

Family ENGagement in Intensive Care Environments (FENICE): A quasi-experimental study protocol

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Abstract

Even if health care professionals should take into account the active involvement of families in Intensive Care Units (ICUs), little research that investigates family member's contributions to care and includes its outcomes on both the family itself and the patient care, is available. The aim of this research project is to assess the effects of a family engagement program on family members' satisfaction and on patients' well-being and quality of life. A quasi-experimental study with two non-randomized groups (94 per each group) will be performed in two general ICUs of an Academic Italian Hospital. The intervention will be carried out in a single ICU and it consists of family members' involvement in the care of their loved ones by means of bed physical exercises and simple care tasks. Participants will be evaluated through manifold outcomes: family satisfaction, assessed with the FS-ICU tool within 48 hours after ICU discharge; patients' sense of well-being, measured with a visual analogue scale within 30 minutes after the time period of a visit; and the quality of life, investigated with the SF-12 questionnaire within the first 48 hours after admission to ICU,

at three and six months after ICU discharge by telephone. From July 2020, 188 subjects are going to be enrolled throughout the year. The latest data will be collected in December 2021 to allow the completion of the follow-ups of all participants. First, this study constitutes a significant step in a research agenda aimed at deepening the nursing sensitive outcomes in ICUs and the quality of hospital care. Secondly, the results of this study might have the potential to provide a better understanding of how families may modify patients' outcomes and whether family members would benefit from an involvement program.

Introduction

The well-being of patients and their relatives is considered fundamental in the care of critically ill adult patients and one of the top five research priorities among intensive care nurses.¹ The concept of "family engagement" in Intensive Care Unit (ICU) has expanded to the point where Health Care Professionals (HCPs) should now consider the role of the family as no longer of passive consultation, but rather of active involvement.²

A recent scoping review has investigated the extent of literature on patient and family involvement in ICUs between 2003 and 2014.³ The authors identified five components of family participation, that focused on involvement as: i) being present; ii) receiving care and meeting needs; iii) communicating and receiving information; iv) participating in the decision-making process; and v) contributing to care.³ A more recent clinical review in 2018 has summarized the concept of "engagement" by defining it as a mechanism to take action with people and to share with them information and decisions, and a way to achieve patient- and family-centered care.⁴ In addition, authors designated as "family" each family member, close relative, and caregiver with whom the patient spent most of the time.⁴

Where "family involvement" has been documented, the contributions have primarily considered family's attendance in ICU rounds,⁵⁻⁷ followed by the participation in fundamental care, such as bathing and massaging,⁸ in psychological patients' care,⁹ in ventilator weaning programs,¹⁰ and in research experiences.¹¹

Regarding the outcomes, the family members' involvement in the ICU patient care seems to improve patients' psychological recovery, well-being, and satisfaction levels,¹² while their post-traumatic disorders and depression were found to be reduced.¹³ Recently, family engagement in professional care has been recognized as a Nursing Sensitive Outcome (NSO),^{14,15} that is a patient or caregiver's state, behavior, or perception associated to nursing interventions.¹⁶ Accordingly, assessing family members' satisfaction should be considered a way to improve the quality of critical care provided to families of patients in ICU environments.¹⁷

To date, little research investigating family members' contributions to care in ICUs, including its outcomes on family itself and on

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Ethical Committee: This protocol was approved by the Regional Ethics Committee of the Friuli Venezia Giulia, Italy (CEUR-2020-Sper-012).

Trial registration: ClinicalTrials.gov, Identifier: NCT04311190. Registered on March 17, 2020. Available from: <https://clinicaltrials.gov/ct2/show/NCT04311190?term=fenice&draw=2&rank=1>.

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patient care, is available.³ We hypothesized that engaging families in the care of critically ill patients could improve outcome both at family and at patient levels. Thus, the aim of this project is to assess the effects of a family engagement program on family members' satisfaction and on patients' well-being and Quality of Life (QoL).

