



BMJ Open Family coaching during Spontaneous Awakening Trials and Spontaneous Breathing Trials (FamCAB): pilot study protocol

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ABSTRACT

Introduction Many patients in the intensive care unit (ICU) require weaning from deep sedation (Spontaneous Awakening Trials, SATs) and mechanical ventilation (Spontaneous Breathing Trials, SBTs) in their journey to recovery. These procedures can be distressing for patients and their families. The presence of family members as ‘coaches’ during SATs/SBTs could provide patients with reassurance, reduce stress for patients and families and potentially improve procedural success rates.

Methods and analysis This study will be executed in two phases:

1. Development of a coaching module: a working group including patient partners (i.e., former ICU patients or family members of former ICU patients), researchers, and ICU clinicians will develop an educational module on family coaching during SATs/SBTs (FamCAB). This module will provide families of critically ill patients basic information about SATs/SBTs as well as coaching guidance.
2. Pilot testing: family members of ICU patients will complete the FamCAB module and provide information on: (1) demographics, (2) anxiety and (3) satisfaction with care in the ICU. Family members will then coach the patient through the next clinically indicated SATs and/or SBTs. Information around duration of time and success rates of SATs and/or SBTs (ability to conduct a complete assessment) alongside feedback will be collected. ICU clinical staff (including physicians and nurses) will be asked for feedback on practicality and perceived benefits or drawbacks of family coaching during these procedures. Feasibility and acceptability of family coaching in SATs/SBTs will be determined.

Discussion The results of this work will inform whether a larger study to explore family coaching during SATs/SBTs is warranted.

Ethics and dissemination This study has received ethical approval from the University of Calgary Conjoint Health Research Ethics Board. Results from this pilot study will be made available via peer-reviewed journals and presented at critical care conferences on completion.

INTRODUCTION

Many patients in the intensive care unit (ICU) require mechanical ventilation and deep

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study will explore inclusion of families in intensive care unit (ICU) weaning procedures.
- ⇒ This study has been designed alongside former ICU patients and families of ICU patients.
- ⇒ Families may not be comfortable with being present during Spontaneous Awakening Trials and Spontaneous Breathing Trials, leading to hesitancy to participate in the study.
- ⇒ Restricted visitation due to viral respiratory illnesses may limit family presence in the ICU.

sedation. As recommended by the Society of Critical Care Medicine’s Clinical Practice Guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption in Adult Patients in the ICU,¹ patients are weaned from sedation and mechanical ventilation with Spontaneous Awakening Trials (SATs) and Spontaneous Breathing Trials (SBTs)² in their journey to recovery. SATs and SBTs are often paired together in clinical practice³ and can reduce the duration of mechanical ventilation, length of stay in ICU and hospital, and frequency of adverse events and mortality.^{4 5}

While beneficial, SATs and SBTs are recognised to be anxiety-provoking and distressing procedures for ICU patients and their families.^{6–8} For patients, distress may be reduced by family (i.e., family member, close friend) presence and supportive family behaviours such as normalising talk and touching.^{9 10} Although the specific effect of family presence on the psychological burden of patients undergoing SATs and SBTs has not been investigated, the presence of family has been reported to ease stress for patients in ICU settings overall and is encouraged by researchers, clinicians and clinical practice guidelines in the field.^{11 12} Family presence

has also been reported to improve morale among ICU patients and facilitate positive clinical outcomes (i.e., increased length of weaning trials, weaning success) during ventilator weaning.^{13–17} Studies of patients who have undergone weaning from mechanical ventilation have anecdotally reported feeling comforted, calmed and reassured by the presence of family.^{6 18–21} Former ICU patients have recalled there being ‘something about touch [of a family member]’ and that it was ‘nice to know they [family] were there’.¹⁵

The positive effects of family presence noted in critical care settings have also been observed in other acute care environments, including obstetrics, paediatrics^{22 23} and emergency care.²⁴ Beyond family presence, coaching-type behaviours by family members have been found to be beneficial in the peripartum period and have been encouraged by healthcare professionals for decades.^{25 26} Coaching of women giving birth by significant others, close female family members (often mothers and sisters) and close friends has been explored in detail and has been reported to reduce child delivery time, rate of caesarean birth and stress.^{25–28} In acute paediatric care settings, parental coaching behaviours (e.g., reassuring speech, non-procedural talk, humour) have been reported to mitigate procedural stress and facilitate coping in paediatric patients.²⁹

Critical illness and admission of a loved one to the ICU can bring about increased psychological burden for families of ICU patients.^{30 31} Family presence and engagement have been shown to reduce psychological burden (ie, anxiety, depression) on families, even during difficult procedures such as cardiopulmonary resuscitation,²⁴ and can improve satisfaction with ICU care.^{10 32} This represents an opportunity to work with families as partners in conducting SATs/SBTs, applying two elements of the Society of Critical Care Medicine’s ICU Liberation bundle in conjunction: *Both SAT and SBT and Family engagement and empowerment* (‘F’).

