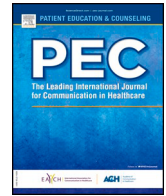




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Family-clinician shared decision making in intensive care units: Cluster randomized trial in China

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ABSTRACT

Objective: To investigate if a Family-Clinician Shared Decision-Making (FCSDM) intervention benefits patients, families and intensive care units (ICUs) clinicians.

Methods: Six ICUs in China were allocated to intervention or usual care. 548 patients with critical illness, 548 family members and 387 ICU clinicians were included into the study. Structured FCSDM family meetings were held in the intervention group. Scales of SSDM, HADS, QoL2 and CSACD were used to assess families' satisfaction and distress, patients' quality of life, and clinicians' collaboration respectively.

Results: Comparing the intervention group with the control group at post-intervention, there were significant differences in the families' satisfaction ($P = 0.0001$), depression level ($P = 0.005$), and patients' quality of life ($P = 0.0007$). The clinicians' mean CSCAD score was more positive in the intervention group than controls ($P < 0.05$). There was no significant between-group differences on ICU daily medical cost, but the intervention group **demonstrated shorter number of days'** stay in ICU ($P = 0.0004$).

Conclusion: The FCSDM intervention improved families' satisfaction and depression, shortened patients' duration of ICU **stay**, and enhanced ICU clinicians' collaboration.

Practice implications: Further improvement and promotion of the FCSDM model are needed to provide more evidence to this field in China.

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1. Introduction

Shared Decision-Making (SDM) is a collaborative process that allows patients, or their surrogates, and clinicians to make health-care decisions together, taking into account the best scientific evidence available, as well as the patient's values, goals, and preference [1]. Despite reaching consensus in accordance with the patient's

values, providing comfort and support to the family or surrogate is also a key element of SDM [2]. Families consistently rate communication with the ICU staff as being one of their most important concerns [3], and the majority of family members want both themselves and physicians to participate in decision-making [4]. However, deficiencies and breakdown in communication may contribute to a number of crucial consequences in patient care, including: the use of expensive treatments that do not align with patients' values and preferences [5–7]; unmet communication needs [8] such as prompt explanation of the condition and treatment

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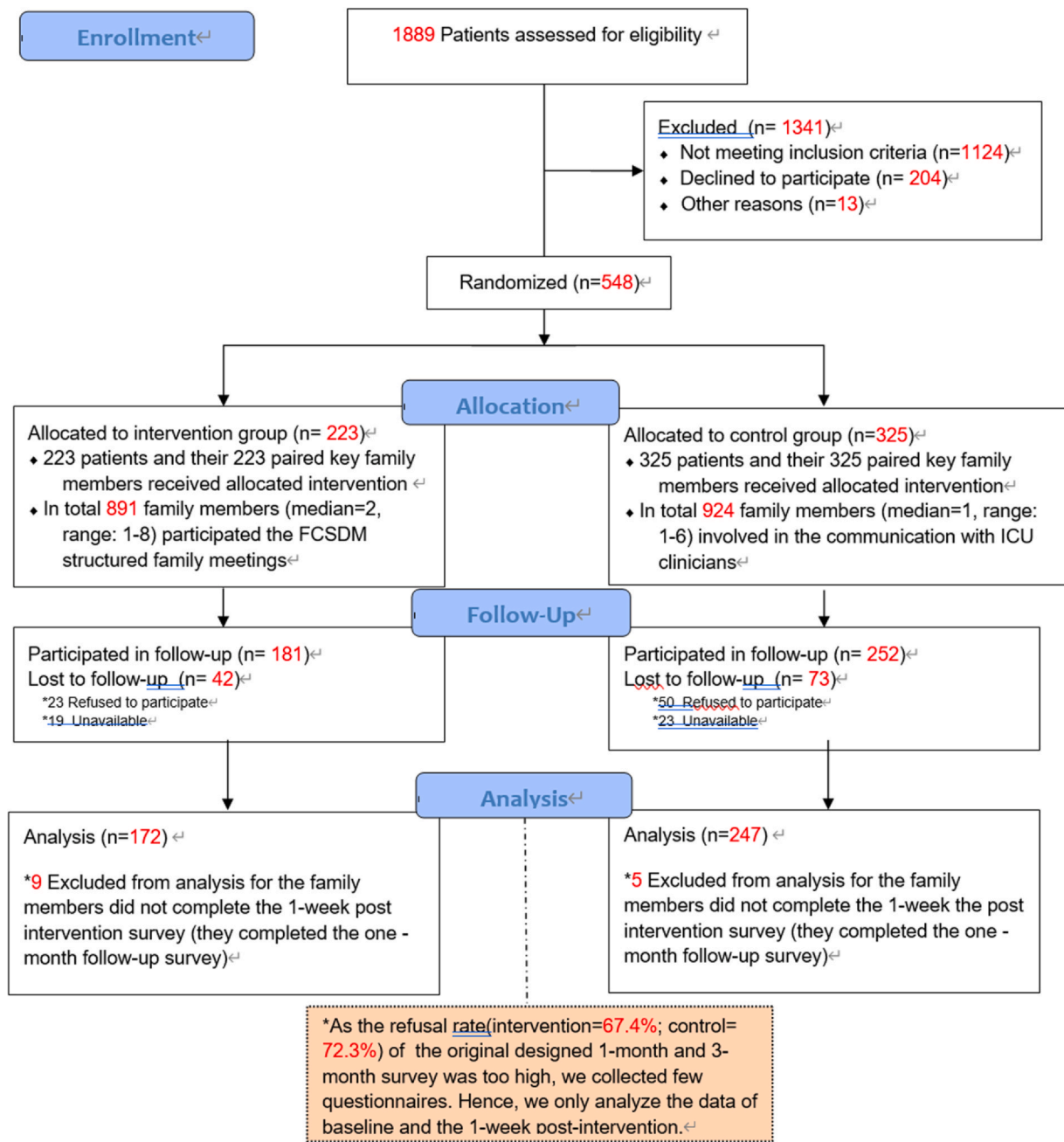