Materials and Methods

Research hypothesis and expected outcomes

- i) At family level: Families of critically ill patients in the family engagement group will show a higher general satisfaction as compared to those families in the control group.
- ii) At patient level: The family-involved patients' group will show
 - a) an increased sense of well-being after the daily visiting period, and
 - b) a better QoL after ICU discharge (three and six months) as compared than the control group.

Study Design

A quasi-experimental study with two non-randomized groups will be performed by following the CONSORT (CONSolidated Standards Of Reporting Trials) guidelines.¹⁸ Figure 1 shows the CONSORT flow diagram corresponding to the present study.

Setting

This study will be conducted in two general ICUs of an Academic Hospital in the Northeast of Italy equipped with 900

beds. ICU A and B (beds = eight/each) provide care for both ventilated and non-ventilated patients and mixed medical, surgical, and trauma patients admitted directly through the Emergency Department (ED) or other hospital wards. Each ICU environment is a traditional open space, in which beds are separated by curtains. Staff is composed of Registered Nurses (RNs), with a nurse-to-patient ratio of 1:2, Medical Doctors (MD) and Nursing Assistants (NAs). Generally, the average ICU Length Of Stay (LOS) is 5.0 days and the average ICU occupancy rate is 80.2%.

Sampling and sample

This study will involve two groups of family members of patients who will be admitted to two ICUs. Specifically, in the intervention group, family members will be actively involved in the care of their relative; in the control group, patients will receive the usual care provided only by the nurses. Given the setting of the ICUs, with one open space shared by patients and visitors, participant randomization is not feasible. Moreover, to reduce the risk of inter-group contamination, ICU-A will be assigned to the intervention group and ICU-B to the control group.

A consecutive sampling method will be adopted to recruit the expected family members of adult patients (≥ 18 years) in both the intervention and the control groups in the same period, from July 2020 to June 2021. Inclusion and exclusion criteria for the study population are shown in detail in Table 1. Patients' withdrawal criteria will be as follows: discharge from ICU, transfer to another hospital, or death. The withdrawal criterion for family members will be the unexpected suspension of daily visiting.

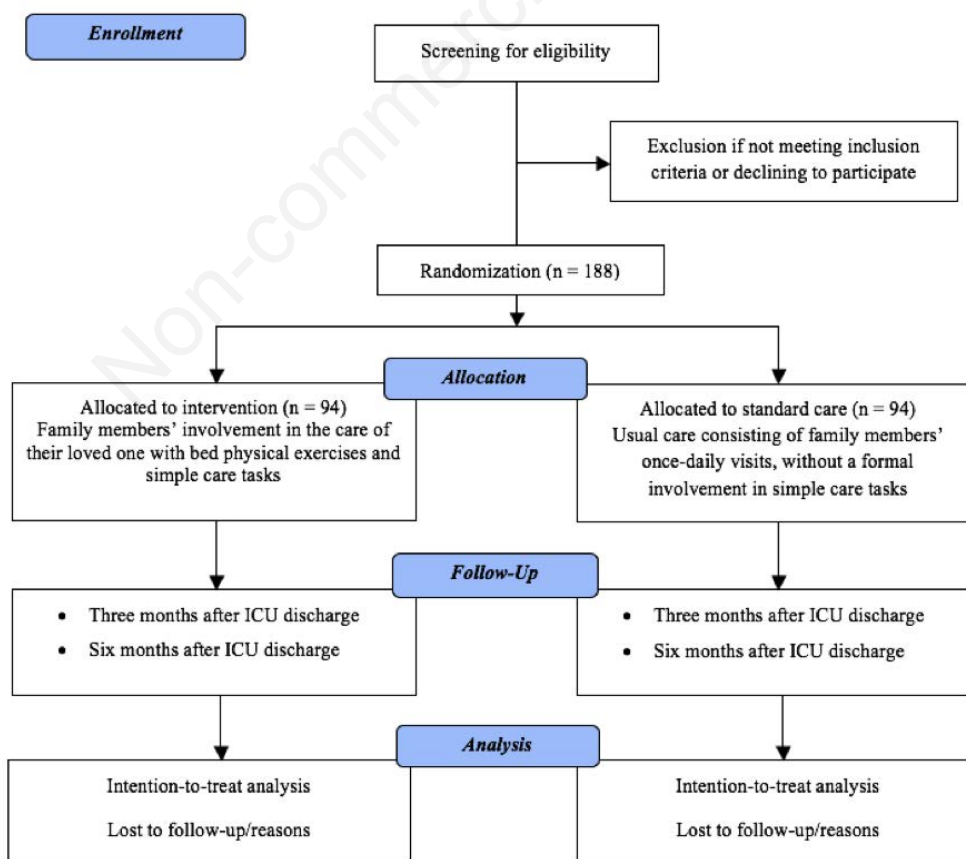


Figure 1. Flow chart of the study protocol.