This pilot study will identify key methodological and operational considerations needed to design a larger study to test the hypothesis that family coaching of patients during SATs/SBTs improves clinical outcomes for patients and reduces anxiety and stress for families. To explore the value of family presence and coaching during SATs/SBTs, this study aims to:

1. Develop a coaching module (including information and guidance) for families to coach ICU patients as they undergo SATs and SBTs.
2. Pilot test family coaching in ICU settings to determine feasibility and acceptability, as well as collect the following preliminary data to inform subsequent evaluations (if found to be feasible and acceptable):
 - Patient and family demographic information.
 - Measures of family anxiety and satisfaction with care in the ICU.
 - Duration and success rates of SATs/SBTs.
 - Feedback from ICU clinical staff on practicality of family coaching during SATs/SBTs.

METHODS AND ANALYSIS

The two aims of this study will be executed sequentially and are described below (summarised in [figure 1](#)).

Development of the FamCAB module

Working group

The research lead (ASh) will convene a working group to discuss priorities and design a family coaching module during SATs/SBTs (*FamCAB module*) for families of critically ill patients. This working group will consist of multiple stakeholders including patient partners (BGS, SK), an ICU physician (HTS), and researchers including trainees and staff (ASo, CJ, KMF). The working group will meet bimonthly to (1) determine the informational needs of family members of critically ill adults regarding coaching during SATs/SBTs, and (2) develop a coaching module to teach family members information about SATs/SBTs and how to best coach the patient. Minutes will be circulated by email to working group members after each group meeting. Feedback from group discussion will be incorporated into building the FamCAB module by the research lead (ASh) and any newly created or revised contents will be circulated back to the group by email. This process will occur iteratively until a consensus is reached on the FamCAB module content and style.

Coaching module content

A systematic search and review of existing coaching literature for families in clinical circumstances will be done to determine the content for the coaching module. The coaching module will be written at a sixth-grade reading level and will be assessed using the Patient Education Materials Assessment Tool for Print materials³³ to ensure that individuals with varying educational backgrounds and health literacy can understand the information presented. Proposed features of the coaching module are shown in [table 1](#) and include information around SATs/SBTs, family role in these procedures and resources to access more information. The coaching module will be assembled into a video format and undergo several cycles of reiterative revision until the working group deems the module ready for pilot testing in a clinical setting.

Pilot testing family coaching during SATs/SBTs

After the development of the FamCAB module, family coaching during SATs/SBTs will be pilot tested in adult ICU settings. Baseline measures for family member anxiety and family satisfaction with patient care in the ICU will be collected.

Study setting, participants and recruitment

Critically ill adults and accompanying family members (or close friends) will be recruited from the four-adult medical-surgical ICUs and one cardiovascular surgical ICU in Calgary, Canada. Patients will be eligible for inclusion in this study if they are 18 years of age or older and have clinically indicated upcoming SATs/SBTs. Family members of patients will be eligible for inclusion in this study if they are 18 years of age or older, able to