Fig. 1. Flow of patients and family members.

options, sufficient communication time, prognosis predicting; and symptoms of psychological distress among families [9,10].

End-of-life (EOL) care is the care and support for terminally ill patients, with the relief and prevention of suffering and improvement of quality of life as the main goal [11]. Compelling evidence indicates that there are serious deficiencies in EOL care in ICUs, leading to patterns of care that do not meet patients' needs and preferences, and lead to overuse of expensive, burdensome treatments [3]. These deficiencies jeopardize patient-centered care, increase the risk of adverse bereavement outcomes for families, and lead to a substantial waste of the limited health care resources.

Under traditional Confucian culture which is characterized by a family centered focus, in which most or all of the Chinese family take the major obligation of making decisions for the patients [12]. They often experience additional psychological burden, especially when confronting decisions of end-of-care such as forgoing life support or

maintaining aggressive potential life-saving measurement [13]. To achieve a shared decision that respects the patient's values and preferences, and in addition, respects the families' opinion and choice, is a relatively challenging task for both clinicians and families. Chinese physicians have much lower awareness of patients' preferences because of limited consulting time as a result of medical staff shortages, and overwhelming workload [14], and, in some cases, tensions between the health care providers and patients that hinder effective communication can occur [15,16]. Studies indicate that in China there are serious deficiencies in clinician-family communication and the way in which clinicians support families in their surrogate role [17–19].

In recent years, studies have been conducted in the ICU populations to improve patient-centered care, family-clinician communication, and reducing family distress with various interventions [20–22]. However, literature review unveiled that there were limited

Table 1
Characteristics of the Patients and Families' Baseline.^a

Characteristic	Control group (n = 325)	Intervention group (n = 223)	P value
Patients			
APACH II ^b , Mean (SD)	20.65(6.37)	24.65(5.89)	<0.0001
Primary diagnosis – No. (%)			<0.0001
Respiratory	44(13.5)	69(30.9)	
Cancer	28(8.6)	33(14.8)	
Cardiovascular	30(9.2)	24(10.7)	
Cerebrovascular	59(18.2)	39(17.5)	
Gastrointestinal	48(14.8)	16(7.2)	
Sepsis	13(4.0)	12(5.4)	
Trauma	49(15.1)	3(1.4)	
Other	54(16.6)	27(12.1)	
Age-year, Mean (SD)	57.62(16.72)	67.87(16.07)	<0.0001
Female sex, No. (%)	98(30.2)	85(38.1)	0.0218
Married, No. (%)	272(83.7)	176(78.9)	0.001
^c Education			0.0629
High school or above, No. (%)	123(36.0)	95(42.6)	
Less than high school, No. (%)	202(59.7)	125(56.1)	
^c Profession, No. (%)			<0.0001
Worker or Staff	122(37.5)	145(65.0)	
Farmer	123(37.9)	41(18.4)	
Unemployed and others	65(20.0)	34(15.2)	
Key Family members			
Age, Mean (SD)	40.81(12.15)	44.26(12.89)	0.0019
Female sex, No. (%)	139(42.8)	95(42.6)	0.0614
^c Relationship to patient, No. (%)			0.0054
Spouse	57(17.5)	24(10.8)	
Child	218(67.1)	180(80.7)	
Siblings	13(4.0)	4(1.8)	
Other	24(7.4)	13(5.8)	
Married, No. (%)	272(83.7)	195(87.4)	0.1699
^c Education			<0.0001
High school or above, No. (%)	181(55.7)	180(80.7)	
Less than high school, No. (%)	130(40.0)	41(18.4)	
^c Profession, No. (%)			<0.0001
Worker or Staff	151(46.5)	136(61.0)	
Farmer	76(23.4)	13(5.8)	
Unemployed and others	85(26.2)	70(31.4)	

^a From Student's *t*-test or Pearson's chi-squared test.
^b APACH II: Acute Physiology and Chronic Health Evaluation II.
^c There were absent data on patient/family's education, profession and relationship. Therefore, the percentage was not 100%.

Table 2
Family related outcomes.

