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CLINICAL TRIAL

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A randomised controlled trial of a nutrition and a decision support intervention to enable partnerships with families of critically ill patients

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Abstract

Aims and Objectives: The aim of the study was to investigate the effect of supporting family members to partner with health professionals on nutrition intakes and decision-making and to evaluate intervention and study feasibility.

Background: Family partnerships can improve outcomes for critically ill patients and family members. Interventions that support families to engage with health professionals require evaluation.

Design: A multi-centre, randomised, parallel group superiority Phase II randomised controlled trial.

Methods: In nine intensive care units (ICUs) across three countries, critically ill patients ≥60 years, or those 55–59 years with advanced chronic diseases and expected ICU length of stay >72 h and their family member were enrolled between 9 May 2017 and 31 March 2020. Participants were randomised (1:1:1) to either a decision support or nutrition optimisation family-centred intervention, or usual care. Primary outcomes included protein and energy intake during ICU and hospital stay (nutrition intervention) and family satisfaction (decision support). Study feasibility was assessed as a composite of consent rate, intervention adherence, contamination and physician awareness of intervention assignment.

Results: We randomised 135 patients/family members (consent rate 51.7%). The average rate of randomisation was 0.5 (0.13–1.53) per month. Unavailability (staff/family)

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was the major contributor to families not being approached for consent. Declined consent was attributed to families feeling overwhelmed (58/126, 46%). Pandemic visitor restrictions contributed to early study cessation. Intervention adherence for the decision support intervention was 76.9%–100.0% and for the nutrition intervention was 44.8%–100.0%. Nutritional adequacy, decisional conflict, satisfaction with decision-making and overall family satisfaction with ICU were similar for all groups.

Conclusions: Active partnerships between family members and health professionals are important but can be challenging to achieve in critical care contexts. We were unable to demonstrate the efficacy of either intervention. Feasibility outcomes suggest further refinement of interventions and study protocol may be warranted.

Relevance to Clinical Practice: Interventions to promote family partnerships in critical illness are needed but require a greater understanding of the extent to which families want and are able to engage and the activities in which they have most impact.

Reporting Method: This study has been reported following the Consolidated Standards of Reporting Trials (CONSORT) and the Template for Intervention Description and Replication (TIDieR) guidelines.

Patient or Public Contribution: Patients and caregivers were engaged in and contributed to the development and subsequent iterations of the two family-centred interventions use in this study.

Clinical Trial Registration Number: Trial registration. Clinicaltrials.gov, ID: NCT02920086. Registered on 30 September 2016. First patient enrolled on 9 May 2017 https://clinicaltrials.gov/ct2/results?cond=&term=NCT02920086&cntry=&state=&city=&dist=.

KEYWORDS
critical illness, decision-making, end-of-life, family, intensive care unit, nutrition status, partnerships, patient and family engagement, randomised trial, supportive care

1 | INTRODUCTION

Spurred by the movement of patient-centred care, healthcare organisations worldwide are encouraging and even mandating a focus on patient and family engagement. Engagement requires both health professional and patient/family to work together to promote and support family involvement in health and to demonstrate commitment to respectful, two-way dialogue and shared decision-making (Burns et al., 2018). Types of engagement range from information sharing to more active forms including partnership and shared leadership, which may be undertaken in different contexts such as direct care, organisational design and governance and policy making (Carman et al., 2013). Underpinning engagement is the intention for healthcare providers to actively partner with the patient and/or their family to improve healthcare delivery and patient outcomes.

> **What does this paper contribute to the wider global community?**
>
> - Engaging families in care in the intensive care unit can positively influence outcomes for both patients and families.
> - Health professionals should assess families' readiness to engage in care during critical illness and tailor support strategies to individual needs.
> - Interventions to support family engagement in critical illness are needed, but more research is required to understand what works for whom and in what context.

2 | BACKGROUND

During episodes of critical illness, the ability of patients to actively engage with health providers is often limited; consequently, engaging with family members is important to ensure informed and shared clinical decision-making (Institute of Patient- and Family-Centered Care, n.d.; Davidson et al., 2017). Family engagement can improve outcomes for critically ill patients (Goldfarb et al., 2017; Parker et al., 2015; Rosa et al., 2017) and family members (Olding et al., 2016). For families, engagement in care delivery can improve psychological well-being and satisfaction with care (Johnson et al., 2019; McIlroy et al., 2019). Yet, in a recent international survey of patient and family engagement in the intensive care unit variable uptake of engagement initiatives was reported (Kleinpell et al., 2018).

Guidelines for family-centred care in the intensive care unit are available but few recommendations focus on family engagement (Davidson et al., 2017). Families do indicate willingness to participate in care (Garrouste-Orgeas et al., 2010) and care discussions, although this varies according to context and individual preferences. In a qualitative-descriptive multisite study undertaken in 26 intensive care units (ICUs) across 10 countries and five continents, Naef et al. (2021) showed that nurses held and exerted more power than families and there was considerable variability in nurses' practice of engaging families. The nurse's attitude and perception of the family influenced family engagement and was also shaped by the ICU context. They highlighted the need for ICU nurses to recognise the families' contribution to the process of patient recovery and the need for families to be supported through this process. However, in the context of critical illness, most studies to date have focused on families receiving support from healthcare providers rather than as active partners in care delivery (Olding et al., 2016).

A recent systematic review of 19 studies of family engagement interventions in the neonatal, paediatric and adult ICU context demonstrated that family engagement interventions improved various outcomes. However, most studies were undertaken in neonatal ICUs, and were of also of low to moderate quality. (McAndrew et al., 2022) Only four of the 19 studies were undertaken in the adult ICU context; three more than a decade ago. The three older trials showed some positive effects from family engagement interventions, but none were randomised trials. One was a pre-test, post-test, non-equivalent control group trial (Mitchell et al., 2009), one a time series (Black et al., 2011) and the third a small post-test only study, with no comparison group (Davidson et al., 2010). The fourth, and most recent study included in this review was a prospective cohort study, where the feasibility and acceptability of a family-centred intervention designed to optimise nutrition during and following recovery from critical illness was evaluated (Marshall et al., 2016). All 51 family participants considered the intervention acceptable and would participate in similar interventions in the future, if given the opportunity.

More recently, Fiest et al. (2020) evaluated the diagnostic accuracy of family-administered tools to detect delirium in critically ill patients after first assessing the feasibility and acceptability of this approach (Krewulak et al., 2019). Although the initial work demonstrated that administration of the FAM-CAM and Sour Seven questionnaire by family caregivers to detect delirium in the ICU was feasible and acceptable, engagement in this activity was not desired by all. The diagnostic accuracy of these tools was fair, but lower than using established clinical assessments administered by clinicians.

Barriers to engaging with health professionals have been identified as mechanistic (how to do this), contextual (team is too busy) and cultural (fear of being burdensome; Bell et al., 2018). There is a clear need to develop and evaluate strategies that encourage and support families of ICU patients to engage with health professionals. Several attempts have been made to address this need; two that show promise are multicomponent interventions that are: (1) focused on decision support (The Canadian Researchers at the End of Life Network, 2017; Suurdt, 2008); and (2) focused on advocating for best nutrition practices, both which align with our earlier work (Marshall et al., 2016, 2017). Shared decision-making is an area of existing research where protocolised family support interventions could significantly decrease ICU length of stay (LOS) and reduce potentially inappropriate life-sustaining treatments as demonstrated in a recent systematic review and meta-analysis (Lee et al., 2019). However, clinical trials included in this review used interventions to developing the capacity of family members to partner with health professionals. Nutrition is well-recognised as important in recovery from critical illness throughout hospitalisation and after discharge. Existing research shows that nutritional adequacy can be suboptimal in ICU, on the ward and after hospital discharge (van Zanten et al., 2019). Since repeated, sustained efforts over the past few years have not significantly improved the total amount of calories and protein delivered via the enteral route (Tatucu-Babet & Ridley, 2022), innovative and multifaceted approaches are warranted. Partnering with families to advocate for optimal nutrition in ICU is feasible and acceptable to patients, families and health professionals (Marshall et al., 2016, 2017). Although decision support and nutrition are two distinct areas, they both share a similar intent that the interventions are designed to support families in developing a partnership role with health professionals.

