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Original Article

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

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ABSTRACT

Background: Observational studies have shown an association between family participation in intensive care unit (ICU) rounds and better family-centred outcomes. However, evidence from randomized studies on the impact of family participation in ICU rounds is lacking. The objective of this pilot study was to evaluate the feasibility of a randomized trial for family participation in ICU rounds and 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 the intervention

RÉSUMÉ

Contexte : Des études d'observation ont montré qu'il y avait un lien entre une participation des familles aux tournées à l'unité des soins intensifs (USI) et de meilleurs résultats centrés sur la famille. Toutefois, il existe peu de données issues d'études à répartition aléatoire sur l'effet d'une participation des familles aux tournées à l'USI. L'objectif de cette étude pilote était d'évaluer la faisabilité d'un essai à répartition aléatoire sur la participation des familles aux tournées à l'USI et d'obtenir des estimations préliminaires de l'effet pour orienter un futur essai sur l'efficacité.

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] Therefore, a growing need exists 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 obtain preliminary estimates of effect. If conducting one is feasible, the results of this study could be used to inform a large, multicentre effectiveness trial.

Methods

Study design

This study 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, but the study was terminated early following an interim analysis, owing 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 what is termed the "family engagement team" at the study

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(participation in rounds) or usual-care group. Following ICU discharge, family member participants completed the family satisfaction (Family Satisfaction in the Intensive Care Unit Survey [FS-ICU]). Feasibility metrics were recruitment (≥ 10 participants per month), uptake (≥ 80%), and follow-up (≥ 80%). Effectiveness was measured by between-group differences in survey score at follow-up.

Results: A total of 27 participants were recruited over 8 weeks. A total of 44% of family members (27 of 61) who were approached agreed to participate. Nonparticipation was due most commonly 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 a higher level of satisfaction with care, compared to the usual-care group (87.3 vs 74.7, $P = 0.03$, respectively).

Conclusions: Family participation in cardiovascular ICU rounds is feasible and effective at improving family satisfaction. Our findings will inform the design of a planned, larger, multicentre study to evaluate the effectiveness of family participation in ICU rounds to improve family-centred outcomes. Trial registration number: NCT05528185.

Méthodologie : Des membres de la famille de patients admis à l'USI cardiovasculaires d'un hôpital universitaire de soins tertiaires ont été affectés de façon aléatoire à l'intervention (participation aux tournées) ou au groupe de soins habituels. Après la sortie de l'USI, les participants ont rempli le questionnaire sur la satisfaction des familles à l'égard de l'unité des soins intensifs (FS-ICU, pour *Family Satisfaction in the Intensive Care Unit*). Les paramètres de faisabilité étaient le recrutement (≥ 10 participants par mois), l'adhésion (≥ 80 %) et le suivi (≥ 80 %). L'efficacité a été mesurée par les différences des scores au questionnaire entre les groupes lors du suivi.

Résultats : Au total, 27 participants ont été recrutés sur une période de 8 semaines. Chez les membres des familles qui ont été invités à participer, 44 % (27/61) ont accepté. Le refus était le plus souvent attribuable à un manque d'intérêt (n = 20; 64 %). Tous les membres des familles affectés à l'intervention (n = 16) ont été présents pour les tournées (adhésion de 100 %). Des données de suivi ont été obtenues pour 23 participants (85 %). Le taux de satisfaction à l'égard des soins a été plus élevé chez les membres des familles ayant participé aux tournées que dans le groupe de soins habituels (87,3 % contre 74,7 %; $p = 0,03$; respectivement).

Conclusions : La participation des familles aux tournées dans les USI cardiovasculaires est faisable et est efficace pour améliorer la satisfaction des familles. Nos résultats guideront la conception d'une plus grande étude multicentrique planifiée visant à évaluer l'efficacité de la participation des familles aux tournées dans l'USI pour améliorer les résultats centrés sur la famille. Trial registration number: NCT05528185.

institution, which involves collaboration with a patient/family partner in the design (ie, 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 to be anyone with a biological, legal, or emotional relationship with the patient, and whom the patient wished 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 included another family member participating in the study (ie, only one family member could attend rounds) and inability to communicate in English or French.

Recruitment process

First, we obtained verbal consent from patients to approach their family member. If patients 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 the involvement of 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, 8 am-5 pm).