	Unadjusted Analysis		Adjusted Analysis ^a			p value
	Control group Mean ± SD	Intervention group	Control group Mean (95%CI)	Intervention group	Estimated Effect of Intervention (95%CI)	
Satisfaction (SSDM)^b						
No. of families assessed	247	171				
Total score	68.54 ± 10.79	73.60 ± 8.67	69.39 (67.47–71.32)	73.44 (70.95–75.92)	4.04 (1.98–6.11)	0.0001
Distress (HADS)^c						
No. of families assessed	247	168				
Total score of Anxiety	10.09 ± 4.89	8.61 ± 4.48	10.03 (9.04–11.02)	9.63 (8.37–10.89)	-0.4 (-1.45 to 0.65)	0.4527
Total score of Depression	10.44 ± 4.90	7.67 ± 4.88	10.25 (9.21–11.28)	8.67 (7.35–10.0)	-1.57 (-2.67 to -0.47)	0.0052
Total score of A&D	20.52 ± 9.02	16.29 ± 8.63	20.27 (18.41–22.13)	18.31 (15.94–20.69)	-1.96 (-3.94 to -0.02)	0.0518

Abbreviation: SSDM, Satisfaction on Shared Decision-Making. HADS, Hospital Anxiety and Depression Scale.
^a The adjusted analysis included the following covariates: Sex, age, marriage, relation to patient, education, profession, residence, and patient's APACH II score.
^b Scores on the SSDM range from 0 to 80, with higher scores indicating better satisfaction.
^c Scores on the HADS range from 0 to 42, with higher scores indicating worse symptoms.

original RCT studies focusing on the intervention of SDM in ICU settings [22]. This indicates an important gap in our understanding. In our study, we developed a Family Clinician Shared Decision-Making (FCSDM) model [23], and applied this new model and tested the hypothesis that the intervention could improve families' satisfaction and distress, improve the patients' end-of-life experience, decrease the patients' medical costs and shorten their length of stay in ICU. In addition, we expected the coordination among the ICU clinicians to improve as well.

2. Methods

2.1. Trial design

We conducted a clustered multicenter randomized trial to compare the FCSDM meeting (intervention) with usual care (control), aimed at improving the decision-making process in ICU setting. The study was registered at Chictr.org.cn (ChiCTR2000035040), the project protocol is accessible via this article ([Appendix](#)).

2.2. Study setting and randomization

Six tertiary hospitals with similar size in Hunan province in China (The Second Xiangya Hospital of Central South University, The Third Xiangya Hospital of Central South University, The Second Affiliated Hospital of Nanhua University, The Hunan Tumor Hospital, The First Changsha Hospital, The First Changde Hospital) participated in the study. Six ICUs in these hospitals (1 ICU/hospital) were recruited as the study settings. The ICUs were randomized by drawing lots either into delivering the intervention (n = 3) or acting as controls (n = 3). Patients, family members and clinicians in these ICUs were accordingly assigned into either group.

2.3. Participant eligibility and recruitment

We recruited ICU patients with very poor prognosis and met any one of the following inclusion criteria: (1) terminal cancer with multi-organ failure; (2) severe intra-cerebral hemorrhage; (3) end-stage COPD and respiratory failure; (4) advanced malignancy and shock; (5) any disease with a score of 20 or higher on the Acute Physiology and Chronic Health Evaluation II (APACH II). We recruited the eligible family member who identified **themselves** as the key surrogate decision-maker of the patient, with **an age over 18 years** and with no communication barriers. Reasons for loss-to-follow-up were considered, which included the poor doctor-patient

Table 3
Patient related outcomes – ICU medical cost, length of stay in ICU and ICU discharge disposition.

Outcomes	Unadjusted Analysis		Adjusted Analysis ^b		Estimated Effect of Intervention (95%CI)	p value
	Control group	Intervention group	Control group	Intervention group		
	Mean(SD)		Mean(95%CI)			
ICU medical cost^a						
Total medical cost, Mean (SD)	99,310.55(120,150.28)	98,297.19(93,738.69)	108,007 (85,602–130,412)	89,619 (63,507–115,732)	-18387 (-41320 to 4545.50)	0.1158
Daily medical cost, Mean (SD)	8602.75(7321.03)	8285.19(4993.96)	8001.76 (6692.84–9310.68)	8576.62 (7051.08–10102)	574.86 (-764.90 to 1914.62)	0.3996
Length of stay in ICU						
Days of stay, Mean (SD)	17.51(34.34)	13.51(13.22)	21.7031 (16.0959–27.3104)	11.3414 (4.8062–17.8766)	-10.3617 (-16.1011 to -4.6224)	0.0004

^a The medical costs were calculated with Chinese currency RMB Yuan.

^b The adjusted analysis included the following covariates: Sex, age, marriage, relation to patient, education, profession, residence, and patient's APACH II score.

Table 4
Patient related outcomes–QoL2.