3 | METHODS

3.1 | Aims and design

This international multi-centre, randomised, parallel group superiority Phase II randomised controlled trial was undertaken to assess preliminary efficacy of the study interventions and to evaluate study and intervention feasibility. We hypothesised that by engaging families in (1) multifaceted nutritional strategies that engage families in care of their family member would increase nutritional intake and optimise physical recovery in older critically ill patients at high nutrition risk and (2) multifaceted decision support strategies would reduce family members psychological distress, improve family satisfaction with decision-making and reduce the duration of ICU stay for decedents. Before undertaking a larger effectiveness trial, evaluation of study and intervention feasibility was necessary. We hypothesised that these multifaceted, family engagement interventions would be feasible to implement as judged by enrolment, consent rates and intervention adherence.

The study was conducted with three groups; one usual care group, a nutrition intervention group and a decision support group. We chose to use three groups to allow comparison of each intervention group with the usual care group to understand the overall treatment effect of each intervention. To control for the possibility that the extra time and attention provided to families through the interventions may alter their perception of care and influence the outcomes of interest we will compare treatment effects between the two intervention groups (LaFave et al., 2019).

The study was conducted between May 2017 and March 2020 in nine ICUs—five in the United States of America, three in Canada and one in Australia. The study has been reported according to the Consolidated Standards of Reporting Trials (CONSORT Guidelines; Schulz et al., 2010) and the Better reporting of interventions: template for intervention description and replication (*TIDieR*) checklist (Hoffmann et al., 2014).

3.2 | Participants

The study interventions were intended for ICU patients who were nutritionally high-risk and/or those at risk of dying in the ICU or during subsequent hospitalisation. Consequently, we recruited critically ill adult patients over the age of 60 years, or those between 55 and 59 years if they had one or more diagnoses of chronic obstructive lung disease, congestive heart failure, cirrhosis, cancer or end-stage dementia. To be eligible, patients needed a clinician-projected duration of ICU dependence for >72 h from the point of screening. ICU dependency was defined as one or more of the following: (i) invasive or non-invasive mechanical ventilation, (ii) renal replacement therapy, (iii) vasopressors or (iv) artificial nutrition because of their underlying illness. Patients were excluded if they were not expected to survive for 72 h after initial screening, were expected to have life-sustaining interventions withdrawn in the subsequent 72 h, after uncomplicated elective surgery, or receiving organ transplantation.

After trial commencement we expanded our inclusion criteria to include those between 55 and 59 years if they had one or more diagnoses of chronic obstructive lung disease, congestive heart failure, cirrhosis, cancer or end-stage dementia. This decision was based on clinician feedback with several sites identifying patients in these categories would also potentially benefit from either intervention.

Adult family members were eligible if they were the nominated or legally appointed substitute decision maker, expected to visit at least three times per week and able to communicate in English.

3.3 | Randomisation and allocation concealment

Patients were screened as soon as practical after ICU admission. Consent and proxy consent to obtain patient data was obtained within 72 h of ICU admission by the research nurse.

Randomisation and allocation concealment were achieved using a web-based randomisation system. Permuted blocks of a random, undisclosed size, stratified by site, were used to allocate patients 1:1:1 to (i) the nutrition intervention, (ii) the decision support intervention or (iii) usual care by the site investigator. Blinding of participants and those delivering the intervention was not possible due to the nature of the interventions. Those performing data analysis were unaware of group allocation (Polit, 2011). All data were analysed using an intention-to-treat analysis.

3.4 | Interventions

Family members in all groups received usual care which included ad hoc verbal information about the ICU and the patient's condition, and social and emotional support as required. Two theoretical frameworks *Facilitated Sensemaking* (Davidson, 2010; Davidson et al., 2010) and *Lightening our Load* (Vandall-Walker & Clark, 2011) which promote engagement with families by appreciating the importance of their roles and creating opportunities to participate in communication, decision-making and bedside care were used when developing these interventions. The interventions were designed to empower family members and develop their capacity to partner with health professionals with the goal of achieving improved patient care and outcomes while also providing families with a sense of purpose derived from active participation in care. The nutrition intervention, *OPTimal nutrition by Informing and Capacitating family members of best practices*, is a multicomponent intervention designed to help families gain the confidence and skills to audit and advocate for optimal nutrition during and following recovery from critical illness. The feasibility and acceptability of this intervention had been established in earlier work (Marshall et al., 2016, 2017). The web-based decision support intervention, *My ICUGuide*, was designed to support family to engage in a shared decision-making process with health professionals regarding treatment goals and was previously pilot tested (Suurdt, 2008). Figure 1 provides an outline of intervention components and timing of delivery. Interventions were delivered in person in the ICU by a registered nurse, medical officer or dietitian who were part of the site study teams. Additional detail of the interventions has been published elsewhere (Heyland et al., 2018; Van Scoy et al., 2017) and are provided in Appendix 1.

3.5 | Outcome measures

For the purpose of this phase II study, we are evaluating more proximal (short-term) outcomes and process measures. Nutrition and decision support outcomes were assessed for all groups to enable comparisons across all three groups. The primary nutrition-related outcome is included protein and energy intake during ICU and hospital stay. Secondary nutrition-related outcomes are hypothesis generating and include consumption of oral nutrition supplements and hand grip strength at or before hospital discharge. The primary outcome for decision support was family satisfaction with decision-making as measured using the Family Satisfaction with the ICU Survey (FS-ICU). The FS-ICU is a reliable and validated instrument for measuring satisfaction with care (Cronbach's a coefficient 0.92) and decision-making (Cronbach's a coefficient 0.88; Wall et al., 2007). Secondary outcomes

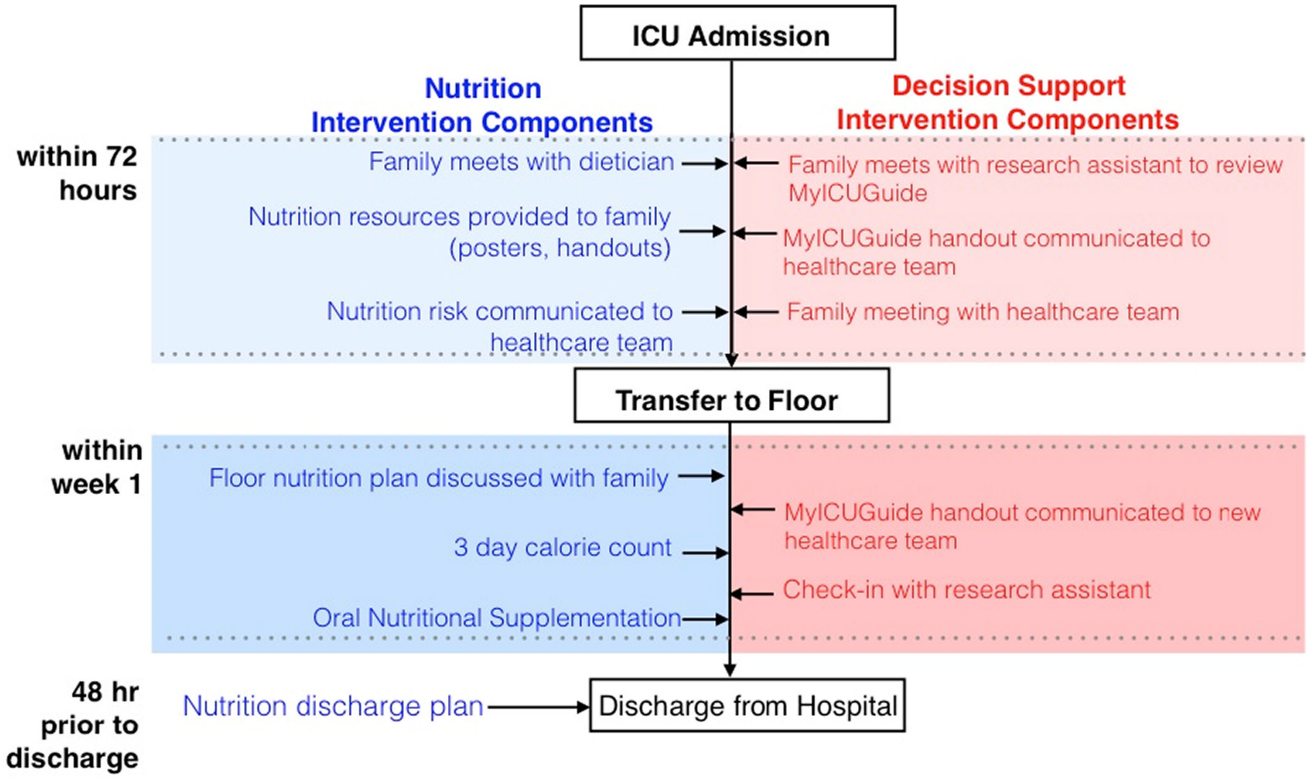

FIGURE 1 Intervention components and timing of delivery.

