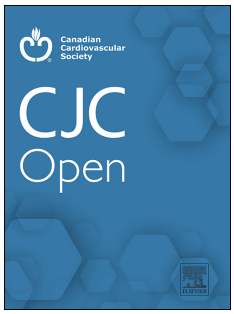

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Family Participation in Cardiovascular Intensive Care Unit Rounds: A Pilot Randomized Controlled Trial

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Short Title: Family Participation in CICU Rounds: A Pilot RCT

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Abstract

Background

Observational studies have shown an association between family participation in intensive care unit (ICU) rounds and better family-centered outcomes. However, there is a lack of evidence from randomized studies on the impact of family participation in ICU rounds. The objective of this pilot study was to evaluate the feasibility of a randomized trial for family participation in ICU rounds and to obtain preliminary estimates of effect to inform a future effectiveness trial.

Methods

Family members of patients in the cardiovascular ICU at an academic tertiary care hospital were randomized to intervention (participation in rounds) or usual care. Following ICU discharge, family member participants completed the family satisfaction (FS-ICU) questionnaire. Feasibility metrics were recruitment (≥10 participants/month), uptake (≥80%), and follow-up (≥80%). Effectiveness was measured by between group differences in FS-ICU score at follow-up.

Results

There were 27 participants recruited over 8 weeks. 44% (27/61) of family members approached agreed to participate. Non-participation was most commonly due to lack of interest (N=20; 64%). All family members randomized to the intervention (N=16) were present for rounds (100% uptake). Follow-up data were available for 23 participants (85%). Family members who participated in rounds had higher satisfaction with care compared to the usual care group (87.3 vs 74.7, P=0.03, respectively).

Conclusion: Family participation in cardiovascular ICU rounds is feasible and effective at improving family satisfaction. Our findings will inform the design of a planned larger multicenter study to evaluate the effectiveness of family participation in ICU rounds to improve family-centered outcomes.

Introduction

Family engagement in care is a key element of critical care medicine delivery.[1] Family participation in intensive care unit (ICU) rounds is an engagement strategy that enables family members to communicate and be involved in decision-making with the healthcare team. Family participation in ICU rounds has been shown in observational studies to be associated with improved communication and family satisfaction.[2]

Family members often wish to be more involved in their loved one's care; a study of family members of ICU patients found that 97% of family members had a high interest in participating in rounds.[3] However, patient and family engagement practices are not implemented to the same degree in every ICU. An international survey of 345 ICUs from 40 countries found that only 43% allowed family participation during rounds. Barriers to family engagement in the adult ICU include unit culture, staff resistance, and uncertainty about the benefits of such practices.[4] Most of the observational evidence supporting family participation in rounds is from the pediatric critical care setting.[5,6] There is therefore a growing need for better evidence regarding the feasibility and potential benefits of family participation during adult critical care rounds.

Thus, we conducted a pilot study to evaluate the feasibility of a randomized study of family participation in ICU rounds, and to obtain preliminary estimates of effect. If feasible, the results of this study could be used to inform a large, multicenter effectiveness trial.

Methods

Study design

This was a pilot randomized controlled trial comparing an intervention of family participation in team rounds with usual care in a cardiovascular ICU at an academic tertiary care hospital in Montreal, Canada, over a 2-month period in summer 2022. The initial recruitment target was 64 participants over a 6-month period, however, the study was terminated early following an interim analysis due to achieving feasibility objectives. Institutional ethics approval was obtained for this study. The study was registered on clinicaltrials.gov (FAM-CICU trial; NCT05528185). The study was overseen by the Family Engagement Team at the study institution, which involves collaboration with a patient/family partner in design (i.e., participant materials) and selection of family-important outcome measures.

Population and eligibility criteria

Family members of people admitted to the cardiovascular ICU were approached for participation in the study. Family members were considered anyone with a biological, legal, or emotional relationship with the patient, and whom the patient wishes to have involved in their care.[7] Inclusion criteria were expected patient length of stay > 48 hours, age ≥ 18 years, and willingness to participate in morning rounds (either in person or virtually) if offered. Exclusion criteria include another family member participating in the study (i.e., only one family member could attend rounds) or inability to communicate in English or French.

Recruitment process

First, we obtained verbal consent from the patient to approach their family member. If the patient could not provide verbal consent due to incapacity, then the surrogate decision-maker, as documented in the medical chart, was approached for participation. We included family members of people without capacity because these vulnerable patients may be the most likely to benefit from someone who can advocate for their care decisions.[8] If the surrogate decision-maker was not

present in the room, research personnel contacted the surrogate decision-maker by phone. Informed consent was obtained from family members who expressed interest in participating in the study. We recorded the number of family members who were unwilling to participate in team rounds and the reason why they declined to participate. Recruitment was conducted by a single research team member during standard daytime hours only (Monday to Friday, 8am-5pm).