	Unadjusted Analysis		Adjusted Analysis #		Estimated Effect of Intervention (95%CI)	p value
	Control group	Intervention group	Control group	Intervention group		
	Mean ± SD		Mean (95%CI)			
Quality of life (QoL2)^a						
No. of patients assessed	241	172				
Total score of QoL2	72.68 ± 17.32	62.45 ± 18.91	71.33 (67.27–75.38)	63.94 (59.27–68.62)	-7.38 (-11.61 to -3.15)	0.0007

Abbreviation: QoL2, Quality of Life scale for terminal cancer patients.

The adjusted analysis included the following covariates: Sex, age, marriage, relation to patient, education, profession, residence, and patient's APACH II score.

^a Scores on the QoL2 range from 0 to 100, with higher scores indicating better health status.

Table 5
Post-intervention comparison of CSACD.^a

Items	Control group (N = 50)	Intervention group (N = 57)	P value
	Mean ± SD	Mean ± SD	
1. Nurses and physicians planned together to make the decision for patient	6.12 ± 0.8	6.16 ± 1.16	0.233
2. Open communication took place as the decision was made	6.00 ± 0.88	6.35 ± 0.77	0.016
3. Decision-making responsibilities were shared between nurses and physicians	5.88 ± 1.24	6.21 ± 0.88	0.122
4. Physicians and nurses co-operated in making the decision	5.88 ± 1.12	6.26 ± 0.86	0.03
5. Nurses and physicians each actively represented their professional perspectives on patient's needs	6.06 ± 0.77	6.40 ± 0.86	0.003
6. Decision making was coordinated	5.90 ± 0.89	6.25 ± 0.99	0.008
7. How much collaboration occurred in making the decision?	5.92 ± 1.03	5.89 ± 1.46	0.417
8. How satisfied were you with the collaboration when making decision?	5.1 ± 1.3	5.74 ± 1.04	0.013
9. How satisfied were you with the decision made for the patient?	5.62 ± 1.05	5.89 ± 0.92	0.202

^a CSACD, Collaboration and Satisfaction about Care Decisions.

relationship in China and the high death rate of patients leading families to decline follow up surveys due to bereavement. Ethical approval (**No. 2014-6-23**) was obtained from the Institutional Review Board of the Third Xiangya Hospital of Central South University, which was recognized by the participating hospitals. Written informed consents were obtained from the participating ICU clinicians and families.

2.4. FCSDM intervention

Before the implementation, we conducted a two-day's intensive "Train-the-Trainer" (TTT) workshop for the key ICU clinicians from the intervention group. Clinicians who received the TTT training were responsible for their own ICU's ongoing training and facilitation. The intervention team consisted of one attending physician, one junior physician and one nurse. Senior physician, director and

head nurse joined the team as needed. The structured FCSDM family meeting was the core of the intervention with **the** following major contents: (1) explained the patient's current condition, treatments, prognosis, etc.; (2) commented on the above debriefing and checked whether the families fully understood the information; (3) elicited families' perspectives on the patient's medical care; (4) explored the patient's willingness by asking the families (if the patient can communicate, ICU clinicians can ask the patient euphemistically); (5) provided various options of medical care, explained pros and cons of each option; (6) clinicians and families fully discussed and expressed their own views; (7) listened to the families attentively, were open to their opinions, and expressed empathy at least once; (8) focused on patient-centeredness, respected their **wishes**, and reached the care decision supported by both clinicians and families. At least one FCSDM family meeting was conducted during the patient's stay in the ICU.

2.5. Usual care

The control group continued with their usual clinician-family communication which characterized by the following aspects: 1) one doctor talked to one or several family members in most cases; 2) the conversation was unstructured and dominated by the clinicians; 3) mainly focused on topics of medical costs and prognosis.

2.6. Outcomes

We chose the scale of Satisfaction on Shared Decision-Making (SSDM) [24] to evaluate the families' satisfaction on SDM. The scale is comprised of 16 items and with good reliability in other study (Cronbach's alpha = 0.89) [24] and in our study (Cronbach's alpha = 0.97). We used the Hospital Anxiety and Depression scale (HADS) to assess families' distress (Cronbach's alpha = 0.76 [Anxiety], 0.79 [Depression]) [25–27]. We used the Quality of Life scale for terminal cancer patients (QoL2) to assess patients' life quality. The scale has 12 items and with five total score ranks (from very poor to very good), and its Cronbach's alpha is 0.79 [28]. We used the Collaboration and Satisfaction about Care Decisions (CSACD) scale for the ICU clinicians. The CSACD contains 7 questions concerning collaboration between clinicians and 2 questions about satisfaction with the decision-making. The scale obtained good reliability in its original study (Cronbach's alpha = 0.93) [29] and in our study (Cronbach's alpha = 0.87). We only calculated the patient's cost in ICU. Average costs were calculated to enable easy comparison was transformed to a daily index of cost by dividing total costs by days of ICU stay.

2.7. Data collection and analysis

Patients' illness condition, medical cost, days of ICU stay were acquired from the hospital information database. Baseline surveys were **administered** to the families at the enrollment **using** paper questionnaires. Post-intervention surveys were conducted within one week after the patient died in or was discharged from ICU by **using** online questionnaires. Participants were asked to complete the scales independently and put them into a locked box (paper questionnaires) or upload to the database powered by www.wjx.cn (online survey). Only the research assistants and the PI had access to the data.