included decision conflict score (10-item Decisional Conflict Scale). The 10-item Decisional Conflict Scale elicits uncertainty in health-related decision-making, factors contributing to uncertainty and perceived effectiveness of decision-making. It has a test–retest reliability coefficient of 0.81 and reported internal consistency of 0.78–0.92 (O'Connor, 1995). Trial feasibility was determined by assessing the consent rate, intervention adherence, contamination and physician awareness of intervention assignment.

3.6 | Sample size

A total sample size of 150 patients and their family members (50 per group) was identified. We anticipated enrolling 10–20 patients/family members per site to allow contextual assessment of intervention feasibility.

For each intervention, we performed a sample size calculation for one of the key short-term outcomes of each intervention. Our earlier research indicates that the average nutritional adequacy of patients during their ICU stay will be 40%–50% with a standard deviation of 30% (Cahill et al., 2010). We aim to detect a small but clinically meaningful increase in nutritional adequacy of approximately 20%. Under these assumptions 50 patients per group will achieve 92% power at a two-sided alpha = 0.05. For the decision support intervention, we powered the trial to evaluate family satisfaction with decision-making. In the REALISTIC-80 study (Heyland et al., 2015), the standard deviation of the FS-ICU24 'Decision-making' domain was 11. An increase in 5.5 points (a medium effect size) was considered plausible and clinically important. With 50 evaluable subjects per group, we would achieve 71% power at a two-sided alpha = 0.05 to detect a 5.5-point difference between groups.

With 50 participants per group, assessment of binary variables of study feasibility, such as follow-up, contamination and intervention adherence, could be estimated within ±14% and any variable with a rate <15% or >85% could be estimated to within ±10%.

3.7 | Data collection

We collected demographic data for patients and families at baseline and were guided by recommended baseline measures for nutrition studies in ICU (Davies et al., 2022; Heyland et al., 2016) and although similar guidance is not available, these baseline measures appear appropriate for decision support as well. During the patient's ICU stay we collected data on nutrition risk, nutrition prescription and intake, hand grip strength, use of life-sustaining treatments, length of ICU and hospital stay, treatment limitations in ICU and mortality. Data collected for family participants included demographic data, family satisfaction with ICU care and decision conflict. Process data were collected to assess feasibility and included consent and enrolment rates, intervention adherence assessed by the research assistant, and physician awareness of the interventions. Exposure for an intervention to which participants were not assigned was also collected. Full details of the data collected are provided in Appendix 2.

TABLE 1 Patient characteristics at baseline.

Characteristic	All participants (n = 128)	Usual care (n = 44)	OPTICs (n = 44)	Decision support (n = 40)
Age (years)	72.6 ± 8.1 (59.0–92.0)	71.5 ± 8.2 (60.0–92.0)	73.4 ± 8.2 (59.0–89.0)	73.0 ± 8.0 (59.0–88.0)
Sex (male)	82 (64.1%)	31 (70.5%)	26 (59.1%)	25 (62.5%)
Marital status				
Married/living as married	89 (69.5%)	30 (68.2%)	31 (70.5%)	28 (70.0%)
Type of ICU admission				
Medical	85 (66.4%)	27 (61.4%)	30 (68.2%)	28 (70.0%)
Surgical elective	7 (5.5%)	2 (4.5%)	3 (6.8%)	2 (5.0%)
Surgical emergency	36 (28.1%)	15 (34.1%)	11 (25.0%)	10 (25.0%)
Primary ICU admission diagnosis				
Neurologic	34 (26.6%)	10 (22.7%)	12 (27.3%)	12 (30.0%)
Respiratory	27 (21.1%)	9 (20.5%)	7 (15.9%)	11 (27.5%)
Sepsis	22 (17.2%)	8 (18.2%)	8 (18.2%)	6 (15.0%)
Trauma	14 (10.9%)	7 (15.9%)	3 (6.8%)	4 (10.0%)
Cardiovascular/Vascular	13 (10.2%)	5 (11.4%)	5 (11.4%)	3 (7.5%)
Gastrointestinal	13 (10.2%)	5 (11.4%)	5 (11.4%)	3 (7.5%)
Hematologic	2 (1.6%)	0 (0.0%)	1 (2.3%)	1 (2.5%)
Orthopaedic	2 (1.6%)	0 (0.0%)	2 (4.5%)	0 (0.0%)
Other	1 (0.8%)	0 (0.0%)	1 (2.3%)	0 (0.0%)
Admitted following chronic, declining illness	39 (30.5%)	12 (27.3%)	15 (34.1%)	12 (30.0%)
Length of hospital stay prior to this ICU admission	(128) 2.2 ± 6.0 (0.0–42.1) 0.2 [0.0 to 1.4]	(44) 2.0 ± 4.5 (0.0–23.7) 0.2 [0.0 to 1.4]	(44) 2.6 ± 6.7 (0.0–32.7) 0.3 [0.0 to 1.6]	(40) 2.0 ± 6.7 (0.0–42.1) 0.2 [0.0 to 1.1]
Baseline SOFA score	(128) 9.1 ± 3.6 (1.0–18.0)	(44) 9.6 ± 3.7 (2.0–18.0)	(44) 8.7 ± 3.4 (2.0–16.0)	(40) 9.0 ± 3.7 (1.0–18.0)
APACHE II score	(128) 20.8 ± 7.6 (6.0–43.0)	(44) 20.5 ± 7.4 (7.0–43.0)	(44) 21.3 ± 6.8 (6.0–39.0)	(40) 20.7 ± 8.8 (7.0–40.0)
Charlson Comorbidity Index	(128) 2.3 ± 2.5 (0.0–13.0) 2.0 [0.0 to 3.0]	(44) 2.7 ± 3.1 (0.0–13.0) 2.0 [1.0 to 3.5]	(44) 2.1 ± 2.3 (0.0–9.0) 1.5 [0.0 to 3.0]	(40) 2.0 ± 1.9 (0.0–8.0) 2.0 [0.0 to 3.0]
Functional Comorbidity Index	(128) 1.5 ± 1.4 (0.0–6.0)	(44) 1.5 ± 1.5 (0.0–6.0)	(44) 1.6 ± 1.3 (0.0–4.0)	(40) 1.6 ± 1.4 (0.0–5.0)
Hospital admissions (last 12 months)	(127) 1.2 ± 1.8 (0.0–11.0)	(43) 1.4 ± 2.2 (0.0–9.0)	(44) 0.9 ± 1.2 (0.0–5.0)	(40) 1.2 ± 2.0 (0.0–11.0)
ICU admissions (last 12 months)	(128) 0.5 ± 0.8 (0.0–4.0)	(44) 0.5 ± 0.9 (0.0–4.0)	(44) 0.4 ± 0.7 (0.0–3.0)	(40) 0.5 ± 0.8 (0.0–3.0)
Body mass index	(128) 28.5 ± 7.2 (15.0–54.0)	(44) 27.1 ± 5.6 (17.6–41.5)	(44) 29.5 ± 8.7 (15.0–54.0)	(40) 29.0 ± 6.8 (17.6–43.8)
Malnutrition screening tool	(128) 1.2 ± 1.4 (0.0–5.0)	(44) 1.2 ± 1.6 (0.0–5.0)	(44) 1.1 ± 1.2 (0.0–4.0)	(40) 1.1 ± 1.3 (0.0–5.0)
Palliative performance score < 70[a] at baseline	51 (60.5)	12 (27.3)	21 (47.7)	18 (45.0)
SF-36 (Physical function)	(126) 53.5 ± 38.1 (0.0–100.0) 52.5 [15.0 to 95.0]	(42) 59.3 ± 35.7 (0.0–100.0) 70.0 [30.0 to 95.0]	(44) 47.2 ± 37.3 (0.0–100.0) 37.5 [7.5 to 87.5]	(40) 54.4 ± 41.2 (0.0–100.0) 60.0 [12.5 to 97.5]
Clinical Frailty Scale				
Non frail	83 (64.8)	32 (72.7)	25 (56.8)	26 (65.0)
Frail	44 (34.4)	12 (27.3)	18 (40.9)	14 (35.0)