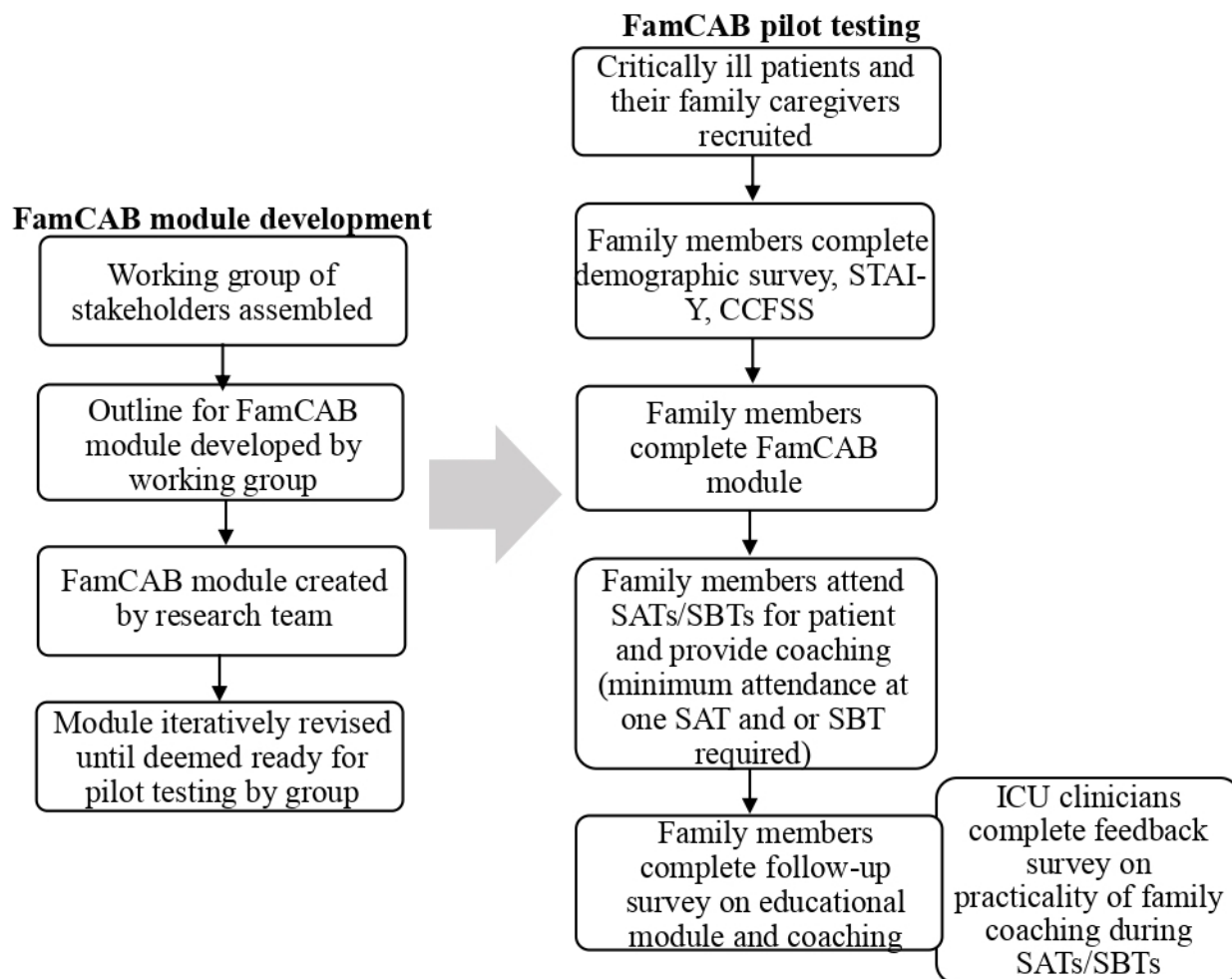


Figure 1 Study flow chart showing a summary of the procedures for FamCAB module development and subsequent pilot testing. CCFSS, Critical Care Family Satisfaction Survey; ICU, intensive care unit; SAT, spontaneous awakening trial; SBT, spontaneous breathing trial; STAI-Y, State-Trait Anxiety Inventory.

FamCAB coaching module outline (draft)	
Introduction to Spontaneous Awakening Trials (SATs) and Spontaneous Breathing Trials (SBTs)	<ul style="list-style-type: none"> ▶ What are SATs/SBTs? ▶ Who needs SATs/SBTs? ▶ Why are SATs/SBTs done? ▶ Where are SATs/SBTs done?
Family role in SATs/SBTs	<ul style="list-style-type: none"> ▶ Being present during SATs/SBTs and what to expect. ▶ How to coach the patient as they go through SATs/SBTs (<i>using approaches the family is comfortable with</i>).
Resources	<ul style="list-style-type: none"> ▶ Supporting yourself during difficult procedures. ▶ Resources.
ICU, intensive care unit.	

communicate in English (understand, read, speak), able to provide informed consent in writing and available to attend upcoming SAT(s) and/or SBT(s).

Nurses at the study ICUs will be asked to inform a trained member of the research team if a patient and family member(s) meet the study criteria. A trained member of the research team will approach the family members of critically ill patients, provide them information on the study and obtain informed written consent. If a family member consents to be part of the study, the patient will be enrolled through surrogate consent.

Procedure and data collection

After recruitment, family members will be asked to complete a demographic questionnaire providing information such as their age, gender, ethnicity, highest level of education completed, and relationship with the patient in ICU (online supplemental additional file 1). In addition, family members will complete the State-Trait Anxiety Inventory^{34 35} and the Critical Care Family Satisfaction Survey.^{36 37} Following these assessments, a trained

research team member will present the family members with the FamCAB coaching module in its entirety in a video format.