All analyses were performed on an intention-to-treat basis. Student's *t*-test, Pearson's chi-square test, and **linear** mixed models were used. Outcomes were adjusted for patients' age, sex, marriage, education, profession, residence area, relationship, and APACH II scores. All tests for significance were two-sided. Significant findings were defined as *p* value less than or equal to 0.05. The software SPSS 24 and STATA v14 were used.

3. Results

3.1. Overview of the project

From Jan. 2016 to Dec. 2019, we completed the study enrolling 548 eligible subjects of paired patients and their families (intervention group, *n* = 223; control group, *n* = 325) (Fig. 1). The study population was described in Table 1. Notably, the patient's mean APACH II score in the intervention and control groups were 24.65 (SD = 5.89) vs. 20.65 (SD = 6.37) (*P* < 0.0001), and the between group difference in diagnosis was significant (*P* < 0.0001) (Table 1).

3.2. FCSDM family meeting and usual communication

The intervention group held 257 FCSDM family meetings in total with an average of 1.13 meetings per patient. The duration of the

meetings ranged from 12 to 68 min. The number of patients' families who participated in the meetings ranged from 1 to 8. We conducted a fidelity assessment (items = 9, total score = 18) in the intervention group to test the fidelity between the FCSDM model and the structured family meeting. Audio recordings of 25 FCSDM family meetings were randomly collected from the intervention group, and the results indicated that the fidelity was good (mean = 15.56, SD = 2.54). Communication between ICU clinicians and patients' families in the control group varied, and the duration of the communication ranged from 5 to 47 min with 1–6 family members participating in the talks.

3.3. Family related outcomes

After adjustment for differences in baseline characteristics and additional covariates, there was a significant difference between the intervention group and control group on the mean score of the SSDM (73.44 vs. 69.39; beta coefficient, 4.04; 95% CI, 1.98–6.11; *P* = 0.0001) (Table 2). There was significant difference between the intervention group and control group on families' mean depression score (adjusted, 8.67 vs. 10.25; beta coefficient, -1.57; 95% CI, -2.67 to -0.47; *P* = 0.005), but there were no significant differences on families' mean HADS A&D total score and on families' mean anxiety level (Table 2).

3.4. Patient related outcomes

There was no significant difference between the intervention group and control group on the ICU daily costs (adjusted mean cost, RMB 8001.76 vs. 8576.62 [approximately \$1219 vs. \$1307], beta coefficient, 574, 95% CI, -765 to 1915, *P* = 0.40) (Table 3). The mean duration in the ICU of the intervention group was 4 days shorter than the control group (13.51 vs. 17.51), and after adjustment the difference was significant (adjusted mean days, beta coefficient, -10.36, 95% CI, -16.10 to -4.62, *P* = 0.0004) (Table 3). Regarding the patients' quality of life, after adjustment the mean score of QoL2 demonstrated a significant difference between the intervention and control group (63.94 vs. 71.33; beta coefficient, -7.38; 95% CI, -11.61 to -3.15; *P* = 0.0007) (Table 4). After adjustment, the between group difference on choice of comfort care was not significant (*p* = 0.097).

3.5. Clinician related outcomes

The ICU clinicians' rating of the collaboration was significantly better in the intervention group than in the control group. The baseline comparison had no significant difference except one item (*P* < 0.05). On completion of the project the intervention group obtained higher score than the control group in 5 items including communication, cooperation, assertion, coordination, and satisfaction with collaboration on SDM, and the difference was statistically significant (*P* < 0.05) (Table 5).

4. Discussion and conclusion

4.1. Discussion

In this study, we found that the FCSDM intervention delivered by the ICU team increased the families' ratings of satisfaction, improved their depression level, and shortened the patients' length of stay in ICU while without significant impacts on medical cost. We also observed an improved perception of better collaboration among ICU clinicians who conducted the intervention. We interpret these findings from the following perspectives.

Similar to prior studies which adopted intervention such as integrated communication and consultative communication [20,30,31], we obtained positive results on enhancing patients' families' satisfaction of the SDM process. We think the improved

family satisfaction was mainly driven by four reasons: (1) the ICU clinicians' communication skills enhanced after receiving the intensive training, they were more empathetic and demonstrated more patience when talking with the families; (2) the family meetings were well-organized and seemed **to have a formal structure rather than simply performing** casual talk, thus family members may have an impression of being professionally treated; (3) the families became well-informed with detailed explanations; (4) the families were invited to participate in the decision-making and their perspectives were fully respected by the ICU clinicians. **This set of results is of great significance** especially for the Chinese health care system as it offers a practical pathway to alleviate the tense doctor-patient/family relationship in China.

Our findings are not consistent with previous studies [20,21,32] concerning the patients' medical costs. We propose three possible explanations. First, cultural differences must be considered. Influenced by the Confucian filial piety culture ("Life and death matter big" or "a living dog is better than a dead lion"), Chinese families might be reluctant to give up on the life-saving treatments for the patients, which in turn yielded higher costs in ICU. Second, the imbalance of illness severity could not be excluded. As the patients in the intervention group were more severely ill (mean APACH II score was higher, $P < 0.001$) than those in the control group, higher medical costs were predictable.