TABLE 1 (Continued)

Characteristic	All participants (n=128)	Usual care (n=44)	OPTICs (n=44)	Decision support (n=40)
Missing	1 (0.8%)	0 (0.0%)	1 (2.3%)	0 (0.0%)
Lives alone	19 (14.8%)	6 (13.6%)	8 (18.2%)	5 (12.5%)
Usual residence – home	109 (85.2%)	35 (79.5%)	40 (90.9%)	34 (85.0%)
Ethnicity				
Caucasian/White	95 (74.2%)	30 (68.2%)	36 (81.8%)	29 (72.5%)
Asian/Pacific Islander	18 (14.1%)	8 (18.2%)	4 (9.1%)	6 (15.0%)
African/Black North American	5 (3.9%)	3 (6.8%)	1 (2.3%)	1 (2.5%)
East Indian	3 (2.3%)	0 (0.0%)	1 (2.3%)	2 (5.0%)
First Nations/Inuit/Metis, Aboriginal, or Native American	1 (0.8%)	1 (2.3%)	0 (0.0%)	0 (0.0%)
Hispanic	3 (2.3%)	2 (4.5%)	0 (0.0%)	1 (2.5%)
Other (specify)	3 (2.3%)	0 (0.0%)	2 (4.5%)	1 (2.5%)
Patient documented treatment preferences				
Yes	53 (41.4%)	20 (45.5%)	16 (36.4%)	17 (42.5%)
No	70 (54.7%)	22 (50.0%)	26 (59.1%)	22 (55.0%)
Unsure	5 (3.9%)	2 (4.5%)	2 (4.5%)	1 (2.5%)

Abbreviations: APACHE, acute physiological and chronic health evaluation; ICU, intensive care unit; SOFA, sequential organ failure assessment.
[a]PPS < 70 is indicative of unlikely survival for more than 6 months (Harrold et al., 2005).

3.8 | Ethical considerations

The trial was approved by the Human Research Ethics Committee at Gold Coast Health (HREC/17/QGC/32) and ethics boards at each participating site. In-person consent was provided by the participating family member. The study protocol has been previously published (Heyland et al., 2018). The study was registered on 30 September 2016 at Clinicaltrials.gov, ID: NCT02920086.

3.9 | Data analysis

The distribution of the continuous outcomes above are described by group and compared among groups using a mixed-effects model with treatment arm as a fixed effect and site as a random effect. Due to the limited number of sites in this clinical trial, we performed a sensitivity analysis, treating site as a fixed effect. For the binary outcomes, we used the Mantel–Haenszel test stratified by site. At this exploratory stage, we did not adjust p values for multiplicity of tests. Feasibility outcomes are described by group as rates with 95% confidence intervals. Reasons for loss to follow-up, lack of intervention adherence, and contamination are tabulated.

4 | RESULTS

Demographic data for patients and family members were similar between the three groups. Most patients were male (n=82, 64.1%), the mean age was 72.6 ± 8.1 years and mean Acute Physiology and Chronic Health Evaluation Score was 20.8 ± 7.6 (Table 1). Family members were mostly female (n=94, 73.4%) with a mean age of 58.2 ± 14.8; 52.3% (n=67) were a spouse or partner of the patient (Table 2).

4.1 | Preliminary efficacy outcomes

For the nutrition outcomes, there were no statistically significant differences between the three groups, with the exception that energy adequacy (the proportion of prescribed energy delivered to the patient) in the ICU was higher in the decision support group compared with both the usual care group and the nutrition intervention group. Intake on hospital wards was compromised by missing data (67/128, 52.3% missing) with no differences between the groups for protein or energy intakes or consumption of oral nutrition supplements. There was also no difference in the median hand grip strength (see Table 3).

Decision support outcomes (i.e. decisional conflict, satisfaction with decision-making and overall family satisfaction with ICU) were similar for all groups (Table 4). Clinical outcome measures including ICU and hospital mortality, and ICU and hospital length of stay for survivors were similar between the three groups (Table 5). The ICU length of stay for decedents was longer for the decision support group (12.1 [7.1–17.7]) than the nutrition intervention group (8.1 [6.0–16.8]) and usual care group (9.6 [5.2–21.4]).

TABLE 2 Family member characteristics.

Family members	All participants (n = 128)	Usual care (n = 44)	Nutrition intervention (n = 44)	Decision support (n = 40)
Age	(128) 58.2 ± 14.8 (19.0–92.0)	(44) 58.1 ± 16.1 (19.0–92.0)	(44) 60.0 ± 12.0 (32.0–87.0)	(40) 56.4 ± 16.2 (24.0–81.0)
Sex (male)	34 (26.6%)	11 (25.0%)	11 (25.0%)	12 (30.0%)
Relationship to patient (%)				
Spouse/Partner	67 (52.3)	27 (61.4)	21 (47.7)	19 (47.5)
Parent	6 (4.7)	4 (9.1)	1 (2.3)	1 (2.5)
Daughter/Son	49 (38.3)	13 (29.5)	18 (40.9)	18 (45.0)
Sister/Brother	5 (3.9)	0 (0.0)	3 (6.8)	2 (5.0)
Other	1 (0.8)	0 (0.0)	1 (2.3)	0 (0.0)
Highest education level (%)				
Primary school or less	1 (0.8)	1 (2.3)	0 (0.0)	0 (0.0)
Some high school	8 (6.3)	5 (11.4)	1 (2.3)	2 (5.0)
High school graduate	24 (18.8)	9 (20.5)	8 (18.2)	7 (17.5)
Some college or university	51 (39.8)	15 (34.1)	19 (43.2)	17 (42.5)
University degree	30 (23.4)	11 (25.0)	10 (22.7)	9 (22.5)
Post Graduate University degree	14 (10.9)	3 (6.8)	6 (13.6)	5 (12.5)
Preference for participation in patient care n (%)				
Preference for minimal or no involvement	33 (25.8)	10 (22.7)	12 (27.3)	11 (27.5)
Preference for maximum involvement	95 (74.2)	34 (77.3)	32 (72.7)	29 (72.5)
How close the family member was to the patient (%)				
Moderately close	6 (4.7)	3 (6.8)	3 (6.8)	0 (0.0)
Very close	33 (25.8)	9 (20.5)	10 (22.7)	14 (35.0)
Fully close	69 (53.9)	22 (50.0)	25 (56.8)	22 (55.0)
Self	20 (15.6)	10 (22.7)	6 (13.6)	4 (10.0)
Abbreviated Miller Behavioural Style Scale (%)				
High monitors	58 (45.3)	19 (43.2)	21 (47.7)	18 (45.0)
Low monitors	70 (54.7)	25 (56.8)	23 (52.3)	22 (55.0)
Information needs (%)				
Would like a lot of information	33 (82.5)	0 (0.0)	0 (0.0)	33 (82.5)
Would want some information	7 (17.5)	0 (0.0)	0 (0.0)	7 (17.5)
Speaks a language other then English	42 (32.8)	14 (31.8)	13 (29.5)	15 (37.5)
Ethnicity (%)				
Asian/Pacific Islander	19 (14.8)	8 (18.2)	6 (13.6)	5 (12.5)
African/Black North American	5 (3.9)	2 (4.5)	2 (4.5)	1 (2.5)
Caucasian/White	94 (73.4)	31 (70.5)	33 (75.0)	30 (75.0)
East Indian	2 (1.6)	0 (0.0)	0 (0.0)	2 (5.0)
Hispanic	4 (3.1)	3 (6.8)	0 (0.0)	1 (2.5)
Other (specify)	4 (3.1)	0 (0.0)	3 (6.8)	1 (2.5)
Health status (%)				
Excellent	53 (41.4)	19 (43.2)	18 (40.9)	16 (40.0)