Sample size calculation

The sample size calculation is based on the target population of the study, which is composed of family members. Yet, no studies have evaluated the specific effect of the implementation of a family involvement program in ICUs on family's perceived satisfaction. However, previous studies estimated the effect of structured communication and support programs on the satisfaction of family members of critically ill patients with the FS-ICU tool,^{19,20} in which the mean of FS-ICU total score before intervention was 55.3 (± 10.3) and after intervention was 61.4 (± 17.7). Based on this, a sample of 188 patients (94 per each group) is the adequate requirement for the present study. This will result in a mid-scale effect size of 0.41, at a 5% significance level with a power of 80% and an allocation rate of 1:1. The sample size of this study was calculated with the software G*Power (version 3.1.9.4).²¹ Thus, each family member will be included together with his/her loved one who is being taken care for in ICU (94 per each group).

Despite light sedation being considered a routine therapy in the ICU settings of this study, a variety of reasons, including neurological, physiological, and communicative disabilities, can prevent patients' accurate estimation of their well-being by means of self-

reported measures. This group of patients may include unconscious, deeply sedated and intubated patients, as well as those with a cognitive impairment or a head and maxillofacial trauma. For this reason, the researchers could not extend the sample size evaluation to the patient's well-being outcome.

Intervention and control group

The intervention will be carried out in a single ICU (ICU-A) and will engage family members in the care of their loved one with bed physical exercises and simple care tasks, as reported in Table 2. Trained nurses will provide families with written and verbal information about their involvement in the above-mentioned care activities (day 1: patient's admission to ICU) and will strictly supervise their engagement during the daily visiting hours (from day 2 to the transferring into another unit/ward). No intervention will be implemented without the approval of nurses and physicians who daily evaluate patients' conditions. Each session of family involvement will last for at least one hour per patient/day. In the case of signs of respiratory, hemodynamic or neurovegetative distress, the session will be immediately suspended by any HCP and the reasons of such decision will be appropriately communicated to the family member. The interven-

Table 1. Inclusion and exclusion criteria for patients and family members

	Include	Exclude
Family member	Adult (18 years of age and older)	Pediatric population (< 18 years old)
	Expected to stay in ICU at least three days to ensure adequate exposure to ICU environment	If patient meets any of the following criteria:
	Suffering from either high or low acuity conditions	- Unsafe airways
		Airways - Hypoventilation/hyperventilation
		- PaO ₂ /FiO ₂ < 200mmHg
		Breathing - pH < 7.30
		- SpO ₂ < 92%
		- Respiratory rate > 35/min
		- Heart rate < 50/min
		- Heart rate > 130/min
	Circulation - Mean arterial pressure between 60 to 80 mmHg	
	- Having mechanical heart/blood pressure support (e.g. intra-aortic pump balloon)	
	- Intense diaphoresis	
	- Prone position	
	- Intracranial pressure monitoring	
	Disability - Hypersensitivity to touch (e.g. epileptic status)	
	- Psychomotor agitation or anxiety status (e.g. RASS scores +1 to +5)	
	- Suppurating/infective/inflammatory/burned skin conditions	
	Exposure - Unstable fractures	
	- Peripheral intravenous line on the hands	
	- Terminally ill conditions	
Patient	Adult (18 years of age and older)	Pediatric population (< 18 years old)
	Being the patient's spouse, or in a blood relation, or next of kin, and/or a person with whom the patient spends most of the time	Lack of propensity or interest in participating in the study
	Willing to visit the patient daily	
	Willing to participate in the study	

RASS = Richmond Agitation Sedation Scale.

tion group will be formed of maximum eight patients, corresponding to the ICU-A bed availability. In the ICU-B, patients will receive the usual care consisting of a once-daily visit of at least one hour by family members without their formal involvement in simple care.