Interventions targeted at lowering families' distress have yielded various outcomes [20,21,33–36]. In our study, the families in both groups experienced psychological distress, which is consistent with previous studies [9,37]. As mentioned in the previous section on cultural factors, Chinese families take greater responsibility both financially and psychologically for patients than their Western counterparts. Our study shows that the SDM intervention may lower families' depression level, however more research is needed in this area.

Concerning the shortened length of stay in ICU, our findings are consistent with several previous RCT studies [20,34,36,38,39] that implemented similar family meeting or clinician-family communication interventions. There was no significant **difference** in patient's quality of life at baseline. However, patients in the intervention group had lower QoL2 scores after discharge from the ICU. This might be related to their higher APACH II score, indicating more severe illness than the control group.

The collaboration among the intervention ICU physicians and nurses improved to some extent after the intervention. Our findings showed that nurses' active participation increased, collaboration between the physicians and nurses were enhanced, the decision process was better coordinated, and clinicians' satisfaction about the decision-making increased. **To work as a team has many advantages as teamwork is more professional, organized, and efficient** [40,41].

Our study has several strengths. First, the structured FCSDM family meeting and communication skill training framework match well with the Policy Statement on Shared Decision Making in ICUs [1], which means a good fidelity to the concepts and deployment strategy of the SDM. Second, it is the first RCT study to construct a **novel SDM model which not only has a formal framework but also includes a practical application road-map**, and to evaluate its effectiveness from multiple perspectives in China. In 2020, a new law entitled "The Basic Medical Care and Health Promotion" went into effect in China, and SDM was proposed for the first time. Our study provides evidence of practical implementation strategy of the SDM in China.

Our study also has several limitations. First, our sample was limited to one province of the country, which may influence its representation. Second, we experienced major loss-to-follow-up for families. **Third**, there were imbalances between two groups in baseline characteristics, which might be caused by the relatively

small sample size and small number of participating ICUs. Although we used appropriate statistical analysis to adjust **for these** differences, we cannot exclude the possibility that residual confounding factors influenced the findings [20].

A recent review on evaluating decision-making strategies in the ICU [22] demonstrated mixed results, with some studies showing evidence of beneficial effect, while others showed no effect or negative effect on length of stay in ICU/hospital, satisfaction, mortality, costs and psychological complaints. **This paradoxical finding, from the review**, unveils the complexity of the study population and the effectiveness of the intervention strategy. However, the review concluded that the decision-making process in the ICU could be enhanced by frequent family-meetings with predefined topics. The results of our study suggest that it is feasible to implement a well-structured SDM family meeting. Further research is needed to refine the intervention strategy and enhance the compliance of the recruited families on completing the follow-up.

4.2. Conclusion

In conclusion, the FCSDM intervention improved families' satisfaction and depression in comparison to usual care. The intervention may be associated with shorter ICU stays but did not affect patients' medical costs. ICU clinicians worked more coordinated with the application of the FCSDM intervention.

4.3. Practice implications

Practice on medical shared decision-making in China is very limited. Further improvement and promotion of the FCSDM model are needed to provide more evidence to this field, among which, culture difference and health care system adaptation are needed to be considered.

CRediT authorship contribution statement

Xinchun Liu: Conceptualization, Methodology, Validation, Formal analysis, Data curation, Writing – original draft, Writing – review & editing, Visualization, Supervision. **Gerald Humphris:** Conceptualization, Methodology, Writing – review & editing, Supervision. **Aijing Luo:** Conceptualization, Methodology. **Mingshi Yang:** Conceptualization, Methodology, Investigation, Resources. **Jin Yan:** Conceptualization, Methodology. **Shaohua Huang:** Investigation, Resources. **Siyu Xiao:** Writing – review & editing. **Ailian Lv:** Investigation, Resources. **Guobao Wu:** Investigation, Resources. **Peigen Gui:** Investigation, Resources. **Qingyan Wang:** Validation, Data curation. **Yudong Zhang:** Investigation, Resources. **Yaxin Yan:** Formal analysis, Validation, Formal analysis, Data curation. **Nie Jing:** Investigation, Resources. **Jie Xu:** Formal analysis, Data curation.

Declarations of interest

None.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.pec.2021.10.004](https://doi.org/10.1016/j.pec.2021.10.004).