TABLE 2 (Continued)

Family members	All participants ($n = 128$)	Usual care ($n = 44$)	Nutrition intervention ($n = 44$)	Decision support ($n = 40$)
Very good	40 (31.3)	12 (27.3)	12 (27.3)	16 (40.0)
Good	27 (21.1)	9 (20.5)	10 (22.7)	8 (20.0)
Fair	7 (5.5)	3 (6.8)	4 (9.1)	0 (0.0)
Poor	1 (0.8)	1 (2.3)	0 (0.0)	0 (0.0)
Experience with making medical decisions at the end of life (%)				
Yes	48 (37.5)	18 (40.9)	16 (36.4)	14 (35.0)
No	80 (62.5)	26 (59.1)	28 (63.6)	26 (65.0)
How important is spirituality or religion in your life? (%)				
Extremely important	29 (22.7)	11 (25.0)	8 (18.2)	10 (25.0)
Very important	36 (28.1)	9 (20.5)	20 (45.5)	7 (17.5)
Somewhat important	26 (20.3)	10 (22.7)	6 (13.6)	10 (25.0)
Not very important	18 (14.1)	7 (15.9)	5 (11.4)	6 (15.0)
Not at all important	19 (14.8)	7 (15.9)	5 (11.4)	7 (17.5)
Identifies with a formal religious group or practice	110 (85.9)	38 (86.4)	36 (81.8)	36 (90.0)
Location of last residence (%)				
Rural	28 (21.9)	7 (15.9)	11 (25.0)	10 (25.0)
Urban	100 (78.1)	37 (84.1)	33 (75.0)	30 (75.0)

4.2 | Feasibility

During the study period, 474 patients and family members met eligibility criteria and 261 (55.1%) were approached for consent. Of these, 135 were enrolled (consent rate 51.7%) and randomised to usual care ($n = 46$), the nutrition intervention ($n = 44$) or the decision support intervention ($n = 45$). Across the nine participating sites, the number of patients randomised varied (range 1–46) with a median of 10 patients randomised per site. The average randomisation rate per month was 0.5 (range 0.3–1.53). The site with the highest randomisation rate per month (1.53 patients per month) had a research coordinator who was dedicated to this study with no other responsibilities. Inability to approach the family in the ICU owing to staff or family unavailability was the primary reason why eligible participants were not approached for consent. For those who were approached for consent, 58/126 (46%) declined because they felt too overwhelmed with their loved one's illness. Enrolment ceased early due to Coronavirus disease 2019 pandemic visitation restrictions. Patient flow through the study is depicted in Figure 2.

Adherence to intervention components for the decision support intervention ranged from 76.9–100.0% and for the nutrition intervention were 44.8%–100.0% (Table 6). Contamination was assessed for the first 46 participants (usual care $n = 17$; nutrition intervention $n = 14$; decision support intervention $n = 15$); no contamination was observed, and collection of these data was ceased to reduce participant burden.

While most physicians were aware that the patient was enrolled in the trial, 45% were unable to recall group assignment (Table 7).

5 | DISCUSSION

This multi-centre, randomised, parallel group superiority clinical trial was designed to evaluate the effects of two theory-informed, interventions developed to empower family members to partner with health professionals on patient care and outcomes. We were unable to demonstrate that either intervention resulted in a statistically or clinically significant difference in the outcomes of interest despite reasonable intervention fidelity. Specifically, for the nutrition intervention energy adequacy in the ICU was higher for the decision support group than for the nutrition intervention or control group although the reason for these results was unclear. Nutrition intake in the hospital wards was compromised owing to missing data which has also been reported in studies of nutrition intake after ICU discharge (Ridley et al., 2019). We had hypothesised that muscle strength would be increased as a result of improved nutrition adequacy but were unable to demonstrate any difference between groups for this measure. For the nutrition intervention, some components were the responsibility of clinical rather than research staff and availability may have impacted intervention adherence and may have influenced these findings. For example, less than a third of participants reviewed the nutrition education booklet after the initial education session. Despite using teach-back as a method to check comprehension (Yen & Leasure, 2019) it is not uncommon for patients or families to be confused after information is initially presented to them. They may not recognise a lack of comprehension and consequently may not have felt the need to review information or seek additional information from health professionals.

TABLE 3 Nutrition-related outcomes.

Nutrition-related outcome	Usual care ($n = 44$)	Nutrition intervention ($n = 44$)	Decision support intervention ($n = 40$)	*p* Value: Usual vs. nutrition	*p* Value: Usual vs. decision support	*p* Value: Nutrition vs. decision support
Nutritional adequacy during the ICU stay (%)						
Energy adequacy	50.7 ± 30.0	49.2 ± 24.2	61.0 ± 28.7	.79	.11	.04
Protein adequacy	49.2 ± 30.9	47.4 ± 30.7	55.4 ± 32.2	.79	.37	.25
Consumption of oral nutrition supplements *n* (%)						
Patient received any ONS in hospital	17 (38.6%)	17 (38.6%)	15 (37.5%)	.88	.93	.96
Patients received 2 or more ONS	6 (13.6%)	7 (15.9%)	6 (15.0%)	.70	.58	.95
Oral intake on hospital wards (3-day calorie count) (*n*) mean ± SD						
Calories (kcal/day)	(15) 933.9 ± 622.1	(15) 1061.6 ± 546.6	(10) 1024.1 ± 698.0	.56	.84	.88
Protein (g/day)	(15) 41.8 ± 24.5	(15) 44.3 ± 26.7	(10) 46.0 ± 27.5	.80	.77	.88
Hand grip strength						
(*n*) median (Q1–Q3)	(43) 22 (0–40)	(40) 21 (0–36)	(37) 19 (0–34)	.98	.41	.89

For the decision support intervention decisional conflict, satisfaction with decision-making and overall family satisfaction with ICU were similar for all groups. Intervention delivery was coordinated by the research team and there was greater adherence to the intervention compared to what was observed in the nutrition intervention, suggesting dedicated resources may be required for multifaceted and complex interventions such as these. Given both interventions were premised on developing partnerships with the healthcare team it is not surprising that satisfaction with decision-making and overall family satisfaction was similar between the two intervention groups.

Prior to undertaking a larger effectiveness trial, it was important for us to assess efficacy of more proximal outcomes and assess study and intervention feasibility. We prespecified a target of >75% of eligible patients to be approached for consent but fell short with only 44.9% being approached. Not approaching family members for consent mostly occurred because these families visited outside regular business hours when research staff were unavailable. Missed opportunities to recruit eligible participants in studies is not unusual. Burns et al. (2013) in their study of research recruitment practices in critical care, reported that 140/452 (31%) of eligible consent events were achieved; consent was missed or unable to be done for operational reasons for 57.4% of eligible patients suggesting that perhaps our pre-determined targets were overly optimistic.

Variability in research support and infrastructure at each site may have also influenced recruitment rates and is an important consideration to minimise barriers to undertaking clinical research (Gehrke et al., 2019). While we did not collect data on visiting patterns of family members, understanding when family are most likely to be present is critical, recognising that this may change during a patient's hospitalisation. This is particularly important where interventions involve substantial and sustained family member engagement. This can subsequently inform research operations such as recruitment and consent, which are typically undertaken by research coordinators who are not often available during the evening or on weekends (Burns et al., 2013).