Family members will then be asked to attend the next scheduled SAT and/or SBT in person at the bedside to provide the patient with coaching during the procedure. If more than one trial is expected, family members will be encouraged to attend multiple trials. Family members will be provided with a follow-up survey (online supplemental additional file 2) and asked to complete the survey after attending a minimum of one SAT/SBT. This survey will collect their subjective experiences with attending the SAT/SBT and using the FamCAB coaching module. A research team member will be present to facilitate the completion of study tasks and record observations during the trial that may be important to consider when designing a larger future study. Patient data including demographic information, previous delirium and/or agitation, duration of SATs/SBTs and clinical team's notes on the SATs and/or SBTs will be obtained from eCritical,³⁸ a common population-based provincial critical care clinical information system.

Clinical staff from the ICU who are present during the SATs/SBTs will be asked to complete a short survey on their experiences with family presence and coaching (online supplemental additional file 3). Staff responses will be collected confidentially.

Sample size and power consideration

As this study is the first to create a specific role for families in weaning patients from sedation and mechanical ventilation in the ICU, we estimate that identifying 70 eligible participants (ie, families of those needing SATs/SBTs) in our study sites over our study period will allow us to estimate a participation rate of 30% to within a 95% CI of $\pm 10.7\%$. Our sample size is based on projected study timelines and enrolment rates that have been observed in previous pilot work completed by our research team.³⁹

Statistical analysis

We will calculate descriptive statistics (median (IQR); number (percentage)) for all study variables, as appropriate. We will determine the acceptability of the FamCAB coaching module by calculating the proportion of eligible family participants who consent to participate in the study in addition to the experiences reported by family participants and clinicians. Feasibility of the module and family coaching will be determined by calculating the number of consented families who are able to coach during an SAT and/or SBT.

Ethics and dissemination

This study has received ethical approval from the University of Calgary Conjoint Health Research Ethics Board and entered into a research agreement with the health custodian at Alberta Health Services. The results of the present study will be disseminated nationally and internationally using both traditional (eg, manuscripts, presentations

at conferences) and non-traditional (eg, social media) dissemination strategies.

Patient and public involvement

The research question addressed by this study was defined alongside former ICU patients and family members of former ICU patients who identified a lack of family support for patients during ICU procedures like SATs/SBTs. These individuals engaged in multiple group meetings discussing the methodology of this study and will be leading the conduct (i.e., recruitment, data collection, data interpretation, dissemination) of this study alongside the research team.

DISCUSSION

Deliverables and implications

The primary deliverable of this study will be a coaching module that enables active involvement of families in weaning patients from mechanical ventilation and sedation (SATs/SBTs). To our knowledge, family engagement in these procedures has undergone limited trial and evaluation. We expect that family coaching during SATs/SBTs will (1) facilitate patient tolerance of SATs/SBTs, potentially leading to earlier weaning from sedation and mechanical ventilation, (2) improve satisfaction in care for patients and their families, and (3) engage and empower families to participate in care. The implications and results of this study could further inform how patient families engage in ICU care and ensure family members are appropriately prepared and informed to support the patient during select ICU procedures. Specifically, the results of this pilot study will inform whether a larger study to evaluate the role for family caregivers in SATs and SBTs is warranted.

Knowledge translation

Multidisciplinary stakeholders (including former ICU patients, ICU healthcare providers and researchers) have co-developed the research aims and procedures reflected in this study protocol. Stakeholders will continue to be engaged in all aspects of the study, including progress review, refinement of the methods, interpretation of data and implementation of the lessons learnt that will help inform the involvement of family members in difficult ICU procedures beyond this study.

Potential limitations

While the methodology of this study has been rigorously designed alongside multiple stakeholders, the research team recognises that family presence during SATs and SBTs could be a distressful time for families. In an effort to mitigate this challenge, mental health resources will be offered to the family member participants in this study. Furthermore, the COVID-19 pandemic may continue to present challenges with family presence in the ICU. In the event that family presence becomes difficult due to COVID-19 considerations, virtual options for family

presence and coaching during SATs and SBTs will be explored, and modifications to the protocol will be discussed with the working group and the relevant ethics committee.

Proposed timeline

It is anticipated that the FamCAB module will take 2 months to design and pilot study recruitment, data collection and data analysis will take approximately 8 months to complete.

Contributors All authors (ASH, CJ, BGS, SK, ASO, KMF, HTS) have contributed to the conceptualisation and design of this protocol. ASH drafted the manuscript. All authors critically revised the manuscript and approved the final submitted version.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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