References

- [1] Kon AA, Davidson JE, Morrison W, Danis M, White DB. Shared decision making in ICUs: an American college of critical care medicine and American thoracic society policy statement. *Crit Care Med* 2016. <https://doi.org/10.1097/CCM.0000000000001396>
- [2] Charles L S, Robert D T, Randall C J, Gavin M J, A M, A A. Worldwide consensus on the principles of end-of-life care for the critically ill: the welpicus study. *Intensive Care Med* 2014.
- [3] Thompson BT, Cox PN, Antonelli M, Carlet JM, Cassell J, Hill NS, et al. Challenges in End-of-Life Care in the ICU: statement of the 5th international consensus conference in critical care: Brussels, Belgium, April 2003: Executive summary. *Crit Care Med* 2004;32:1781–4. <https://doi.org/10.1097/01.CCM.0000126895.66850.14>
- [4] Johnson SK, Bautista CA, Hong SY, Weissfeld L, White DB. An empirical study of surrogates' preferred level of control over value-laden life support decisions in intensive care units. *Am J Respir Crit Care Med* 2011;183:915–21. <https://doi.org/10.1164/rccm.201008-1214OC>
- [5] Lynn J, Teno JM, Phillips RS, Wu AW, Desbiens N, Harrold J, et al. Perceptions by family members of the dying experience of older and seriously ill patients. *Ann Intern Med* 1997;126:97–106. <https://doi.org/10.7326/0003-4819-126-2-199701150-00001>
- [6] Sharma RK, Freedman VA, Mor V, Kasper JD, Gozalo P, Teno JM. Association of racial differences with end-of-life care quality in the United States. *JAMA Intern Med* 2017;177:1858. <https://doi.org/10.1001/jamainternmed.2017.4793>
- [7] Somogyi-Zalud E, Zhong Z, Hamel MB, Lynn J. The use of life-sustaining treatments in hospitalized persons aged 80 and older. *J Am Geriatr Soc* 2002;50:930–4. <https://doi.org/10.1046/j.1532-5415.2002.50222.x>
- [8] Azoulay E, Chevret S, Leleu G, Pochard F, Barbotou M, Adrie C, et al. Half the families of intensive care unit patients experience inadequate communication with physicians. *Crit Care Med* 2000;28:3044–9. <https://doi.org/10.1097/00003246-200008000-00061>
- [9] Azoulay E, Pochard F, Kentish-Barnes N, Chevret S, Aboab J, Adrie C, et al. Risk of post-traumatic stress symptoms in family members of intensive care unit patients. *Am J Respir Crit Care Med* 2005;171:987–94. <https://doi.org/10.1164/rccm.200409-1295OC>
- [10] Wendler D, Rid A. Systematic review: the effect on surrogates of making treatment decisions for others. *Ann Intern Med* 2011;154:336–46. <https://doi.org/10.7326/0003-4819-154-5-201103010-00008>
- [11] Pastrana T, Jünger S, Ostgathe C, Elsner F, Radbruch L. A matter of definition - key elements identified in a discourse analysis of definitions of palliative care. *Palliat Med* 2008;22:222–32. <https://doi.org/10.1177/0269216308089803>
- [12] Liu MJ, Gu Q, Zhao JJ. Impact of forgoing therapy on medical treatments for end-stage critical care patients in ICU. *Chin Nurs Manag* 2013;13:23–6. <https://doi.org/10.3969/j.issn.1672-1756.2013.07.009>
- [13] Shen L, Li L. The influence factor of the family members' decisions about whether to withdraw the sustaining life support of terminal stage patients in ICU. *Nurs J Chin People's Lib Army* 2013;30:1–4. <https://doi.org/10.3969/j.issn.1008-9993.2013.21.001>
- [14] Li B, Sun XY, Wang JF. Reviewing the factors blocking the communication between doctors and patients. *Chin Heal Serv Manag* 2009;26:302–4.
- [15] The Lancet. Protecting Chinese doctors. *Lancet* 2020;395:90. [https://doi.org/10.1016/S0140-6736\(20\)30003-9](https://doi.org/10.1016/S0140-6736(20)30003-9)
- [16] Tucker JD, Cheng Y, Wong B, Gong N, Nie JB, Zhu W, et al. Patient-physician mistrust and violence against physicians in Guangdong Province, China: a qualitative study. *BMJ Open* 2015;5:e008221 <https://doi.org/10.1136/bmjopen-2015-008221>
- [17] Liu YP, Wang XY. Communication between physicians and patients play a important role on improving end-of-life care in ICU. *Med Philos* 2007;28:29–30.
- [18] Hu BB, Zhuang YY. Study for the differences between family members, nurses and doctors in perceiving the needs of critical care family. *J Nurses Train* 2008;23:2216–8.
- [19] Xiao S, Wang L, Edelman EJ, Khoshnood K. Interpersonal factors contributing to tension in the Chinese doctor-patient-family relationship: a qualitative study in Hunan Province. *BMJ Open* 2020;10:1–11. <https://doi.org/10.1136/bmjopen-2020-040743>
- [20] White DB, Angus DC, Shields A-M, Buddadhumaruk P, Pidro C, Paner C, et al. A randomized trial of a family-support intervention in intensive care units. *New Engl J Med* 2018;378:2365–75. <https://doi.org/10.1056/nejmoa1802637>