Similarly, our consent rate was 51.7%, below the benchmark of 60% we considered reasonable for study feasibility; this was higher than our initial pilot work for the nutrition intervention where 51/187 (27.3%) family members consented to participate (Marshall et al., 2016) but lower than the subsequent feasibility assessment (75/113;66.5%) of the same intervention (Marshall et al., 2017). This was likely because in the feasibility assessment the intervention delivery time was extended from 72 h after ICU admission to the first week after ICU admission to accommodate individual family circumstances. Owing to the nature of the decision support intervention we were unable to lengthen recruitment time and recognise the first days after an ICU admission to be highly stressful for family members which may have influenced the consent rate. We were able to randomise one patient every 2 months, suggesting that hundreds of ICUs would be required for a future study to be feasible. Although not always reported, consent rates in other randomised controlled trials or observational studies undertaken in the ICU are much higher than what we were able to achieve (median 86.9%; IQR 71.6–94.1; Garde et al., 2016).

TABLE 4 Outcomes associated with the decision-support intervention.

Decision-support outcome	Usual Care (*n* = 44)	Nutrition intervention (*n* = 44)	Decision support intervention (*n* = 40)	*p* Value		
				Usual vs. nutrition	Usual vs. decision support	Nutrition vs. decision support
Change in decisional conflict						
Uncertainty subscore	(40) −6.9 ± 23.3	(38) −6.9 ± 20.5	(34) −11.0 ± 27.1	.76	.92	.76
Informed subscore	(40) −21.5 ± 32.0	(38) −23.9 ± 30.8	(34) −22.1 ± 35.2	.77	.29	.63
Values clarity subscore	(40) −17.2 ± 35.4	(38) −23.4 ± 31.3	(34) −21.7 ± 38.6	.81	.34	.43
Support subscore	(40) −7.3 ± 14.3	(38) −6.4 ± 20.1	(34) −2.7 ± 12.8	.30	.75	.97
Total score	(40) −13.4 ± 20.3	(38) −15.1 ± 17.7	(34) −14.0 ± 23.8	.72	.59	.58
Family satisfaction with decision making	85.5 ± 16.3	85.4 ± 14.2	87.8 ± 16.4	.87	.47	.54
Overall family satisfaction with ICU	84.7 ± 10.2	83.8 ± 9.7	81.5 ± 11.7	.81	.24	.31

TABLE 5 Clinical outcomes.

Clinical outcome	All participants (*n* = 128)	Usual care (*n* = 44)	Nutrition intervention (*n* = 44)	Decision support (*n* = 40)
	n (%)			
ICU mortality	35 (27.3)	9 (20.5)	12 (27.3)	14 (35.0)
Hospital mortality	40 (31.3)	12 (27.3)	13 (29.5)	15 (37.5)
	Median [IQR]			
Length of stay in ICU among survivors (days)	(88) 11.5 [5.9 to 18.9]	(32) 12.6 [6.9 to 18.7]	(31) 11.0 [5.8 to 19.0]	(25) 10.8 [5.4 to 19.2]
Length of stay in hospital among survivors (days)	(88) 20.8 [15.2 to 34.5]	(32) 18.4 [14.9 to 33.6]	(31) 25.6 [15.6 to 35.0]	(25) 20.1 [14.6 to 34.2]
Time to discharge alive from hospital (days)	(128) 28.6 [15.1 to 91.0]	(44) 26.5 [13.2 to 91.0]	(44) 28.6 [15.9 to 91.0]	(40) 33.6 [15.5 to 91.0]

Abbreviations: ICU, intensive care unit; IQR, interquartile range.

Black et al. (2011) also reported a high consent rate (170/171) and also recruited participants early after the ICU admission. The intervention in this study focused on verbal and physical interaction with the patient rather than partnering with health professionals and therefore may have been more acceptable to more family members. Similarly, Fiest et al. (2020) reported high consent rates of 147/196 (75%) in their study where families completed two delirium assessments. While this involved some activity on the part of the family, it is possible that this task was considered less onerous than our more complex, active and ongoing intervention that involved families actively engaging with health professionals. We used in-person consent with surrogate decision makers, which is reported to be the preferred method (Burns et al., 2017) and employed a pre-consent touchpoint. The addition of telephone-based consent may have been helpful. Introduction of the research coordinator by members of the medical team may help to build trust between the researcher and participant (McDonald et al., 2008) that is central to the consent process (Lane et al., 2021).

The context of our study is another important consideration because it is substantively different than most other ICU studies, wherein interventions are directed at the patient and do not require family engagement beyond providing consent. Our aim was to recruit participants in the first 72 h after ICU admission. This is recognised to be a time of heightened uncertainty and stress for family members (Ruckholdt et al., 2019), which may impede information acquisition and comprehension (Azoulay et al., 2018), particularly when the study interventions involved many steps across the whole of hospitalisation. The stress and uncertainty experienced by families is recognised as a factor that makes decision-making challenging (van

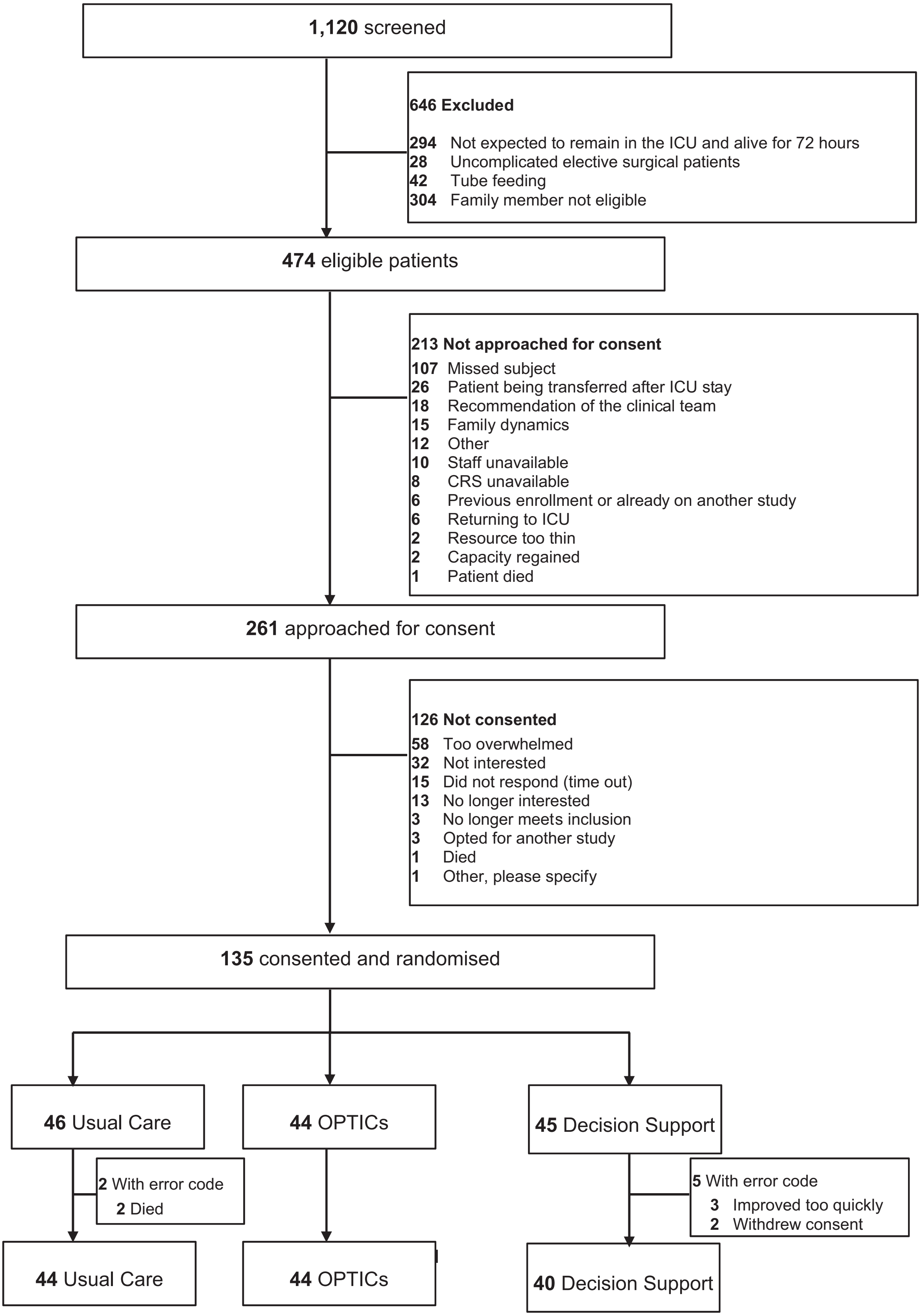

FIGURE 2 Patient flow through the study.