Prior to recruiting participants to the study, the clinical team was informed and educated about conducting rounds with family present. A series of in-service training sessions were provided to the bedside nurses. Attending physicians and housestaff were given a one-page summary of the study, and a document outlining best-practices on conducting rounds with family present. During the course of the study, research personnel reinforced the role of family in rounds with the treating team when needed.

Randomization and blinding

Family members were randomized in a 1:1 ratio with a block size of 8 to either the intervention or usual care using the REDCap randomization module. A larger block size was chosen since small block sizes increase the possibility that the group allocation is predictable if the intervention is unblinded to participants.[9] Blinding is not possible for the intervention group due to the nature of the intervention. To limit bias, we blinded treating healthcare team members to the identity of family members who were randomized to the usual care group. It is possible that the clinical team's interaction with the family member would be altered if they were aware that the family member was enrolled in the usual care group. Similarly, we blinded statisticians who performed the data analysis to group assignments until analyses are completed.

Study arms

The intervention consisted of family participation in daily team rounds, either in person or virtually, as per participant preference. The healthcare team was encouraged to follow the best practice approach for family participation in rounding, which is composed of invitation, orientation, engagement, summary, questions, and communication follow-up, although this structure was not obligatory.[10] First, the family member was invited to participate in the rounds outside their loved one's room. Next, the family member was provided with a brief orientation to the healthcare team members present. The family member was encouraged to participate throughout the rounds. At the end of the rounds, the healthcare team summarized the patient's daily care plan and the family member was prompted to ask questions**.** If the discussion with the family member is prolonged, the care team may request to return after rounds to continue the discussion. If an attending staff physician feels that the family member should not be present during rounds for a particular reason, they could ask the family member to leave. Reasons for asking the family participant to leave were recorded.

Participants who chose to participate in rounds virtually were provided with a personalized link by email to attend rounds. Videoconferencing was done with Microsoft Teams, which is a secure video communications platform routinely used for medical visits. A research team member contacted the participant and performed double identification. The recommended rounding format was the same for virtual rounds as for in-person.

Usual care consisted of interdisciplinary team rounds outside the patient's room each morning without the family member present, as per local standard of practice. The interdisciplinary team consists of a physician, residents, medical students, a cardiovascular specialist pharmacist, and a bedside nurse. The team may also include allied health professionals, such as physiotherapists, occupational therapists, dieticians, respiratory therapists, and/or a social

worker depending on the patient's medical condition and staff availability. The typical structure of rounds consists of the resident or medical student providing a short summary of the patient's reason for admission and any overnight issues. The bedside nurse then provides a report of the patient's current status and laboratory results. The pharmacist then provides a current medication list and may offer suggestions. The attending physician and the medical trainees then enter the patient's room and perform a focused history and physical exam. The medical team then develops the daily care plan, typically outside the room. The care plan may be relayed by the healthcare team to the patient and/or family member at this time. The physician may also perform teaching outside the room or at the patient's bedside.

Outcomes

The primary outcome was feasibility of family participation in cardiovascular ICU rounds, which was evaluated with recruitment rate, uptake, and follow-up rates. The recruitment rate represented the number of family members participating per month of recruitment (target 10 participants per month). The uptake corresponded to the proportion of family members randomized to the intervention that participated in one or more rounds (target ≥ 80%). The follow-up rate represented the number of participating family members that completed the follow-up questionnaires (target ≥ 80%). The primary efficacy outcome was family satisfaction with care following ICU discharge, as measured by the satisfaction with care domain of the Family Satisfaction in the Intensive Care Unit (FS-ICU) tool. The secondary outcome of interest was family engagement, as measured by the Family Engagement (FAME) tool.

Study Instruments

FS-ICU is a 24-item widely used and validated tool to evaluate family satisfaction with care in the ICU setting. The two major domains tested are satisfaction with care (average score of

questions 1-14) and satisfaction with decision-making (average score of questions 15-24). Results are reported with a 0–100 scoring system with higher scores indicating increased care satisfaction.[11,12]

The FAME tool is a 12-item validated tool that evaluates engagement behaviors including family presence, communication/education, decision-making, and direct care contribution.[13] Results are reported with a 0-100 scoring system with higher scores indicating greater engagement in care.

Data collection

At enrolment, family members completed the FAMily Engagement (FAME) questionnaire and study personnel collected sociodemographic information. The following data was captured for each participant: age, gender, racial/ethnic background, relationship to the patient, prior participation in ICU care as a family member, living status (with or without the hospitalized relative), living location (in same city as hospital or out of town), duration of patient's ICU stay, and highest level of education. Following ICU discharge, family members completed the FAME and Family Satisfaction in the ICU (FS-ICU) questionnaires. Study personnel recorded the data pertaining to recruitment, uptake, and follow-up rates.