- [21] Curtis JR, Treece PD, Nielsen EL, Gold J, Ciechanowski PS, Shannon SE, et al. Randomized trial of communication facilitators to reduce family distress and intensity of end-of-life care. *Am J Respir Crit Care Med* 2016;193:154–62. <https://doi.org/10.1164/rccm.201505-0900OC>
- [22] Kerckhoffs MC, Kant M, van Delden JJM, Hoof L, Kesecioglu J, van Dijk D. Selecting and evaluating decision-making strategies in the intensive care unit: a systematic review. *J Crit Care* 2019;51:39–45. <https://doi.org/10.1016/j.jccr.2019.01.029>
- [23] Liu X, Gerald H, Yang M, Yan Y, Wang Q, Qian L. Construction and implementation strategies of the “family-clinician shared decision-making” model. *Chin Hosp Manag* 2021;41:55–9.
- [24] Makoul G, Clayman ML. An integrative model of shared decision making in medical encounters. *Patient Educ. Couns.* 2006. <https://doi.org/10.1016/j.pec.2005.06.010>
- [25] Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67:361–70. <https://doi.org/10.1111/j.1600-0447.1983.tb09716.x>
- [26] Zheng LL, Wang YL, Li HC. Application of hospital anxiety and depression scale in general hospital: an analysis in reliability and validity. *Shanghai Arch Psychiatry* 2003;264–6.
- [27] Wan JG. Reliability and validity analysis of Hospital Anxiety and Depression Scale for inpatients of comprehensive hospital. *World Latest Med Inf* 2018;18:55–6.
- [28] Ye JH, Li ZT, Wang X. Making of self-rating scale for testing quality of life of terminal cancer patients and its trial application. *Chin Nurs Res* 2009;23:1497–9.
- [29] Baggis JG. Development of an instrument to measure collaboration and satisfaction about care decisions. *J Adv Nurs* 1994;20:176–82.
- [30] Higginson IJ, Koffman J, Hopkins P, Prentice W, Burman R, Leonard S, et al. Development and evaluation of the feasibility and effects on staff, patients, and families of a new tool, the Psychosocial Assessment and Communication Evaluation (PACE), to improve communication and palliative care in intensive care and during clinical u. *BMC Med* 2013;11:213. <https://doi.org/10.1186/1741-7015-11-213>
- [31] Kauffer M, Murphy P, Barker K, Mosenthal A. Family satisfaction following the death of a loved one in an Inner City MICU. *Am J Hosp Palliat Med* 2008;25:318–25. <https://doi.org/10.1177/1049909108319262>
- [32] Ahrens T, Yancey V, Kollef M. Improving family communications at the end of life: implications for length of stay in the intensive care unit and resource use. *Am J Crit Care* 2003;12:317–23. <https://doi.org/10.4037/ajcc2003.12.4.317>
- [33] Quenot JP, Rigaud JP, Prin S, Barbar S, Papon A, Hamet M, et al. Suffering among carers working in critical care can be reduced by an intensive communication strategy on end-of-life practices. *Intensive Care Med* 2012;38:55–61. <https://doi.org/10.1007/s00134-011-2413-z>
- [34] Carson SS, Cox CE, Wallenstein S, Hanson LC, Danis M, Tulsky JA, et al. Effect of palliative care-led meetings for families of patients with chronic critical illness: a randomized clinical trial. *JAMA - J Am Med Assoc* 2016;316:51–62. <https://doi.org/10.1001/jama.2016.8474>
- [35] Braus N, Campbell TC, Kwekkeboom KL, Ferguson S, Harvey C, Krupp AE, et al. Prospective study of a proactive palliative care rounding intervention in a medical ICU. *Intensive Care Med* 2016;42:54–62. <https://doi.org/10.1007/s00134-015-4098-1>
- [36] Lautrette A, Darmon M, Megarbane B, Joly LM, Chevret S, Adrie C, et al. A communication strategy and brochure for relatives of patients dying in the ICU. *New Engl J Med* 2007;356:469–78. <https://doi.org/10.1056/nejmoa063446>
- [37] Cameron JI, Chu LM, Matte A, Tomlinson G, Chan L, Thomas C, et al. One-year outcomes in caregivers of critically ill patients. *New Engl J Med* 2016;31:486–92. <https://doi.org/10.1056/nejmoa1511160>
- [38] Lee HW, Park Y, Jang EJ, Lee YJ. Intensive care unit length of stay is reduced by protocolized family support intervention: a systematic review and meta-analysis. *Intensive Care Med* 2019. <https://doi.org/10.1007/s00134-019-05681-3>
- [39] Garrouste-Orgeas M, Max A, Lerin T, Grégoire C, Ruckly S, Kloeckner M, et al. Impact of proactive nurse participation in ICU family conferences: a mixed-method study. *Crit Care Med* 2016;44:1116–28. <https://doi.org/10.1097/CCM.0000000000001632>
- [40] Tan M, Yang L, Wang H, He X. Application of medical integration cooperation mode in the thyroid surgery clinic. *Chin Hosp Manag* 2016;36:27–9.
- [41] Wang C, Chang Y, Zheng Y, Wang Z, Li Y, Yang Y, et al. Application of multi-disciplinary doctor-nurse collaboration team on the perioperation management of geriatric hip fractures, Chinese. *J Reparative Reconstr Surg* 2019;33:1283–6.