Prior to recruiting participants to the study, the clinical team was informed and educated about conducting rounds with family members present. A series of in-service training sessions were provided to the bedside nurses. Attending physicians and house staff members were given a one-page summary of the study, and a document outlining best-practices on conducting rounds with family members present. During the course of the study, research personnel reinforced the role of family members 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 (for Research Electronic Data Capture) randomization module. A larger block size was chosen, as 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, owing 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. The clinical team's interaction with the family member could have been altered if they were aware that the family member was enrolled in the usual care group. Similarly, statisticians who perform the data analysis are blinded to group assignments until analyses are completed.

Study arms

The intervention consisted of family participation in daily team rounds, either in person or virtually, 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 e-mail to attend rounds. Videoconferencing was done with Microsoft Teams, which is a secure video communications platform used routinely for medical visits. A research team member contacted the participant and performed double identification. The recommended rounding format was the same for virtual as for in-person rounds.

Usual care consisted of interdisciplinary team rounds outside the patient's room each morning without the family member present, per the 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 member 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 (with a target of 10 participants per month). The uptake corresponded to the proportion of family members randomized to the intervention who participated in one or more rounds (with a target of $\geq$ 80%). The follow-up rate represented the number of participating family members who completed the follow-up questionnaires (with a target of $\geq$ 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 Survey (FS-ICU). The secondary outcome of interest was family engagement, as measured by the **Fam**ily **E**ngagement (FAME) tool.

Study instruments

The FS-ICU is a 24-item widely used and validated tool to evaluate family satisfaction with care in the ICU setting. The 2 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 satisfaction with care.[11,12]

The FAME tool is a 12-item validated tool that evaluates engagement behaviours, 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 enrollment, family members completed the FAME questionnaire, and study personnel collected sociodemographic information. The following data were 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 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 $\pm$ standard deviation, and differences between groups were tested using the Student t test or analysis of variance, as applicable. Categorical data were presented as frequencies and percentages, and differences between groups were compared using the χ^2 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, in the case of crossovers between the groups (ie, 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 the goal of having about 22 total participants based on our recruitment targets, which could provide enough data to evaluate feasibility.[14] We considered a 2-sided P-value ≤ 0.05 to be significant. Analyses were performed using SPSS 27.0 statistics software (Microsoft, Armonk, NY).

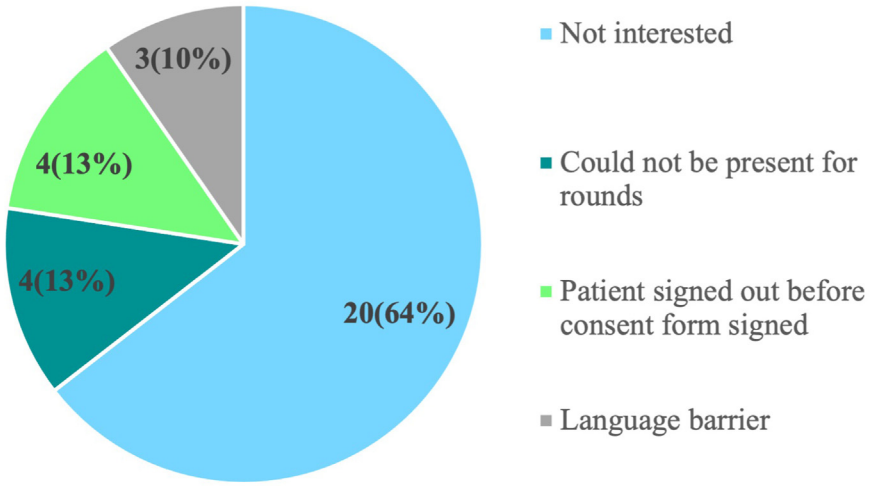

Figure 1. Reasons for nonparticipation.

Results

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

A total of 16 family members were randomized to the intervention, and 11 family members were 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 no crossovers between groups occurred.

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, $P = 0.03$). A trend was seen toward a higher overall satisfaction score in the intervention group, compared with that in the control group (82.6 ± 10.2 vs 72.5 ± 20.8, $P = 0.07$). Scores were higher 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 cardiovascular ICU doctors (items 1, 2b, 5, and 9, respectively; all $P \leq 0.05$; Supplemental Table S1). No between-group differences occurred in the overall or individual FAME scores (all $P > 0.05$; Supplemental Table S2).