Data Analysis

Descriptive statistics were used to compare the groups. Continuous variables were presented as mean ± standard deviation, and differences between groups were tested with the student's t or the ANOVA tests, as applicable. Categorical data were presented as frequencies and percentages and differences between groups were compared using the chi-squared test or the Fisher exact test, as applicable. The primary analysis was intention to treat. We planned on performing a

per protocol analysis as well if there were crossovers between the groups (i.e., participants randomized to the intervention did not participate in rounds or participants randomized to usual care did participate in rounds). An interim analysis was planned after 8-weeks to determine if feasibility measures were met. An 8-week timeframe was considered reasonable to achieve about 22 total participants based on our recruitment targets, which could provide enough data to evaluate feasibility.[14] We considered a two-sided P-value ≤ 0.05 as significant. Analyses were performed using SPSS 27.0 Statistics software (Microsoft Corp, Armonk, NY).

Results

There were 27 family members who participated in the study over the 8-week recruitment period (mean 13.5 participants per month) out of 61 family members approached (44%). Reasons for non-participation given by family members are reported in Figure 1, with the most common being a lack of interest. The study was stopped early after the interim analysis due to feasibility targets being met.

There were 16 family members randomized to the intervention and 11 family members randomized to the usual care group. The study groups were similar in terms of demographic variables (Table 1). All 16 family members in the intervention group participated in at least 1 rounding session (uptake 100%; Table 2). The mean number of rounds with family member present was 1.7±1.4. Three-quarters (N=12; 75%) participated in person and one-quarter (N=4; 25%) participated virtually. No family member who was randomized to usual care was present during rounds. A specific per-protocol analysis was not performed as there were no crossovers between the groups.

Follow-up data were available for 21 participants (85% follow-up rate; Table 3). The FS-ICU satisfaction with care score was higher in the intervention group than in the usual care group (87.3±9.9 vs 74.7±19.5, P=0.03). There was a trend toward a higher overall satisfaction score in the intervention group compared with the control group (82.6±10.2 vs 72.5 ± 20.8, P=0.07). There were higher scores for the intervention group pertaining to the following questionnaire items: concern and caring by the ICU staff, symptom management, coordination of care, and skills and competence of CICU doctors (items 1, 2b, 5 and 9, respectively; all $P \leq 0.05$; Supplemental Table S1). There were no between-group differences for the overall or individual FAME scores (all P>0.05; Supplemental Table S2).

Discussion

We performed a pilot pragmatic randomized trial to evaluate whether a family participation in rounding intervention in a cardiovascular ICU was feasible and to obtain preliminary effect estimates. The study met the target recruitment rate, uptake level, and follow-up participation rates. The intervention improved family satisfaction with care and there was a trend towards improved overall satisfaction.

The recruitment rate is a crucial aspect of randomized controlled trials as it is one of the main reasons for the early abandonment of trials.[15] At a single center we achieved a recruitment rate of 13.5 participants per month with only one research team member recruiting during daytime hours. It is possible that the recruitment rate could be further increased by approaching family members in the evening or on weekends, as some family members might be interested in participating in family rounds virtually but may not be able to be physically present in the morning. The recruitment rate could also be higher in centers with increased patient volume. Additional strategies could also be considered to increase recruitment further, such as family information

packages on unit arrival that could inform family members about potentially participating in healthcare team rounds.

All participants in the intervention arm attended at least one healthcare team rounds. The high uptake of the intervention was likely due in part to only including participants who expressed a desire to participate in the intervention. In addition, participants were given the option of virtual attendance in rounds if they could not be present physically. One-quarter of participants in the intervention group attended rounds virtually. Virtual participation in ICU rounds can overcome known barriers to in person participation in care team rounds, such as healthcare-related (visitation restrictions and infection control risk) and family member-related (distance to hospital, health, work, and financial) barriers.[16] Allowing participant choice for mode of ICU round attendance is a pragmatic approach that could be considered for in larger multicenter trial design.