Family members' recruitment and involvement

Table 3 illustrates the recruitment and the involvement processes for family members.

Data collection and measurements

All data will be collected daily by two researchers (MD, AP), together with the nursing and medical staff of the Department of Anaesthesia and Intensive Care, and professionally trained medical and nursing students. Data collection will include both clinical information and paper-based questionnaires. The anonymized paper data will be stored by the researchers (see authors) of the present study.

Sociodemographic and clinical data

At the time of admission to ICU, within the routinely admission assessment, patients' demographics (age, gender), clinical characteristics (diagnosis, comorbidities, Glasgow Coma Scale [GCS] and Richmond Agitation-Sedation Scale [RASS] scores), anthropometric measures (weight and height, both required to calculate the Body Mass Index [BMI]), and previous habits (e.g., cigarette smoking) will be assessed. Simultaneously, the family member's information, including age, gender, education, relation to patient and profession, will be collected with an *ad hoc* form.

Intervention

Every day, each activity performed by the family member in the intervention group will be recorded in a pre-established form. The grid will report data, time, type of activities, and their duration (in minutes). In case of clinical deterioration during the intervention, this will be immediately stopped by the nurse and/or physician in charge of the patient's care. The intervention group will be formed of maximum eight patients, corresponding to the ICU-A bed availability.

Outcomes

At family level: Family satisfaction, assessed with the FS-ICU tool,^{22,23} will be self-reported by family members within 48 hours after a patient's discharge from ICU.

At patient level: i) A patient's sense of well-being will be measured with a visual analogue scale (VAS) within 30 minutes after the family involvement for the intervention group and in the same span of time after the ICU visiting hours for the control group;²⁴ ii) The QoL will be investigated with the SF-12²⁵ questionnaire within the first 48 hours after admission to assess pre-admission QoL,²⁶ at three and six months after ICU discharge by telephone (patient or family members).

FS-ICU

The FS-ICU questionnaire includes 24 items; 14 inquire about families' satisfaction with care and 10 explore their satisfaction with decision-making.²² All items are scored on a five-point Likert scale (from 1=very dissatisfied to 5=very satisfied) except one item which is dichotomous (yes/no). All questions included the

Table 2. Family involvement: care activities

High acuity patients (when a patient is mechanically ventilated and under analgosedation)	Low acuity patients (when a patient is awake and collaborative)
Open and close the fingers	Massages
Open and close the toes	Arms and legs position changes
Physical presence with touch at least 60 minutes/day	Washing face
Hair brushing	Assisting with rehabilitation exercises
Reading texts of interest to the patient (e.g., newspapers)	Encouraging/assisting with eating and drinking under nurses' strict supervision

Table 3. Details of the intervention protocol

Step 1 – Day one (patient's admission to ICU)

The researcher^a verifies if the patient meets the inclusion criteria.
If yes, the researcher^a proceeds with step 2.

Step 2 – Day one (family members' first visit to the ICU)

The researcher^a verifies if the family member meets the inclusion criteria.
If yes, the researcher^a provides information about the intervention (including how to talk to the patient, advice on where to sit or stand at the bedside and on how to open and close the interaction, as well as on the activities in which family members can be involved). The education session will last at least half an hour. Moreover, the researcher^a discusses the study details with the family, identifies with them a family member as a reference, and ascertains decisions regarding consent.

If the written consent is provided, data collection starts with step 3.

Step 3 – Day two to transfer to ward (during the ICU-stay)

The researcher^a actively seeks opportunities to promote the family access to the patient, maximizing the time available for the family to be with s/he and encouraging them to interact by talking and holding the patient's hand. In addition, the researcher^a promotes the implementation of the activities described in Table 2 by recording them in the *ad hoc* grid.