Beusekom et al., 2016) and it is possible that this contributed to an increase in declined consent evidenced by half of family participants approached in our study who declined to participate because they felt too overwhelmed at this early phase of their family member's illness. Perhaps we might have had more success if we approached families later during the course of illness but for decision support

TABLE 6 Intervention adherence.

Decision support intervention components	(*n* = 40[a]) %(95% CI)
My ICU Guide Questionnaire[b] completed	39/40 97.5% (92.7–100%)
Study posters displayed in the patients' ICU room	39/40 97.5% (92.7–100%)
My ICU Guide Education	40/40 100%
Family shown www.myicuguide.com on an electronic device	31/40 77.5% (64.6–90.4%)
My ICU Guide Questionnaire results communicated to the health care team	40/40 100%
Family meeting scheduled with the ICU health care team to review goals of care	36/39[c] 92.3% (83.9–100.0%)
Regular follow-up with the patient and family in the ICU	36/37[d] 97.3% (92.1–100.0%)
Communication of the My ICU Guide's output to the attending physician and clinical team looking after the patient on the ward	24/26[e] 92.3% (82.1–100.0%)
Review the patient's medical record after ICU discharge for documented evidence of the My ICU Guide results	22/26[e] 84.6% (70.8–98.5%)
Study posters displayed in the patient's room on the ward	20/26[e] 76.9% (42.8–80.2%)
Nutrition Intervention Components	(*n* = 44[a])
Study posters displayed in the patient's ICU room	44/44 100%
Review of Nutrition Education Booklet, ICU videos, with the family	44/44 100%
Communication of the patient's nutrition history to the health care team	44/44 100%
Dietitian follow-up with the patient and family in the ICU (minimum once per week)?	36/38[f] 94.7% (70.4–93.2%)
Re-review of the Nutrition Education Booklet, viewing the ward videos with family	23/31[g,h] 61.3% (44.1–78.4%)
Nutrition Diary completed by the family	16/31[g,h] 51.6% (34.0–69.2%)
Nutrition care plan for the ward	21/31[g,h] 67.7% (51.3–84.2%)
Study posters displayed in the patient's room on the ward	18/31[g,h] 77.4% (62.7–92.1%)
Dietitian follow-up with the patient and family on the ward	23/31[g,h] 74.2% (58.8–89.6%)
Three-day calorie counts completed on the ward	22/31[g,h] 71.0% (55.0–87.0%)
Nutrition care plan for home reviewed by the dietitian with the patient and/or family	22/31[g,h] 44.8% (26.7–62.9%)

Abbreviations: CI, confidence interval; ICU, intensive care unit.

[a]Denominator adjusted to reflect participants to whom the intervention component ought to have been delivered.

[b]Preferences for use of Life-Sustaining Therapies and 10-item Decisional Conflict Scale (DCS).

[c]1 Patient died in ICU before the meeting could be held.

[d]Treatment withdrawn for one patient, one patient discharged early and healthcare team recommended one family not be followed up for psychosocial reasons.

[e]14 Patients died in ICU.

[f]Treatment withdrawn for 4 participants; 2 participants discharged early.

[g]12 Patients died in ICU.

[h]1 Patient had treatment withdrawn and died on the ward.

TABLE 7 Physician Awareness Assessment.

Physician awareness assessment	All participants (n = 119)	Usual care (n = 41)	Nutrition intervention (n = 42)	Decision support (n = 36)
	n (%)			
The physician was aware this patient was part of the IMPACT trial	99 (83.2)	30 (73.2)	36 (85.7)	33 (91.7)
Physician awareness of group allocation (%)				
Nutrition intervention	21 (17.6)	0 (0.0)	21 (50.0)	0 (0.0)
Decision-support intervention	21 (17.6)	0 (0.0)	0 (0.0)	21 (58.3)
Control group	23 (19.3)	21 (51.2)	1 (2.4)	1 (2.8)
Do not know	52 (43.7)	19 (46.3)	19 (45.2)	14 (38.9)
Missing/Declined	2 (1.7)	1 (2.4)	1 (2.4)	0 (0.0)

Abbreviation: CI, confidence interval.

interventions, the early the engagement, we surmised that it would be more likely that the intervention would have greater impact.

The interventions in this study required partnership between the family and health professional, representing the highest level of family engagement (Carman et al., 2013) and perhaps requiring a preference for maximal engagement. Almost three-quarters of our participants had attended college or university, so it is possible these participants had a higher level of health literacy (Protheroe et al., 2017) and may have felt that they had the capability required to actively participate in the intervention. Health literacy has previously been identified as a potential barrier to family participation (Marshall et al., 2017). Context and capability have also been identified as factors that influence willingness to engage, and are interconnected (Sieck et al., 2019). The admission of a patient to the ICU can influence their family member's self-efficacy, willingness and resources, all which influence their perceived capability to engage with health professionals and consequently consent rates.

The willingness for families to partner with health professional in these types of interventions may have influenced participation in this study. Azoulay et al. (2003) previously reported that families (88.2%) believed that families should be provided the opportunity to participate in patient care yet only one-third wanted to do so. A more recent study suggests that engagement in patient care is important but that families lack confidence that their participation would impact care consequently families were less willing to engage in care (Burns et al., 2020).

In this trial, we randomised family members to one of two interventions or to the control group, an approach which did not accommodate preference or allow for intervention modification or tailoring. Intervention flexibility and adaptability is a characteristic of successful interventions (Grol & Wensing, 2013) and could be accommodated into future versions of the intervention. Preference should also be considered in relation to trial design. Research participants may decline study involvement to avoid allocation to an intervention group which does not align with their preferences. One strategy to address consent rates and intervention adherence might be to consider the use of a preference clinical trial in which at least some of the participants are able to select group assignment. This pragmatic approach may more appropriately reflect real-world contexts and may help identify intervention effectiveness in the context of those who may choose to engage with the intervention (Kowalski & Mrdjenovich, 2013).

5.1 | Limitations

The strengths of this study include a robust process of intervention development and refinement, and the evaluation of the interventions in ICUs from three countries. It is clear, however, that the reality of trying to implement family engagement in a contextually complex situation such as critical illness is challenging. In this clinical trial, we were unable to demonstrate statistically or clinically significant differences in the primary outcomes identified for each intervention. Study feasibility against our pre-determined targets was also not able to be demonstrated. The impact of local resources and supports available to families was not explored in detail and it is possible that this influenced recruitment rates and family experiences. Our work has highlighted that we have much to learn about how families want to engage with health professionals in the care of a critically ill relative, and under what circumstances. This includes identifying when families might be most open to considering participating in research and care delivery. While not an explicit focus of this work, facilitation of family engagement by clinicians is important and how to support clinicians in this role requires further exploration.

6 | CONCLUSION

In health care, meaningful engagement and active partnerships with patients and family members are important components of patient- and family-centred care but can be challenging to achieve in acute and critical care contexts. We were unable to demonstrate intervention efficacy or study feasibility primarily because consent rates were low. Intervention adherence was moderate suggesting that for those who do consent, participation in most intervention components was acceptable, although further refinement of the interventions may be warranted.

7 | RELEVANCE TO CLINICAL PRACTICE

Interventions to promote family partnerships and engagement in the context of critical illness are in development but require a greater understanding of what types of engagement might be best suited to which individuals, and in what contexts are these most likely to be achieved and effective.