Follow-up data were available for the vast majority of participants. We ascertained outcome data as soon as possible post-ICU discharge, often while the participant's loved one was still hospitalized in an acute care ward. In our cardiovascular ICU it is very rare for patients to be transferred directly home from the critical care unit. Thus, follow-up outcome measurement shortly following discharge is a viable strategy to maintain a high follow-up rate. The multicenter Rehabilitation and Recovery in Patients after Critical Illness and Their Family Caregivers (RECOVER) study that followed family members after their loved one's were discharged from the ICU similarly reported a high percentage of family members completing their questionnaire assessment (94%) within 7 days of ICU discharge.[17]

Previous observational studies have reported that family presence on rounds is associated with increased family satisfaction.[18-20] Our pilot randomized trial found that family participation in ICU rounds led to increased family satisfaction with care. It is possible that higher levels of

family satisfaction are mediated by the information transfer that occurs during rounds, increased confidence in the care team, and the opportunity to ask questions about their loved ones' care.[21-23]

There was no difference in the family engagement score in the overall family engagement score between the two groups. This was perhaps due to the small sample size or due to the single engagement dimension (family presence) involved in the intervention. Additional family engagement domains may need to be incorporated into the intervention to improve the overall family engagement score. Nevertheless, our study provided baseline satisfaction and family engagement scores that can be used to inform sample size determination for future studies.

Despite professional society recommendation for incorporating family members in team rounds, there is evidence that actual practice is lacking.[24,25] A major barrier for clinicians for family presence on rounds is insufficient evidence to support the practice. There is a strong need for high quality evidence to support family participation in rounding. This study represents an initial effort to determine the feasibility of such a randomized intervention and to determine preliminary effect estimates to guide a planned larger multicenter study.

This study is subject to limitations. First, this was a small single-center pilot study in an in an academic tertiary care cardiovascular ICU. As such, the results may not be generalizable to other settings or contexts. Second, there was an imbalance in numbers between the treatment arms. We used a large block size to protect against the research team predicting the group assignment sequence. However, since one group assignment occurred with greater frequency at the beginning of the block, a mid-block inequality occurred since the study was terminated midway through a block. Nonetheless, there were no baseline sociodemographic differences between the two groups. Third, the intervention arm was necessarily unblinded due to the nature of the intervention. To

mitigate bias, healthcare providers were blinded to the usual care arm and initial data analysis was blinded to group assignment.

Conclusions

A pilot randomized trial of family member participation in team rounds found that it was feasible and led to increased family satisfaction with care. There is a need for a larger multicenter randomized trial to generate definitive evidence for the effectiveness of a family rounding strategy in critical care.

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Conflicts of interest
None

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Table 1. Demographics of family members

Demographics	Intervention (N=16)	Control (N=11)	P-value
Age (years), mean ± SD	52.8 ± 15.6	53.4 ± 15.2	0.93
Gender, N (%)			0.66
Female	11 (68.8)	9 (81.8)	
Male	5 (31.2)	2 (18.2)	
Race/ethnicity, N (%)			0.32
White (non-Hispanic)	11 (68.8)	8 (72.7)	
White (Hispanic)	0 (0)	1 (9.1)	
Black	0 (0)	0 (0)	
Asian	3 (18.8)	1 (9.1)	
Indigenous	2 (12.5)	1 (9.1)	
Other	0 (0)	0 (0)	
Level of education, N (%)			0.39
Did not complete secondary school	1 (6.2)	0 (0)	
Completed secondary school	2 (12.5)	2 (18.2)	
Had some post-secondary education	5 (31.2)	2 (18.2)	
University degree	5 (31.2)	6 (54.5)	
Graduate degree	3 (18.8)	1 (9.1)	
Living status, N (%)			0.70
Living with patient	7 (43.8)	6 (54.5)	

Table 2. Characteristics of the intervention

Demographics	**Intervention (N=16)**
Language, N (%)	
English	14 (87.5)
French	2 (12.5)
Context, N (%)	
In-person	12 (75)
Virtual	4 (25)
Present for rounds, B (%)	16 (100)
Number of rounds with family member present, mean ± SD	1.7 ± 1.4

Table 3. Primary and secondary efficacy outcomes

	Intervention	Control	P-value
FS-ICU Scores, mean ± SD			
Satisfaction with Care	87.3 ± 9.9	74.7 ± 19.5	0.03
Satisfaction with Decision-Making	75.6 ± 13.0	69.3 ± 23.3	0.27
Overall Satisfaction	82.6 ± 10.2	72.5 ± 20.8	0.07
Item 1 (Concern and Caring by ICU Staff)	94.2 ± 11.0	78.1 ± 20.9	0.03
Item 2b (Symptom Management)	90.9 ± 12.6	71.4 ± 17.3	0.02
Item 5 (Coordination of Care)	90.4 ± 12.7	68.8 ± 25.9	0.01
Item 9 (Skill and Competence of ICU Doctors)	92.3 ± 12.0	71.9 ± 20.9	0.03
Post-FAME, mean ± SD			
Total	74.0 ± 17.4	78.7 ± 17.6	0.55

Legend. Only FS-ICU questionnaire items that were statistically significant were included in the table. The other items had a P-value > 0.05 and are reported in Supplemental Table S1.

Figure 1. Reasons for non-participation