On daily basis, the researcher^a evaluates both the availability of the family member to participate, and the patient's clinical conditions before engaging the family member. Furthermore, the researcher^a supervises all activities performed by the family member and provides feedback of encouragement.

ICU = Intensive Care Unit, a the authors and/or a member of the research team.

“not applicable” optional response. Data will be collected from all participants via self-administered questionnaires (written).

SF-12

Originally developed from the Medical Outcomes Study (MOS) 36-item Short-Form Health Survey (SF-36), the SF-12 tool consists of 12 questions and measures eight domains: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health.^{25,27} A score ranging from 0 (indicating the worse health status) to 100 (the best health status) is assigned to each domain. Domain scores can be summarized into a Physical Component Score (PCS) and Mental Component Score (MCS). Data will be collected on all participants via a combination of self-administered questionnaires (written) during the ICU-stay and telephone interviews post-discharge.

Data analysis

Collected data will be entered into a Microsoft Excel® worksheet. All statistical analysis will be performed using the SPSS software version 25 (SPSS Institute Inc., USA) and the statistical significance set at $p < 0.05$. Continuous variables (e.g. age, LOS) will be displayed as mean and Standard Deviation (SD) if normally distributed or median and quartiles otherwise. Normality will be assessed by using the Kolmogorov-Smirnov test. Nominal variables (e.g. gender, reason of admission) will be calculated as absolute numbers and percentage. Student's unpaired t-test will be used to analyze comparisons between means; Blom's transformation will be used if normality test fails. Categorical variables will be analyzed using the chi-squared test for independence. A continuity-corrected chi-squared statistic or Fisher's exact test to evaluate the null hypothesis of this study in case of expected frequencies < 5 in contingency tables will be applied. Moreover, the scores of FS-ICU and SF-12 obtained from the two groups will be examined using the analysis of covariance (ANCOVA).

Once half of the sample is reached (47 per each group), an ad interim analysis will be performed to assess i) whether the intervention is feasible in terms of family members acceptability and willingness to participate in the study, and ii) whether a statistically significant difference regarding family satisfaction between groups is already noticeable (p -value set to 0.05). According to the results (e.g., study dropout rates and consent refusal, treatment difference larger or smaller than expected), the intervention and/or sample size calculation will be changed, and a new research protocol will be developed. However, this study has not stopping rules.

Ethical considerations

The current study will be conducted according to the criteria set by the declaration of Helsinki; each patient legally authorizes a representative and/or a family member will provide written informed consent for all study procedures. Family members will be informed about withdrawing from the study at any time without affecting the care provided. The participants' privacy and personal information will be protected, and data will be anonymously analyzed. In addition, both ICUs are equipped to ensure patients' privacy during the visiting and intervention time (e.g. large spaces, beds separated by curtains). Lastly, this protocol was approved by the Regional Ethics Committee of the Friuli Venezia Giulia (CEUR-2020-Sper-012).

Results

Beginning from July 2020, 188 subjects are going to be

enrolled throughout the year. The latest data will be collected in December 2021 to allow the completion of the follow-ups of all participants.

Discussion

To our best knowledge, very few works^{19,20} have studied the relationship between engaging families' interventions and NSOs in ICUs. This protocol constitutes a significant step in a research agenda aimed at deepening the NSOs' reliability across the ICUs and useful to proxy monitoring the quality of hospital care. The results of this study might have the potential to provide additional evidence for family participation in bedside care in ICUs, and a better understanding of how family members and critically ill patients may benefit from the involvement itself.

Regarding dissemination, the results of the present study will be firstly presented and discussed at professional meetings by conducting a stakeholders' consultation. Then, research findings will be disseminated in scientific journals and at national and international conferences.

Conclusions

Despite international bodies prioritizing the well-being of families and patients in ICU, current literature lacks practical underpinnings and examples to promote the involvement of family in the care of the critically ill patients. This study protocol aimed at examining the effect of a family engagement program on NSOs at both family- and patient-level. The results may provide valuable insight into the quality of care delivered. ICU nurses and physicians need to become convinced that families can be routinely involved in care activities; family engagement can optimize patients' outcomes including well-being and quality of life, and increase family satisfaction with care in ICU.

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