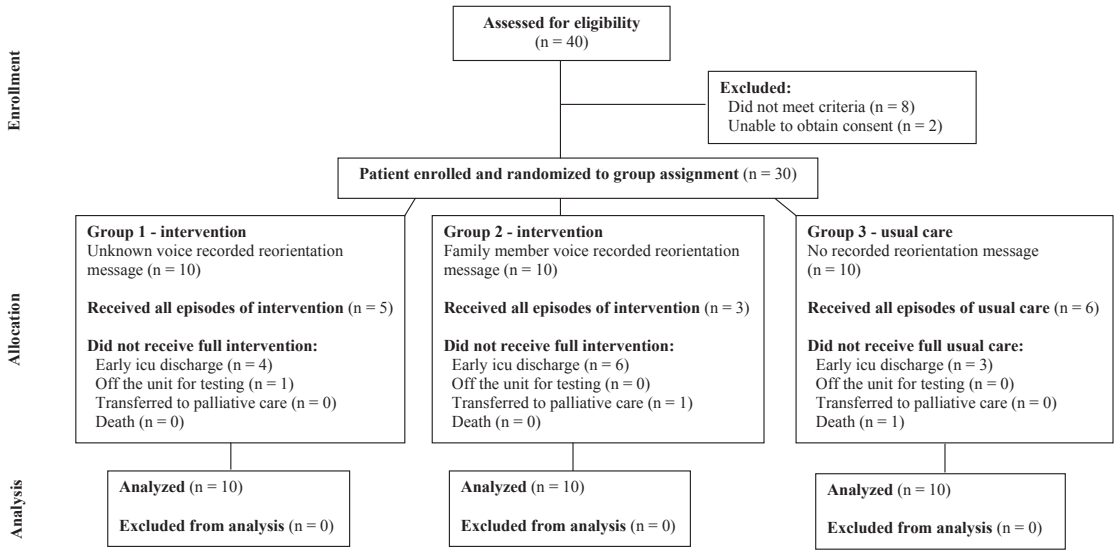

Fig. 1. CONSORT study flow.

environment to the patient. We thought that messages delivered in a voice familiar to the patient might result in greater attention to the messages and be comforting. This study tested the hypothesis that providing ongoing orientation to the ICU environment through recorded audio messages would reduce risk of delirium in critically ill adults; both familiar voices (family voice) and an unfamiliar voice (unknown voice) were tested against no recorded voice (control).

Methods

A three group, prospective, randomized controlled trial (RCT) design was used to examine the effects of the automated reorientation intervention on delirium. Ten subjects were randomized to receive automated reorientation messages in a family member's voice (family voice group), ten subjects received the same messages in an unfamiliar voice (unknown voice group) and ten subjects (control group) did not receive any automated reorientation messages. The study CONSORT diagram is presented as Fig. 1.

Human subjects protection

The study was approved by the hospital where data were collected and by the Institutional Review Board of the university. Signed consent was obtained from subjects or their legally authorized representatives. Twelve subjects provided consent for themselves, and consent was obtained from legally authorized representatives for the 18 subjects who were unable to consent for themselves.

Sample

Subjects were eligible if they were over 18 years old and within 24 h of ICU admission. Exclusion criteria included anticipation by the clinical provider of imminent patient death, medical contraindication to the intervention (for example, psychiatric auditory hallucinations, or profound deafness), or inability to speak either English or Spanish. Subjects were recruited in 5 ICUs in a large urban level I trauma center in the Southeastern United States. A total of 30 subjects were randomized into 3 groups by the biostastician co-investigator (MJ) prior to the first enrollment using a computerized random number generator.

Automated reorientation intervention

Intervention development

A draft script of reorientation messages was developed based on published research by our team and others about patients' recall of ICU experiences.[17–19] The script was refined based on reviews of 3 critical care experts, and further adjustments to message volume, length, and speaker location were made following input from healthy nurse volunteers in the ICU setting. The original script was developed in English; a Spanish version was translated from English by a certified medical translator and back-translated.

Message description

Each message was scripted, was no longer than 2 min long, included the subject's name (preferred name as recommended by the subject's family), and used simple terms at a 5th grade reading level. Other than the subject's name, the recorded message was not specific to any patient condition, procedure, or family situation. Each message was delivered only during daytime hours (to provide general time orientation), stated that the message was recorded, and reoriented the subject frequently throughout the day to help them understand they were in the ICU. Additional message elements followed in random order, and provided information about the critical care environment, the visual and auditory stimuli to be expected, and the availability of providers and family. Random ordering of elements within the recorded message at each delivery was designed to reduce message repetition. The elements of the reorientation message are presented in Table 1.

The script for messages was recorded by a family member of the family's choice (for the family voice group) or by a bilingual female research staff person (for the unknown voice group). Selection of the English or Spanish script was based on the family's decision regarding which language would be most meaningful to the subject. The messages were digitally recorded through a sound card and stored as a standard Microsoft wave file.

Intervention delivery

At predetermined time intervals over 3 days in the ICU (every hour for 8 h during the daytime hours, beginning at 9:00 am and ending at 4:00 p.m.), a recorded message was played back in the patient's room through the room's television audio system. The