Table 1. Demographics of family members

Demographic	Intervention (N = 16)	Control (N = 11)	*P*
Age, y	52.8 ± 15.6	53.4 ± 15.2	0.93
Gender			0.66
Female	11 (68.8)	9 (81.8)	
Male	5 (31.2)	2 (18.2)	
Race/ethnicity			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			0.39
Did not complete secondary school	1 (6.2)	0 (0)	
Secondary school	2 (12.5)	2 (18.2)	
Some postsecondary 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			0.70
Living with patient	7 (43.8)	6 (54.5)	

Values are mean ± standard deviation, or n (%), unless otherwise indicated.

Table 2. Characteristics of the intervention

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

Values are n (%), or mean ± standard deviation.

Discussion

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

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 centre, we achieved a recruitment rate of 13.5 participants per month, with only one research team member recruiting during daytime hours. Possibly, 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 might also be higher in centres with a higher patient volume. Additional strategies also could be considered to increase recruitment further, such as providing family members with information packages upon their arrival on the unit that could inform them about the potential to participate in healthcare team rounds.

All participants in the intervention arm attended healthcare team rounds at least once. The high uptake of the intervention was likely due in part to the inclusion of only those participants who expressed a desire to participate in the intervention. In addition, participants were given the option of attending rounds virtually 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 barriers (visitation restrictions and infection control risk) and family member-related barriers (distance to hospital, health, work, and financial).[16] Allowing participant choice regarding mode of ICU round attendance is a pragmatic approach that could be considered for use in larger multicentre trial design.

Follow-up data were available for the vast majority of participants. We acquired 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, very rarely are patients 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 multicentre Rehabilitation and Recovery in Patients after Critical Illness and Their Family Caregivers (RECOVER) study, which followed family members after their loved one's discharge from the ICU, similarly reported that a high percentage of family members completed 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. One possibility is 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 overall family engagement score between the 2 groups. This lack of difference may have been due to the small sample size or the fact that only a single engagement dimension (family presence) was 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 the professional-society recommendation for incorporating family members in team rounds, evidence

Table 3. Primary and secondary efficacy outcomes

Outcome	Intervention	Control	*P*
FS-ICU scores			
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			
Total	74.0 ± 17.4	78.7 ± 17.6	0.55

Values are mean ± standard deviation, or *P* value.

Only Family Satisfaction in the Intensive Care Unit Survey (FS-ICU) items that were statistically significant are included in the table. The other items had a *P* value > 0.05 and are reported in Supplemental Table S1.

FAME, **Fam**ily **E**ngagement tool; ICU, intensive care unit.

indicates that actual practice of this recommendation is lacking.[24,25] A major barrier for clinicians regarding family presence on rounds is insufficient evidence of benefit to support the practice. A strong need exists for high-quality evidence supporting family participation in rounding. This study represents an initial effort to determine the feasibility of such a randomized intervention and garner preliminary effect estimates to guide a planned larger multicentre study.

This study is subject to limitations. First, this was a small, single-centre pilot study in an academic tertiary-care cardiovascular ICU. Given this, the results may not be generalizable to other settings or contexts. Second, the numbers in the treatment arms were not balanced. We used a large block size to protect against the research team predicting the group assignment sequence. However, given that one group assignment occurred with greater frequency at the beginning of the block, a mid-block inequality occurred, as the study was terminated midway through a block. Nonetheless, the 2 groups had no baseline sociodemographic differences. Third, the intervention arm was necessarily unblended, owing 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 such participation was feasible and led to increased family satisfaction with care. A larger multicentre randomized trial is needed to generate definitive evidence for the effectiveness of a strategy involving family member presence on rounding in critical care.

Ethics Statement

Institutional ethics approval was obtained for this study. The study was overseen by the Family Engagement Team at the study institution, which involves collaboration with a patient/family partner in design (ie, participant materials) and selection of family-important outcome measures.

Patient Consent

The authors confirm that patient consent forms have been obtained for this article.

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Disclosures

The authors have no conflicts of interest to disclose.

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Supplementary Material

To access the supplementary material accompanying this article, visit *CJC Open* at https://www.cjcopen.ca/ and at https://doi.org/10.1016/j.cjco.2023.05.002.