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CONFLICT OF INTEREST STATEMENT

There is no conflict of interest to disclose.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX 1

INTERVENTION DESCRIPTION

Prior to the study commencing, those delivering the intervention underwent standardised training. The nutrition intervention was delivered by a registered dietitian who was responsible for providing care to patient in the intensive care unit. In some sites, the dietitian was supported by a registered nurse. The My ICU Guide intervention was delivered by a registered nurse who had experience caring for critically ill patients and their families.

Both interventions were delivered to individual participants face-to-face in the ICU with information supplemented by printed material and video resources.

Nutrition study intervention

In brief, the nutrition intervention involved an early meeting between the ICU dietitian and the family. During this meeting, the Malnutrition Screening Tool (MST) was completed with input from the family and the degree of nutritional risk was communicated to the family and members of the healthcare team. Families were educated about nutritional support approaches in the ICU strategies to assist families to interact with health professionals were introduced. The teach-back technique was used to ensure understanding of the information provided (Caplin & Saunders, 2015). This information was supplemented with printed and video-based resources to reinforce this information (https://criticalcarenutrition.com/research/optics/study-tools and https://criticalcarenutrition.com/resources/optics-nutrition-tools; Clinical Evaluation Research Unit, 2022).

Throughout the ICU stay, regular contact between the ICU dietitian and family was encouraged to address any new or outstanding questions. Close to the time of ICU discharge, the dietitian provided additional information about the patient's current nutritional status and post ICU nutrition plan. This would include information about the ward-based nutrition plan and any patient-specific issues such as continued nutritional support (e.g. continuation of enteral or parenteral nutrition, use of oral nutrition supplements, specialised oral diets), and any safety concerns (e.g. dysphagia, dietary restrictions). This information was supplemented with printed and online material (https://criticalcarenutrition.com/research/optics/study-tools and https://criticalcarenutrition.com/resources/optics-nutrition-tools; Clinical Evaluation Research Unit, 2022). A nutrition diary, to be completed by the family member, was provided once the patient was able to resume oral intake for the purpose of supporting conversations between the patient and family about nutrition intakes and goals. Three-day calorie counts were completed weekly to capture protein and energy intake once the patient was on the ward. Two or more oral nutrition supplements, anticipated to provide an additional 400 kcal/day, were provided to all patients, regardless of group allocation as this is considered standard care because of the known positive impact on patient outcomes (Philipson et al., 2013). In the nutrition intervention group, family members were provided information about the benefits of ONS, were encouraged to advocate for these to be provided to patients and to motivate the patient to consume the ONS. Prior to hospital discharge, the dietitian worked with the patient and family to develop a post-discharge nutrition plan and provided this information in writing.

Decision-support intervention

Information on principles of shared decision-making, experiences to expect during the ICU stay and advice on coping with stress was provided to families. This information was provided as printed material 'My ICU Guide' and supplemented with online resources (see https://www.myicuguide.ca/). A summary of the content of the My ICU Guide is provided in the table below. This content was reviewed with the family and the teach-back method was used to ensure understanding (Caplin & Saunders, 2015). A hard copy of the content was given to family members and a link provided to the website so that they could revisit and review materials. My ICU Guide Questionnaire was completed by family members and the results were verbally communicated to the healthcare team and a copy of the report was included in the patient's medical record. Within the 72h following review of the My ICU Guide and completion of the Questionnaire, a family meeting with the attending physician and bedside nurse was arranged to review patient goals of care.

Components of the My ICU Guide (Heyland, Davidson, Skrobik, Roze des Ordons, et al., 2018).

Section	Description
1. Orientation and education about the ICU	Provides a general overview of the intensive care unit (ICU) including key ICU terms, treatments, and roles of various clinicians who work in the ICU Describes common processes in the ICU, including resuscitation and comfort measures, organ donation, Power of Attorney, and substitute decision-making (SDM) Defines commonly used vocabulary in the ICU
2. When a loved one is in the ICU	Provides suggestions for coping strategies for family members of an ICU patient Encourages family member visitation Offers advice about how to ask questions in the ICU Encourages family to seek support or keep a journal during the ICU stay
3. Looking after yourself	Reinforces the importance of self-care for families of ICU patients Encourages family members to sleep, eat, and maintain healthy physical activity Provides ideas for how to inform and communicate with other family and friends about the patient's progress
4. Making decisions in the ICU	Describes and encourages shared decision-making Defines the role and responsibilities of family members in SDM Defines the roles of clinicians in decision-making Provides resources available to help with the decision-making process
5. Help us to get to know you and your family member	Family directed questionnaire asking information about the patient's personal characteristics Assess family members' state of mind and emotional status Assesses patient's clinical status and frailty
6. Informational preferences	Identifies family member's desire for information and level of health literacy
7. Values history tool	Assesses patients' values and preferences (as reported by family members) Questionnaire helps family members articulate patient's view of quality of life, value conflicts, impact of decisions on others, and religious/spiritual/cultural beliefs
8. Decision preferences	Elicits family member's preferences for extent of information sharing and preferred role in decision-making Identifies others who should be involved in decision-making Measures residual decisional conflict

Abbreviations: ICU, intensive care unit.

APPENDIX 2

DATA COLLECTION

Patient-related data	
Demographic data obtained from medical record	**Demographic data obtained from family member**
1. Age	1. Palliative Performance Scale (PPS) (Anderson et al., 1996)
2. Sex	2. Physical Function Domain of SF-36 (Ware, 1996)
3. Living Status (alone, with someone at home, supervised residential setting, nursing home, other)	3. Clinical Frailty Scale (Rockwood & Mitnitski, 2011)
4. APACHE II (Knaus et al., 1985)	4. Nutrition History and usual weight
5. Baseline SOFA score (Moreno et al., 1999)	5. Marital status
6. Type of admission to ICU (medical/elective surgery/emergency surgery)	6. Ethnic group
7. Following chronic, declining illness or acute onset	7. Education
8. Length of stay in Hospital prior to this ICU admission	8. Religion
9. Primary ICU diagnosis as per APACHE II taxonomy	
10. Charlson Comorbidity (Charlson et al., 1987)	
11. Functional Comorbidity Index (Groll et al., 2005)	
12. # hospitalisation in last 12 months*	
13. # Emergency Room visits in last 12 months*	
14. # ICU admissions in last 12 months*	
15. Home location: rural vs urban	

Patient-related data	
Demographic data obtained from medical record	**Demographic data obtained from family member**
16. Religion*	
17. Height	
18. Weight	
19. Advanced directives (presence and details)*	
Baseline nutritional status and nutrition-related data	
Malnutritional Screening Tool (Ferguson et al., 1999)	
Nutrition Risk in Critical Illness score (Heyland et al., 2011)	
Daily protein and energy prescription and intake	
3-day calorie counts on the ward	
Clinical data	
Use of life-sustaining treatment (mechanical ventilation, vasoactive drugs, renal replacement therapy)	
Length of stay in ICU	
Length of stay in hospital	
Medical orders for administration, withholding, or withdrawing of life-sustaining treatment before ICU admission and during ICU stay	
ICU discharge destination	
Secondary outcome measures	
Protein and Energy intake in ICU and hospital stay	
Consumption of oral nutrition supplements	
Hand grip strength	
Mortality	
Family-related data	
Demographic data	
Relationship to patient	Experience with end-of-life decisions for others
Age	Religion
Sex	Importance of religion or spirituality
Education	Location of residence (urban/rural)
Language	Decision-making preferences
Ethnicity	How close you feel to your family member?
General health	Family engagement survey
Secondary and tertiary outcome measures	
Family satisfaction with ICU Care Scale (FS-ICU 24) (Heyland & Tranmer, 2001; Wall et al., 2007)	
10-item Decisional Conflict Scale (O'Connor, 1995)	
Feasibility and process outcomes	
Consent rate	Intervention fidelity
Enrolment rate	Intervention adherence
Physician awareness assessment	

Abbreviations: APACHE, acute physiologic and chronic health evaluation; ICU, intensive care unit; SOFA, sequential organ failure assessment.